ENHANCING WOMEN’S ACCESS TO ESSENTIAL MEDICINES IN NIGERIA:

A Reconsideration of the Patent Framework of the TRIPS Agreement to Improve Access to Medicines, as a Right to Health and a Means to Human Development in Nigeria

Submitted by Jennifer Heaven Mike to the University of Exeter as a thesis for the degree of Doctor of Philosophy in Law in November 2016

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Signature:…… Jennifer Heaven Mike ............................
Abstract

The overall objective of this study is to promote the human rights to health of Nigerian women to have access essential medicines, to enhance their human capabilities for human development. This thesis argues for an improvement of women’s access to medicines within the context of patent law and rights in the international IP regime of the Trade Related Aspect of Intellectual Property (TRIPS) Agreement and Nigeria’s national patent system.

Towards this goal, the thesis makes the point that patent law and its exclusive rights, both the TRIPS Agreement and national law of Nigeria, do not exist in a social welfare vacuum. The legal text of patent law, which confers rights on inventors when enforced, translates to many other things outside the sphere of property rights; indeed, it can be a matter of life and death. It is argued in this regard that patent right could, in effect, interfere with access to medicines and therefore, the right to health and prospects for human development. The thesis therefore argues that, in the construction, interpretation and enforcement of patent law in Nigeria, there is a need to take into consideration its impact on public health.

It is against this backdrop that the research assesses the legal framework of pharmaceutical patents and the implications for women’s access to medicines, from a right to health and human development perspective. This interdisciplinary study is with a view to suggesting ways in which Nigeria’s patent system can be more human development and human rights friendly in the interest of public health, particularly, the use of the TRIPS flexibilities to enhance access to life-saving medicines in Nigeria.
Since Nigeria as a member of the World Trade Organisation, is bound by its treaty obligation to adopt the provisions of the TRIPS Agreement, the thesis makes proposals for ways in which the Nigerian government and law-makers, can adapt the patent rules and the flexibilities to suit development objectives and promote public health within the benchmark allowed in TRIPS.
In this respect, this thesis critically investigates the practical implications of the available flexibilities and options in the TRIPS Agreement that can be used to address the effects of patents on access to medicines. While this thesis concedes the view that the hindrances to accessibility of essential drugs in Nigeria are multi-faceted and demand a multi-dimensional approach for a lasting solution, it is specifically argued that the TRIPS flexibilities are significant means for addressing the challenges of affordable access to important health treatments within the context of patent law. However, it is emphasised that utilising the flexibilities will require that Nigeria’s patent system is strategically designed to take full advantage of the available safeguards and options. To this end, this study recommends ways to incorporate the flexibilities to enhance access to medicines in Nigeria while avoiding the technical and regulatory pitfalls that have trailed the enforcement of the flexibilities by other developing countries.
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Dedicated to my mother Nanre Favour Bello

Thank you for believing in my dreams and taking the steps to make it a reality

To my late father Mike Okwudili Mogekwu,

I hope your baby made you proud
ENHANCING WOMEN’S ACCESS TO ESSENTIAL MEDICINES IN NIGERIA:

A Reconsideration of the Patent Framework of the TRIPS Agreement to Improve Access to Medicines, as a Right to Health and a Means to Human Development in Nigeria

1. Introduction

Health is Wealth¹

If we did not have a patent system it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it.²

1.1 Objective and Study Focus

The objective of this study is to promote the right to health of Nigerian women to have access to life-saving medicines in order to enhance their capabilities for human development including leading long and healthy lives. In this respect, this thesis argues for women’s access to essential pharmaceuticals at an affordable cost within the scope of patent law and rights.

To achieve this vision, this thesis appraises the public health implications of the patent protection of pharmaceuticals in the international intellectual property (IP) regime of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), and the existing flexibilities, with particular emphasis on the national patent system in Nigeria. This thesis argues that the

¹ Anonymous.
flexibilities in TRIPS provide a significant avenue for ensuring that the right to health is not compromised by the patent laws in Nigeria. Therefore, ways in which Nigeria can effectively utilise the legal exceptions, drawing on analysis and examples from other countries will be recommended.

1.1.1 Why Women?
In conducting the study in this thesis, the argument for increased access to medicines in Nigeria is considered within the socio-economic, traditional and cultural challenges that Nigerian women encounter. While it is acknowledged that the problem of access to medicines is one that affects everyone — males, females and children, particularly the poor in developing countries, — the central focus of this study is upon women in Nigeria. This is because women, especially those in developing countries face diverse social, economic and cultural challenges that often make access to healthcare and medicines particularly difficult for them.

The particular focus on women’s health and access to essential medicinal treatments in this thesis is not to say that men’s health is not as important as women’s health. In addition, the focus on women is not based solely on the fact that women have special needs over and above men’s but, because some fatal illnesses that affect women in many developing countries and their inabilities to access health treatments can also be traced to their subordinated social and

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3 The word ‘women’ in this study signifies the female gender. The scope is wide enough to take into account young girls, however, the emphasis is on women of child bearing age.
economic situation, gender-related barriers and biological predispositions.\(^5\) Therefore, understanding the health-related experiences and social positions of men and women is fundamental to analysing the various ways which women may experience problems of accessing medicines within the context of trade rules in a different and sometimes more severe manner.\(^6\) However, this thesis does not focus solely on the socio-economic and cultural barriers women face in accessing medicines. Instead, the thesis advocates for a consideration of the ways which patent rights could also impact on their access, in the light of their social, economic and cultural circumstances.

In the assessment of access to medicines, discussions have focused on the disparity between developing and developed countries. Within states, however, social inequalities and discrimination on grounds of gender can further exacerbate the problem. Scholars have emphasised the social and cultural nature of the differences between men and women, particularly, their unequal power and status in society that should be included in health and development debates.\(^7\) Gehl Sampath, for example, argues that an adequate response to women's health in the area of treatments should be sensitive to the various dimensions of the access problem.\(^8\)

The analysis in this thesis is relevant because it demonstrates the constituent reality of the access to medicine phenomenon, and exposes the issues taken for granted in examining the effects of patent rights on medicines, as well as

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\(^7\) Gita Sen, Asha George and Piroska Östlin, ‘Engendering Health Equality: A Review of Research and Policy’ in Gita Sen, Asha George and Piroska Östlin, Engendering International Health: The Challenge of Equity (MIT Press 2002) 1-11; Sally Macintyre, Kate Hunt and Helen Sweeting, ‘Gender Differences in Health: Are Things Really as Simple as They Seem?’ in Michael Bury and Jonathan Gabe (eds), The Sociology of Health and Illness: A Reader (Routledge 2013) 161-170; Sarah Gammage and others (n 4) 1-12.

\(^8\) Sampath (n 6) 258.
development at global and national levels. Thus this thesis, from a patent standpoint, will focus on and analyse the challenges that women face in accessing healthcare and medicines in order to make a case for their increased access, as a means of realising their rights to health in Nigeria.

This thesis, however, makes a case for women’s rights to health, not only for their development but also for that of the Nigerian society as a whole. Hence the recommendations have wider implications for everyone in Nigeria—women, children and men. In the same way, although this study focuses on women, the TRIPS Agreement and Nigeria’s patent system, policies and practices, the result of the study can have a wider effect on the global IP framework and policy; hence other developing countries can draw on its recommendations.

1.1.2 Study Focus on Nigeria

It is appropriate to point out the rationale for the focus of this study on Nigeria. Patent rights are essentially national rights; the enforcement and interpretation are territorial.\(^9\) Thus, the barriers that pharmaceutical patents present to accessing medicines are largely jurisdictional.\(^10\) Also, though the international IP laws in TRIPS expanded the protection of intellectual property rights (IPRs) on a global scale, their impact and enforcement lie within the national jurisdiction of members of the World Trade Organization (WTO). This study will, therefore, focus on Nigeria as a developing country, although references and examples are frequently drawn from other developing and developed countries.

According to the World Bank, with a population of an estimated 170 million people, Nigeria is the most populous country in Africa.\(^11\) In addition, Nigeria as a

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\(^9\) However, in international trade matters, Members of the WTO can bring an action to the dispute settlement body (DSB) when one Member is alleged to have violated their obligations to the WTO.

\(^10\) Although this problem can have a spill-over effect in countries that rely on imported medicines.

country is the one of the richest nations in that continent with an estimated GDP of US$522.6 Billion.\textsuperscript{12} Because of its size, economic development and global participation, the country plays a significant role in influencing progress and development within the whole West Africa region and, indeed, the African continent.\textsuperscript{13}

The healthcare exigencies and the need for medicines in Nigeria also provide a contextual basis to argue for access to drugs as a right to health within the context of patent law and rights, and a broader interpretation of patent exceptions and TRIPS-related flexibilities to promote this access. Moreover, the country also offers a social context that is necessary for the gendered aspect of this study, being largely a patriarchal society. For instance, one scholar observes that the structure of social relations is based on the ‘system of social stratification and differentiation on the basis of sex, which provides material advantages to males while simultaneously placing severe constraints on the roles and activities of females.’\textsuperscript{14}

Furthermore, by adopting Nigeria as the case study, the thesis is approached from the basis of both personal and professional knowledge gathered from the experience of living and working there. Also, personal knowledge of the mitigating factors to women’s development resulting from their lack of access to quality health care has been garnered from years of living in Nigeria.

In order to accomplish the foregoing study objective, the thesis considers Nigerian’s international patent law obligations and argues that in conforming to

\textsuperscript{12} ibid. As of 2015.

\textsuperscript{13} For example, Nigeria was one of the ten developing countries that initially objected to the proposal presented by the US and some other developed countries to incorporate matters relating to IP, particularly patents, into the framework of GATT and the WTO. See Duncan N Matthews, "Trade-Related Aspects of Intellectual Property Rights: Will the Uruguay Round Consensus Hold?" (2002) CSGR Working Paper No. 99/02, 9. Available at <http://dx.doi.org/10.2139/ssrn.319545> accessed 17 May 2015.

the globalised IP standards in the TRIPS Agreement, Nigerian patent law should be designed to serve the country’s national health objectives. This study also makes proposals for ways of addressing the issues that have arisen in the context of the patent system and access to medicine by ensuring that the Nigerian government, in becoming TRIPS compliant, makes full use of all the legal exceptions and health-related options, including the flexibilities in the TRIPS Agreement in a development-oriented manner. Significantly, therefore, the result and recommendations of this research are expected to have policy implications in Nigeria.

1.2 Methodological Framework and Approach

This thesis adopts a doctrinal methodology to examine, analyse and evaluate the issues that have arisen in the context of patent protection of pharmaceuticals and its effect on women’s human right to access medicines and, consequently, their human development. To this end, this study employs a doctrinal approach to analyse the effect and role of patent law, particularly within the context of pharmaceuticals, health and development. In doctrinal research, the essential features of legal rules and case law are identified and critically examined, and the relevant aspects are synthesised to explain areas of difficulty, ‘establish an arguably correct and complete statement of the law on the matter at hand’ and predict areas for future development.¹⁵ The intention in this thesis is to gain an insight into the research questions, examine the significance of the law and analyse the issues that have arisen in respect of the international and national legal protection of pharmaceutical patents and the problem of access to medicines.

The advantage of a doctrinal approach is that it provides a critical exposition of legal rules, norms, case law and precedent; it traces the discovery and development of the law and delineates the goals and objectives of the law.\textsuperscript{16} That is, it centres around the question ‘what is the law’ and clarifies the nature of the law.\textsuperscript{17} This thesis analyses, compares and evaluates the legal regime of patents, including the exceptions, as contained in the TRIPS Agreement, Nigerian statutes, and also explores case law, court rules and legislative Draft Bills. The research also relies on the official text of international laws, conventions and international human rights instruments. Since the study is also based on a multilateral international agreement (the TRIPS Agreement), the thesis makes reference to the national legal statutes operating in other WTO members including India,\textsuperscript{18} the United Kingdom (UK) and the United States (US), and regional and national laws of other countries where the law and jurisprudence are more developed. UK laws and decided cases are particularly relevant to this study since Nigeria’s legal system, including patent law, is based on the English legal system and its customary traditions.\textsuperscript{19} In addition, the study takes into account the judicial decisions by the WTO Dispute Settlement Body.

\textsuperscript{17} Monirul Azam, \textit{Intellectual Property And Public Health In The Developing World} (Open Book Publishers 2016).
\textsuperscript{18} India’s legal jurisprudence, judicial interpretations and implementation of the provisions of the TRIPS Agreement is particularly useful in suggesting ways that Nigeria can develop its own patent system as well as interpret and implement the patent law within the context of public interest and access to medicines. This is justified on the grounds of the similarity in legal history and socio-economic environment as the two countries are both products of British colonial administration. The legal systems and patent laws of the two countries, therefore, have colonial origins in English jurisprudence. Coincidentally, they both enacted national Patents Acts in 1970. The two developing nations are members of the WTO. Equally, both countries govern in similar democratic political climates, face comparable HIV/AIDS and other health challenges and are inundated with development and poverty challenges. However, India has proactively amended its patent laws in accordance with the TRIPS Agreement’s IP standards and made important exceptions for the public interest whilst doing so. The government and third parties have effectively utilised the flexibilities for public health purposes and the courts have elaborated on the importance of interpreting patent law in favour of public health, rights to health and access to medicines.
\textsuperscript{19} This is by virtue of colonisation and the transplantation of the English legal system to Nigeria.
While primary sources provide the basis for the study, secondary sources such as law reports, scholarly analysis and empirical studies, books, journals, policy documents and reports, also provide rich sources of information and support. This research extends its focus beyond legal sources. The approach adopted is to consider the relationship of the law to other disciplines where relevant to the arguments including literature from economics, public health, gender studies, sociology, philosophy, and development theories. In particular the study draws inspiration from the capabilities and human development principles\textsuperscript{20} to justify a broad and liberal interpretation of patent law and its legal exceptions in favour of access to essential drugs. This thesis also considers the effect of the law in a practical context, beyond the scope of the legal rules. Thus the thesis relies on research, information and literature in development and human rights sources, official reports of United Nations, human rights and other health organisations, healthcare laws and policies, writing and empirical research of scholars in the field of human development, gender/feminist studies, and international law.

The choice of conducting a desk-based research is primarily based on the fact that most of the information required for this thesis is already contained in documented sources and official reports. The official documents and empirical research relied on provide reliable, broad and contextualised accounts of the problems and issues of access to medicines, particularly affordable drugs, in Nigeria. Empirical research has been conducted by the Nigerian Ministry of Health, World Health Organization, other scholars and international organisations which offer a broader approach and more data than I could have achieved within the scope of this thesis. The existing studies were conducted on

\textsuperscript{20} This human development approach relies considerably on the capabilities approach associated with Martha Nussbaum and the Nobel Laureate Amartya Sen's description of development as the expansion of human capabilities and freedoms.
a large-scale, covering all the geopolitical zones in the country, and provide a representative report of the current state of affairs; they provide invaluable resources and insights into the healthcare system in Nigeria, women's state of health and the myriad issues that confront their quest to access important medical treatments, and its effect on their development priorities from a broader perspective. These data also provide statistical support for the implementation, enforcement and flexible use of the TRIPS-compliant flexibilities by the Nigerian legislative, judicial and executive authorities to address the challenges of access within the context of patent law.

It was the original intention to combine the doctrinal analysis with an empirical investigation into the issues of access to medicines in Nigeria, using field research, survey instruments and interviews to explore the research questions. In particular, I considered conducting empirical research to ascertain the extent to which women in Nigeria face the difficulty of accessing medicines vis-à-vis patents. However, there were challenges due to the difficulty of conducting research in the volatile areas and conflict zones of the northern and middle belt regions of Nigeria, the challenge of getting ethics approval for research of this nature from the university and the resources that would be required as Nigeria is a large country in terms of land mass and is one of the most populated countries in Africa. Furthermore, conducting an alternative small scale study in few locations would not provide statistically representative data: my thesis could not rely on a small scale study to justify the national policy and legislative intervention, broad implementation, enforcement and interpretation of patents, including the flexibilities, in favour of access to medicine, the rights to health and human development, as such a finding would only reflect the situation in some segments of Nigerian communities. It was therefore decided to rely on
existing studies as noted above. I also encountered significant administrative and bureaucratic challenges when I tried to conduct interviews at the government ministries, the patents registry and other relevant organisations in Nigeria.  

Notwithstanding, this research project is significantly doctrinal, critically appraising the law in a particular context and produces recommendations that are expected to have policy and legislative implications in Nigeria.

**1.3 Hypothesis / Theoretical Assumptions**

The fundamental premise of this research is that the patent law, rights and international IP system in the TRIPS Agreement and Nigeria should not be a hindrance to accessing important lifesaving medicines; rather, that the law and IP system can play a more active role in encouraging access to medicines in Nigeria and other developing countries. This thesis, therefore, hypothesises that within the patent system lie challenges and solutions to the problems of access to important lifesaving medicines. Indeed, it is acknowledged that patents can be tools for the enhancement of societal wellbeing and progress; however, unless the formulation, enforcement and interpretation of patents, the regulatory framework and legal exceptions are properly designed to take into account basic human considerations such as health, the adverse cost of patents will

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21 I had frustrating encounters when I tried to carry out interviews in Nigeria. I visited Nigeria on three different occasions to conduct interviews (in 2013, 2014 and 2015). The purpose of the interviews was to elicit information on a broad range of questions such as the registration and administration of pharmaceutical patents, state of the ratification process for the implementation of the TRIPS Agreement in Nigeria administration, the reasons for the inadequate implementation of the flexibilities into the patent system and many others issues pertinent to the objective of this thesis. Many government officials were unwilling to grant interviews or were unavailable to grant the interviews. Some directed me to other government departments or ministries as the appropriate authorities to entertain my questions. The officials in the latter ministries redirected me back to the earlier visited ministries. In other instance, the appropriate authority to entertain the interview questions redirected me to other staff that were not very useful as interviewees. In the end, I had to rely on secondary sources as I had limited time to conduct the study in Nigeria.
obscure the benefits. In this respect, the flexibilities can play an important role in ensuring that patent rights do not constitute a barrier to the public function of the patent system and access to important pharmaceuticals. Nonetheless, the provisions of the legal remedies and flexibilities in national laws will not facilitate access unless they are effectively utilised and interpreted in the interests of public health. So conceived, this analysis proceeds on the hypothesis that an appropriately regulated patent system and flexibilities can contribute to, and facilitate, women’s access to medicines, leading to human development in Nigeria and other developing countries facing a comparable issue of access.

1.4 Intellectual Contribution to Existing Knowledge

The impact of pharmaceutical patent rights on access to essential medicines is a global issue that has been extensively and widely debated. Much has been said on this issue, yet so much is left unsaid in this debate. Even the most ardent critics of the effect of patent rules do not fully engage with the social context in which these problems exist. For example, current literature on this issue offers limited engagement with the circumstances and events that shape how certain groups, such as women, encounter additional difficulties in accessing essential drugs in particular societies. This research departs from the dominant approach to the problems of access to medicines within the context of patent protection and offers a different approach to framing the debate. This research approaches the issue of access by examining the legal provisions of patents and the ways in which the patent protection of pharmaceuticals can have particular implications for women’s health and human development. This aspect of gender sensitivity, which examines women’s social roles, exigencies and interests, is positioned to influence the content and enforcement of patents
in a way that reflects women's need to attain a good state of health and enhance their capacities for sustainable development. This premise is based on the assumption that women play a central role in society and the family; hence their health, welfare and wellbeing are of utmost importance to any development-oriented society.

The thesis also contends that the problem of access to medicines in the context of patent raises human rights concerns especially the right to health, life and development. In particular, this study focuses on the connection between women’s human rights to health and the impact of global patent protection of pharmaceutical drugs on health. This study further argues that accessing essential medicine is relevant to the realisation of the right to health and pursuit of human development because medicine is a major determinant of good health and it is a vital element to human wellbeing and survival.

In addition, most scholarship on the role and purpose of patents in national and international TRIPS regimes has focused on the positive effect of IP on innovation and economic development. It is widely assumed that the protection will encourage dissemination of the invention for technological progress which would, in turn, facilitate economic growth, and as an incentive mechanism, encourage additional inventions. Thus, the focus is on the role that the patent rights play in increasing innovation and economic growth rather than the distribution of the patented resources and human development benefits of patents.

This thesis contends that the fundamental purpose of the patent system and its rules in encouraging innovation is to promote public interest and advance social goals. Viewed from this angle, a patent, apart from being a right to an intellectual property, is a social instrument for human development. To this end, the thesis argues in terms of the social benefits to be derived from patent protection. Accordingly, the goal of IP protection is to promote social development, human needs and economic progress as per Articles 7 and 8 of the TRIPS Agreement. In this thesis, this development outcome is conceptualised in terms of building basic human health capabilities. This critical evaluation of access to medicines from a sustainable human development perspective, helps us to understand the role of patents in enhancing basic living standards, people's quality of life and its far-reaching implications for the capability of women to be 'able to have good health, including reproductive health.'

In this sense, the granting, interpretation and enforcement of private intellectual patent rights vis-à-vis access to medicines, policymakers and the courts should take note of the social welfare and public interest of society as a whole.

Ultimately, the goal of this study is to promote access to essential medical treatments, drugs, and other health commodities that are critical aspects of women's right to health and human development.

1.5 Research Question

This thesis is motivated by one fundamental question: How can the reconsideration of the patent protection of essential medicines from a right to

health perspective enhance women’s access to medicines and contribute to their capabilities for human development in Nigeria?

Other questions that guide this research are:

1. How is patent law relevant to the issue of access to medicines? To what extent do patents give sufficient market power to introduce and maintain high prices? How is the effect of this on access to essential drugs?

2. To what extent have women’s experiences been included within the purview of mainstream discourse on access to essential drugs as a human rights entitlement?

3. Do the provisions of human rights to health impose a duty on states to ensure that the granting and utilisation of patent rights do not impact adversely on public health, particularly access to medicines?

4. How is the patent system linked to human development? How can the human capabilities approach reshape our imagination of the development goals of patents and the TRIPS Agreement to contribute to human development?

5. How could the TRIPS flexibilities be interpreted and implemented in such a way that guarantees women’s right to health and access to medicines in Nigeria?

1.6 Overview of Chapters

The introductory Chapter of this thesis provides a general overview and context in which it is set. This section outlines the focus, hypothesis and objectives of
the study. The chapter describes the significance of the study, research problems and gap in the literature. The chapter also further identifies the preliminary issues in the analysis and general framework of the study.

Chapter II provides a general overview of the role and function of the patent system, with particular focus on the public welfare aspect, to reveal the social welfare purpose of patent law. It will further analyse and question underlying justifications and assumptions and the purpose of the patent system in both the TRIPS Agreement and Nigerian law to reconceptualise the links between pharmaceutical patents and access to medicines.

Chapter III analyses in detail the literature on the effect of pharmaceutical patents on access to medicines. In particular, it identifies how patent law can affect prices, the cost of medicines and consequently, access. Also, the link to the unavailability of pharmaceuticals for diseases predominant in many developing countries is identified. The relevance of women’s health in the study is also presented. In so doing, the chapter considers the distinct needs, rights and experiences of women, particularly Nigerians, with regard to their health. The chapter argues for the inclusion of women’s distinct needs in finding a solution to the issue of accessing medicines in the international IP regime and Nigeria’s patent law.

In Chapter IV, human rights principles and norms provide the underlying basis on which this thesis argues for women’s access to medicines. The proposals in this chapter set out a framework for a human rights approach to scaling up access to medicines in Nigeria and other developing countries. The chapter argues that states (particularly Nigeria) have a human rights duty to meet the basic healthcare needs of their people, including ensuring that patent rights do
not interfere with the accessibility to medicines. This analysis also aims to examine how human rights can influence the interpretation and enforcement of patents for broader access to medicines. The chapter also evaluates the intersection between private pharmaceutical patent rights and women’s rights to health.

Chapter V is devoted to answering the question: what might a human development-oriented patent system, which aims to develop basic human capabilities to be healthy through access to medicines, look like? Fundamentally, how can the human capability approach to development change the current perception and approach to patents? Having made a case for the consideration of public health in the previous chapters, the research further argues for access to medicines by ‘rethinking’ patents as instruments for enhancing human capabilities and human development. Conversely, it is argued that patents could affect the accessibility to affordable medicines which is significant to human development.

Chapter VI critically evaluates the current implementation status of TRIPS in Nigeria. The study principally examines the Nigerian pharmaceutical patents legal regime and the practical measures undertaken so far to maximise the benefits of TRIPS and its flexibilities. In doing so, it questions the effectiveness of the legal health-related solutions offered by the international TRIPS Agreement within the context of Nigeria and other developing societies. Thereafter, this chapter recommends ways in which the Nigerian government can utilise the flexibilities in the TRIPS Agreement to improve access to reasonably affordable medicines.
Chapter VIII draws some conclusions and recommends the way forward. In so doing, the final chapter of the study suggest ways in which Nigeria can promote women’s access to new pharmaceuticals and support rights to health and development in the context of its patent system, particularly through the proactive use of the TRIPS-compliant flexibilities. This chapter further suggests several other courses of action for the Nigerian government to adopt in order to promote access to medicines and address the public health challenges of its citizens.
CHAPTER II: EXAMINING PATENTS, THE TRIPS AGREEMENT AND NIGERIA’S PATENT SYSTEM FROM A PUBLIC WELFARE PERSPECTIVE

2.1 Introduction

Before making a case for Nigerian women’s access to affordable and essential medicines within the context of the patent framework, it is pertinent to first identify what a patent is, the international and national laws for the protection of patents, and the basic underpinnings of the patent system, from a public welfare perspective. This study provides a background and context that is essential to understanding the key issues and laws that run through this thesis.

A commonly perceived notion of a patent is that the protection is instrumental to promoting innovation, technological advancement and scientific progress for public benefit. From a pharmaceutical patent standpoint, a patent is also assumed to play an important role in encouraging pharmaceutical R&D, technology transfer (TT) and foreign direct investments (FDI) which, in turn, facilitate the availability of important medicinal resources to society. These assumptions are encapsulated in the theoretical justifications underpinning the patent system and the IP rights of inventors. This chapter assesses these philosophical supports of patent rights and argues instead for a need to focus on the public welfare benefit of having a patent system. This welfare-purpose-driven approach to patents is to gain a contextual appreciation of the advantage that patent law and system offer to society from a user’s point of view. It is argued that approaching patents from a public welfare perspective would give the policymakers, the courts and other relevant authorities’ in Nigeria greater flexibility to formulate, implement and interpret pharmaceutical patents in the
interests of the public and also fulfil the objective of enhancing women’s access to essential health treatments.

Since this study focuses on the effects of the international protection of patents on access to medicines in the localised setting of Nigeria, the chapter provides a descriptive overview of the international framework for patents. The study highlights the policy context, scope and objective for the existence and protection of patents at international level, specifically, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). This exposition aims to provide a base for the contextual background to the subsequent analysis of the relationship between patents, the problem of access to medicines and the available health-related flexibilities that can be utilised to safeguard public health.

As the case study for this thesis is primarily focused on Nigeria, this chapter critically evaluates the development of the patent system in Nigeria from a public interest and welfare perspective. Specifically, in view of a patent’s role in encouraging research and development (R&D) and the consequences of patents to women’s accessibility to medicines, the issue raised in this chapter is whether historically, the western-style patent system in Nigeria was suitably structured to enhance domestic technological and scientific growth, pharmaceuticals R&D and generally promote the public’s interest. The study also examines the reasons for any inadequacy and the current issues with the system with respect to public health.

The argument made here is that the Nigerian patent regime originated as a colonial product, thus its regulation of intellectual knowledge and invention was shaped by foreign authorities that paid little attention to local contexts, socio-
economic conditions and the technological state of development.\textsuperscript{1} This section also argues that following independence, Nigeria has relied on this unstructured system created during the colonial era, leading to inconsistencies in policy articulation, formulation and implementation of patent law, which can have significant implications for the accessibility to medicines.

2.2 Defining Patents

A patent is a legal protection or government-granted authority that confers its owner with certain, limited exclusive rights,\textsuperscript{2} namely, to exclude others from using, making and/or dealing with the patented invention/product without a licence or permission of the owner, for a specified limited period of time, within the territory it is granted.\textsuperscript{3} This exclusive and monopoly authority essentially permits the inventor to ‘exclude competitors from the marketplace’ and control unauthorised access to the patented invention.\textsuperscript{4} It is this exclusive right given to innovators that raises concerns with regards to accessing medicine as will be discussed in the next chapter.

Patents are not granted for every invention. The invention must satisfy the pre-determined conditions for the grant of a patent right to inventors, which dictate

\textsuperscript{1} Ikechi Mgbeoji, ‘African Indigenous Knowledge Systems and Patents: Is the Patent System Relevant to the Native Healers of Southern Nigeria?’ in Emmanuel K Boon and Luc Hens (eds), Indigenous Knowledge Systems and Sustainable Development: Relevance for Africa (Kamlra-Raj Enterprises 2007) 78-81. (Stating that the patent system, as imposed on African peoples, was part of the colonial project to remodel non-Western peoples and cultures in the image of Europe on the hypothesis that indigenous peoples had no pre-existing institutions worthy of respect.) See also G Sipa-Adjah Yankey, International Patents and Technology Transfer to Less Developed Countries: The Case of Ghana and Nigeria (Avebury 1987) 98.

\textsuperscript{2} Cynthia Ho, Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights (Oxford University Press 2011) 17.


that the inventors or invention address an identifiable problem or provide a new and useful solution that is of high inventive quality.\(^5\)

To justify the existence of the patent system, it is commonly argued that a patent’s exclusivity and monopoly rights will not only encourage innovation and reward inventors; it also facilitates the availability of the invention and also spurs others to further invent around the disclosed invention.\(^6\) And in the international WTO trade platform, patents as well as other IPRs, would promote economic and social development, rapid technology transfer trade and the attraction of FDI.\(^7\)

However, among IP specialists, industry specialists and commentators, the widely unsubstantiated view that a patent is the ideal mechanism for encouraging innovation and technological development, is not universally accepted, especially considering the underlying adverse implication for competitions, incremental research and development (R&D), public health and consequently, the enhancement of human development.\(^8\)

### 2.3 Theoretical Justifications of the Patent System

#### 2.3.1 The Natural Law and Labour Theory

The natural law theory is rooted in the recognition of the inherent natural rights of inventors to their ideas and the products of their mental and intellectual

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\(^5\) Specifically, these essential thresholds for the granting of patents are: ‘novelty’ (the invention must be new); utility or industrial applicability (i.e. it must be useful or have industrial relevance); and be an inventive step or non-obvious (above the current or existing state of art or science). John H Barton, ‘Non-Obviousness’ (2003) 43(3) IDEA 475, 476.


This point is further discussed in the next chapter.

\(^8\) The role of IP as an engine of innovation by providing the necessary incentives versus its adverse impact on public health and innovation has been debated extensively by scholars. Some of the arguments will be touched upon in the following chapters.
labour. Proponents therefore, argue for the moral right of an inventor to control their inventions and reap the results of their intellectual efforts.

The most influential argument for natural rights emerged from the writings of John Locke who believed in the natural entitlement to life, liberty and personal ‘labour of property.’ To the philosopher Locke, a human being is born with a set of natural rights which entitles him to the enjoyment of these rights including the preservation of his property. Locke’s main proposition is that every man has a natural right to the earth given by God ‘in common’. However, when a person appropriates a natural endowment by mixing his labour with it, he adds something of his own to it which ought to be protected from exploitation by others. Accordingly, therefore, man has a natural right to the products of his labour, a right which should be protected by society. Locke also argues in his labour theory that the right to property is justified because every man has a property in his own person. The natural law/labour principle is therefore premised on the ontological assumption that people have a right to property, to the exclusion of all others, to the extent that they have expended their labour to it.

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13 Locke (n 11) paragraph 26.

14 Ibid paragraph 27.


16 Locke (n 11) paragraph 27.

Hettinger sums up John Locke’s justification of property rights thus: John Locke’s version of this labor justification for property derives property rights in the product of labor from prior property rights in one’s body. A person owns her body and hence she owns what it does, namely, its labor. A person’s labor and its product are inseparable, and so ownership of one can be secured only by owning the other. Hence, if a person is to own her body and thus its labor, she must also own what she joins her labor with – namely, the product of her labor.

Hettinger (n 10) 100.
The proposition that a man owns a property right by removing something out of the state of nature and mixing his labour to it has been questioned by other commentators. Robert Nozick dismisses this labour premise by asking why a person acquires ownership by mixing his labour with something in common, instead of losing his labour. He uses an analogy of a person pouring a can of tomato juice into the ocean. He asks if a person, through the act of pouring the juice and ‘mixing one’s labor’ with the ocean, acquires the ocean or loses his can of tomato juice?\(^{17}\) The question essentially raises issues with the conceptualisation that a person owns a right to a property by mixing his labour with a common endowment.

The labour and natural right argument has been extended to intellectual property rights (IPRs), including patents, as a consequence of intellectual labour. As a natural right, this theory presupposes that society, represented by the state, is duty bound to recognise, protect, and enforce the natural rights and interests of patentees.\(^{18}\) This argument is often canvassed with regards to the human rights entitlement of patent holders and other IPRs.\(^{19}\)

Nevertheless, the notion that patent rights are the inherent rights of an inventor which the state recognises, finds strong opposition.\(^{20}\) The primary shortcoming in applying the ‘natural’ theory to patents is the nature of the protection itself. A patent, previously mentioned, is basically a statutory instrument granted by the state.\(^{21}\) A number of scholars reject this argument and criticise the inherent natural law postulate for failing to reflect the essential statutory creation and


\(^{19}\) This justification is also at the root of the moral and material human rights prescription of IP as further discussed in Chapter IV. (See subsection 4.7.3.1.)


\(^{21}\) See subsection 2.2 above.
nature of patents, which is fixed and limited to specific exclusive privileges.\textsuperscript{22} For instance, the UN Secretary-General echoes the point that ‘patent legislation has never been based solely on the concept of the patent as the confirmation of an inherent, rather than the creation of a statutory, property right.’\textsuperscript{23} The Secretary-General further reasons that ‘such a concept would have left no room for statutory limitations on patent rights such as the fixed term of a patent, its forfeiture for failure to work them, its exclusion for inventions in certain fields.’\textsuperscript{24}

\textbf{2.3.2 The Contract and Incentive-to-disclosure Theory}

Another support for patents is the ‘Social Contract/Public Disclosure of Secret’ justification. As Waelde and others in \textit{Contemporary Intellectual Property: Law and Policy} identify, a patent is often defined as ‘a form of social contract between the patentee and the state, whereby the award of a patent monopoly is given in return for public disclosure of the invention.’\textsuperscript{25} The contract theory therefore hypothesises that a patent is a contractual agreement, in which the state grants temporal property rights in exchange for securing the disclosure of the innovative knowledge and advantages of an intellectual endeavour.\textsuperscript{26} The crux of this \textit{quid pro quo} social contract reasoning is that this public disclosure also presents an opportunity for others to invent further around the disclosed invention; thus a patent is presumed to be a catalyst for incremental technological scientific and industrial progress, as well as conferring a public benefit (the so-called ‘teaching function’).\textsuperscript{27}

\textsuperscript{22} Mgbeoji, \textit{Global Biopiracy: Patents, Plants, and Indigenous Knowledge} (n 18) 19-20.
\textsuperscript{23} United Nations, \textit{The Role of Patents in the Transfer of Technology to Developing Countries: Report of the Secretary-General} (Martinus Nijhoff 1964) 9.
\textsuperscript{24} ibid
\textsuperscript{25} Waelde and others (n 4) 371.
\textsuperscript{27} Waelde and others (n 4) 371; Alexandra Zaby, \textit{The Decision to Patent} (Physica-Verlag 2010) 1-2; Hestermeyer (n 10) 30-31; Machlup and Penrose (n 9) 26.
There are, however, shortcomings in this theory. The theory erroneously assumes that patent protection is the only reason why inventors disclose their inventions to the public and consequently, the ideal mechanism for the encouragement of further innovations and ensuring public access. According to the observation by IP scholars, ‘the inventor discloses his secret only if he expects his profits from a temporary monopoly enforced by the state to be greater than those from an uncertain monopoly guarded by a tenuous secrecy.’

Opponents of the disclosure theory, therefore, object to the incentive function the disclosure is presumed to present by suggesting that, without patent, important inventions and their benefits would remain a secret. Pharmaceutical companies, for example, are mainly corporate entities whose ‘disclosure’ of their medicinal products is driven by profit incentives.

In another instance, the disclosure/contract rationale presupposes that innovations are products of a necessary infrastructure (patents) and the welfare cost of the monopoly is worth the increased benefit to a particular technical/scientific field. This assumption is however, called into question considering the long term detrimental welfare cost to health and human development in poorer countries. Also this assumption may ignore the fact...
that a monopoly can be used to block competition and reduce access to the disclosed invention as expounded in the next chapter.\textsuperscript{32}

Irrespective of the inherent limitations of this theory of patents, the importance of public disclosure should not be underestimated.\textsuperscript{33} The disclosure and enablement requirements in patent applications lie at the heart of patent law and the hypothetical ‘bargain’ aspect of the patent system as protection-for-disclosure.\textsuperscript{34} In this sense, the exclusive rights to exclude others from illegally appropriating a patented invention are not merely conferred as gifts; it is assumed that the right is in exchange for the disclosure of the invention and how it is practiced to the general public.\textsuperscript{35} From the point of view of society at large, the disclosure requirement is useful for securing the public returns of patent and innovations.\textsuperscript{36} It can be said that, from the public’s perspective that disclosure and statutory enablement conditions for patents require that society gains something from the disclosed invention. Ideally, the disclosure criterion is intended to benefit the public by encouraging improvements or follow-on designs around the patent; ‘thus bringing a flow of innovations to the marketplace.’\textsuperscript{37} Consumers should then benefit from the availability of useful technologies and products, such as essential pharmaceuticals, whose development was facilitated by the disclosed invention.

However, many proponents of the disclosure theory seem to focus on the ‘inventive’ or ‘teaching’ function of patent specification from the patentee’s


\textsuperscript{33} Waelde and others (n 4) 372.

\textsuperscript{34} ibid.; Bently and Sherman (n 3) 406.

\textsuperscript{35} Bently and Sherman (n 3) 537.

\textsuperscript{36} However, whether or not the disclosure sufficiently enables and promotes societal welfare is a different matter.

perspective rather than looking at the benefit that society can get from the disclosed invention. Beyond the theoretical foundations of the contract theory, it is important to recognise the importance of the disclosure from a public welfare standpoint. This thesis argues that users would derive better benefits from this patent advantage if they could access and use the products that have been disclosed.

2.3.3 The Best Incentive-to-Innovate Theory

Another view of the patent system holds that patents present an opportunity for inventors to invest in innovative enterprises and, consequentially, disclose the knowledge and result for public benefit.\(^{38}\) The incentive theory, according to Machlup and Penrose, supposes that the patent system creates the necessary incentive for inducing an adequate amount of desirable inventions to society.\(^{39}\) For his part, Adusei adds that the patent system is seen to provide an important inducement for inventors to make available to society, particular beneficial objects.\(^{40}\) In this manner, the inventive argument theorises that patents are fundamental incentives to encourage inventive undertakings, technology transfer, and facilitate R&D and economic development.\(^{41}\)

The underlying rationale for this utilitarian justification and economic incentive argument is straightforward: without patents, inventors — and, in the case of medicines and vaccines, pharmaceutical companies, — who invest time and ingenious efforts in medical R&D to produce efficacious drugs, will not get a

\(^{38}\) This literature is summarised in Machlup and Penrose (n 9) 10, 21-25; Fritz Machlup, An Economic Review of the Patent System: Study of the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, United States Senate, 85th Congress, Second Session, Study No 15 (U.S. Government Printing Office 1958) 33; Sigrid Sterckx ‘Patents and Access to Drugs in Developing Countries: An Ethical Analysis’ (2004) 4(1) Developing World Bioethics 58, 66-67. This discussion is further touched upon in subsections 3.6.2.1 of Chapters III and 5.3.1 of Chapter V.


\(^{40}\) Adusei (n 31) 121.

\(^{41}\) Adusei (n 31) 121.
One scholar summarises the basic assumption of this ‘encouragement-to-invent’ argument thus: ‘[w]ithout the prospect of an exclusive right to use the invention, and hence a possibility of recouping the money invested in the development of the invention, too little inventing would be done.’

From this perspective, increased profit from a patent’s exclusivity privilege is an incentive to innovate since inventors are most likely to invest in R&D and inventive enterprises because they are guaranteed a monopoly over the invention. A patent protection which guarantees profits on investments is therefore, a stimulus to the availability of new, innovative products.

For example, studies indicate an increase in the use of patents as an investment strategy, and its importance in the decision to invest in a particular innovative activity such as pharmaceuticals R&D. As a corollary therefore, the patent system further encourages the patent owner to invest in the creation of additional inventions.

As with the public disclosure rationale, the incentive justification presumes that patent protection further stimulates innovation around the available invention which, in turn, provides a useful avenue for public utility.

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46 Lee (n 39) 47-50.
47 The importance and effect of patents on inventiveness and creativity is best represented in the views by Professor JB Clark in his ‘Essentials of Economic Theory’ (ch. xxi) that the patent system is important because without the system, there would be little inventing, and that there would be very little adoption of the invention by other producers. Accordingly, it would be small profit accruing to any one from the use of it and smaller ones from making it. Why should one entrepreneur incur the cost and risk of experimenting with a new machine if another can look on, ascertain whether the device works or not, and duplicate it if it is successful? [...] The system which gave a man no control over the use of his inventions would result in a rivalry in waiting for others rather than an effort to distance others in originating improvements. This fact affords a justification for one variety of monopoly.

He concludes that ‘[p]atents stimulate improvement, and the general practice of the nations indicates their recognition of this fact.’
its contribution to economic efficiency and technological progress, this utilitarian argument of the patent system tends to bring the benefit of a patent closer to the general social and public good. Within the narrow incentive view, therefore, patents are assumed to be the reason why people invest in innovation. Not surprisingly, proponents of patents argue that ‘without patent protection, the world would have been deprived of the innovative medicines which have saved countless of lives.’ As Oguamanam also puts it, ‘the wheel of creativity will falter or ultimately grind to a halt’ without this incentive system. The ‘Encouragement-to-Innovate’ justification is however, questioned for failing to establish a clear evidential connection between the grant of patents and inventive progress. For example, Mgbeoji noted that:

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The most fundamental difficulty in making any rational claim for or against the alleged relationship between patents and inventiveness is the impossibility of separating out other factors contributing to technological inventiveness, such as ‘local resource endowment, education of the labour force, availability of capital, and dynamism of the local market.’
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As with the disclosure theory, ironically, patent protection, by building a monopoly fence around some core inventions, can create an obstacle to the improvement of the patented invention by others and the benefits that flow from

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48 For example, Pigou writes from a utilitarian perspective that:

- The patent laws aim, in effect, at bringing marginal private net product and marginal social net product more closely together. By offering the prospect of reward for certain types of invention they do not, indeed, appreciably stimulate inventive activity, which is, for the most part, spontaneous, but they do direct it into channels of general usefulness.


53 Mgbeoji, Global Biopiracy: Patents, Plants, and Indigenous Knowledge (n 18) 21; ibid.
the widespread use of the patented article.\textsuperscript{54} This has led some scholars to argue that a patent’s monopoly right has stunted more innovations than it encouraged.\textsuperscript{55} Also, the exclusive privilege has ‘caused more brilliant schemes to be put aside than the want of them could ever have induced men to conceal.’\textsuperscript{56} On the contrary, advocates of the patent system argue that a patent comes at no cost to anybody since it does not deprive others of anything that they had before or anything that is not the property of the inventor.\textsuperscript{57} Rather, the patent system only delays the unlicenced use of the right holder’s invention to the public for a limited period of time, after which others are welcomed to use it as they deem fit.\textsuperscript{58} On the other hand, however, it is argued that, the patent system could actually deprive others of the opportunity to prospect, discover and use the same idea that the patent holder was fortunate enough to have conceived before others, or was the first to file for patent protection, as the case may be in some jurisdictions.\textsuperscript{59} Furthermore the argument is limited in assuming that the exclusive privilege will ‘cost nothing’ to society.\textsuperscript{60} A patent gives an exclusive privilege to the original inventor and so it can affect how others can use the patented invention. For example, inventors, who are mainly pharmaceutical companies in the case of pharmaceutical patents, might want to make the most of the monopoly privilege during the short period of the patent term, including charging high prices for the patented invention or licence. The exercise of this right can have an effect on accessibility to essential medicines, especially for the poor in developing countries.\textsuperscript{61}

\textsuperscript{54} Machlup and Penrose (n 9) 23-24.
\textsuperscript{55} ibid 24.
\textsuperscript{56} ibid 24.
\textsuperscript{57} ibid
\textsuperscript{58} ibid
\textsuperscript{59} ibid
\textsuperscript{60} See Jeremy Bentham, \textit{The Rationale of Reward} (R Heward 1830) 318.
\textsuperscript{61} This will be examined in the next chapter.
2.3.4 The Reward Theory

In a similar argument to the inventive theory, a patent is seen to offer a reward for inventive enterprise by securing the proprietary rights and interests of the inventor to capture a return on their investment in the inventive activity.\textsuperscript{62} This ‘reward theory’ maintains that a patent is a reward by government for creating a novel invention and disclosing a useful innovation that would otherwise remain a secret.\textsuperscript{63} This view essentially emphasises the bestowal of a patent as a reward or ‘prize’ for an inventor’s intellectual and creative genius effort,\textsuperscript{64} or as one commentator puts it, ‘opportunities to gain a reward in the market-place.’\textsuperscript{65} To the supporters of this reward approach, a patent is an important incentive for an inventor to apply human ingenuity and introduce a new solution to human problems. Conversely, without the ‘prize’ or ‘award’ incentive of patents, important inventions would not be made or offered to the public, as inventors only come forth with their inventions because they are guaranteed a reward.\textsuperscript{66} That is, like the disclosure rationale, the reward theory reasons that, without the reward and incentive that a patent exclusive right confers, inventors would not carry out research or disclose the results for society’s benefit. As Bentham argues, ‘[a]n exclusive privilege is absolutely necessary in order that what is sowed, may be reaped.’\textsuperscript{67} Accordingly, without patents, anyone could easily


\textsuperscript{64} Adusei (n 31) 118.

\textsuperscript{65} Zemer (n 10) 12.

\textsuperscript{66} Ibid

\textsuperscript{67} Bentham (n 60) 318.
imitate or duplicate other’s inventions and competition resulting from this imitation would reduce earnings on the investment. ⁶⁸

To further quote Jeremy Bentham on the issue,

[…] that which one man has invented, all the world can imitate. Without the assistance of the laws, the inventor would almost always be driven out of the market by his rival, who finding himself, without any expense, in possession of a discovery which has cost the inventor much time and expense, would be able to deprive him of all the deserved advantages, by selling at a lower price.

Bentham concludes that:

An exclusive privilege is of all rewards the best proportioned, the most natural, and the least burdensome. It produces an infinite effect, and it costs nothing. ⁶⁹

From a pharmaceutical patents standpoint, the strength of Bentham’s argument is that it advocates the granting of patent protection as a reward to innovators, which is a form of a return on their inventive activities, especially in cases where huge cost has been expended in, for example, the pharmaceutical R&D process for new medicines. This reward rationale justifies the granting of patents because it would be unfair to allow others, who have not invested the time, labour, money, ingenuity and effort to develop the invention, a ‘free ride’ on the invention.⁷⁰ As revealed in the next section, this ‘freeriding’ and piracy concerns presented a compelling argument for the inclusion of IP rights within the multilateral trade fora and influenced the argument by developed countries, prominently as the US, for the adoption of the TRIPS Agreement.⁷¹ Besides

⁶⁹ Bentham (n 60) 318.
⁷⁰ Sterckx, ‘The Moral Justifiability of Patents’ (n 15) 255.
⁷¹ For example, the Preamble to the TRIPS Agreement highlights this objective by explicitly referring to the need to protect private interests. The Preamble states thus: ‘[d]esiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights.’ See also Jean O Lanjouw and Iain Cockburn ‘Do Patents Matter?: Empirical Evidence after GATT’ (2000) NBER Working Paper No. 7495, 5-6; Duncan N Matthews, ‘Trade-Related Aspects of Intellectual Property Rights: Will The Uruguay Round Consensus Hold?’ (2002) Centre for the Study of Globalisation and Regionalisation Working Paper No. 99/02, 5-6. Also available at
preventing others from unduly misappropriating the invention, this patent reward it is argued, provides a utilitarian avenue for society as a whole to benefit from the invention.\textsuperscript{72}

The reward theory has also been criticised for assuming that it is the profit award which drives innovation.\textsuperscript{73} It has been pointed out that several inventions and inventive activities have been and would be undertaken without the consideration of a patent ‘reward.’\textsuperscript{74} Another major critique of the reward and incentive-to-innovate approaches is that it does not give a complete view of the function of the patent system by assuming that a patent is a reward for an incentive for inventive activity.\textsuperscript{75} It is argue that patent does not exist solely as a reward mechanism to patentees or to confer rights to inventors. As will be shown below, the patent system essentially exists to confer a benefit on both inventors and the public. Equally, approaching patents from the right holder’s perspective gives greater weight to the instrumentality of the patent holders, and the sanctity of patent right to innovation to measure the appropriateness of the patent system. Adopting a concept of patents solely from the right holder’s point of view focuses attention on the need to prevent patent infringements and the appropriation of the right holder’s intellectual creations and inventions; this can obfuscate the importance of actually extracting the social benefit of the patent system to the public and consequently, to users and consumers.

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\textsuperscript{72} Machlup and Penrose (n 9) 20-21.
\textsuperscript{73} Adusei (n 31) 118; Ikechi Mgbeoji, ‘Beyond Patents: The Cultural Life of Native Healing and the Limitations of the Patent System as a Protective Mechanism for Indigenous Knowledge on the Medicinal Uses of Plants’ (n 49) 4.
\textsuperscript{74} Adusei (n 31) 118.
\textsuperscript{75} Edmund W Kitch (n 62) 266; de Carvalho (n 63) 27-36.
2.4 Patent Law in a Social Welfare and Development Context

While this thesis shares the view that the theoretical justifications for the patent system are not always satisfactory, it is not disputed that in its own terms, the patent system could provide an important utilitarian means for securing the dissemination of technological knowledge embedded in an invention and the availability of important technologies such as medicines. For example, Lord Oliver in the United Kingdom (UK) case of *Asahi Kasei Kogyo KK’s Application* aptly captured this objective thus:

> The underlying purpose of the patent system is the encouragement of improvements and innovation. In return for making known his improvement to the public the inventor receives the benefits of a period of monopoly during which he becomes entitled to prevent others from performing his invention except by his licence.

Along this line, patents and other IPRs are seen to protect the economic investment effort expended in the development of the invention; thus, a patent is a means to stimulating the innovation of essential products for society’s benefit. However, it is argued that there is a need to focus on the public advantage of the function of the patent system to society.

Though the patent system and the economic incentive implications of guaranteeing protection may encourage innovation and promote the development of new and useful products, it is argued in this thesis that patent

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76 However, it appears that patents may be more effective in bringing the product to the market than actually encouraging increased R&D in itself. This is more obvious in the case of neglected diseases majorly affecting poorer parts of developing countries as will be examined in the next chapter. See JH Barton, ‘Patent Scope in Biotechnology’ (1995) 26 (5) International Review of Industrial Property and Copyright Law 605, 614.


essentially serves a larger societal purpose. In other words, the public and social benefit derivable from the patent system is not a mere incidental aspect of patent law. Broadly speaking, a patent aims to confer as much privilege and benefit to the public, including other inventors/researchers, users and consumers, as it does the patent right holders. The public policy and social development element of a patent system lie in the reasons and threshold principles for the grant of the patent and the requirement for disclosing the result of the innovation and technology in an enabling manner, in the patent claim. As mentioned in subsection 2.3.2, a patent is not merely granted in recognition of an inventor’s ingenuity and scientific/technological progress. There is a belief that the scientific and technological advancement is original, useful and significant enough to be protected and that it contributes to the field of knowledge, thus patents aim to promote social goals.

Apart from the public welfare and health benefits accruable from innovation such as essential medicines, the policies underpinning the novelty requirement, which aims to prevent others from monopolising matters already existing in the public domain, bears further emphasis. The underlying rationale for the novelty standard is to prevent the appropriation of ‘prior art,’ that is, knowledge that is already publicly available, patented, published or in use before a patent application was filed.\(^79\) It can be argued that this requirement takes into account public considerations. This patentable requirement illustrates that the patent system considers the public’s welfare and acknowledges the importance of ensuring that society is not prevented from having access to an existing public or common knowledge. In this sense, society is only willing to strike a bargain of granting monopoly rights to the inventor in exchange for disclosure after they

\(^{79}\) Waelde and others (n 4) 436-437; Bently and Sherman (n 3) 529, 532, 537; Bengt Domeij, *Pharmaceutical Patents in Europe* (Kluwer Law International 2000) 159.
determine that the invention is innovative (i.e. new or a significant improvement) and would not otherwise be publicly available more ‘quickly.’

This point is important to understanding that the patent system contemplates the public and its welfare. Why then should the patent system be used to constitute a barrier to public welfare?

Furthermore, the underlying basis of the inventive step is to determine whether the patentee makes a substantial contribution by advancing the state of art or field of technological and scientific knowledge, which would benefit society. The requirement of the inventive step is significant to the argument in this thesis that patent is purpose-driven, the purpose being to encourage the development and availability of new and significant technologies and inventions. Thus, a patent, as aforementioned, is more than a reward or an incentive for inventive activity. The patent system anticipates that the invention itself must have a significant purpose and confer a substantial advantage to society. However, it is argued that the benefit accruable to the public would have a better development impact if the public were able to access the invention. For example, a ground-breaking drug for the treatment of HIV/AIDS-related complications would no doubt, be useful to public health. An inventor who has brought about this new therapeutic treatment and seeks a patent in return for making it available will be offering a significant advantage to society. Its therapeutic benefit to society would, however, be better enhanced if patients were given the opportunity to access and use the drug to ameliorate their health.

Bently and Sherman (n 3) 530. The use of the word ‘quickly’ here is deliberate. It is assumed that an invention is a solution to a technical problem or a satisfaction of society’s needs posed by consumer demand. As ‘necessity is the mother of invention,’ it is conceivable that others would arrive at the same solution to the problem at a later time than the patentee did. However, having found a solution to the problem first (or indicated interest to seek patent protection first), the inventor promises to disclose his invention sooner rather than later, before others arrive at, or disclose the same result. Machlup and Penrose (n 9) 28.

Waelde and others (n 4) 448-449.
From a public policy point of view, the industrial applicability criterion also establishes that patents should satisfy some social function and contribute to societal goals and welfare through its utility and industrial applicability purpose. This is a point supported by Kuanpoth, that, the requirement of industrial applicability aims to enhance industrial and economic progress from the application of new technologies to practical spheres of development in a manner that responds to the needs of society. In a related manner, the invention must indicate that it serves a useful and meaningful purpose. In the case of medicines, for example, a patent application for an HIV/AIDS medicinal treatment would indicate that the invention serves some curative or health sustenance purpose. Likewise, the invention must be capable of being replicated and reproduced through the same means. This requirement is fashioned to ensure that a patented invention not only indicates an important advancement but that it can also be made and used in at least one field of scientific, industrial, technical and agricultural activity. This means that innovators do not invent ‘in the dark.’ The patent system expects that their inventions should have some public interest connotations and be a response to society’s welfare needs.

Thus, a patent is another mechanism for guaranteeing the public access to a new and significantly useful invention. Rather than being seen as a mere system for conferring and recognition of patentee’s rights, as Bently and Sherman put it, the ‘patent registration should be seen as a process in which

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83 Bently and Sherman (n 3) 440.
84 Bently and Sherman (n 3) 440-441.
85 de Carvalho (n 63) 27.
policy goals are implemented and enforced. This point has been articulated by the United States (US) Supreme Court in the case of *United States v Masonite Corp.* The US Supreme Court took the view that ‘[t]he promotion of the progress of science and the useful arts [i.e. technologies] is the “main object” [of the patent system]; reward of inventors is secondary and merely a means to that end.’ In line with this assertion, the US Supreme Court in *Motion Picture Patents Co. v Universal Film Mfg. Co.* shared a similar view that ‘the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is “to promote the progress of science and useful arts.”’ The court’s logic makes sense within the context of the public-related patents argument in this thesis.

The requirement to work a patent further strengthens the social policy aspect of patent system. In some countries, patent law requires that the patented invention is worked or exploited although the consequence of not working or exploiting the patent varies from country to country. In some instances, non-working of a patent may lead to a revocation of the patent licence and justify the grant of a non-voluntary licence to a third party wishing to exploit the invention or government non-commercial use in the public interest. In many instances, public interest (e.g. health, environment, economic/technological and scientific development, defence and national security, development of vital sectors, ...
misuse of patent monopoly rights and dependent patents) is given paramount importance and primacy with regards to patent law and rights.

In the case of compulsory licences, for example, society’s interest is taken into account to limit the exclusive rights of patent owners, even without the patentee’s permission, where it is expedient to do so. What this indicates is that the patent system does not exist solely in the interest of patent holders, in fact, where a patent is not serving its public purpose, the law can intervene to redirect it to ensure it does so. Therefore, public welfare is a necessary element of the patent system. As reiterated by the US Supreme Court in the anti-competition related case of *United States v Masonite Corp.*

> whilst the remuneration of genius and useful ingenuity is a duty incumbent upon the public, the rights and welfare of the community must be fairly dealt with and effectually guarded. Considerations of individual emolument can never be permitted to operate to the injury of these.

The argument made here is not whether the patent system actually leads to technological, pharmaceutical or scientific progress, but to emphasise that the patent system is not intended to leave the public out of its consideration. Consequently, since the material and objective nature of a patent indicates that the system exists within a certain public policy purpose, it is important for policymakers and the courts to take into account the public-driven aspect of the patent system in the design and interpretation of patent law and rights. From an access to medicines perspective, it should include the human and social

91 [1942] 316 U.S. 265, 278.
92 ibid (quoting from Mr. Justice Deniel in *Kendall v Winsor* [1858] 21 How. 322, 329.
93 In making this argument, this thesis is not oblivious to the criticism of the disclosure/enablement criterion. As pointed out by critics, despite the disclosure and enablement requirements, the actual disclosure in the patent claim may be incomplete, too technical and inadequate to enable others to utilise the disclosed knowledge. Luigi Alberto Franzoni (n 29) 112. Nonetheless, the arguments made here proceed on the assumption that, in a perfect world, the disclosed information in the patent application alone should be sufficient to facilitate the improvement and follow-on design as anticipated by patent law. Yu, *Intellectual Property and Information Wealth: Issues and Practices in the Digital Age* (n 37) 115.
development objectives of the system to users of the intellectual results and products.

In sum, there is a need to redirect the focus of patents to the benefits that society stands to gain from them. In this thesis, the point is made that the public benefit of having a patent system would be better enhanced if people actually had access to the patented technology and medicines and that the protection does not stifle incremental innovations which would benefit the public.

With this public perspective in mind, the next section examines the international system for the protection of patents, particularly, the TRIPS Agreement. This exposition also assesses the public nature of the system and its limitations. The introduction of the TRIPS Agreement and minimum IP standard in the Agreement has raised concerns with regards to patent rights and their effect on access to medicines; hence, the Agreement is significant to the analysis in this thesis.

2.5 The TRIPS Agreement from a Public Health and Access to Medicines Perspective

States generally sign up to treaties and international agreements to increase the social and economic welfare of their citizens. Equally, these international treaties and agreements serve the overall goal of integrating global interests and interdependence for better technological, social, economic and human development. In the context of enhancing the public’s socio-economic and technological development, the international trade-related TRIPS Agreement also underlies a public objective. It is often argued that all IPRs, including patents, in the TRIPS Agreement can promote socio-economic development by encouraging innovative R&D of medicines, technology transfer, FDI and
economic growth, which could also enhance the availability of and access to the products of this increased development within an international trade context.\textsuperscript{94}

On the other hand however, the provisions of the Agreement have been the subject of criticism and debate on the grounds that they could restrict access to important life-saving health treatments, particularly for the poor in developing countries,\textsuperscript{95} or limit the obligations of governments to fulfil their national duty to safeguard public health, as was the case in South Africa,\textsuperscript{96} Thailand\textsuperscript{97} and Brazil.\textsuperscript{98} To increase understanding of the TRIPS Agreement and the debate on the role of its patent system in underpinning the problems of access to medicines, it is first necessary to briefly consider the scope and negotiating history of the Agreement.

\subsection*{2.5.1 The TRIPS Agreement Negotiations}

The TRIPS Agreement was negotiated as part of the Uruguay Round mandate within the General Agreement on Tariffs and Trade (GATT) framework of the WTO.\textsuperscript{99} Contrary to some opinions,\textsuperscript{100} IP rules were contained in some GATT Articles.\textsuperscript{101} These pre-TRIPS provisions set the scene for the emergence of the


\textsuperscript{96} The cases of South Africa and Brazil are further examined in subsection 6.4 of Chapter VI.

\textsuperscript{97} In this case, the United States challenged the decision by the Thai Government to issue compulsory licence for patented HIV/AIDS drugs. ’t Hoen (n 50) 23.

\textsuperscript{98} In 2001, the United States instituted an action at the WTO Dispute Settlement Body (DSB) against the compulsory licensing provisions of Article 68 of the Brazilian Intellectual property law. ibid 24. (This case is further examined in Subsection 6.4 of Chapter VI.)

\textsuperscript{99} For a comprehensive history of the negotiation see Daniel Gervais \textit{The TRIPS Agreement: Drafting History and Analysis} (3nd edn, Sweet & Maxwell 2003). See also ’t Hoen (n 50) 9.

\textsuperscript{100} Ho (n 2) 59. (stating that ‘IP norms were never been part of the GATT framework’)

\textsuperscript{101} Article IX (6) of GATT, for instance, contained rules relating to marks of origin. See General Agreement on Tariffs and Trade (GATT) (1867 UNTS 187; 33 ILM 1153 1994) [Hereinafter GATT 1994].
TRIPS Agreement.\textsuperscript{102} In Article XX (d) of GATT, contracting parties could adopt measures ‘necessary to secure the compliance with laws or regulations which are not inconsistent with the provisions of this Agreement including […] protection of patents, […] and the prevention of deceptive practices.’\textsuperscript{103} The Article adds that the measures should not ‘result in unjustifiable discrimination between countries or be a disguised restriction on international trade.’\textsuperscript{104} This way, IP was generally considered in the context of GATT ‘as an “acceptable obstacle” to free trade,’\textsuperscript{105} although the United States (US) had begun to perceive these “acceptable obstacles” as unacceptable in the 1970’s.\textsuperscript{106} The international debate on the adoption and relevance of the TRIPS Agreement started when the more developed countries intensified efforts to include issues relating to IP into the global trading system and strengthen the standard of IP protection at the international trade level.\textsuperscript{107} At the Punta del Este Uruguay Round of multilateral trade negotiations in 1986, developed countries, prominently the US backed by Japan, presented a proposal to the Preparatory Committee appointed by GATT, to include aspects of IP on the agenda for the Round.\textsuperscript{108} The US justified the incorporation of IP on the trade agenda by putting forth the argument that developing countries were ‘free riding’ and

\begin{flushleft}
\textsuperscript{102} Gervais, \textit{The TRIPS Agreement: Drafting History and Analysis} (n 99) 5
\textsuperscript{103} ibid
\textsuperscript{104} Article XX (d) of GATT 1994.
\textsuperscript{105} Gervais, \textit{The TRIPS Agreement: Drafting History and Analysis} (n 99) 8
\textsuperscript{108} Carolyn Deere, \textit{The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries} (Oxford University Press 2009) 47. According to Peter Drahos, other developed countries including Canada, Switzerland, European Communities (EC) and UN organisations such as WIPO, were also vocal in pushing for intellectual property provisions during the negotiations of the multilateral trade rules, but the US was the most influential player. Peter Drahos, ‘Four Lessons for Developing Countries from the Trade Negotiations Over Access to Medicines’ (2007) 28 Liverpool Law Review 15.
\end{flushleft}
pirating technologies from developed countries, and that failure to enforce
intellectual property standards was an unfair trade practice.\textsuperscript{109}
From the outset, the developing countries, mostly represented by the Group of
Ten - Argentina, Brazil, Cuba, Nigeria, India, Egypt, Nicaragua, Peru, Tanzania
and Yugoslavia - vehemently opposed the inclusion of IPRs in issues of
international trade.\textsuperscript{110} In particular, Brazil and India were most vocal in opposing
the widening of the scope of GATT by incorporating IP minimum standards in
the trade forum and argued that it would undermine developing countries’
sovereignty in advancing their national development and health policies.\textsuperscript{111}
They also argued that matters relating to IPRs were outside the scope of
GATT’s competence and should be left out of the negotiations.\textsuperscript{112} They
contended that issues relating to IP and counterfeit goods were more suited to
the exclusive jurisdiction of World Intellectual Property Organization (WIPO).\textsuperscript{113}
Moreover, it was contested that the IP system was not suited to stimulating
developing countries’ innovative capacity.\textsuperscript{114} In a detailed paper elaborating the
developing countries’ perspectives on the negotiation, India argued that:

It would […] not be appropriate to establish within the framework of the General
Agreement on Tariffs and Trade any new rules and disciplines pertaining to the
standards and principles concerning the availability, scope and use of intellectual

\textsuperscript{109} Simon Walker, The TRIPS Agreement, Sustainable Development and the Public Interest: Discussion Paper (IUCN 2001) 8; Matthews (n 71) 5-6.
This point is further mentioned in subsection 2.5.2.
\textsuperscript{111} Drahos, ‘Developing Countries and International Intellectual Property Standard-Setting’ (n 107) 773; Walker (n 109) 8; Peter Drahos and John Braithwaite, Information Feudalism: Who Owns the Knowledge Economy (New Press 2003) 114.
\textsuperscript{112} Stoeva (n 110) 95-96; Drahos and Braithwaite (n 111) 114-115.
\textsuperscript{113} Simon Walker (n 109) 8; Peter Yu ‘The Objectives and Principles of the TRIPS Agreement’ (2009) 46 Houston Law Review 978, 984.
property rights. In our view, therefore, there can be no linkage between the basic principles relating to intellectual property rights and the GATT system.\textsuperscript{115}

The impending constraints to technological transfers and dissemination, the effect on generic competition and the increase in the cost of pharmaceutical and agricultural products in developing countries were also at the root of the resistance by the developing nations.\textsuperscript{116} India, particularly, expressed concern that the ‘monopolised and restrictive character’\textsuperscript{117} of exclusive IPRs ‘had wide implications’ for socio-economic and technological development, especially with regards to food production and healthcare.\textsuperscript{118} India further made the submission that developing countries should be allowed to exclude the patenting of pharmaceuticals, food, and chemical products from IP protection.\textsuperscript{119}

In spite of these objections, issues relating to the grant and protection of IPRs were included on the agenda of the Uruguay Round.\textsuperscript{120} At the end of a protracted period of negotiations, the TRIPS Agreement, with detailed rules for the general protection of IPRs, was adopted within the confines of multilateral trade rules at Marrakesh on April 1994 and entered into force on 1 January 1995. Nonetheless, the perspectives and views of both developing and developed countries on the significance of IP, particularly within a trade forum, are still divided.\textsuperscript{121}

The introduction of the TRIPS Agreement was a game changer for the international protection of IP, in that the Agreement for the first time introduced


\textsuperscript{116} t’Hoen (n 50) 10.

\textsuperscript{117} Government of India, GATT.MTN.GNG/NG11/W/37 (n 115) paragraph 3.

\textsuperscript{118} paragraph 4 ibid. See also t’ Hoen (n 50) 9-10.

\textsuperscript{119} Matthews (n 71) 9.

\textsuperscript{120} Government of India, GATT.MTN.GNG/NG11/W/37 (n 115) paragraph 7-8.

\textsuperscript{121} Yu, ‘The Objectives and Principles of the TRIPS Agreement’ (n 131) 980.
a uniform minimum standard for the creation and implementation of IP through the instrumentality of the WTO.\textsuperscript{122} Consequently, all WTO Members were required to implement the minimum patent standards in the Agreement, regardless of each member’s different level of economic and human development.\textsuperscript{123} The TRIPS Agreement contains substantive rules for the protection, availability and use of IPRs, as well as provisions for the administration and enforcement of IPRs.\textsuperscript{124} Patents granted to inventive products and processes that meet the conditions of newness, inventiveness (non-obviousness) and industrial applicability.\textsuperscript{125}

Although WIPO is a pre-TRIPS international organisation that promotes and regulates international IP,\textsuperscript{126} TRIPS introduced rules linking IP to trade, thus making private IP rights synonymous with trade issues. Furthermore, unlike the IP provisions in other international treaties and agreements, states can be sanctioned through the WTO’s Dispute Settlement Body (DSB) with respect to their obligation under the TRIPS Agreement.\textsuperscript{127}

\subsection*{2.5.2 A Preliminary Critique of the TRIPS Agreement}

The negotiation background leading to the emergence of the TRIPS Agreement reveals why the scope and content of the Agreement is one of the most debated components of the WTO trading system. It also says a great deal about the reasons why the system, despite its public interest objectives and flexibilities, is

\begin{footnotesize}
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\item \textsuperscript{122} t’Hoen (n 50) 9.
\item \textsuperscript{123} As stated previously, some countries were given an extension of the deadline to comply with TRIPS’s implementation.
\item \textsuperscript{124} Part III of the TRIPS Agreement.
\item \textsuperscript{125} Article 27(2). For a further discussion of the negotiation of the TRIPS Agreement see Peter Drahos and Braithwaite (n 111)
\item \textsuperscript{126} The organisation administers and regulates the Bern and Paris conventions respectively.
\item \textsuperscript{127} Susan K Sell, Private Power, Public Law: The Globalization of Intellectual Property Rights (Cambridge University Press 2003) 9. (Observing that ‘infractions in intellectual property can lead to sanctions on goods.’)
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seen not to cater to the social development needs of people in developing countries, particularly the poor.

A review of the negotiations leading to the emergence of the Agreement indicates that there was no consensus on the ways in which this system was relevant to the development priorities of all WTO Members, especially since many developing countries were mainly consumers rather than producers of IP. From a social and health policy perspective, developing countries expressed concern that the cost of the protection to crucial areas such as public health might be too high, yet the private interests of innovators, perceived benefits of FDI and technology transfer outweighed the development and healthcare concerns of people in developing countries.

Several scholars are in agreement that the introduction of IP into matters of global trade is at variance with the core purpose of opening up international borders for trade relations. Essentially, IP, as an exclusivity based system which creates monopolies, was protectionist in nature, hence it had little or no place in matters of trade. Indeed, t’Hoen asked ‘what was an agreement that created monopolies – which inherently restrict free trade and competition – doing in an institution whose main purpose was to encourage free trade and global competition?’

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128 ibid 8.
130 Commenting on the negotiation leading up to the TRIPS Agreement and final text, Professor Gervais writes,
132 t’Hoen (n 50) 9.
Other commenters note that developing countries conceded to the Agreement due to pressure from powerful, developed countries.\textsuperscript{133} The US, for example, threatened countries with trade sanctions and barriers using the so-called USTR ‘Special’ Section 301 provision of the Omnibus Trade and Competitiveness Act 1988, making it clear that the country would not hesitate to do same to other countries who were not IP compliant.\textsuperscript{134} The expectation was that the multilateral dispute settlement mechanism of the WTO would deter the US from taking unilateral action on the basis of the Trade Act.\textsuperscript{135} Despite this, however, the US has continued to arbitrarily use Section 301 to impose sanctions for ‘non-compliance with adequate standards’ of IP.\textsuperscript{136} It is also pertinent to note that the emergence of the TRIPS Agreement was facilitated by the support of pro-IP multinational businesses and corporations.\textsuperscript{137} This group, led by large pharmaceutical and copyright industries, intensely lobbied the United States Trade Representative (USTR) to include issues relating to IPRs into the international trade framework.\textsuperscript{138} These patent and copyright-reliant industries and businesses were vocal in putting forth the

\begin{itemize}
  \item Correa, ‘The TRIPS Agreement and Developing Countries’ (n 129) 423. Scholars such as Primo Braga and Fink noted that: The United States has continued to put unilateral pressure on countries where it felt that weak IPR systems disadvantaged U.S. companies. The two most prominent cases in this context were the dispute with Argentina on pharmaceutical patents, which in 1997 led to the removal of 50 per cent of Argentina’s benefits under the generalized system of preferences (GSP); and the dispute with South Africa, also on pharmaceutical patents, where the U.S.A reached a ‘joint understanding’ with South Africa in late 1999. The U.S. government did not initiate settlement proceedings under the WTO in these cases, partly because both countries were still under transition with regard to their TRIPS obligations and partly because some aspects of these disputes related to matters where the TRIPS Agreement has no specific obligation (e.g. parallel imports) or where the outcome of WTO arbitration would be highly uncertain (e.g. compulsory licences).


Deere (n 108) 49. The US routinely applied pressure by invoking Section 301 to investigate and sanction countries for ‘inadequate’ IP standards. Brazil, Argentina, India, Thailand, the People’s Republic of China and Taiwan were subject to US retaliatory measures. For further commentary on these disputes and discussions, see Alan O Sykes, ‘Constructive Unilateral Threats in International Commercial Relations: The Limited Case for Section 301’ (1992) 23 Law and Policy in International Business 263; Peter Drahos, ‘Developing Countries and International Intellectual Property Standard-Setting’ (n 107) 774.


ibid

ibid

ibid

ibid 5; Ho (n 2) 59.

133\textsuperscript{133} Correa, ‘The TRIPS Agreement and Developing Countries’ (n 129) 423. Scholars such as Primo Braga and Fink noted that:

The United States has continued to put unilateral pressure on countries where it felt that weak IPR systems disadvantaged U.S. companies. The two most prominent cases in this context were the dispute with Argentina on pharmaceutical patents, which in 1997 led to the removal of 50 per cent of Argentina’s benefits under the generalized system of preferences (GSP); and the dispute with South Africa, also on pharmaceutical patents, where the U.S.A reached a ‘joint understanding’ with South Africa in late 1999. The U.S. government did not initiate settlement proceedings under the WTO in these cases, partly because both countries were still under transition with regard to their TRIPS obligations and partly because some aspects of these disputes related to matters where the TRIPS Agreement has no specific obligation (e.g. parallel imports) or where the outcome of WTO arbitration would be highly uncertain (e.g. compulsory licences).


Deere (n 108) 49. The US routinely applied pressure by invoking Section 301 to investigate and sanction countries for ‘inadequate’ IP standards. Brazil, Argentina, India, Thailand, the People’s Republic of China and Taiwan were subject to US retaliatory measures. For further commentary on these disputes and discussions, see Alan O Sykes, ‘Constructive Unilateral Threats in International Commercial Relations: The Limited Case for Section 301’ (1992) 23 Law and Policy in International Business 263; Peter Drahos, ‘Developing Countries and International Intellectual Property Standard-Setting’ (n 107) 774.


ibid

ibid

ibid

ibid 5; Ho (n 2) 59.
argument that third parties, particularly in developing countries were ‘free riding,’ imitating and pirating technologies from developed countries and these acts were creating an unfair disadvantage to inventors and creators in the more developed countries.\textsuperscript{139} Fearing further loss of profit from alleged piracy and IPRs infringement in developing countries, the group submitted a report to the USTR for the establishment of a conducive international trade environment, ‘in which intellectual property was respected and protected.’\textsuperscript{140} The role that this business group played greatly shaped the framework of TRIPS as an instrument for the protection of private rights within an international trade context.\textsuperscript{141} Providing critical insight into factors that informed the eventual outcome of the Agreement, Braithwaite and Drahos argue that perhaps TRIPS would have been more sympathetic to the developmental concerns of developing countries if the negotiators had not been influenced by the demands of the pro-IP lobbyists.\textsuperscript{142} Although the Preamble, and Articles 7 and 8 of TRIPS Agreement, as will be discussed in the next section, contain provisions that sought to promote the public interests and make the IP system development friendly, it can be said that the fate of TRIPS with regard to the protection of monopolistic private IP rights was sealed from its foundation.

The TRIPS Agreement was also actively promoted as a strategic instrument for FDI, technology transfer, and an avenue for market access and enhancement of international trade.\textsuperscript{143} Thus developing countries were lured by the potential benefits in textile, agricultural and access to other trade markets to accede to

\textsuperscript{139} Matthews (n 71) 4.
\textsuperscript{140} ibid 6.
\textsuperscript{141} See the previous mention in subsection 2.3.2.
\textsuperscript{143} Donald P Harris, 'TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet Back against the United States' (2005) 25 Northwestern Journal of International Law & Business 99, 108-109; Correa, 'The TRIPS Agreement and Developing Countries' (n 129) 420. (It is noteworthy that the central focus of this chapter is however, not on whether IP promotes economic development, FDI and trade, but on how it fosters or impedes access to the existing products of pharmaceutical innovation.)
and impose stronger IP standards than most had under their national laws.\textsuperscript{144} Deere notes in this connection that some developing countries were swayed by promises of technological development and economic gains to accede to the TRIPS Agreement.\textsuperscript{145} However, whether the Agreement is sufficient to encourage the purported benefits and development, particularly to the developing or least developed world, is still open to debate.

In spite of the claims that TRIPS was necessary for the technological and economic development of members, there was no empirical evidence to indicate that stringent IP rules alone would facilitate this development, especially in developing countries.\textsuperscript{146} In the case of FDI, for example, IP scholars and economists, including Carlos Primo Braga, Carsten Fink and Keith Maskus, demonstrate that stronger IP fosters foreign investment if the country has an effective industrial structure, competitive market and capacity to assimilate the foreign goods and technologies.\textsuperscript{147} As Fink and Maskus pointed out, ‘[a] poor country hoping to attract inward FDI would be advised to improve its overall investment climate and business infrastructure than to strengthen its

\textsuperscript{144} Timmermans and Hutadjulu (n 135) 11. It was also noted that many developing countries accepted the Agreement to gain access to the rich markets in, or opportunities for aid from developed countries. Keith Maskus, ‘Intellectual Property: Balancing Incentives with Competitive Access’ in Richard Newfarmer, \textit{Global Economic Prospects and the Developing Countries} (The International Bank for Reconstruction and Development and The World Bank 2002) 129.

\textsuperscript{145} Carolyn Deere points out that IP advocates often argue that ‘stronger IP protection would encourage foreign direct investment (FDI), innovation, and technological transfer, and spur the development of national cultural and creative industries.’ Deere (n 108) 9.

\textsuperscript{146} While evidence suggests that IPR is essential for investment in chemicals and pharmaceutical R&D, the bulk of this evidence holds true for the industries in many developed countries. The CIPR reports in this respect that ‘IPRs may be a significant factor in the decision by firms to invest. But the investment decision is contingent on many factors. For most low technology industries, of the kind that less technologically advanced developing countries are likely to attract, IPRs are unlikely to be a relevant factor in the investment decision.’ Commission on Intellectual Property Rights, \textit{Integrating Intellectual Property Rights and Development Policy} (Commission on Intellectual Property Rights 2002) 23.

patent regime sharply, an action that would have little effect on its own.\textsuperscript{148} With limited industrial infrastructures and weak technological structures, there was little to suggest that increased IP protection would facilitate the supposed technological development, FDI and technology transfer to developing countries.\textsuperscript{149} In the case of patent protection, for example, many developing countries may lack the necessary industrial, technical and manpower capacity to effectively draw on the benefits of a patent system. As Maskus argues, if stronger IP protection always led to more FDI, then ‘recent FDI flows to developing economies would have gone largely to sub-Saharan Africa and Eastern Europe […] [instead of] China, Brazil, and other high-growth, large-market developing economies with weak IPRs.’\textsuperscript{150}

Moreover, increased technological development and social benefits are historically associated with flexible and weaker IP protection in developing countries.\textsuperscript{151} India, for example, relied on malleable IP laws to achieve a great level of technological advancement and develop its pharmaceutical sector.\textsuperscript{152}

Ironically, developed countries such as the US had lax IP laws until the early


\textsuperscript{149} Correa, ‘The TRIPS Agreement and Developing Countries’ (n 129) 420.

\textsuperscript{150} Maskus, ‘The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer’ (n 147) 129.

\textsuperscript{151} Commission on Intellectual Property Rights, \textit{Integrating Intellectual Property Rights and Development Policy} (n 146) 22. Scherer also observes that ‘[i]t is reasonably well established in the economics literature that, especially in a world of AIDS and resistant tuberculosis epidemics, low-income nations enjoy higher economic welfare when they can free-ride on pharmaceutical innovations made and patented in the first world than when they must pay monopolistic prices for the newest and most effective drugs.’ FM Scherer, ‘A Note on Global Welfare in Pharmaceutical Patenting’ (2004) 27(7) World Economy 1127, 1127.

\textsuperscript{152} The Indian Patent Act of 1970 disallowed product patents for drugs. Only processes could be patented, and that too only for a period of five years. Sudip Chaudhuri, \textit{The WTO and India’s Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries} (Oxford University Press 2005) 37. This law was based on the recommendation of the Ayyanger Committee against product patents on the ground that monopoly rights over products limits access to vital products such as food and medicines by granting absolute powers to MNC at the expense of public interest. N Rajagopala Ayyangar, \textit{Report on the Revision of the Patents Law} (Ministry of Commerce and Industry Manager of Publications, 1959). The absence of product patents enabled the industry to perfect the art of reverse engineering and copying of foreign patented products, which led to an increase in the local production of medicines. Furthermore, the Patents Act created a conducive environment for competition to thrive in the pharmaceutical market by eroding the monopoly powers of MNC to patent final products of innovative medicines. William J Bennett, ‘Indian Pharmaceutical Patent Law and the Effects of Novartis Ag v. Union of India’ (2014) 13 Washington University Global Studies Law Review 535, 541-542.
1980’s. Many European countries and the US were accused of violating the IPR of other countries right into the twentieth century. As Ta-hong Chang argues, developed countries were kicking away the ladder by ‘demanding from developing countries institutional standards that they themselves had never attained at comparative levels of development.’ Indeed, one scholar observes that ‘the old era of IP was as much a consequence of intellectual capitalism as a cause of it, and […] was not a necessary condition for the emergence of the industries and technologies that fostered it.’

Equally, the Commission on Intellectual Property Rights (CIPR) observes that developing countries in their nascent stage of development require different IP policies according to their levels of development. The CIPR states in this respect that:

[...] for most developing countries with weak technological capacity, the evidence on trade, foreign investment, and growth suggests IP protection will have little impact. Nor is it likely that the benefits of IP will outweigh the costs in foreseeable future. For more technologically advanced developing countries, the balance is finer. Dynamic gains may be achieved through IP protection, but at a cost to other industries and consumers.

It appears, therefore, that higher IPR provisions are more suitable for countries that have achieved a considerable level of industrial growth. That way, it supports the capacity for greater industrial, scientific and technological efficiency. For developing countries with insufficient manufacturing or technological capacity, the rules may not confer significant benefits, conversely,

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153 Sell (n 127)13.
154 Ha-joon Chang, Kicking Away the Ladder: Development Strategy in Historical Perspective (Anthem press 2003) 2, 126.
155 ibid 10, 135.
the patent rules may also have the effect of restricting access to pharmaceuticals for the poor.

Nevertheless, on the positive side, the goals, principles and objectives of the TRIPS Agreement contain provisions that take into account the needs of both producers and users of IP as well as some development concerns of developing countries.

2.5.3 Goals of the TRIPS Agreement from a Public Interest Standpoint

There are two ways of thinking about the goals and function of the TRIPS Agreement. First, it is a legal institution that provides rules for the protection and regulation of private proprietary rights of an innovation or invention. For this purpose, the Preamble recognises the need for ‘the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights,’ and reiterates that IP rights are private rights. The provisions in the Agreement generally provide exclusive and time-specific IP-related rights and privileges. These IP rules and rights are, however, not devoid of public interest and welfare objectives.

A second approach is to view the TRIPS as an instrument for promoting trade, scientific and technological advancement, as well as human, social and economic development through the instrumentality of IP protection. For example, the Preamble to the Agreement highlights this objective by explicitly referring to the need to protect IPRs and promote international trade relations by reducing

[...] distortions and impediments to international trade [...] taking into account the need to promote effective and adequate protection of intellectual property rights,

See the Preamble to the TRIPS Agreement. As private rights, matters relating to IP are issues for determination by civil law and procedures.
and to ensure that measures and procedures to enforce intellectual property rights
do not themselves become barriers to legitimate trade.\(^{159}\)

The TRIPS Agreement also aims to promote a developmental objective for IP to contribute to technological innovation, knowledge-based economic growth and technological diffusion. This intention is expressed in the Preamble to the Agreement which recognises ‘the underlying public policy objectives of national systems for the protection of intellectual property including development and technological objectives.’\(^{160}\) In the context of public health, it suggests that WTO members can take into consideration, the developmental needs of their citizens to have access to medicines under their national systems.\(^{161}\) It also means that members can implement the Agreement in a manner that promotes their national technological and R&D priorities, public interest and health objectives. This public welfare development goal of the TRIPS Agreement is consistent and can be read together with the WTO goals which state that:

\[\ldots\] relations in the field of trade and economic endeavour should be conducted
\textit{with a view to raising standards of living}, ensure full employment and a large and steadily growing volume of real income and effective demand and expanding the production of and trade in goods and services, while allowing for the optimal use of the world’s resources in accordance with the objective of sustainable development,\[\ldots\] and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development.\(^{162}\)

In this manner, while the WTO’s IP system has been framed as an instrumental institution for the creation and protection of IP, which includes patented

\(^{159}\) Preamble to the TRIPS Agreement.

\(^{160}\) Preamble to the TRIPS Agreement.

\(^{161}\) This argument is consistent with Article 1(1) of the TRIPS Agreement which states that ‘[m]embers shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.’ Sisule F Musungu, ‘The TRIPS Agreement and Public Health’ in Carlos María Correa and Abdulqawi Yusuf (eds), \textit{Intellectual Property and International Trade: The TRIPS Agreement} (Kluwer Law International 2008) 427.

pharmaceutical products and processes, its underlying objective lies in a broader development mandate.

### 2.5.4 The Public Interest Objectives and Principles of the TRIPS Agreement in Articles 7 and 8

Article 7 has been described as the balancing and 'interpretive provision' of the TRIPS Agreement.\(^{163}\) It sets out the principal objective of the Agreement and plays a central role in the interpretation and enforcement of TRIPS.\(^{164}\) The provision states that IP protection and implementation should promote technological innovation and dissemination, and also links this protection to the promotion of social and economic development as follows:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Significantly, this provision delineates the core public interest objectives of the TRIPS Agreement.

The first objective envisages that the protection and recognition of IPRs should result in improvements in technology, knowledge and innovation. This supports the argument made earlier in subsection 2.4 that a patent, a form of IP, is not an end in itself. It can be said that this provision not only describes the technological purposes of the IP provisions in the TRIPS Agreement, it

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\(^{163}\) Gervais, _The TRIPS Agreement: Drafting History and Analysis_ (n 99) 203; Yu, 'The Objectives and Principles of the TRIPS Agreement' (n 113) 981.

The interpretative and balancing importance of Article 7 was reflected in the Canada-Patent Protection for Pharmaceutical Products dispute before the WTO Dispute Settlement Body (DSB). See Canada - Patent Protection of Pharmaceutical Products - Complaint by the European Communities and their Member States: Report of the Panel (WT/DS114/R, March 17 2000). This case is also considered in detail in Chapter VI of this thesis, subsection 6.10.

\(^{164}\) Yu, 'The Objectives and Principles of the TRIPS Agreement' (n 113) 981.
encapsulates the public agenda behind the Agreement and defines IP protection as a means to an end.\footnote{Yu, ‘The Objectives and Principles of the TRIPS Agreement’ (n 113) 1004-1005.} Thus, IP is an instrument for the advancement of technological dissemination, knowledge and innovation, which should also promote socio-economic development and public welfare. This point was made further by the submission of developing countries, including Nigeria, to the TRIPS Council before the Doha Ministerial Conference that, ‘Article 7 [...] clearly establishes that the protection and enforcement of intellectual property rights do not exist in a vacuum. They are supposed to benefit society as a whole and do not aim at the mere protection of private rights.’\footnote{Council for Trade-Related Aspects of Intellectual Property Rights ‘Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela’ (IP/C/W/296, 2001) Paragraph 18. Available at <https://www.wto.org/english/tratop_e/trips_e/paper_develop_w296_e.htm > accessed 17 July 2016. See also Yu, ‘The Objectives and Principles of the TRIPS Agreement’ (n 113) 1004-1004.}

The second objective seeks to protect and promote both the interests and contributions of authors/innovators as IP producers, at the same time as the interests of users of IP who, according to Correa, are ‘interpreted as encompassing final consumers as well as producers of goods and services that utilize technological knowledge.’\footnote{Carlos Maria Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (Oxford University Press 2007) 19.} Thus not only does IP in TRIPS grant rights to and impose obligations on innovators, it also acknowledges the ‘equal’ rights and obligations of public users to access and use intellectual products and technological knowledge.\footnote{Yu, ‘The Objectives and Principles of the TRIPS Agreement’ (n 113) 12.} This objective can be invoked as a support for public health and access to medicines. From a public health perspective, it can be argued that it envisages that patients, as users, should gain some advantage from medicines which are products of intellectual creation. To gain this benefit, however, it is obvious that patients will need access to the drugs.
This second objective also reflects the need to find a balance between encouraging incremental creativity innovation and promoting users’ and society’s interests.\textsuperscript{169} The balance, according to Gervais, should be assessed using well-established IP legal principles and identified that the balance entails:\textsuperscript{170}

a) rewarding or compensating creators and inventors for innovation and;

b) promoting the interest of businesses and the public at large in securing access to science, technology and culture.

Gervais concludes that ‘[i]n order to stimulate innovation, this balance must be maintained.’\textsuperscript{171}

While it is argued that maintaining this balance is essential to stimulate incremental innovation,\textsuperscript{172} the question remains, how can this balance be achieved? Gervais provides insight into the outline of this ‘balance.’ At the policy level, it requires granting inventors rights in a manner that allows them to recoup investment costs without hindering competition or future innovation.\textsuperscript{173} In other words, inventors’ right must be weighed against the need for the public and users to access the products and information about the innovation.\textsuperscript{174} While this is ideal, in practice, finding a balance between protecting the short-term interests of IP owners whilst simultaneously promoting long-term investment in innovation and creativity and benefits to users is hard to achieve. Sometimes, the interests of IP producers and users might conflict. This is often the case where tension arises between the need to provide incentives for pharmaceuticals R&D and the need to access essential drugs.


\textsuperscript{170} Gervais, The TRIPS Agreement: Drafting History and Analysis (n 99) 204.

\textsuperscript{171} ibid 204.

\textsuperscript{172} ibid

\textsuperscript{173} ibid

\textsuperscript{174} ibid
The third objective, reflects the need to take into account ‘social and economic welfare,’ development and the advancement of both IP producers and the public in the protection, interpretation and enforcement of IP. In this manner, TRIPS seeks to strike a balance between the objectives of promoting IP as an incentive to encourage invention, and requiring the protection to contribute to social-economic, welfare and technological development goals. The emphasis is important because it positions the TRIPS Agreement not only as an instrument for the protection of IP rights but also as a means for promoting societal welfare and development as argued in the preceding section of this chapter. The provisions of Article 7 can be read together with Paragraph 19 of the Doha Ministerial Declaration which states that ‘[i]n undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.’ The Resource Book on TRIPS and Development also makes the point that Article 7 clearly indicates that the negotiators of TRIPS did not intend to ‘abandon a balanced perspective on the role of intellectual property in society.’ Thus, the Agreement intends that patent rules should play a significant role in promoting, not hindering the public welfare and interests.

Article 8 is another ‘interpretative or normative principle’ of the TRIPS Agreement that further state the public policy objective of patents and other IPRs in the Agreement. Its importance has been acknowledged by Professor Peter K Yu as a framework to limit the exclusive rights granted to IP holders in

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177 ibid
the interests of the public.\textsuperscript{178} Provided it is consistent with the general standard in TRIPS, the provision of Article 8 permits members to promote the public interest in sectors of vital importance to their socio-economic development, with particular stress on nutrition and health. Article 8(1) provides that:

Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

Thus, WTO members are allowed some flexibility to pursue their public policy objectives by incorporating and implementing measures, including policies, to safeguard the national public interest, health, nutrition and socio-development priorities in their domestic laws.\textsuperscript{179} According to Professor Correa,

Article 8.1 broadly recognizes Members’ rights ‘in formulating or amending their laws and regulations’[…] [I]t does not only refer to laws and regulations on IPRs but to measures adopted in other fields, for instance, those that restrict the manufacture or commercialization of IPR-protected goods. Issues concerning the application of Article 8.1 may, hence, arise in two contexts, one fully within the IPR realm, and another one outside it, but with implications on the protection of IPRs.\textsuperscript{180}

Importantly, Article 8(2) adds support to the Article 8(1) by recognising the need to adopt appropriate measures to prevent the abuse of patent rights by

\textsuperscript{178} Yu, ‘The Objectives and Principles of the TRIPS Agreement’ (n 113) 1008-1009.

\textsuperscript{179} In European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs the Panel in interpreting Article 8 stated that

These principles reflect the fact that the TRIPS Agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather provides for the grant of negative rights to prevent certain acts. This fundamental feature of intellectual property protection inherently grants Members freedom to pursue legitimate public policy objectives since many measures to attain those public policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement.


\textsuperscript{180} Carlos María Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (n 167) 104.
patentees, including practices that unduly restrain trade, or hamper technology transfer, in a TRIPS-consistent manner.\textsuperscript{181}

In summary, from a public health point of view, the Preamble, Articles 7 and 8 of the TRIPS Agreement outline the importance of the Agreement in the interests of society and importantly, the promotion and safeguarding of public health. It is imperative therefore, to approach this international IP system from this perspective.

From the above public interest discussion of patents, the next section examines the Nigerian patent system. The section also inquires whether the patent framework in Nigeria is explicitly public welfare-friendly and reasons for any inconsistencies.

2.6 THE ADAPTATION OF A WESTERN STYLE PATENT SYSTEM IN NIGERIA: AN ENQUIRY INTO THE EVOLUTION OF PATENT LAW AND ITS INADEQUACIES

The development of the patent law and system in Nigeria can be best split into two key eras for analytical convenience: the colonial and post-colonial periods.

2.6.1 Colonial Development of Intellectual Property and Patent System

It is plausible to say that the evolution of the patent law and system in Nigeria was devoid of underlying national or public interest considerations. Reasons may be traced to its colonial origins. The current patent system is a product of the British colonial administration. The introduction of the English Legal System

\textsuperscript{181} The Article provides that

Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

See more at Yu, ‘The Objectives and Principles of the TRIPS Agreement’ (n 113) 1010-1013, 1016.
including patent laws was part of the administrative framework of the British colonial authorities in the colonies comprising present-day Nigeria.\(^\text{182}\) The first national patent legislation in Nigeria was the Patents Ordinance No.17 of 1900 of the Colony of Lagos.\(^\text{183}\) At the same time, the Patents Proclamation Ordinance No.27 of 1900 was made applicable to the Protectorate of Southern Nigeria\(^\text{184}\) and the Patents Proclamation Ordinance No.12 of 1902 was subsequently applied to the Protectorate of Northern Nigeria.\(^\text{185}\) The legal rules provided for the establishment of patents offices and an administrative system for the regulation, granting and control of patents in Nigeria.\(^\text{186}\) The administration of patents was under the control of a registrar and his deputy.\(^\text{187}\) Applications were made to the patents office for the registration and granting of patents for inventions and appeals against decisions, if any, were made to the Attorney-General.\(^\text{188}\) Successful patents were thereafter granted in the name of the British Crown by the High Commissioner.\(^\text{189}\)

The Patent Ordinance and Patent Proclamation Ordinances of 1900 and 1902, with subsequent amendments, were repealed after the 1914 amalgamation of the Northern and Southern Protectorates into Nigeria.\(^\text{190}\) Following the unification of the Protectorates, the Patent Ordinance No. 30 of 1916 was made

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\(^{185}\) ibid

\(^{186}\) Galus Ezejiofor, ‘The Law of Patents in Nigeria: A Review’ (1973) 5(9) The Journal of Legal Pluralism and Unofficial Law 39, 40. The patent administration system was similar to the English administrative system and the Registrar exercised a function that was carried out by the Comptroller of the patent office in Britain. ibid 40.

\(^{187}\) Ezejiofor (n 186) 40.

\(^{188}\) ibid

\(^{189}\) ibid

\(^{189}\) Mwalimu (n 183) 518-519. (The Patent Ordinance of No. 30 1916 was in force in other British colonies like Sierra Leone, Uganda and Hong Kong before its inception in Nigeria on 13 July 1916.) Umahi (n 182) 9.  

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to apply to all parts of the newly created Nigeria.\textsuperscript{191} The 1916 Ordinance with amendments was later renamed and re-enacted as the Registration of United Kingdom Patents Ordinance No. 6 of 1925.\textsuperscript{192}

The 1925 Ordinance was a radical departure from its predecessors.\textsuperscript{193} One of the fundamental changes was that a patent could no longer be granted in Nigeria.\textsuperscript{194} Effectively, it terminated the independent patent registration system in Nigeria, and instead, established a system of patent registration that was dependent on the granting of patents in the United Kingdom (UK).\textsuperscript{195} By this extension, patent rights granted in the United Kingdom were valid in Nigeria, provided the application to register the patent was made to the Registrar of patents in Nigeria within three years from the date of the patent in the UK.\textsuperscript{196} By way of illustration, an inventor, whether a Nigerian, or anyone who desired a Nigerian patent protection, could only procure one by first obtaining a UK patent before registering the same invention in Nigeria.\textsuperscript{197} The validity of the Nigerian patent remained in force as long as the patent was still active in the United Kingdom.\textsuperscript{198}

A possible explanation for terminating the autonomous system was that the colonial masters wanted to save the cost of maintaining an independent patent office and employing knowledgeable technical staff to evaluate patent

\textsuperscript{191} As contained in Cap. 141 of 1923 edition of Laws of Nigeria and Lagos. ibid
\textsuperscript{192} Issued in Chapter 182 Laws of the Federation of Nigeria and Lagos 1958.
\textsuperscript{194} Ezejiofor (n 186) 41.
\textsuperscript{195} ibid 42; Yankey (n 1) 117-120.
\textsuperscript{196} For instance, a patentee in the UK or a person claiming through him could within three years of achieving a UK patent, apply for a patent to the Registrar of patents in Nigeria to have his patent recognised and registered. See Section 3 of the 1925 Ordinance. Ezejiofor (n 186) 42.
\textsuperscript{197} Ezejiofor (n 186) 42; Yankey (n 1)118.
\textsuperscript{198} Section 7 of the 1925 Ordinance; ibid
In effect, the autonomous Nigerian patent system that had been in existence under the 1900-1916 Ordinances, was terminated. Ezejiofor (n 186) 42; Yankey (n 1) 117-120.
applications in Nigeria.\textsuperscript{199} It is also likely that the lack of local expertise on the patentability of inventions, and the required personnel with technical knowledge of the patent system necessitated the adoption of the UK dependent Ordinance.\textsuperscript{200} This is made obvious in the justification for adopting the Ordinance by the Attorney-General of the Colony of Nigeria in the report on the draft Patent Ordinance of 1916:

> It is frequently impossible to obtain locally that expert advice which is required by the authority responsible for deciding whether or not a patent should be granted, and in the circumstances it is submitted that persons desiring to obtain protection in Nigeria, for an alleged invention may probably be required to satisfy first the Patents Office in the United Kingdom that his invention is one for which a patent should be granted.\textsuperscript{201}

Thus, rather than train the required local officers at the patent office or employ additional technically knowledgeable staff to handle patent applications in Nigeria, the British authorities thought it best to simply alter the extant autonomous patent system and instead, align it with the UK’s. Another reason for this variance may simply be the administrative convenience of protecting the colonial territorial interest.\textsuperscript{202}

Besides the onerous time delay of obtaining a patent in this system, the most serious disadvantage of this dependency arrangement is that it took away the opportunity to build local expertise, train indigenous Nigerians to evaluate patent applications, or develop an IP culture that would cater for local needs.\textsuperscript{203}

\begin{itemize}
\item \textsuperscript{199} Bankole Sodipo, Piracy and Counterfeiting: GATT, TRIPS and Developing Countries (International Economic Development Law 1997) 30-31.
\item \textsuperscript{200} Yankey (n 1) 115.
\item \textsuperscript{202} Sodipo (n 199) 30-31.
\item \textsuperscript{203} Commentators note, for example, that there was there was no formal training on the art of invention to local artisans. Sodipo (n 199) 31.
\end{itemize}
Gaius Ezejiofor observes that the imposed patent system also took away the sovereignty and independence of Nigeria as a state to order its domestic and local affairs.\textsuperscript{204} It also produced a cumbersome and inconvenient process for the registration of an invention.\textsuperscript{205}

From the historical description above, it is clear that patent law in Nigeria was introduced in order to entrench the dominance of the imperial power and not for the usual justification of increasing or supporting innovation and promoting the productivity of national inventions. The common rationale for the patent system is that it is a hallmark for technological/scientific development and economic growth, since it spurs inventiveness and R&D and technology transfer as suggested above.\textsuperscript{206} Also, historical analyses indicate that the IP and patent system of many industrialised countries evolved from the need to protect and encourage local inventors, promote the dissemination of inventions and develop national industries.\textsuperscript{207} However, the introduction of patent system in Nigeria, and neighbouring West African countries such as Ghana, that shared the same British law, did not rest on the usual technological development argument, neither was it meant to serve the national interest, nor support indigenous innovative growth, nor encourage the development of the relevant sectors in Nigeria.\textsuperscript{208} There is no evidence to indicate that the patent system was directed towards facilitating technological and economic development in Nigeria.

From its functional and administrative structure, it appears that the patent system was enacted for the benefit of the colonial interest, to protect the

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\item[\textsuperscript{204}] Ezejiofor (n 186) 44.
\item[\textsuperscript{205}] Sections 5 and 6 of the 1916 Ordinance; ibid
\item[\textsuperscript{206}] See the arguments in subsections 2.3.2, 2.3.3 and 2.3.4.
\item[\textsuperscript{207}] Sodipo (n 199) 50.
\item[\textsuperscript{208}] Yankey (n 1) 104-106
\end{itemize}
\end{footnotesize}
material base and mineral resources of the colonised regions. Many analysts agree that the strategy adopted by the colonial powers was mainly for purposes associated with imperialist interests and control of trading rights among the colonies. Ruth Gana provides a useful account of how Europe’s conceptualisation of law influenced the development of IP in developing countries during colonialisation. Reflecting on this process, Ruth Okediji Gana assesses that IP was more than a mere regulation; it was ‘a central technique in the commercial superiority sought by European powers in their interactions with each other beyond Europe.’ Accordingly, it was ‘characterised by efforts to secure national economic interest against other European countries in colonial territories.

One great puzzle is how the foreign-dependent patent system could possibly function as an instrument for promoting national innovation and technological development in Nigeria when there was no framework that would ensure local benefits, such as the skills training of local patent agents or the education of inventors on the importance of a patent system for them.

Despite these shortcomings, the 1925 Ordinance in Nigeria remained in force until 1970, well after independence.

2.6.2 The Post-Colonial Patent System in Nigeria

Following Nigeria’s independence in 1960, the independent Nigerian Government failed to redress the issue of patent registration’s dependency on

209 ibid 8.
210 Deere (n 108) 36.
213 ibid 325.
214 Sodipo (n 199) 31.
the Britain system until ten years after the country regained its right to sovereignty.\textsuperscript{215} In spite of the fact that some new industries were being set up that were exclusively or partly owned by Nigerians and foreign parties after independence, the IP laws were not amended accordingly to conveniently enable local inventors to register their patents.\textsuperscript{216} This national policy shortfall might have been a result of the fact that in a few years after independence, the commencement of a civil war disrupted the Government’s proposed national development plans and the military administration in power was preoccupied with other pressing national issues.\textsuperscript{217}

The case of \textit{Rhone-SA Poulenc and May & Baker v Lodeka Pharmacy} in 1965 set the pace for the revision of an independent patent system and administration in Nigeria.\textsuperscript{218} The facts of the case are as follows. The first claimant, in 1951, registered a patent in the UK for an ‘improvement in or the new phenothiazine derivatives.’\textsuperscript{219} In 1957, the patent was afterwards registered under the 1925 UK Patent Ordinance with the second plaintiff as a subsidiary and exclusive licensee of the first claimant. The second plaintiff, May and Baker commenced the sale and distribution of the product under the name ‘\textit{Largactil}.’ In 1964, the Federal Ministry of Health, Nigeria engaged the services of the defendant, a local pharmaceutical firm, to supply the patented product in large quantities to the Ministry of Health. The claimants commenced actions against the defendant alleging an infringement of their patent rights. The defendant, whilst acknowledging the patent rights of the claimants, contended that the

\textsuperscript{216} Ezejiofor (n 186) 44; Sikoyo, Nyukuri and Wakhungu (n 193) 19.
\textsuperscript{218} Lagos Law report (L.L.R) 9.
\textsuperscript{219} Yankey (n 1) 122-123.
supply was for public use by the Federal Ministry of Health and so the public interest use would override the infringement claim. The defendant consequently relied on the Government use provision in Section 46 (1) of the United Kingdom Patents Act 1949 which states that:

Notwithstanding anything in this Act, any Government department, and any person authorised in writing by a Government department, may make, use, and exercise any patented invention for the service of the Crown in accordance with the [...] provision of this section.

In the determination of the case, the trial judge held that the defendants could not rely on the public use provision as under the UK Patent Act. Although Ikpeazu J (as he then was) agreed that section 46(1) of the UK Patent Act was an express Act that specifically confers power to Government departments to override the patentee’s rights, his Lordship was of the view that the UK Patents Act 1945 did not apply in totality to Nigeria, and so Section 45(1) could not be relied on by the defendant. Furthermore, the only significant effect the UK Patent Act had was in respect to the rights and privileges that ensued from the issuance of a certificate after the registration of a UK patent in Nigeria pursuant to Section 6 of the 1925 Patents Registration Ordinance.

It appears that the judge did not allow the application of the United Kingdom Patent 1949 Act in Nigeria because there was no clear indication that the UK’s Patent Act had entire applicability in Nigeria, and it was not expressly or implicitly stated that all its provisions had been extended to Nigeria by the 1925 Registration Ordinance except with regards to a certificate of registration under Section 6 of that Ordinance.220 His Lordship further observed that to limit the patentee’s exclusive rights for public policy reasons, the Nigerian legislature

220 Yankey (n 1) 125.
had to expressly make provisions conferring powers to the government department to grant permission to unauthorised third parties who wished to supply the patented product. In the absence of this provision, section 46 (1) of the 1949 UK legislation could not grant such powers. The judge concluded that this had not been done in Nigeria; hence the legislature did not intend the power to exist.

Significantly however, the outcome of the decision in the case led to the promulgation of the Patent (Limitation) Decree of 1968.221 Similarly to the provisions of section 46 (1) of the UK Patent Act, the Decree made provisions for the use of certain inventions in the public’s interest by the government and authorised third parties in Nigeria.222 The law also contains certain provisions for the use of a patented article in the event of emergencies to purchase, make, vend, use and exercise the patented invention for any purpose at the discretion of the Commissioner in the interest of the public.223 Unfortunately, under section 5(1) and (2) of the Decree, the provisions and effect of the United Kingdom Patent Act of 1949 were fully extended to Nigeria.224 Effectively, the entire provisions of the UK patent laws were made to apply in Nigeria. There was absolutely no reasonable justification for this incorporation.225 The Nigerian legislative authority could have simply amended its laws to include the same provisions (including exceptions) as the UK Act if the intention had been to rely on similar provisions in the UK Patent Act.

A review of the Patent (Limitation) Decree of 1968 shows that it was enacted out of necessity, therefore it merely adopted the United Kingdom’s Patents Act

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221 Yankey (n 1) 126.
222 Section 1(1) of the Decree. Ezejiofor (n 186) 39-43; Mwalimu (n 183) 519-520.
223 Section 15 Patents (Limitation) Decree of 1968. See also Ezejiofor (n 186) 39-43; Mwalimu (n 183) 519-520.
224 Mwalimu (n 183) 520.
225 Yankey (n 1) 129.
of 1949 and the previous 1925 Ordinances as the statutory law regulating the patent system in Nigeria and made amendments thereof only subject to the minor modifications introduced in the Decree.\textsuperscript{226} In any case, there was no reason for Nigeria to adopt the same standards and provisions of UK patent law, considering the stage of its technological and economic development at that time. There was little to indicate that the Patent Decree showed an appreciation for indigenous inventive activity or set out to deliberately encourage local innovation or to spur further inventions to promote the public’s welfare.\textsuperscript{227} As Yankey noted, the Decree was not founded on any national planning consideration or a coherent and comprehensive national technology policy.\textsuperscript{228} It is little wonder that this Decree was also ill-suited to encourage the innovative progress of the new indigenous industries that were springing up after independence.\textsuperscript{229} For example, the grant of patents was still subject to a registration system in the UK.\textsuperscript{230} This process proved too cumbersome and inconvenient to the registration of new inventions.\textsuperscript{231} Thus ironically, the country was no longer under colonial administration, yet it sustained reliance on its former colonial authorities’ laws.


In the light of the above noted inadequacy of the Patent Decree 1968, the Patents and Designs Decree of 1970\textsuperscript{232} (now the Patents and Designs Act 1970 (PDA)) was enacted to set out provisions for a national statutory and

\textsuperscript{226} Ezejiofor (n 186) 44.
\textsuperscript{227} Ibid 44.
\textsuperscript{228} Yankey (n 1) 211.
\textsuperscript{229} Ezejiofor (n 186) 44.
\textsuperscript{230} Section 5(1) of the Decree.
\textsuperscript{231} Ezejiofor (n 186) 39-43.
\textsuperscript{232} No. 60 of 1970.
administrative patent regime.\textsuperscript{233} The PDA contains detailed provisions for the procurement of patents in Nigeria and sets out to facilitate inventive enterprise in the budding indigenous industries.\textsuperscript{234} Effectively, the PDA made provisions for the establishment of an independent national patent system to grant patents to new inventions or significant improvements that possesses high inventive qualities and are industrially inclined.\textsuperscript{235}

Nonetheless, at the time the legislation was passed, there was no national policy consideration or technology planning to ensure the practical public benefit of having a patent system, neither was the system designed to suit the economic structures and needs of the country at that time.\textsuperscript{236} For instance, the patent legislation provided an exclusive set of rights to the patent holder for a period of twenty years. While some developing countries such as India reviewed their patent laws to reduce the patent term and remove product patent protection to make it flexible and more responsive to the country’s development policy and industrial objectives, Nigeria’s patent law from the onset was stringent.\textsuperscript{237} Historically, the patent terms of the current industrialised and more developed countries was less than twenty years and they subsequently amended their laws as compelled by industrial needs.\textsuperscript{238} As observed by Shyllon, Nigeria was yet to formulate a national economic and development


\textsuperscript{235} Section 1-19 of the Patents and Designs Act of 1970.

\textsuperscript{236} Yankey (n 1) 107; Umahi (n 182) 4.

\textsuperscript{237} Kuanpoth, (n 82) 46.

\textsuperscript{238} For example, the UK Statute of Monopolies of 1623 and the first UK Patent Act of 1852 granted monopoly privileges for the term of 14 years or less before it was subsequently amended to a 20 year term. Peter Drahos, \textit{The Global Governance of Knowledge: Patent Offices and Their Clients} (Cambridge University Press 2010) 98.
policy for technological progress and growth of national industries at that time, thus there was no need for a stringent patent policy.\textsuperscript{239}

Perhaps, this legislative development is a reflection of the circumstances of its enactment. The PDA relied heavily on the draft International Bureau for the Protection of Intellectual Property (BIRPI)’s Model Law for Developing Countries.\textsuperscript{240} Nigerian IP scholars Professor Adewopo and Shyllon noted in this respect that the PDA, while relying heavily on the Model Law, did not proceed on the basis of any defined or underlying national policy consideration.\textsuperscript{241}

Though the Model Law supposedly emphasised innovation and technological development for developing countries, in practice it was influenced by pressure from industrialised countries for developing countries to join the international ‘community of nations’, thereby subjecting them to the same patenting standards as the more developed and industrialised countries.\textsuperscript{242} Reflecting on the rationale for modelling the PDA according to the provisions of the Model Law, some scholars opine that Nigeria and some developing countries did so in the belief that it would afford the country an opportunity to gain increased access to trade, patented foreign technology and information from the industrialised countries.\textsuperscript{243} Accordingly, the then Acting Chief Registrar of Nigeria actively participated in the negotiations and the enactment of the draft Model Law; hence Nigeria simply adopted the provisions of the Model Law as

\textsuperscript{239} Shyllon (n 183) 143.


\textsuperscript{242} Umahi (n 182) 4.

\textsuperscript{243} Umahi (n 182) 5. (Arguing that many developing countries including Nigeria, relied on the BIRPI Model Law in the belief that it would enable them benefit from transfer of patented foreign technology for national development.)
the blueprint for Nigeria’s patent system without an assessment of its benefits for the country, nor was it informed by any national policy consideration.\textsuperscript{244}

From an access to medicines perspective, although the PDA provides for compulsory licence and government use of patents and excludes certain inventions from patentable inventions,\textsuperscript{245} the flexibilities and patent exceptions in the PDA are inadequate for the purpose of sufficiently enhancing the availability and accessibility to affordable essential medicines in Nigeria, to be discussed in detail in Chapter V. Also, Nigeria is a member of the WTO and is thus bound to the terms and provisions of the TRIPS Agreement, however, the country is yet to incorporate and domesticate the Agreement including its health related flexibilities.\textsuperscript{246}

Although Nigeria enacted a law that had its foundation in a colonial creation, it now needs to be designed in a manner that will suit local needs and requirements in its traditional terrain to adequately encourage the inflow of important health-related technologies, stimulate innovative activities, and promote the circulation of knowledge in relevant sectors such as the pharmaceutical industry. As will be argued in Chapter VI, the system should also be flexible to promote access to affordable essential medicines.

In addition, patent protection may have negative consequences for public health, diffusion and competition, especially when it limits access to essential knowledge and products of innovation at an affordable cost. It is, therefore, imperative to carefully strike a balance between promoting innovative

\textsuperscript{244} Shyllon (n 183) 143; Yankey (n 1) 211.

\textsuperscript{245} This is set out in three sections. Section 1-11 regulates the grant and registration of patent, the second section from 12-22 controls design and the general provisions are found in sections 23-33. There are two schedules to the Patent and Designs Act.

\textsuperscript{246} As required under Section 12(1) of the 1999 Nigerian Constitution. Section 12 of the 1999 Nigerian Constitution states that all treaties must be passed into law and domesticated by the Nigerian National Assembly to have national effect. Hence the ratification process of the WTO TRIPS Agreement is subject to a national legislative act to be binding.
pharmaceutical R&D activities in Nigeria, promoting further innovations and facilitating the availability of cheaper generic drugs and also, promoting competition to facilitate better access to medicines. The key to striking this balance lies in the patent system through its patentable requirements and exclusions, its patentability criteria including the legal exceptions to patent rights, and the public interest related-flexibilities. In agreement, the Organisation for Economic Co-operation and Development (OCED) point out that appropriately suited patent subject matters, patentability threshold, and patent breadth or term of protection are basic tools within the patent systems that policy-makers and the government can use to enhance innovation and promote dissemination and diffusion of knowledge.

In sum, there is no evidence to indicate that patent law in Nigeria was developed based on a clear IP development-oriented policy or formulated to deliberately promote the public interest in Nigeria. Indeed, one scholar, commenting on the changes made from when patent law was initially introduced by the colonial administration to the post-independent patent law in many African countries, noted that their laws were based on mere aspirations of having an independent patent system, or to comply with international obligations. It is no wonder that patent law in Nigeria is not adequately structured to accommodate all the issues that arise within the context of patents and access to medicines such as the incorporation of all the available health-related flexibilities.

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247 This is elaborated in Chapter VI.
250 The flexibilities are the subject of discussions and analysis in Chapter VI.
2.7 Conclusion: Approaching the Patent System from a Public Health or User Perspective to Promote Women’s Access to Essential Medicines

The point made in this chapter is that the statutory requirements of the patent framework indicate that the system does not completely disregard the public. This finds support in the observation by the UK Commission on Intellectual Property Rights that IPR privileges should not be considered as an end in theirselves, rather, they are a means to an end, ‘as instruments of public policy which confer economic privileges on individuals or institutions solely for the purposes of contributing to the greater public good’. In this regard, it is argued that since one of the aims of the patent system is to promote the development goals of society, the exclusive control right which it confers upon inventors should not stand in the way of this fundamental objective. Thus, a patent right granted to innovators should promote, not hamper, public health. The system’s benefit to society’s interests must be evaluated in the light of this public interest goal. When the patent system is approached in the light of its public welfare objectives, it is expected that the interpretation and enforcement must take into account this basic social function and development purpose of the patent system. With this goal in mind, this thesis makes a case for Nigerian women’s access to medicines within the context of their socio-economic and cultural setting. In this connection, this thesis argues for ways to improving access to essential health treatments within the context of patent law, especially through the use of the TRIPS-compliant flexibilities and patent rights exemptions, where patent right threatens this access.

In closing, a patent, as an instrument for promoting better health, would require that people can actually derive the benefits, through access to the patented invention or medicine. The next chapter evaluates the debate on the adverse public health effect of patent rights on the accessibility to affordable life-saving treatments, particularly for poor women in Nigeria and other developing countries.
CHAPTER III: THE FRAMEWORK FOR THE INTERNATIONAL PROTECTION OF PATENTS, WOMEN’S HEALTH IN NIGERIA AND THE ISSUE OF ACCESS TO MEDICINES

Health is not everything, but, without health, everything else is nothing.¹

3. Introduction

For the purpose of the study in thesis, access to affordable essential medicines is identified as having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour’s walk from the homes of the population.² The concept of access to medicines generally encompasses the idea that everyone should have the equitable means, facilities and opportunities to have, obtain and use safe life-saving drugs for health treatment purposes.³ Access to a secure, affordable, regular, sustainable and good quality supply of life-saving essential medicines is, however, not adequate, especially in developing countries, including Nigeria.⁴

Access to medicines is not only a public health conundrum; the problem of access also raises concerns with regards to the patenting of medicines. The patenting of pharmaceuticals is often at the forefront of the debate on the effects of patent rights on the availability of, and affordable access to, life-saving treatments, mainly for people living in developing countries.

³ In this study, the use of the word ‘medicines’ includes: drugs, vaccines or medicinal substances used for the treatment, cure, prevention and management of diseases and illnesses. The words ‘drugs,’ ‘treatments,’ ‘resources,’ ‘medicinal products,’ ‘cure’ and ‘pharmaceuticals’ are sometimes used interchangeably to signify the same meaning.
Against this background, this chapter examines the problems of access to medicines within the context of patent rights in Nigeria and the international debate on the relevance of the Trade Related Aspect of Intellectual Property Rights (TRIPS) Agreement, particularly the ways in which the intellectual property (IP) rules in the Agreement could impact adversely on access to essential medicines. In conducting the analysis, the chapter particularly highlights the distinct public health needs and interests of women in their quest for access to essential medicines in Nigeria. This is borne out of a need to make a case for women’s right to health by pointing to a range of legal, socio-economic and other factors, both in Nigeria and within the international trade system that can positively or negatively influence their health outcomes. Essentially, this chapter adds a gendered dimension to the problems of access to medicines within the scope of patent law. Principally, it surmises that, although the problems of access to medicines in Nigeria can be traced to socio-economic, cultural and limited infrastructural factors, patent provisions can also potentially bear upon women’s access to important healthcare treatments.

This chapter is divided into two parts. The first sets the tone for the study by outlining the general challenges of the Nigerian health care system and also the distinct health needs of its women. In addition, the general health condition and problems of access to medicines in Nigeria are discussed. This part argues that, although men and women face similar constraints and difficulties in relation to accessibility to medicines, due in part to socio-economic factors, harmful traditional, cultural and religious practices, the experience of women are exacerbated to varying degrees. It is therefore argued that on any national

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5 This chapter does not claim to make an assessment of a gender-specific effect of TRIPS on access to medicines as there is no empirical basis to make such an assertion. Nonetheless, the chapter makes analogical analysis of the possible adverse effect of patents in TRIPS on women’s health, taking into account their socio-economic and cultural circumstances, in the absence of empirical evidence.
process to improve access to medicines requires multifaceted efforts. Specifically, in this thesis, it is argued that these should include a consideration of the ways in which patent rights could impede women’s accessibility to affordable essential medicines.

The second part relates the problems of access to the widespread international debate on the ways in which patent rights could hinder accessibility to life-saving medicines. This analysis also explores the unintended consequences and repercussions of patent rights on the cost of medicines and availability of drugs to women. In particular, the focus is on the patent provisions in the TRIPS Agreement which extend to pharmaceuticals and the consequential trickle-down effect on the price and the availability of medicines. Similarly, it outlines the problems associated with the patent system’s inadequacy on promoting investment in medicinal products for neglected diseases that affect women and the poor in many parts of the developing world.

To put the research in context, this chapter starts with an examination of the health care system in Nigeria.

PART I: THE NIGERIAN HEALTHCARE SYSTEM AND THE ISSUE OF ACCESS TO MEDICINES

3.1 Essential Medicines: Improving Access to Life-saving and Important Pharmaceuticals

While medicines are vital to maintaining, improving and restoring health, as well as for preventing and treating illnesses and diseases, essential medicines are important medicinal treatments that can save lives and improve health when
used appropriately, and available at affordable prices.\textsuperscript{6} The World Health Organization (WHO) defined essential medicines as 'those that satisfy the priority health care needs of the population.'\textsuperscript{7} Accordingly, these are medications that everyone should have appropriate access to, at all times to improve their health.

Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.\textsuperscript{8}

In 1977, the WHO noted that essential medicines are 'of utmost importance, basic and indispensable, and necessary for the healthcare needs of the populations.'\textsuperscript{9} Importantly, access to essential drugs is recognised as fundamental to the realisation of the right to health.\textsuperscript{10}

Essential medicines are selected on the basis of certain criteria. They are selected with due regards to the 'disease prevalence, public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness.'\textsuperscript{11} There is no universal identification of all essential medicines; however, the definition of essential medicines by the WHO is widely adopted as the parameter for categorising essential medicines. The implementation of

\textsuperscript{6} World Health Organization, 'Equitable Access to Essential Medicines: A Framework for Collective Action' (WHO Policy Perspectives on Medicines No. 008, World Health Organization2004) 1. According to the Oxford Dictionary, Essential is defined as 'absolutely necessary or extremely important.’ Following this definition, essential medicines are medicines that are considered absolutely necessary, important and indispensable to good health and indeed, human survival. Angus Stevenson (ed), Oxford Dictionary of English (3rd edn Oxford University Press 2010)

\textsuperscript{7} When the World Health Assembly convened in 1975, it introduced the concept of essential medicines and national drug policies. The WHO developed the first essential medicines list in 1977 and since then the list has been revised every 2 years. ibid

\textsuperscript{8} ibid


\textsuperscript{10} See Paragraph 12(a), 17 of the General Comment no 14. In paragraph 43(d) the provision of essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs is a minimum core obligation of the State to fulfil, respect and protect the right to health. Accessing essential medicines as a right to health is the central subject of chapter IV

which is intended to be flexible and adaptable to many different situations.\textsuperscript{12} The WHO states that which medicines are to be regarded as 'essential' is a matter of national responsibility; although further guidance is provided on how to determine and select essential medicines.\textsuperscript{13}

The WHO publishes a Model List of essential medicines although each country is encouraged to prepare and publish their own list by taking into account their development, health and national priorities.\textsuperscript{14} Though the list is not designed as a global standard, it is a guide for countries to adopt and adapt where necessary in the development of their national and institutional essential medicines list.\textsuperscript{15}

The first Model List of Essential Medicines was launched in 1977.\textsuperscript{16} It was designed to serve as a blueprint for the most effective, affordable and safe medicine to meet important healthcare needs and priorities.\textsuperscript{17} The most recent list is the 19th Model List of Essential Medicines, prepared by the WHO Expert Committee in April 2015. The WHO essential Model List contains a core list and a complementary list of essential drugs.\textsuperscript{18} The essential medicines list (EML) of a country is vital to improving and maintaining health as it gives priority status to safe and high-quality medicines that address a country’s public health

\textsuperscript{12} World Health Organization, 'Equitable Access to Essential Medicines: A Framework for Collective Action' (n 6)
\textsuperscript{13} ibid
\textsuperscript{14} Over 150 countries including 95% of developing nations have published an official essential medicines list. The essential medicines list enables health authorities, especially in developing countries, to optimise pharmaceutical resources. United Nations, Millennium Development Goal 8: Delivering on the Global Partnership for Achieving the Millennium Development Goals-MDG Gap Task Force Report 2008 (United Nations 2008) 36.
\textsuperscript{15} World Health Organization, 'Essential Medicines' (n 11); World Health Organization, 'Equitable Access to Essential Medicines: A Framework for Collective Action' (n 6)
\textsuperscript{16} ibid
\textsuperscript{18} According to the WHO, ‘the core list presents a list of minimum medicine needs for a basic health-care system, listing the most efficacious, safe and cost–effective medicines for priority conditions. Priority conditions are selected on the basis of current and estimated future public health relevance, and potential for safe and cost-effective treatment. The complementary list presents essential medicines for priority diseases, for which specialized diagnostic or monitoring facilities, and/or specialist medical care, and/or specialist training are needed.’ World Health Organisation, ‘WHO Model List of Essential Medicines 19th List (April 2015)’ (World Health Organization 2015). Also available at <http://www.who.int/selection_medicines/committees/expert/20/EML_2015_FINAL_amended_AUG2015.pdf>
challenges, whilst also taking into account the cost effectiveness of the medicinal treatment.\textsuperscript{19}

Most studies on access to essential medicines particularly with respect to pharmaceutical patents tend to focus on essential treatments for HIV/AIDS, TB, malaria and neglected tropical diseases in developing countries. While medicines for these diseases and illnesses are important and part of the argument in this study, the concept of essential medicines for this thesis is broader in scope. It also encompasses medicines for women's reproductive and sexual health problems, i.e. medicines to ensure healthy pregnancy and delivery, contraceptives and medicines for prevention and treatment of sexually transmitted infections (STIs), HIV/AIDS and pregnancy-related illness and death.\textsuperscript{20} Contraceptives are essential medicines to the extent that it is necessary to curtail early and unwanted childbearing, and prevent unplanned pregnancies, especially where the pregnancy can be damaging to the health, wellbeing and human development of women.\textsuperscript{21} Access to contraceptives can also limit the termination of unwanted pregnancies and the option of unsafe abortion. The WHO revealed that unsafe abortion poses a significant risk to health, particularly in poorer nations.\textsuperscript{22}

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\textsuperscript{20} See Jane Cottingham and Marge Berer, 'Access to Essential Medicines for Sexual and Reproductive Health Care: The Role of the Pharmaceutical Industry and International Regulation' (2011) 19 Reproductive Health Matters 69–84. (Observing that the majority of research and development, manufacture and distribution of drugs including sexual and reproductive, is in the hands of private profit-making pharmaceutical companies that hold patent rights to their creations.)
\textsuperscript{21} Contraceptive here refers to the medicinal contraceptive. However, it can still be argued that Condom, as a form of birth control and family planning, should be categorised as essential since it can offer protection against unplanned pregnancy and significantly protect against HIV or other sexually transmitted diseases (STDs). If HIV/AIDS and STD's can be prevented, accessing essential medicines for treatments of the diseases would be less of an issue. This analysis is outside the scope of this thesis.
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Unsafe abortions kill an estimated 68,000 women every year, representing 13% of all pregnancy-related deaths. In addition, they are associated with considerable morbidity; for instance, studies indicate that of every five women who have an unsafe abortion, at least one suffers a reproductive tract infection as a result; some of these infections are serious, leading to infertility.\(^{23}\)

In a similar manner, sexual and reproductive ill-health can result in sexual dysfunction and other gynaecological conditions such as severe menstrual problems, urinary and faecal incontinence due to obstetric fistulae, uterine prolapse, and pregnancy loss.\(^{24}\) This can lead to maternal and perinatal mortality. Consequently, this retards development, where the people affected are unable to make choices and exercise free will to make development choices.

Studies also indicate that poor reproductive health and sexual health problems, including complications arising from early childbearing, HIV infection and sexually transmitted infections (STIs) are significant disease burdens in developing countries and also, essential medicines for reproductive health are often not available to the majority of women who need them.\(^{25}\) A survey further estimated that many couples who are at risk of unplanned or unintended pregnancy and would choose birth control using effective modern contraceptives are unable to do so.\(^{26}\) Also, reproductive and sexual health

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\(^{23}\) World Health Organization, 'Reproductive Health Strategy to Accelerate Progress towards the Attainment of International Development Goals and Targets' (n 22) 14.


\(^{26}\) World Health Organization, 'Family Planning/Contraception: Fact sheet' (n 21) 11; Sophie Logez and others (n 19); World Health Organization, 'Reproductive Health Strategy to Accelerate Progress towards the Attainment of International Development Goals and Targets' (n 22).
problems such as maternal, perinatal mortality and gynaecological health-related complications are said to be a significant disease burden for women of reproductive age.\textsuperscript{27}

Besides reducing the need and associated risk of abortion, contraceptive and medicinal resources for family planning will enable women to make informed decisions about their reproductive and sexual health. For instance, women can control childbearing until resources are available for adequate nutrition, health care and education.

As will be discussed in Chapter IV, the right to health contains freedoms and entitlements. These freedoms include the right to control one's health and body including sexual and reproductive rights, and as such medicines for reproductive health and contraceptives are an essential part of a women's right to health.\textsuperscript{28} Thus it is argued that the right to access essential medicines, including contraceptives and pharmaceuticals for reproductive and sexual health, is not only a fundamental aspect of the human right to health and imperative to achieving good health, it is also a means by which individuals and women can build their health capabilities and enhance their human development. As will be discussed in detail in Chapter V, the capabilities approach to development, wellbeing and justice emphasises the importance of people's choices, freedoms and the opportunities to do and be what they term as valuable and lead the kind of lives they choose to lead.\textsuperscript{29} Thus Martha Nussbaum, a foremost capabilities scholar, argues that 'being able to have good health, including reproductive health' is one of the core capabilities that

\textsuperscript{27} World Health Organization, 'Reproductive Health Strategy to Accelerate Progress towards the Attainment of International Development Goals and Targets' [n 22] 11.

\textsuperscript{28} Paul Hunt, 'The Right To Health: Key Objectives, Themes, and Interventions Questions for Reflection and Discussion' in Burns H Weston and Anna Grear (eds), Human Rights in the World Community: Issues and Action (University of Pennsylvania Press 2016) 189.

\textsuperscript{29} Jocelyn Dejong 'Capabilities, Reproductive Health and Well-being' (2006) 42 The Journal Of Development Studies' 1151.
should be supported by all democracies.\textsuperscript{30} Therefore, reproductive health treatments, contraceptives and family planning medications as essential medicines that can enhance a woman’s ability to choose if and when to become pregnant, determine the number and spacing of children, and reduce the need for risky abortions, pregnancy-related complications and maternal mortality from early childbearing, enhances their capabilities and in so doing promotes human development.\textsuperscript{31}

There is thus a need to improve access to essential medicines that can give women the means to expand and improve their health capabilities and make health-related choices.\textsuperscript{32} These drugs can also present opportunities for women to be in good health and pursue other development goals.\textsuperscript{33}

Essential medicines are expected to be readily available and accessible within the context of a functional and viable healthcare system and services.\textsuperscript{34} The WHO identifies that provision of secure and sustainable access to essential medicines is dependent on four main factors: rational selection and use of medicines; affordable prices; sustainable financing; reliable health and supply systems.\textsuperscript{35} Rational selection and use reflects the importance of ensuring that essential medicines have the right balance of efficacy, safety, quality and are appropriate for use.\textsuperscript{36} Likewise, each individual should have and use this medication, in the most appropriate dosage, forms and strength, for an


\textsuperscript{31} Dejong (n 29) 1161.

\textsuperscript{32} It is worth noting that this thesis does not focus only on the sexual and reproductive essential medicines.

\textsuperscript{33} This argument covers drugs to prevent pregnancies (contraceptives), treat pregnancy related complications and protect or improve sexual and reproductive health.

\textsuperscript{34} Ka, Pradhan and Mohanta (n 17) 10.


\textsuperscript{36} ibid
adequate duration, with the suitable information and follow up treatment.\textsuperscript{37} The selection and rational use of essential medicines is the first steps towards improving access; these essential medicines should be cost-effective and available at affordable prices.\textsuperscript{38} In this thesis, it is argued that the State is under an obligation to ensure that the prices of patented essential medicines are not prohibitively beyond the reach of its populations. The flexibilities, as identified in Chapter VI, are important as a means to ensure that a patent does not constitute a challenge to accessing essential medicines. In addition to being available at a reasonable price, a reliable, regular and proper drug supply system, good pharmaceutical procurement practice and a suitable health system for distribution are vital in the quest to promote access to essential medicines.\textsuperscript{39} It is also important that there is sufficient research and development (R&D) for new and more effective drugs.\textsuperscript{40} The WHO also emphasises the need to ensure access through sustainable increased public funding for health and adequate health insurance especially for the poor.\textsuperscript{41}

This four-part framework is formulated to guide and coordinate actions to guarantee access to essential medicines. These four factors must be put in place if access to medicines is to be increased in Nigeria. It is within this context that this thesis argues for increased access to essential medicinal treatments in Nigeria.

To further put the research in context, the next section examines the health care system in Nigeria.

\textsuperscript{37} Ka, Pradhan and Mohanta (n 17) 11.  
\textsuperscript{39} ibid  
\textsuperscript{40} ibid  
\textsuperscript{41} ibid
3.2 An Overview of the Nigerian Healthcare System

Nigeria is estimated to be home to more than one-fifth of the entire population of sub-Saharan Africa.\(^\text{42}\) However, the general public healthcare system can best be described as struggling, underfunded, and in a ‘state of disarray’.\(^\text{43}\) Since its independence in 1960, the Nigerian authorities have made efforts to improve the life and livelihood of the citizens. While progress has been recorded in the education, financial and economic sectors, the provision of an adequate healthcare system remains a perennial problem in Nigeria.\(^\text{44}\) Factors such as inadequate medical infrastructures, services and health facilities, insufficient technological and medical equipment, and a shortage of highly skilled personnel, especially in the rural parts of the country, contribute to the poor state of the health care system.\(^\text{45}\) A report on the pharmaceutical market in Nigeria indicates that inadequate basic infrastructures and lack of access to affordable medicines are further challenges of the healthcare system.\(^\text{46}\) Low investment in, and underfunding of essential healthcare delivery services and facilities has also marred the health system’s operational effectiveness.\(^\text{47}\) In


\(^{47}\) Oxford Business Group (n 43) 325.
2013, the amount spent on health per person by the Nigerian government was US$31 and although it varies by region, this is an estimated thirty six percent of the spending required to provide the necessary basic universal healthcare to the people.\textsuperscript{48}

The health system’s ineffectiveness is compounded by the lack of an appropriate political and strategic approach to address the healthcare challenges of the population.\textsuperscript{49} The poor performance of the health system is worsened by the absence of a coordinated multi-sectoral approach to address the constraints, and a proactive effort to manage the many problems of access to adequate healthcare by the government.\textsuperscript{50} The WHO, in relating the problems of access to medicines to the structure and organisation of a health care system, observed that ‘[w]ell performing health systems offer high levels of access, and poorly performing ones result in a large number of people being excluded from medicines as well as other forms of treatment, prevention and care.’\textsuperscript{51} This weak healthcare system and lack of other necessary infrastructures in Nigeria therefore, present a gloomy picture for the quest to access medicinal treatments.\textsuperscript{52}

The lack of an effective health system to facilitate the procurement of treatments for major diseases such as HIV/AIDS, tuberculosis (TB), malaria,
etc., makes the health care situation even more daunting.\textsuperscript{53} Nigeria has recorded one of the highest levels of HIV/AIDS, malaria, and tuberculosis (TB) in the sub-Saharan African region.\textsuperscript{54} In 2013, the Joint United Nations Programme on HIV/AIDS (UNAIDS) indicated that Nigeria had one of the largest numbers of HIV infections in the world.\textsuperscript{55} By this estimate, women in sub-Saharan Africa, including Nigeria, account for fifty eight percent of the total number of people living with HIV.\textsuperscript{56} Conversely, UNAIDS stated in 2014 that only twenty percent of people infected in Nigeria had access to the required antiretroviral therapy.\textsuperscript{57} Nigeria also records the fourth largest incidence of TB infection, with approximated 373,682 new cases annually.\textsuperscript{58} This is in addition to the prevalence of other tropical and communicable diseases.\textsuperscript{59} Most of these diseases are treatable with effective medications; however, accessibility and affordability of the necessary treatments pose a challenge.\textsuperscript{60}

The Federal Government of Nigeria has made commendable policy efforts to improve the healthcare needs of its people, yet the policies have not been effectively executed as a result of a low commitment by government and the relevant implementation authorities.\textsuperscript{61} To restructure and increase the


\textsuperscript{54} James A Johnson and Carleen H Stoskopf, \textit{Comparative Health Systems: Global Perspectives} (Jones and Bartlett Publishers 2010) 313.


\textsuperscript{57} Ibid 19.


\textsuperscript{59} Kalu N Kalu, Chinele Ogbuaru, and Ikechukwu Ogbuaru, ‘Nigeria’ in James Johnson and Carleen Stoskopf (eds), \textit{Comparative Health Systems: Global Perspectives} (Jones & Bartlett Learning 2010 Sudbury) 313.

\textsuperscript{60} Federal Ministry of Health, \textit{Revised National Health Policy 2004} (n 45) 3.

\textsuperscript{61} World Health Organization ‘The Nigerian Health System’ 25. Available at
performance of the health care system, for example, the government adopted the National Health Policy (NHP) to improve the quality of health care delivery and services. The NHP contains some important provisions to strengthen the national health system and provide efficient health service delivery that can increase access to quality healthcare and medicines if strictly adhered to. However, the current state of the healthcare system indicates poor implementation of the NHP. Among many other policy measures to improve health status, particularly funding of health care, the National Health Insurance Scheme (NHIS) Act was also set up in 1999 to reduce the cost burden and financing of health services. The impact of this insurance scheme has been limited by factors such as insufficient sustainable funding of the scheme, uncoordinated management and poor implementation.

Various other reforms have been put in place to address the state of healthcare in Nigeria. With the aim of controlling and treating the scourge of diseases

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62 The largest responsibility for public healthcare falls on the Nigerian Federal Government through the Federal Ministry of Health (FMoH). The Federal Ministry is responsible for providing health services and medicines, policy guidance, planning and technical support to the overall health system in Nigeria, coordinating the implementation of the National Health Policy, as well as establishing health management information system in the Country.) ibid 21.
63 For example, the stated objective of the 2004 Revised Policy is ‘[t]o strengthen the national health system such that it will provide effective, efficient, quality, accessible and affordable health services that will improve the health status of Nigerians through the accelerated achievement of the health-related Millennium Development Goals.’ ibid 7-8. Progress related to this objective has however, been slow and there are challenges to fulfilling these objectives.
64 Other relevant policies include the National Drug Policy (NDP) 2005 to improve the provision of drugs in the country and the National Strategic Health Development Plan (NSHDP) 2009-2015 which is aimed at strengthening the healthcare system, providing cost-effective healthcare interventions and improving the health status of all Nigerians, particularly the poorest and most vulnerable.
such as HIV for instance, the Federal Government established agencies and programmes such as the National AIDS Control and Prevention Programme (NASCPP), the National Action Committee on AIDS (NACA) and the National HIV/AIDS Strategic Framework, in addition to providing antiretroviral treatments at discounted prices.\textsuperscript{67} To address the problems of inadequate healthcare, services and health treatments, the National Health Act 2014 was enacted to provide a framework for the regulation, development and management of the Nigerian health system.\textsuperscript{68}

In light of the foregoing, it is obvious that the Nigerian government is aware of the need for an improved standard of health delivery system; nonetheless, the policy provisions to improve healthcare delivery must be put into practice to fulfil the policy intention of providing the best possible healthcare for all persons living in Nigeria ‘within the limits of available resources.’\textsuperscript{69} Enhancing access to adequate healthcare is an identifiable goal that goes beyond recognising the need for a viable healthcare system. Efforts to deliver this goal will require improvement in access to quality healthcare delivery, medical services and medicinal treatments, at an affordable rate. It also requires a proactive effort to practically facilitate access to good quality healthcare and medicinal treatments, expand the options for better access to health treatments and address all the impediments to accessibility.

\textsuperscript{67} The National Strategic framework replaced the HIV/AIDS Emergency Action Plan (HEAP). International donor assistance from other countries, organisations and donor groups to treat HIV, TB, and malaria has also enhanced the availability of healthcare services. For example, it was announced that the Global fund to fight AIDS approved about $68 million in grants to support the treatment and prevention of deadly diseases such as HIV/AIDS and TB in Nigeria. Ruby Leo, ‘Nigeria: TB, HIV/Aids, Malaria Fund - Global Fund Warns Nigeria’ The Daily Trust (4 May 2013) <http://allafrica.com/stories/201305061604.html> accessed 24 September 2015.

\textsuperscript{68} The Nigerian National Health Act 2014 was signed into law on the 9th Dec 2014. The Act is further discussed in the next chapter.

\textsuperscript{69} See the objective of the Act in Section 1(1) of the Nigerian National Health Act 2014.
3.3 The Quest for Access to Medicines in Nigeria

Access to drugs is a crucial component of a suitable health system. The significance of an available, affordable, accessible and good quality supply of important drugs for the treatment of diseases is indispensible. Indeed, it is the cornerstone of an effective health system. Gaining access to safe and efficient drugs for overall health care, however, remains difficult for some Nigerians.\(^{70}\) With respect to HIV/AIDS treatments, for example, Médecins Sans Frontières (MSF) in 2001 conducted a survey in Lagos on behalf of the Coalition of Civil Society Groups on Access to Essential Medicines (COCSGAEM).\(^{71}\) The survey, which aimed to provide information on the availability and affordability of some antiretroviral (ARV) and medicines for opportunistic infection in the Lagos State, Nigeria, reported that there was generally little stock of the treatments in the facilities visited.\(^{72}\) MSF reported that drugs deemed expensive were deliberately kept out-of-stock due to low demand, and purchased only on request.\(^{73}\)

In addition, a 2002 Baseline Assessment of the Nigerian Pharmaceutical Sector by the Federal Ministry of Health (FMoH) and WHO illustrated that only forty six percent of the basket of twelve key medicines were available in public health facilities and seven percent of these medicines had expired.\(^{74}\) The study demonstrated that, despite the National Insurance Scheme (NIS), financing of medicines is mostly out-of-pocket.\(^{75}\) A survey of household use in the study

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\(^{70}\) Oladepo and others (n 53) 26.  
\(^{71}\) In the study, public and private hospitals, community pharmacies, and drug companies were visited. Médecins Sans Frontières (MSF) and Coalition of Civil Society Groups on Access to Essential Medicines (COCSGAEM) ‘Coalition on Access to Essential Medicines Survey on Access to HIV/AIDS Drugs in Nigeria: Lagos’ (MSF and COCSGAEM 2001) as reported in Peterson and Obileye (n 53) 13.  
\(^{72}\) ibid  
\(^{73}\) In some cases, patients were sent directly to pharmaceutical companies to purchase the drugs. ibid 13. Another research report in 2002 came to a similar conclusion, that the cost of ARV medicines and treatments for HIV-related OI is expensive and out of reach for many Nigerians living with HIV/AIDS. See Peterson and Obileye (n 53) 3.  
\(^{74}\) Federal Ministry of Health and World Health Organisation, Baseline Assessment of the Nigerian Pharmaceutical Sector (Federal Ministry of Health 2002) 6, 24. The study also indicated that 58% of the basket of drugs was available at the public sector warehouse. ibid  
\(^{75}\) ibid 15.
further showed that most respondents (eighty nine percent) purchased their prescribed drugs.\textsuperscript{76} The survey further revealed that the main reason for the inability to purchase drugs was lack of funds (thirty six percent), while twenty eight percent of respondents claimed the relevant medicine was unavailable in public pharmacies.\textsuperscript{77} Furthermore, a reported twenty three percent of the average weekly expenditure of the respondents was on medicines for the treatment of an episode of illness for at least one member of the household.\textsuperscript{78}

The results of this study underscore the need to improve the availability and access to safe, high quality, and affordable efficacious medicines to the Nigerian populace.

The status of access to available and affordable medicines in the studies above is consistent with a 2004 empirical study by the Nigerian Federal Ministry of Health (FMOH), WHO and Health Action International\textsuperscript{79} which revealed that innovator brands cost between two and seven times more than the lowest prices of generic equivalents.\textsuperscript{80} The results of the study also reveal that patients pay between two to sixty four times the international reference prices for drugs in both public and private facilities in Nigeria.\textsuperscript{81} One of the key findings to emerge from this study was that ‘[m]edicines are unaffordable to the majority of Nigerians (90.2%) who live below the income level of US$ 2 a day as well as the government worker that earns a minimum wage of US$1.4 per day.’\textsuperscript{82} The

\textsuperscript{76} ibid 6.
\textsuperscript{77} ibid 6.
\textsuperscript{78} ibid 6, 29.
\textsuperscript{79} The study, which aimed to ascertain the prices of medicines in Nigeria using an international standardised methodology, assessed a total of 129 medicines outlets in both public and private health clinics and pharmacies in a sample representation of the six geopolitical zones in the country. The prices of a basket of 34 prescription medicines were measured. See also, Federal Ministry of Health and others, Medicine Prices in Nigeria: Prices People Pay for Medicines in Nigeria (Federal Ministry of Health 2006) 1-6. Also available at <http://www.haiweb.org/medicineprices/surveys/200409NG/survey_report.pdf> accessed 28 September 2015.
\textsuperscript{80} The study also demonstrated that private health clinics were charging up to 184\% more than the public health facilities and 193\% more than private retail pharmacies. ibid 5, 27.
\textsuperscript{81} ibid 5, 17, 27.
\textsuperscript{82} ibid 5. (Affordability of medicines was measured in relation to the number of days the lowest paid unskilled government worker would need to work to procure a course of treatment for each of ten conditions.)
study also examined and rated the availability of a basket of thirty four medicines as low in all sectors, especially the public and private health clinics.\textsuperscript{83} This study revealed that the high prices of pharmaceuticals could constitute a major hindrance to access to healthcare for women in the country since the burden of purchasing medicines mainly falls on households.

In 2005, a research survey of 122 HIV/AIDS patients by MSF in Lagos also revealed that many are forced to pay for their own treatments, with a reported forty four per cent experiencing multiple treatment interruptions due to financial difficulties.\textsuperscript{84} Describing this deplorable situation, MSF reported that

\begin{quote}
[I]o pay for their care, 39\% of respondents reported borrowing or begging, while 18\% said they had been forced to sell property.\textsuperscript{85} Many patients reported erratic consumption of medicines, including skipping or sharing doses, which can lead to insufficient drug levels in the blood.\textsuperscript{86}
\end{quote}

The study by MSF also corresponds with a study of Nigerians' 'Access to and Rational Use of Medicines at the Household Level' by the FMoH in conjunction with the WHO in 2010.\textsuperscript{87} The objective of the study was to assess the extent to which households in Nigeria had access to medicines to treat acute and chronic diseases. The study was based on random samples from a representation of the six geopolitical zones in the country,\textsuperscript{88} as well as six health facilities in each zone of the six Local Government Authorities (LGAs) comprising three rural and three urban LGAs.\textsuperscript{89} Each location was randomly selected from a list of LGAs in

\textsuperscript{83} ibid 5, 36.
\textsuperscript{85} ibid
\textsuperscript{86} ibid
\textsuperscript{87} Federal Ministry of Health (FMoH) and World Health Organisation (WHO), Access to and Rational Use of Medicines at the Household Level (Federal Ministry of Health Nigeria 2010). Also available at <http://apps.who.int/medicinedocs/documents/s16887e/s16887e.pdf> accessed 16 November 2015
\textsuperscript{88} Nigeria is conveniently divided into six geopolitical zones. The study took random samples from a state in each zone for an equal representation of all the zones. ibid 3.
\textsuperscript{89} ibid 5.
each of the six zones.\textsuperscript{90} A total of one thousand and eighty households were consulted using a newly revised WHO household survey.\textsuperscript{91}

A significant finding was that while geographical access to health facilities and availability of medicines in public and private facilities had improved, there is a concern for the financial burden of households in accessing medicines.\textsuperscript{92} The result of the research indicated that eight point nine percent of households have monthly medicines expenditure that represent more than twenty percent of their total expenditures\textsuperscript{93} and that the cost of medicines constituted a barrier to accessing medicines for almost half of all households.\textsuperscript{94} Key findings of the study were that less than one out of every five households claimed to have obtained medicines free or supported by any form of health insurance and most families pay for medicines out-of-pocket.\textsuperscript{95} In the study, a reported forty nine point four percent of the respondents claimed not to have taken prescribed medicines because the household could not afford to purchase it.\textsuperscript{96}

\begin{table}[h]
\centering
\begin{tabular}{|l|c|}
\hline
\textbf{Indicator} & \textbf{Percentage} \\
\hline
\% respondents who agree medicines are more expensive at private pharmacies & 48.9 \\
\% respondents who can usually afford to buy medicines they need & 53.8 \\
\% respondents who have had to borrow money or sell things to pay for medicines & 46.3 \\
\% respondents who say that prescribed medicines were not taken “because HH cannot afford medicines” & 14.6 \hspace{1cm} All illnesses \\
& 6.9 \hspace{1cm} Acute illness \\
& 27.9 \hspace{1cm} Chronic illness \\
\% respondents who agree that better insurance coverage would increase their use of medicines. & 49.5 \\
\hline
\end{tabular}
\caption{Indicator and Percentage}
\end{table}

\textsuperscript{90} ibid 5.
\textsuperscript{91} ibid 1.
\textsuperscript{92} ibid 1-3, 25-27.
\textsuperscript{93} ibid 12. The study also reports that medicines account for an approximated three point five percent of total household expenditure.
\textsuperscript{94} ibid 7. The study concludes that, ‘affordability of medicines constituted a barrier to access to medicines to about half of households.’ ibid 2.
\textsuperscript{95} ibid 1-2.
\textsuperscript{96} ibid 20. (The calculation is based on the representation in Figure 3.1.)
The study demonstrates that about forty six point three percent of respondents claimed they had to borrow or sell things to afford payment for medicines. The study also revealed that the chronically ill were more affected than those with acute illness as most of them (seventy six percent) were not able to obtain thirty days’ supply of prescribed medicines.

The results and statistics of this study indicate that there is a problem of affordability and access to medicines, especially for the chronically ill in Nigeria. This study also illustrates that safe, effective and affordable medicines may not reach poor people, especially women, who need them the most. This can be seen in the illness characteristics of households which reported that forty three point five percent of women suffered from chronic illnesses and a further forty eight point two percent had acute illnesses. While there is reasonable access to available healthcare facilities, an assessment of the availability of medicines showed that thirty seven percent of households stated that medicines were available at public healthcare facilities and fifty two percent agree that drugs were available at private pharmacies. Compared to the 2002 study by the FMoH and WHO, there appears to be a slight increase in access to medicines in the 2010 study. Nevertheless, with regards to affordability, this increase may

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97 Adapted from the study. ibid 20.
98 ibid 20.
99 ibid 2, 26. The study also reports that about ‘one out of every 3 chronically ill patients did not take medicines because they could not afford them.’ ibid 2.
100 ibid 13-14. It is worth noting that a majority of the respondents in the study were men. (The main acute illnesses reported include fever and headaches (seventy seven percent), acute respiratory tract infections (ARI) (thirty nine percent), and sixty eight percent of these were regarded as either very serious or somewhat serious. The main chronic illnesses reported include hypertension, (thirty two percent), arthritis or chronic body pain (thirty two percent), ulcer or chronic stomach pain (twenty percent), diabetes (twelve percent) and asthma, wheezing or chronic difficulty breathing (eleven percent). The median age of household members with chronic illness was 50 years, and half of those with chronic illness were between 36 and 60 years old.)
101 ibid 17. The study, however, reveal that a reported forty eight point nine percent of respondents claimed that medicines were more expensive at private pharmacies. ibid 20.
be due to the fact that many are forced to take on loans or sell their property to purchase drugs.\(^{102}\)

This result of this study is not surprising considering the socio-economic and financial status of many people in Nigeria who are largely low or middle-income earners.\(^{103}\) The Human Development Report of 2013, for example, ranked Nigeria’s 153rd position as low on the Human Development Index.\(^{104}\) For women, who often earn less than their male counterparts, especially those in the rural areas where poverty is prevalent, affordability becomes a matter of life or death. Also, because women in Nigeria and many developing countries are confronted with adverse social, cultural and traditional-related practices, plus the financial and gender inequalities, as will be discussed, it is possible that they may face the problem of access to healthcare and medicines in a different or more severe way. Equally, drawing a link between the plight of women in Nigerian societies and the conundrum of access to medicines in Nigeria in the studies above, it is possible that the challenges of access to medicines for women in the studies is aggravated by adverse socio-cultural and traditional practices and barriers to accessing to health facilities, low income and unaffordable medicines.\(^{105}\) Consequently, any additional factor such as the high prices of patented pharmaceuticals could pose an added challenge to many people. With many patients in Nigeria financing the purchase of medicines out-

\(^{102}\) ibid 20. See also study by MSF (n 84).

\(^{103}\) ibid 26.


of-pocket,\textsuperscript{106} the high cost of patented drugs and unavailability of cheaper
generic substitutes could significantly constitute a major barrier to accessing
basic and essential medicines.\textsuperscript{107}

It follows from the foregoing that interventions are needed to improve access
and availability of affordable drugs in Nigeria. Among many other means to
improve access, a price control policy must be developed and implemented in
order to monitor and reduce drug prices, and also ensure that the marketing
practices of patentees do not constitute a barrier to the accessibility of essential
pharmaceuticals.\textsuperscript{108} As the study in this thesis is limited to patent law, the focus
is on making a case for an increased access of women to medicines in light of
patent rights.

\section*{3.3.1 The Nigerian National Drug Policy and its Shortfall in Addressing
the Problems of Access to Medicines}

Against the background of inadequacies in the availability, supply and effective
distribution of high quality, efficacious drugs, including the high dependency on
pharmaceutical raw materials and imported finished drugs from other countries,
the Nigerian Government enacted the first National Drug Policy (NDP) in
1990.\textsuperscript{109} To reduce reliance on foreign sources and imported health products,
the 1990 Policy aimed to make the pharmaceutical sector self-sufficient by

\begin{itemize}
\item \textsuperscript{106} Federal Ministry of Health and others, \textit{Medicine Prices in Nigeria: Prices People Pay for Medicines in Nigeria} (n 79) 6.
\item \textsuperscript{107} It is worth noting that the most important limitation of the preceding studies on the state of access to drugs in Nigeria lay in the
fact that there is no specific assessment and report of the situation of women as a distinct group. Further work needs to be done
to specifically reveal ways in which women experience the many dimensions of difficulty in access to medicines for a concerted
effort to address the problem. Notwithstanding, these aforementioned studies provide a reliable indication of the access to
medicine situation, as well as women’s state of health, and are relied on in this thesis to enrich the focus of this study.
\item \textsuperscript{108} While price control is an option to lessen the excessive pricing of medicines, there is currently no legal or regulatory provision
\item \textsuperscript{109} Federal Ministry of Health and World Health Organisation, \textit{National Drug Policy} (Federal Ministry of Health and World Health
Development Organization (UNIDO) 2011) 53. The aims and objectives of the Policy set out to address the inadequate supply of
drugs and to facilitate the availability and distribution of effective, good quality and safe medicines among many other goals.
\end{itemize}
promoting local drug research and development, training highly skilled scientists and research technicians in drug discovery activities, towards the objective of achieving full capacity in drug research, development and manufacturing.\textsuperscript{110} Effectively, this policy yielded some successful results such as the publication of the Essential Drug List (EDL) and a National Drug Formulary (NDF) for the procurement and delivery of good quality essential medicines in Nigeria.\textsuperscript{111}

In spite of these laudable objectives, several lapses were observed in the 1990 NDP.\textsuperscript{112} A post-13 year empirical report on the baseline assessment of the pharmaceutical sector stated that the 1990 NDP has had little effect in adequately improving access to medicines, spurring the national pharmaceutical industry to increase national production of pharmaceuticals and that gaps still exist despite the structures and processes put in place.\textsuperscript{113} Several factors are identified to explain the shortcomings. They include amongst others: the absence of an implementation plan; the lack of an equitable financing mechanism; a deficient budgetary allocation for drugs procurement and research; the absence of legislation to develop the pharmaceutical manufacturing sector and the huge taxes on drugs.\textsuperscript{114} In addition, the Policy did not contain provisions for intellectual property rights (IPRs) and the relevant exceptions and the flexibilities towards the aim of ensuring access to affordable

\begin{itemize}
\item The 1990 Policy also aimed to establish and strengthen the statutory agency responsibility for drug administration and control, and also introduced a drug registration procedure. ibid
\item ibid 9. (Observing that the shortcomings of the 1990 NDP include amongst others, the non-realisation of self-sufficiency in local production of essential drugs, the non-establishment and lack of an effective drug procurement system, the absence of an evolving well-ordered drug distribution system, and other lapses relating to the harmonisation and updating of drug legislation, ‘the effective control of drug advertisement and promotion, the entrenchment of and commitment to rational use of drugs at all levels of health care, and drug research and development etc.’)
\item Federal Ministry of Health and World Health Organisation, \textit{Baseline Assessment of the Nigerian Pharmaceutical Sector} (n 74) 12.
\item ibid 5, 12.
\end{itemize}
and safe medicines. Ultimately, however, the lack of political will and enforcement plans accounted for the failure to achieve its lofty goals.\textsuperscript{115}

In 2003, then 2005, the Nigerian National Drug Policy was revised to formulate effective ways of implementing the Drug Policy’s objectives to guarantee the availability and access to affordable essential medicines.\textsuperscript{116} To achieve this objective, the 2005 NDP sought to make the Nigerian Pharmaceutical industry self-sufficient by promoting and encouraging pharmaceuticals R\&D including the research into and use of herbal and other traditional remedies to meet the healthcare needs of Nigerians.\textsuperscript{117} Furthermore, the 2005 Policy mandated the government to develop a strategy for the R\&D of drugs; training high-level scientist and technicians;\textsuperscript{118} and developing local manufacturing capacity for this purpose.\textsuperscript{119} Importantly, the 2005 NDP, while recognising the importance of patents for research and development in Article 6(14), states that the Nigerian government should ensure that patent protection does not obstruct R\&D and access to affordable medicines. The 2005 NDP further mandates the Nigerian authorities to monitor the impact of International trade agreements on access to essential medicines by Nigerians, and explore the existing health and safety measures in international agreements to ensure access to ‘affordable, good quality and essential drugs.’\textsuperscript{120} Further to this, the Health, Justice and Trade


\textsuperscript{116} The Policy’s objective statement states:

\textit{The goals of the policy shall be to make available at all times to the Nigerian populace adequate supplies of drugs that are effective, affordable, safe and of good quality; to ensure the rational use of such drugs; and to stimulate increased local production of essential drugs.}

ibid 9. See also Federal Ministry of Health, World Health Organisation, Baseline Assessment of the Nigerian Pharmaceutical Sector (n 74) 5.

\textsuperscript{117} Article 6(20). Federal Ministry of Health and World Health Organisation, National Drug Policy (n 109).

\textsuperscript{118} Article 6(7) (1) Article 6(22) ibid

\textsuperscript{119} Article 6(1) and Article 6(9) ibid

\textsuperscript{120} Article 6(14)(i)(ii) ibid

112
Ministers are required to take into account public health considerations of Nigerians in international trade negotiations.\textsuperscript{121} The 2005 Drug Policy further obligates the government to make provisions for a drug distribution system, update other relevant drug and health policies and legislations, establish a pricing policy for procurement of cheap medicines and promote the rational use of drugs at all the levels of healthcare.\textsuperscript{122} Commendably, the Policy sought to guarantee the availability and affordability of drugs with the goal of building a dynamic national production industry.

\textbf{3.3.2 To What Extent Has the Policy Objective for the Availability, Access to Affordable Medicines, Pharmaceutical R&D and Drug Production Been Met in Nigeria?}

An analysis of the pharmaceutical services efficiency and delivery of drugs indicate that positive changes have been recorded although more work needs to be done to fulfil its objective of facilitating increased access to safe, affordable and effective medicines, and improving the performance of the domestic pharmaceutical industry to cater for national medicinal needs.\textsuperscript{123} On the positive side, Nigeria’s pharmaceutical industry remains one of the biggest in West Africa and one of the fastest growing pharmaceutical sectors in the sub-Saharan African region.\textsuperscript{124} Reports demonstrate, however, that despite the 2005 NDP objectives and local production status, Nigeria is still relying heavily on imported high-value drugs from other countries to meet domestic demands.\textsuperscript{125} The local drug industry meets only about thirty to forty percent of the drugs needs in the country and it is estimated that the other sixty to seventy

\begin{itemize}
  \item \textsuperscript{123}ibid
  \item \textsuperscript{124}ibid
  \item \textsuperscript{125}Wambebe and Ochekpe (n 109) iii-iv.
  \item \textsuperscript{126}Wambebe and Ochekpe (n 109) iii
\end{itemize}
percent are imported predominately from India, China, Europe and other industrialised countries.\textsuperscript{126} Besides, raw materials and active ingredients are still sourced from India, the USA, Germany and Indonesia and other foreign countries.\textsuperscript{127} To this end, the national Drug Policy in Nigeria has made commendable efforts; however, the policy alone cannot bring about a positive turnaround in the quest for increased accessibility to essential medicines in Nigeria. Supporting institutions, facilities and capacities should be developed, reformed and strengthened for this purpose. In this thesis, it is also argued that there is a need for the Nigerian authorities to critically look into the ways in which patents can add to the problems of access to pharmaceuticals and in this respect, incorporate and adapt the TRIPS-compliant flexibilities to ameliorate the accessibility issues associated with the IPRs.

Having highlighted the state of the Nigerian health system and the challenges of access to medicines for everyone, the following section underlies other socio-economic and cultural factors that can affect the state of women’s poor health and impinge their access to effective health treatments. The aim of the section is to argue for their improved access to effective healthcare services, facilities and medicines.

\textbf{3.4 Women and Health: An Analysis of the Social System and Cultural or Traditional Factors that Impinge on Women’s Health in Nigeria}

Women have always played a central role in Nigeria, especially in caring for the healthcare needs of the family; however, gender or sex-role ascriptions, social expectations and traditional practices often lead to gender discrimination and

\textsuperscript{126} Ogbonna, Ilika and Nwabueze (n 115) 256-257.
\textsuperscript{127} Ibid 256.
inequality that could have a trickle-down effect on women’s health and their ability to access healthcare treatments.

Nigeria is largely a patriarchal society where most decision-making is in the hands of men and the choices of women, especially in rural areas, are limited. Discriminatory practices against women are primarily based on this patriarchy that defines the social roles of men and women in ways that relegate the latter to an inferior position in the home and society. These inequalities sometimes relate to issues of control in decision-making on where and how to access healthcare. At the household level, men and women tend to perform different roles in the provision of healthcare and control of resources. Women, notably those in the rural areas, are traditionally care providers, whereas men are more often the financial decision makers on issues of healthcare. For example, a 2003 study by Nigeria’s National Population Commission (NPC) and ICF Macro indicates that men have the final say in major domestic issues such as household expenses and purchases and also they make the decisions regarding the survey respondents’ (women) own health care. Also in the study, men are often the sole decision makers in issues relating to children’s health and educational needs, while women are most likely to decide on issues relating to family welfare, such as cooking and household chores. Among unmarried women, the majority of the study’s respondents also indicated that, when applicable, someone else has the final say in the

131 National Population Commission (NPC) [Nigeria] and ORC Macro, Nigeria Demographic and Health Survey 2003 (National Population Commission (NPC) [Nigeria] and ORC Macro 2004) 29, 39-42; This study reports that decision-making in marriages is highly dominated by the husband and it is consistent with results obtained from the 2003 Nigeria Demographic and Health Survey (NDHS) which stated that decision-making in households was dominated by husbands. ibid 25.
132 ibid
decision-making concerning them.\textsuperscript{133} Thus social setting, in addition to other factors, can contribute to determining women’s state of health. In this manner, the underlying distribution of gender roles between men and women in society can limit women’s ability to access resources that could significantly enable them to respond to their healthcare needs. This is particularly where women have lower socio-economic status than their male counterparts, resulting in constraints that could influence their health outcomes.\textsuperscript{134} These gender inequalities can have far reaching consequences on women’s health and well-being in Nigerian society.\textsuperscript{135}

3.4.1 Women and their Health in the Context of Gender-based Barriers and Practices

Gender barriers through cultural and traditional practices have been cited as additional factors that can affect women’s health and influence their access to healthcare services, facilities and medicines in Nigeria.\textsuperscript{136} These gender-related problems are prevalent in societies that subjugate the social status of women and subject them to crude traditional medical practices. Examples of adverse cultural practices are Female Genital Mutilation (FGM),\textsuperscript{137} preferential treatment of male children\textsuperscript{138} and differential access to and utilisation of healthcare facilities by men and women in many communities in Nigeria.\textsuperscript{139} The practice of FGM is largely prevalent in communities that believe the act is necessary to

\textsuperscript{133} ibid 39-40.
\textsuperscript{134} Ezeah and Achonwa (n 130) 47.
\textsuperscript{135} ibid 46-48.
\textsuperscript{136} National Population Commission (NPC) and ORC Macro, Nigeria Demographic and Health Survey 2003 (n 131) 39-40, 127-128; Ezeah and Achonwa (n 130) 47.
\textsuperscript{137} FGM is the practice of cutting, mutilating or removing the external female genitalia for non-medical reasons. World Trade Organization ‘Female Genital Mutilation’ (World Trade Organization 2016) Available at <http://www.who.int/mediacentre/factsheets/fs241/en/> accessed 8 May 2015.
\textsuperscript{138} Lewu (n 129) 227.
\textsuperscript{139} Mairo Usman Mandara, ‘Female Genital Cutting in Nigeria: Views of Nigerian Doctors on Medicalization Debate’ in Bettina Shell-Duncan, Yiva Hermund (eds), Female “Circumcision” in Africa: Culture, Controversy, and Change (Lynne Rienner Publishers 2000) 97-98.
reduce libido and prevent promiscuity.\textsuperscript{140} Apart from the psychological torture, this painful circumcision practice exposes women to infections such as HIV/AIDS, hepatitis B, as well as the danger of haemorrhage, shock and death.\textsuperscript{141} In recent times, several laws and public campaigns have condemned this dehumanising practice in Nigeria.\textsuperscript{142} Nonetheless, it subsists in many rural areas due to the fact that it is deep-rooted in religious beliefs and cultural norms.\textsuperscript{143}

Women are also subjected to other forms of degrading cultural practices such as early/forced marriage, wife inheritance and widowhood humiliation.\textsuperscript{144} Early marriage, especially in the northern part of the country, is a practice that is rooted in religious and traditional beliefs that justify it as necessary to prevent promiscuity, which, in turn, adversely affects women’s health.\textsuperscript{145} Sex and child bearing with an immature body causes many health problems, including Vesico Vaginal Fistula (VVF)\textsuperscript{146} and Recto-Vaginal Fistula (RVF),\textsuperscript{147} reproductive and sexual dysfunction and infertility including cases of chronic pelvic infections, and

\begin{thebibliography}{99}
\bibitem{140} World Health Organization, 'Female Genital Mutilation' (World Health Organization) also available at <http://www.who.int/mediacentre/factsheets/fs241/en/> accessed 22 May 2016.
\bibitem{144} Oluwakemi Amudat Ayanleye, 'Women and Reproductive Health Rights in Nigeria' (2013) 6(2) OIDA International Journal of Sustainable Development 127, 131.
\bibitem{145} TC Okeke, USB Anyaehie and CCK Ezenyeaku, 'An Overview of Female Genital Mutilation in Nigeria' (2012) 2 Annals of Medical and Health Sciences Research 70, 70-72.
\bibitem{147} Armstrong Ukwouma, \textit{Child Marriage in Nigeria: The Health Hazards and Socio-Legal Implications} (Lulu Press 2014) 171.
\bibitem{146} VVF is identified as ‘an abnormal fistulous tract extending between the bladder and the vagina that allows the continuous involuntary discharge of urine into the vaginal vault.’ VVF may be caused by prolonged obstructed labour. Ma Salam, \textit{Principles and Practice of Urology} (Jaypee Brothers Medical P 2013) 487. VVF is highly prevalent in young maternal age births where the physical immaturity of the mother’s body leads to 'cephalopelvic disproportion.' Other factors that influence the high rate of VVF include FGM and poor obstetric facilities and services. Neil Harris and Mary Garthwaite, 'Vesicovaginal Fistulae' (2010) 26 Indian Journal of Urology, 253.
\bibitem{142} Ngianga-Bakwin Kandala, Ngozi Nwakeze and Shadrack Ngianga II Kandala, ‘Spatial Distribution of Female Genital Mutilation in Nigeria’ (2009) 81(5) The American Society of Tropical Medicine and Hygiene 784, 784. For example, states like Akwa Ibom, Ondo, Edo, Delta, Cross Rivers, Bayelsa, Ogun, Osun, and Rivers state in Nigeria have enacted laws to prohibit FGM. Furthermore the African Charter on Human and Peoples' Rights on women’s rights to which Nigeria is a party in Article 5, places an obligation on State Parties to prevent the practices of FGM.
\bibitem{143} TC Okeke, USB Anyaehie and CCK Ezenyeaku, 'An Overview of Female Genital Mutilation in Nigeria' (2012) 2 Annals of Medical and Health Sciences Research 70, 70-72.
\bibitem{147} RVF are ‘abnormal epithelial-lined connections between the rectum and vagina.’ Also known as ‘obstetric fistula,’ it often results from trauma suffered during childbirth and labour. Teresa deBeche-Adams and Jaime Bohl, 'Rectovaginal Fistulas' (2010) 23 Clinics in Colon and Rectal Surgery 99.
\end{thebibliography}
death from childbirth. Scholars also note that religious and cultural practices, such as the purdah system of wife seclusion in the northern parts of the country, are also barriers to accessing healthcare by women. This practice can prevent women from seeking medical attention when necessary. Gender-based violence which includes intimate partner violence, rape and sexual violence, physical battery and psychological harm are also vices that affect women’s health and impinge their fundamental human rights. These violent practices, in turn, have far reaching consequences on women’s physical, sexual and psychological health and wellbeing. Researchers have associated violence and abuse of women with negative health outcomes including physical injuries, reproductive health disorders, HIV and sexual infections, unwanted pregnancy, emotional problems, depression and sleeping disorders. Unfortunately, the inability to access healthcare resources to alleviate their health situation mean that they are severely restricted from regaining good health to pursue other productive activities. For these reasons and many others, this chapter makes a case for their access to medicines. The point being made here is that for women already confronted with these limiting factors, any additional constraint on access to essential

medicines will typically impose a greater challenge to their health outcomes.\textsuperscript{152} The argument in the chapter does not lose sight of the fact that the most logical thing to do is address the socio-cultural and economic root cause of these problems and health concerns. Nonetheless, the problems associated with accessing drugs within the context of a patent right and the effect on their rights to health cannot be underestimated, hence the focus in this thesis.\textsuperscript{153}

### 3.4.2 Biological and Physiological Factors

The specific healthcare needs of women, especially those infected with HIV/AIDS also offer an ethical base to argue for a consideration of women's access to medicines in Nigeria.

Studies indicate that HIV/AIDS incidence is higher for women than it is for men in the sub-Saharan African region.\textsuperscript{154} For various reasons relating to biological and cultural factors, lack of control over sexual interactions and economic hardship, women are more vulnerable to HIV infections.\textsuperscript{155} Several factors, including physiological disposition; sexual behaviour, social attitudes to the infection, cultural norms where women are less likely to negotiate condom use, domestic violence and rape, and so on, work to women's disadvantage with

\textsuperscript{152} It is worthwhile noting that this is not to say that the problems of access are solely attributed to these socio-cultural, traditional, domestic and economic issues. In this thesis, these issues are raised to offer an additional basis to argue for women's right to access medicines.

\textsuperscript{154} For example, the Committee on Economic, Social and Cultural Rights (CESCR) has made the point [...] there is a need to develop and implement a comprehensive national strategy for promoting women's right to health throughout their life span. Such a strategy should include interventions aimed at the prevention and treatment of diseases affecting women, as well as policies to provide access to a full range of high quality and affordable health care, including sexual and reproductive services. Consequently, "[t]he realisation of women's right to health requires the removal of all barriers interfering with access to health services, education and information, including in the area of sexual and reproductive health. It is also important to undertake preventive, promotive and remedial action to shield women from the impact of harmful traditional cultural practices and norms that deny them their full reproductive rights."

\textsuperscript{155} For example, the Committee on Economic, Social and Cultural Rights (CESCR), General Comment No 14, The Right to the Highest Attainable Standard of Health (Twenty-second session, E/C.12/2000/4, 2000) paragraph 21. Also available in United Nations International Human Rights Instruments, ‘Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies’ (HR/GEN/1/Rev.6, 2003) 85. (The right to health is the subject of the analysis in the next chapter.)


regards to the infection. In most parts of the developing world, the increasing spread of the virus amongst younger and pregnant women is attributable to social and cultural practices that encourage older men to have sex with younger women and restrict women’s freedom in negotiating sexual practices.

In Nigeria, as in many other developing countries, mother-to-child transmission (MTCT) is another challenging issue of concern to women and their children. MTCT transpires when HIV is passed on from an infected mother to child either during pregnancy, or delivery, or through breastfeeding. UNAIDS indicate that many children living with HIV had been directly infected by their mothers, primarily in utero, during labour or while breastfeeding. Studies also illustrate that access to antiretroviral medicines can reduce the risk of MTCT to five percent. However, Joint United Nations Programme on HIV/AIDS (UNAIDS) in 2013 reports that less than fifty percent of pregnant women living with HIV in Nigeria have access to essential antiretroviral treatments.

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156 Research has also shown that in some sub-Saharan African societies, women are accused of being the source of infections, and often bear the brunt of promiscuity and immorality name calling, as well as facing countless acts of discrimination and stigmatisation due to their HIV status. Physicians for Human Rights, Futures Group International/POLICY Project and Center for the Right to Health (n 154) 16.


159 For example, in 2009, an estimated 370 000 [230 000–510 000] children were directly infected with HIV through mother-to-child transmission. UNAIDS, Global Report: UNAIDS Report on the Global AIDS Epidemic 2010 (n 55) 63. See also Scott Skinner-Thompson, AIDS and the Law (Wolters Kluwer Law & Business 2015) 1-34.


162 UNAIDS, Global Report: UNAIDS Report on the Global AIDS Epidemic 2013 (n 160) 40. UNAIDS also report in 2013 that women living with HIV in many countries still lack sufficient access to the HIV prevention, treatment care and support services, and
treatment, their babies’ chances of surviving to adulthood are reduced, thus access to and use of antiretroviral drugs to prevent transmission and safeguard children is paramount. For this reason and others, the UN general Assembly Special Session on HIV/AIDS made a case for a response to issues of HIV prevention and treatment in a multi-sectoral and gender-sensitive manner.

Apart from the difficulty posed by HIV/AIDS, studies and scholars have also shown that women are more prone than men to the risk of sexually transmitted diseases (STDs) such as chlamydia and gonorrhea because of their anatomy. Poorer women may also be more susceptible to other diseases that affect their immune systems such as malaria or TB due to problems caused by anaemia and malnutrition.

Maternal mortality rate is another health related issue of concern in Nigeria. A status report by the Nigerian Demographic and Health Survey (NDHS) in 2013 showed that the country has one of the highest maternal mortality rates, with a figure of 576 deaths per 100,000 live births. It was also estimated in 2015 that Nigeria records about 58,000 maternal deaths per year as every ten minutes, one woman dies from pregnancy and childbirth, besides HIV/AIDS, malaria, and TB.

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164 Stuart Berman and Mary L Kamb, ‘Biomedical Interventions’ in Sevghi O. Aral, John M. Douglas and Judith A. Lipshutz (eds), Behavioral Interventions for Prevention and Control of Sexually Transmitted Diseases (Springer 2007) 75.
167 National Population Commission (NPC) and ICF Macro, Nigeria Demographic and Health Survey 2013 (National Population Commission (NPC) and ICF Macro 2013) 278.
The timely availability of affordable health resources, services and medicines can and could have prevented many of these deaths.

3.4.3 Assessing the Impediments to Women’s Access to Medicines and Healthcare in Nigeria

A gender-based assessment of poverty and a review of the literature on social inequalities and health suggest that most women, especially in the rural parts of developing countries, experience limited access to health services and resources. In addition to the aforementioned general health system problems, the healthcare constraints for most women are in the areas of poor maternal care and inadequate access to medical services, health resources and medications.

In Nigeria, a majority of women, mainly in rural areas, are living in poverty. In 2011, the Nigerian National Bureau of Statistics estimated that women constitute sixty five percent of the population living below poverty line. It has been noted that women are often faced with economic hardship, illiteracy and poverty, all of which create barriers to access to health services including

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170 See subsection 3.2.

171 Adedini and others (n 149) 3; O'Donnell (n 170) 2821.

172 Ayanleye (n 141) 127-140, 135.

The lack of economic resources to support the provision of essential health services could significantly contribute to the limited availability and access to quality healthcare and medicines by Nigerian women.

An empirical study by the NDHS in 2003, based on 7,000 households in a representative sample of women and men between the ages of fifteen to nineteen, revealed several impediments in different categories such as physical, social and economic barriers to women’s access to healthcare.

Figure 3.2 Problems in Accessing Healthcare for Women in Nigeria.

The survey, which also assessed the women’s social, economic and health status including their reproductive health, showed that many of the survey respondents cited finance as a problem in accessing medical treatments.

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175 Rebecca Holmes and others, Social Protection in Nigeria: Mapping Programmes and their Effectiveness (Overseas Development Institute 2012) 11.
176 Ojanuga and Gilbert argued for example that many women’s health conditions would be treatable and preventable if health facilities were more easily accessible to women. Ojanuga and Gilbert (n 105) 614.
177 National Population Commission (NPC) [Nigeria] and ORC Macro, Nigeria Demographic and Health Survey 2003 (n 131) 139-140. (Access to healthcare is broadly construed in the study to cover access to health facilities, services and medicines. The National Population Commission periodically conducts this survey with technical and financial support from international bodies and organisations such as: ORC Macro, The US Agency for International Development (USAID), Nigerian government, United Nations Population Fund (UNFPA), the United Nations Children’s Fund (UNICEF), and Department for International Development (DFID). The most recent survey is the 2013 NDHS Report. Suffice to note that this thesis also relies considerably on data and information contained in the Nigerian Demographic and Health surveys of 2003, 2008 and 2013.)
178 Adapted from ibid 141.
A 2008 version of the demographic survey assessed the healthcare situation in Nigeria and revealed that one-third of women had experienced at least one barrier to accessing basic healthcare. The 2008 survey identified several barriers women face when accessing quality healthcare and found, for example, that resource-related barriers constituted one of the most significant impediments. More specifically, the study reports that fifty six percent were constrained by a financial barrier, while forty one percent indicated a lack of drugs at the health facilities as a problem. Other challenging factors were: permission from the decision-maker (mostly men or heads of families) to go for treatment; incapacity, transportation and care-related impediments; illiteracy, and limited physical access to health facilities and medical services.

The most recent demographic survey, published in 2014, based its findings on quantitative and qualitative sampling to demonstrate a similar range of problems for women in accessing healthcare. Particularly, forty two percent of women identified finance as a major barrier to their health. The survey’s findings also demonstrated other impediments to women’s health and well-being, such as domestic violence, illiteracy, lack of good nutrition, cultural practices and other socio-cultural and environmental factors.

An assessment of these surveys suggests that many Nigerian women, predominantly the poor who are uneducated, and reside in the rural locations may not have the necessary access to medicines, especially for the prevention, management and treatment of life-threatening diseases and illnesses. Although

176 ibid 141.
178 ibid 138.
179 ibid 137-138.
180 National Population Commission (NPC) and ICF Macro, Nigeria Demographic and Health Survey 2013 (National Population Commission (NPC) and ICF Macro 2013) 153.
181 ibid 153.
182 ibid 153, 303-328.
the poor access to healthcare services, facilities and medicines for women is not limited to resources and low income, inaccessibility due to finances and cost of drugs makes it even less likely for women to have access to adequate healthcare. As a result of the many factors that obstruct their access to healthcare, women will require specific attention in the efforts to scale up access to the necessary healthcare treatments and medicines in Nigeria. In addition to general healthcare services, goods and facilities, this access to healthcare specifically pertains to preventive and curative drug treatments including fertility control and reproductive health treatments, drugs that treat STDs, HIV/AIDS and the necessary maternity healthcare.

In light of the issues of accessibility to affordable medicines in Nigeria, the next part of this chapter considers the debate on the relevance of granting patent protection to pharmaceutical products and processes and the consequential effect on the availability and access to affordable medicines. This evaluation is conducted from an international patent perspective, particularly the effect of the patents provisions in the TRIPS Agreement on the accessibility of medicines for the poor in developing countries. As Nigeria is a member of the World Trade Organisation (WTO) and is obliged to incorporate and implement the patent provisions of the TRIPS Agreement, the access to life-saving medications and public health issues that have arisen in connection with the IP provisions in the Agreement are significant to the central argument of this thesis.

187 For example, the CESCR has stated that 'a major goal [for states] should be reducing women's health risks, particularly lowering rates of maternal mortality and protecting women from domestic violence.' CESCR, General Comment No 14 paragraph 21.

188 Cottingham and Berer (n 20) 69–84. (Observing that the majority of research and development, manufacture and distribution of drugs including sexual and reproductive, is in the hands of private profit-making pharmaceutical companies that hold patent rights to their creations.)
Part II: PATENTS, THE TRIPS AGREEMENT AND ACCESS TO ESSENTIAL MEDICINES IN DEVELOPING COUNTRIES

3.6: The TRIPS Agreement and Access to Medicines: The International Debate

In the preceding chapter, the relevance and advent of the TRIPS Agreement were discussed.\textsuperscript{189} The fact that the emergence of the global IP system has generated public debate on the effect of patents protection to pharmaceutical innovation and the far-reaching adverse on access to essential medicines was also introduced.\textsuperscript{190} These discussions have centred on whether the benefits of the TRIPS Agreement, which aims to promote technological innovations and investment in research for new and therapeutic drugs, outweighs the cost implications to public health, particularly, for poorer people in developing countries.\textsuperscript{191} Consequently, the patent provisions in the Agreement, which include the support for pharmaceutical innovation, raises an issue that Nigeria has to grapple with to address the challenges of access to medicines in the country.\textsuperscript{192}

\textsuperscript{189} See the discussion in Chapter II, subsections 2.5.1, 2.5.2.
\textsuperscript{190} Ellen FM ‘t Hoen, ‘TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond’ in Jean-Paul Moatti and others (eds), \textit{Economics of AIDS and Access to Care in Developing Countries; Issues and Challenges} (ANRS 2003) 42. Also available at http://www.who.int/intellectualproperty/topics/ip/tHoen.pdf accessed 16 May 2014.
The following discussion highlights the ways in which patent law and rights interact with the campaign for access to medicines from an international standpoint.

3.6.1 Patents in TRIPS for Pharmaceutical Products and Processes

The TRIPS Agreement contains provisions for the protection of products and innovative processes in all technological fields, including pharmaceutical products and processes, chemicals, and plant varieties with some patentability exceptions. Thus all members of the WTO are obligated to establish and enforce the same minimum standard of patent protection for pharmaceuticals — whether produced locally or by international multinational corporations — under their national laws, failing which they may be subject to a complaint before the WTO’s Dispute Settlement Body (DSB). In complying with TRIPS, members may, but are not required, to implement more extensive protection than is required by the Agreement, provided it is consistent with the general standard of the Agreement. Members are given latitude to adopt an appropriate method for implementing the Agreement provided it is in accordance with the national treatment (NT) and most favoured nation (MFN) treatment provisions in Articles 3 and 4 respectively.

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Compared to the Paris Convention, several provisions of the Agreement such as Articles 27(1), 27(3) (b), 28, 30 and 31 (a)-(f) strengthened the minimum standards of patent rights for enforcement in Member countries. Sampath (n 157) 253; Germán Velásquez and Pascale Boulet, ‘Globalization and Access to Drugs: Perspectives on the WTO/TRIPS Agreement’ (World Health Organization Action Programme on Essential Drugs 2015) 21-22.
A particular concern for some developing countries is the obligation to provide legal protection for pharmaceuticals and health products. Before TRIPS, states had the sovereign authority to design their laws governing pharmaceuticals in any manner best suited to their economic situation, technological activities and development priorities. In some countries, patents for pharmaceuticals were limited to process patents and generally favoured local production of generic drugs, hence medicines were generally less expensive than the original product. With the introduction of TRIPS, however, countries lost that sovereignty to craft their national laws in a more flexible way to promote innovation while allowing considerable room for generic competition, since all members were now obliged to adhere to the same minimum rules for products, including pharmaceuticals.

3.6.2 An Inventor’s Right to a Patent in the TRIPS Agreement

To promote technological innovation and development, the TRIPS Agreement, in Articles 27 and 28, provides for the availability of a patent right to inventors. For a minimum period of twenty years, members are mandated to protect the term-specific interest of a patent holder to restrict others from using, making, offering for sale, selling or importing the patented invention without the permission and authority of the rights owner. This right is available without

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196 For instance, t’Hoen observes that when the Uruguay Round of negotiations was launched in 1989, forty nine members out of the ninety eight signatories to the Paris Convention did not grant patent protection to pharmaceutical products. Ten members also excluded patenting of processes and twenty two disallowed chemical processes from patentability. Ellen FM t’Hoen, The Global Politics of Pharmaceutical Monopoly Power: Power Drugs Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public (AMB Publishers 2009) 9.
discrimination as to the place of origin of the invention, the field of technology and whether the invention is produced locally or imported. With respect to pharmaceuticals and medicines, the patent right of inventors is often justified as particularly important in pharmaceuticals R&D. However, whether there is merit in the patent system for pharmaceuticals and, indeed, whether this advantage outweighs or justifies the associated cost is still open to debate and controversy. The justification is further examined.

3.6.2.1 Justifications of the Patent System for the Availability of, and Access to Medicines

As previously discussed in Chapter II, IPRs, particularly patent rights, are perceived to be a mechanisms for innovation and technological development. Likewise the argument in favour of patent-as-incentive as an opportunity for increased innovation, R&D and economic reward for ingenuity, is largely supported in the case of patenting of pharmaceuticals, although this argument is still debatable.

In the pharmaceutical industry, it is widely argued that a patent provides an important incentive for the stimulation of R&D of new and highly therapeutic medicinal treatments and drugs. Because patents do appear to be important in facilitating new breakthrough drugs, the patent protection of pharmaceuticals, it is argued, is particularly relevant to increasing access to medicines.

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198 The TRIPS Agreement, Article 27
199 In subsection 2.3.1, 2.3.3 and 2.3.4 of Chapter II.
200 Christine Greenhalgh and Mark Rogers, Innovation, Intellectual Property and Economic Growth (Princeton University Press 2010) 32-39. (The role of IP as an engine of innovation by providing the necessary incentive and its adverse impact on public health and innovation has been debated extensively in the academic literature. It is however difficult to do justice to the entire debate considering the limited scope of this study.)
202 Culit (n 194) 181.
(IFPMA) argue, for example, that ‘[t]he vast majority of medicines available today would not exist without the incentive provided by intellectual property rights.’

For many reasons, a patent is seen to provide a desirable stimulus for pharmaceutical R&D. First, a patent is generally presumed to be essential to the pharmaceutical sector because it enables inventors to recoup the cost of expenditure on the research and production activities. Scholars and pharmaceutical industry specialists often paint a picture of drug development and production as a complex, unpredictable, long and risky undertaking. Pharmaceutical industry specialists and commentators explain that the R&D process for a new drug (also known as a new molecular entity (NME) or new chemical entity (NCE)) is a capital intensive, time-consuming research process sometimes with uncertain results. In addition, they emphasise that the R&D process for a new drug is a very expensive venture. In 2016, for example, a

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207 See also Pharmaceutical Research and Manufacturers of America (PhRMA), 2015 Biopharmaceutical Research Industry Profile (PhRMA 2015) 13; Ho (n 205) 7-8.
study estimated that it costs an average of US$2.6 billion to develop one new drug in the US.\textsuperscript{208}

Secondly, pharmaceutical companies argue that the granting of exclusive patent protection assures them of financial incentives to further invest funds into the discovery and development of other new medicines.\textsuperscript{209} Analysts are therefore quick to point out that the market advantage of patent exclusivity spurs pharmaceutical companies to invest further in other research ventures.\textsuperscript{210} By conferring a temporal ‘exclusive market position,’\textsuperscript{211} inventors and investors can recover spending costs and also benefit through profits from sales which provide the capital to reinvest in other medicinal R&D undertakings.\textsuperscript{212}

Thirdly, having invested financially and undertaken the risk associated with the development and research of a new drug, a patent secures the inventor’s interest against imitation and commercial appropriation of inventive results, because new drugs can quickly be reverse engineered and reproduced in

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\textsuperscript{208} PhRMA, 2016 Biopharmaceutical Research Industry Profile (n 206) 46. See also, PhRMA, 2015 Biopharmaceutical Research Industry Profile (n 207) 35. It is often argued that the research to find a new drug undergoes several stages of clinical screening, trials and testing, with a substantial number of medicines failing to reach the final stages of production and approval for marketing. PHARMA, Biopharmaceutical Research & Development: The Process Behind New Medicines (n 206) 5-18; Ho (n 205) 4-16; PhRMA, 2015 Biopharmaceutical Research Industry Profile (n 207) 12-13. This position is supported in a report by the IFPMA stating that it takes an estimated ten to fifteen years for a promising new compound to be identified, clinically tested to ensure efficacy and safety, and approved by the US Food and Drug Administration (FDA) before a successful drug is launched. Consequently, few promising compounds actually make it through this process to a safe and effective medicine. To illustrate further, the report states that out of 3,200 compounds tested and developed in 2009 only 25 new medicines made it through to the launching stage. IFPMA, The Pharmaceutical Industry and Global Health: Facts and Figures (n 205) 12. See also Ho (n 205) 7-10. PhRMA stated in 2016 that only an average of 12% of investigative medicines entering clinical trials are eventually approved by the FDA. PHARMA, 2016 Biopharmaceutical Research Industry Profile (n 206) 46. However, although developing a novel drug is an expensive enterprise, pharmaceutical firms are often not solely responsible for bearing this cost. Governments through tax cuts and benefits, donor organisations, charities and private individuals can also play an important role in shouldering the cost of R&D, directly or indirectly. See Ho (n 205) 8.


\textsuperscript{210} CIPR (n 146) 29; Henry Grabowski ‘Patents, Innovation and Access to New Pharmaceuticals’ (2002) 5(4) Journal of International Economic Law 849, 849-860. (Gabrowski reports that a survey of US R&D managers indicates that patent confers an essential competitive advantage of being the first to introduce the product in the market.) ibid 850; Richard C Levin and others, ‘Appropriating the Returns from Industrial Research and Development’ (1987) 3 Brookings Papers on Economic Activity 783. (The survey of R&D managers in the US empirically demonstrates that a patent is very significant in appropriating the benefits of pharmaceutical innovation ventures.)


\textsuperscript{212} PhRMA, 2015 Biopharmaceutical Research Industry Profile (n 207) 26-29
This argument leads commentators to point out that a patent is significant to pharmaceutical firms because it is an effective tool to ward off and control competition.\footnote{FM Scherer, 'The Political Economy of Patent Policy Reform in the United States' [2007] KSG Faculty Research Working Paper Series, 8; Leveque and Ménière (n 211) 21.}

Evidential empirical studies are often presented to demonstrate that a patent is a factor that influences the decisions of pharmaceutical companies to invest in the discovery and R&D of medicines and technological innovations.\footnote{James Bessen and Michael J Meurer, 'Lessons for Patent Policy from Empirical Research on Patent Litigation' (2005) Boston University School of Law Working Paper Series, Law and Economics Working Paper No. 05-22, 10; Kenneth C Shadlen and others, 'Globalization, Intellectual Property Rights, and Pharmaceuticals: Meeting the Challenges to Addressing Health Gaps in the New International Environment' in Kenneth C Shadlen and others (eds), Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries (Edward Elgar Publishing 2011) 2. Reverse engineering and imitation practices in India are cited as examples of the ways in which a patent can secure the interest of an inventor against infringement and free-riding. ibid. Without patents therefore, pharmaceutical companies may struggle to make the profit which is the reward for undertaking the R&D venture. Jean O Lanjouw and Iain Cockburn, 'Do Patents Matter?: Empirical Evidence after GATT' (2000) NBER Working Paper No. 7495, 5.}

For instance, in a study of the British patent system, Taylor and Silberston identify that patent protection is relatively unimportant to many industries, with the notable exception of the pharmaceutical sector.\footnote{See for example, Edwin E Mansfield, 'Patents and Innovation: An Empirical Study' [1986] 32 Management Science 173; Taylor and Silberston (n 205).}

In making the point that ‘[n]o other major industry approaches pharmaceuticals in its degree of attachment to patent protection,’ they report in their study that patents are influential in the operations and pharmaceutical R&D activities of the understudied pharmaceutical firms.\footnote{ibid 231, 250-251, 263-265. However, the pharmaceutical sector stood out in its reliance on patent in the study. Accordingly, they assert that the ‘pharmaceutical industry stands alone in the extent of its involvement with the patent system.’ ibid 250.}

Consequently, they conclude that ‘these operations would not have been created had effective patent protection not been available […]’.\footnote{ibid 250.}

Consistent with this view, a study by Mansfield in 1986 revealed that patents are incentives for research-related drug firms to conduct R&D activities and to develop and market drugs.\footnote{Mansfield (n 215).}

Through a random survey of 100 manufacturing firms, the study shows that the pharmaceutical industry in the
United States was greatly influenced by the patent system in their R&D activities.\textsuperscript{220} In particular, the study demonstrates that sixty to sixty-five percent of pharmaceutical products would not have been introduced or developed without the assurance of patent protection.\textsuperscript{221}

These studies make a compelling case for the argument that the pharmaceutical sector regards patents as particularly important to a high rate of drug research and production.\textsuperscript{222} However, one must be cautious in deducing a generalisation of the claim that patents induce inventiveness and R&D activities in the pharmaceutical sector. Other incentive mechanisms can play an important role in the innovation process and drug production decisions of pharmaceutical firms. A 2002 study of 1,478 R&D labs in the U.S. manufacturing sector in 1994 revealed that no industry relies exclusively on patents as an incentive.\textsuperscript{223} The study reports that firms generally employ a variety of other R&D incentives stemming from lead time advantage, selling complementary products and secrecy to protect their inventions. For instance, at different stages of the innovation process, firms may initially rely on secrecy prior to commercialisation, but maintain competitive advantage through a patent right, aggressive marketing and lead time.\textsuperscript{224} This also holds true for pharmaceutical firms. Although the study records a more significant effect of a patent on pharmaceutical R&D and product innovation of drugs relative to other sectors, the survey also observes that ‘pharmaceutical firms emphasise

\textsuperscript{220} ibid 175.
\textsuperscript{221} ibid
\textsuperscript{222} Admittedly, pharmaceutical innovation and progress has led to a dramatic decline in death rates for diseases such as HIV/AIDS, cancer, polio, and measles.
\textsuperscript{224} ibid
complementary capabilities [such as secrecy] and being first to market in addition to patents.\(^{225}\)

Moreover, even if a patent is sufficient to encourage innovation and research-related activities, the current technological capacity and development reality of many developing countries suggest that the role of a patent as an inducement for innovation may be minimal. In sub-Saharan Africa for example, many countries (except South Africa), lack the required technological/scientific competence and manufacturing infrastructure to direct industrial and scientific activities towards research-intensive drug discovery and production activities.\(^{226}\)

This means that the ability of developing countries to respond to the incentive rationale of a patent is unlikely.\(^{227}\) WIPO recorded for instance that more than eighty percent of patent applications for pharmaceuticals, pharma-chemicals and biotechnology in the period 1995-2006 originated from six countries — the US, Japan, Germany, France, UK, and Switzerland.\(^{228}\)

Clearly, then, patents are crucial policy instruments in guaranteeing the returns on investment in the pharmaceutical sector of the more industrial countries. Nonetheless, this is not to say that patents are irrelevant to the pharmaceutical sector whether directly or indirectly.

### 3.6.3 The Justification of Patents-as-incentives and the Neglected Diseases Argument

\(^{225}\) ibid 8-12.


\(^{227}\) In 2008 Park examined the theoretical and empirical research on the effects of IPRs on innovation and technology transfer and observed that the effect of IPRs on innovation in a country depends on its initial level of IP protection and its stage of economic development. See Walter Park, ‘Intellectual Property Rights and International Innovation’ in Keith Eugene Maskus (ed), *Intellectual Property, Growth and Trade* (Emerald Group Publishing 2008) 230. In particular, the study concludes that ‘stronger IPR have a negative effect on R&D and patenting among relatively weaker IP countries and a positive effect among relatively stronger IP countries.’ ibid 320.

\(^{228}\) Shadlen and others (n 214) 2. This is not surprising since many pharmaceutical industries are concentrated in the more developed countries, with the notable exception of a few developing countries, including India.
A pronounced area where the patent-as-incentive argument has failed to secure or facilitate innovation is in the area of R&D of diseases prevalent in developing countries.\textsuperscript{229} Even where treatments were initially researched and produced, there is the still the issue of the availability of appropriate new drugs to treat infectious diseases due to increasing resistance to existing treatments.\textsuperscript{230} The non-availability of medicinal treatments for infectious and tropical diseases predominantly affecting, or severe in, the developing parts of the world, is more commonly known as the issue of drug availability for ‘neglected’ tropical diseases (NTD).\textsuperscript{231} NTDs have been identified as diseases that ‘affect almost exclusively poor and powerless people living in rural parts of low-income countries.’\textsuperscript{232} Accordingly, ‘[w]hile they cause immense suffering and often life-long disabilities, these diseases rarely kill and therefore do not receive the attention and funding of high-mortality diseases like AIDS, tuberculosis and malaria.’\textsuperscript{233}

Generally, disease burdens are categorised into three groups. Type I diseases such as Hepatitis B, liver diseases, diabetes and cancer, affect people in developing and developed countries in the same proportions.\textsuperscript{234} For these diseases, there is adequate funding and R&D for cures and treatment.\textsuperscript{235} Type II diseases like HIV/AIDS, and TB affect both developing and developing

\textsuperscript{229} The imbalance and dearth of research for neglected diseases affecting the poor in developing countries have received considerable attention in more recent years. Oxfam in 2008 stated that NTDs kill over an estimated 500,000 people yearly. Specifically, OXFAM reports that ‘[i]nfectious diseases remain the main cause of death in Africa, claiming the lives of millions of people every year, especially those of women and children.’ Rohit Malpani, Corinna Heineke and Mohga Kamal-Yanni, \textit{Ending the R&D Crisis in Public Health: Promoting Pro-poor Medical Innovation} (Oxfam Briefing Paper 2008) 6.
\textsuperscript{230} Ramanan Laxminarayan and others, ‘Drug Resistance’ in Dean T Jamison and others (eds), \textit{Disease Control Priorities in Developing Countries} (2nd edn, World Bank 2006) 1031-1032.
\textsuperscript{231} Hestermeyer (n 206) 161-162.
\textsuperscript{235} ibid
countries; however, the incidence of infection is higher in developing countries. While there is funding for these types of diseases, especially in rich countries' markets, the funding is not always proportionate to the disease burden or investment in treatments is insufficient, especially in developing countries. Type III diseases, such as leishmaniasis, onchocerciasis (river blindness), Chagas disease, leprosy, schistosomiasis, lymphatic filariasis, sleeping sickness, TB and dengue fever amongst others, are neglected diseases that exclusively or overwhelmingly afflict people, especially the poor, in developing countries. For these diseases, there is generally limited funding and R&D for cures and treatments. Furthermore, because the disease incidence is predominantly in low and middle income countries, their governments may also lack the financial means to undertake or subsidise R&D expenditure for necessary treatments.

In Nigeria, studies also indicate that the country has one of the highest reported incidences of NTDs such as intestinal helminth infections, schistosomiasis and lymphatic filariasis, especially in the rural areas. The country’s disease incidence ranks fourth or fifth globally behind the more populated Asian nations,

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236 ibid
238 WHO, ‘Defining Disease Types I, II and III’ (n 234) 1. Studies on the effect of patent on pharmaceuticals R&D of neglected diseases indicate that patent appears not to have created the necessary incentive for research investment into new treatments and medicines for diseases prevalent in developing and least-developed countries. See Margaret Kyle and Anita M McGahan ‘Pharmaceuticals Before and After TRIPS’ (2009) NBER Working Paper No. 15468, 19. (They conclude that ‘R&D on neglected diseases is not associated with increases in the potential market size in low-income countries, whether or not those markets provided patent protection. This is not to claim that patents are irrelevant.’) ibid 19.
239 HIV/AIDS and malaria are sometimes identified as neglected diseases. Hunt and others, Neglected Diseases: A Human Rights Analysis (n 232) 3
240 Claude and Weston (n 233); Commission on Macroeconomics and Health, Macroeconomics and Health: Investing in Health for Economic Development (World Health Organization 2001) 77.
such as China, India and Indonesia. In terms of the incidence of vector-borne tropical diseases, Nigeria has one of the highest reported rates of lymphatic filariasis and onchocerciasis in Africa, with an estimated global ranking of third and first place respectively. Nigeria also has an estimated 18 million people at risk from trachoma, with nearly 1.3 million people living with trichiasis. The country also accounts for the third or fourth largest number of new cases of leprosy in Africa (behind Ethiopia and the Democratic Republic of Congo).

These diseases generally afflict the vulnerable poorest, living in rural communities with limited access to quality healthcare.

While not unique to women, the high burden of NTDs may be borne by women, particularly pregnant women and children under their care, because of their vulnerabilities resulting from social and gender determinants, biological and genetic factors, physical and environmental risk, economic, political and poverty-related factors. This high disease incidence could in turn, constitute serious impediments to women’s general well-being and severely affect their physical and reproductive health. Studies provide evidence to indicate that NTDs are factors that can significantly affect women’s reproductive health in developing countries and increase the chances of contracting sexually

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242 Hotez and Kamath (n 241); Derek A Lobo and others, 'The Neglected Tropical Diseases of India and South Asia: Review of their Prevalence, Distribution, and Control or Elimination' (2011) 5 PLoS Neglected Tropical Diseases 5; Hotez, Asojo and Adesina (n 241) 1-4.

243 Vector-borne diseases are transmitted through vectors from living organisms such as mosquitoes, ticks, sandflies, tsetse flies, black flies, fleas etc. These bloodsucking insects ingest disease-producing micro-organisms during a blood meal from an infected host (human or animal) and transmit them to humans. World Health Organization, A Global Brief on Vector-Borne Diseases (World Health Organization 2014) 9. The WHO stated for example that disease burden from malaria (carried by a mosquito host) is heavy in the sub-Saharan African region with an estimated ninety percent of deaths resulting from malaria. ibid 13.


247 World Health Organization, A Global Brief on Vector-Borne Diseases (n 243) 9.


249 Okwa (n 130) 157–163.
transmitted diseases (STIs), as well as entrenching stigmatisation and gender inequalities.\textsuperscript{250} Women suffering from forms of neglected diseases such as female genital schistomiasis are particularly exposed to other severe health problems such as infertility, anaemia, preterm labour, menstrual disorders, painful sexual intercourse and pregnancy complications.\textsuperscript{251} These neglected diseases further cripple economies in many poor communities of the third world.\textsuperscript{252} They leave in their wake significant physical and psychological burdens, in addition to economic hardships resulting from the loss of ‘productivity and high cost associated with long-term care, which in turn, contributes to the entrenched cycle of poverty and ill-health for neglected populations.’\textsuperscript{253} The lack of affordable and efficacious medications to treat these neglected diseases represents an enduring medical challenge to the healthcare needs of people, especially women, afflicted by these diseases in developing countries.

3.6.3.1 Patents and Research for the Development of Treatments for NTDs

While pharmaceutical innovation is on the increase,\textsuperscript{254} this has not been followed by an increase in R&D for these diseases that predominately affect people in the developing world.\textsuperscript{255} For instance, studies indicate that tropical and other diseases concentrated among the poor in developing countries are

\begin{itemize}
\item \textsuperscript{250} Peter J Hotez, ‘Empowering Women and Improving Female Reproductive Health through Control of Neglected Tropical Diseases’ (2009) 3 (11) PLoS Neglected Tropical Diseases 1; Aagaard-Hansen and Chaigna (n 248) 143.
\item \textsuperscript{251} Nawal M Nour, ‘Schistosomiasis: Health Effects on Women’ (2010) 3(1) Reviews in Obstetrics and Gynecology 31-32; Hotez (n 241) 1-3.
\item \textsuperscript{252} Hotez (n 241) 1-3.
\item \textsuperscript{253} Hunt and others, Neglected Diseases: A Human Rights Analysis (n 232) 3.
\end{itemize}
the most neglected in terms of research, development and drug production.\textsuperscript{256}

Of the 1,556 new drugs approved in the period 1975-2004 for instance, only twenty-one were for treatment of NTD.\textsuperscript{257} Eighteen were specifically designated for tropical diseases and only three were approved for treatment of TB (one point three percent), even though NTDs account for an estimated eleven point four percent of the global disease burden.\textsuperscript{258}

The low investment in the development of cures for these diseases is attributed to the insignificant pharmaceutical market of developing countries.\textsuperscript{259} The Commission on Intellectual Property Rights (CIPR) has stated in this regard that the current market conditions and healthcare needs of the poor in developing countries simply do not offer enough incentive to pharmaceutical companies to substantially invest in R&D for NTDs.\textsuperscript{260} CIPR further stated that less than five percent of global spending on pharmaceutical R&D is targeted at NTDs and infectious diseases prevalent in low-income countries.\textsuperscript{261} Even if pharmaceutical companies were to invest in the treatments for neglected diseases, the medicines cannot be sold at a price that would match their profit priorities or cover the R&D cost, given that many people in those countries are poor.\textsuperscript{262}

In reality, the research priorities of pharmaceutical firms and companies follow business and economic rationales as developing countries’ markets lack the economic capital to attract significant R&D, pharmaceutical companies would

\textsuperscript{256} Ibid. Oxfam has stated in this regard that less than ten percent of global health spending is on diseases that afflict ninety percent of the world’s poorest. Malpani, Heineke and Kamal-Yanni (n 229) 5.


\textsuperscript{258} Ibid

\textsuperscript{259} Hestermeyer (n 206) 162


\textsuperscript{261} CIPR (n 146) 32.

rather invest in products that yield financial turnover. As such, their R&D focus is on products that potentially guarantee profit; thus the emphasis is on diseases that afflict the wealthiest in developed countries who can afford to pay for them. Other scholars including Kremer concur, observing that the healthcare needs of the poor in the developing world largely go unmet by pharmaceutical companies’ R&D investment priorities. According to Drahos and Braithwaite, ‘patent-based R&D is not responsive to demands, but ability to pay. The blockbuster mentality of the large pharmas takes them to those markets where there is the ability to pay.’ Consequently, pharmaceutical corporations would rather focus on treatments for high profit yielding illnesses such as mental illnesses, hypertension and erectile dysfunction. It goes without saying that the health needs of the poor in developing countries are not necessarily being addressed by these pharmaceutical companies given the lack of profit inducements.

An illustration is the case of a drug called eflorentine which was designed to fight cancer. It was later discovered to be ineffective as an anti-cancer agent but effective as a treatment for African sleeping sickness (trypanosomiasis). Subsequently, Hoechst Marion Roussel (HMR), the company that developed

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263 Hestermeyer (n 206) 163.
266 Drahos and Braithwaite (n 265) 167.
267 ibid. (However, this is not to say mental illnesses, hypertension and erectile dysfunction are not serious illnesses that deserve treatments.)
this drug, stopped production in 1999 because it was a commercial failure, despite the fact that it could save thousands of lives in Africa. In 2000, HMR transferred the license for eflornithine to the WHO. Together with MSF, WHO began to search for a producer to continue the production of eflornithine for the treatment of sleeping sickness. At the same time, Bristol-Myers Squibb, in 2000, announced the launch of Vaniqa, an eflornithine-based cream for the treatment of unwanted facial and chin hair in women. This profit-oriented venture sparked media attention, with many criticising the pharmaceutical industry of ignoring the poor and treatment for a disease that is killing millions in Africa and other developing countries in favour of a lifestyle treatment. In May 2001, Aventis signed a deal with WHO and MSF to ensure sufficient production and donation of eflornithine by Bristol-Myers Squibb for the therapeutic needs of patients suffering from sleeping sickness. This is in addition to the commitment to support MSF in the supply of the treatment to patients, support continued research and a steady supply of sleeping sickness medicines, as well as surveillance of control programmes. Bayer also agreed to reproduce and support MSF in the supply of two other sleeping sickness drugs, nifurtimox and suramin, in 2001. The bifurcated development of the eflornithine, as a cure for sleeping sickness, with a second profitable use for the elimination of facial hair, highlights concerns about the prioritisation of lifestyle treatments for rich consumers in developing countries over cures for life-threatening diseases affecting the poor in developing countries.

271 ibid; Torreele, Usdin and Chirac (n 269) 19.
272 Torreele, Usdin and Chirac (n 269) 19.
273 ibid
275 As well as two other medicines Melarsoprol and Pentamidine. Torreele, Usdin and Chirac (n 269) 19. (Hoechst Marion Roussel (HMR) was later incorporated into Aventis at this time, Aventis owned the patent right to the drug)
277 ibid
278 Torreele, Usdin and Chirac (n 269) 19.
More recently, the spread of the Zika virus has drawn global attention and heightened the need to find a more sustainable and effective control mechanism to encourage R&D for vaccines and drug treatments for vector-borne and neglected infectious diseases.\textsuperscript{279} As of 3 August, 2016, the WHO highlighted that Zika virus transmission has been reported in about sixty-five developing and developed countries since 2015.\textsuperscript{280} There is currently no vaccine for the prevention and control of the Zika virus infection which is linked to congenital abnormalities, including microcephaly associated with abnormal brain development in infants.\textsuperscript{281} As such, there is need to effectively respond to the vector-borne disease that affects not only the poor regions of developing countries, but also urban regions and developed countries as well. If and when effective vaccines and treatments are available for the virus, there is a need to ensure that the medicines and vaccines reach people living in poorer parts of developing countries at an affordable cost.

Patent law is relevant to this discussion because available patent protection for pharmaceuticals has not resulted in substantial increased benefits in drug development and production of essential drugs to improve access to medicines for the treatment of ‘neglected diseases’ in developing countries.\textsuperscript{282} A large and


Emphasising the importance of a coordinated global effort to address the control of and R&D into neglected tropical and vector-borne diseases and treatments, Dr Dirk Engel, Director of the Department of Control of Neglected Tropical Diseases observed, that ‘[o]ver the decades, dengue and chikungunya showed us that an outbreak response is not enough. Now Zika further emphasises the need for more fundamental and sustained vector control interventions.’ ibid

\textsuperscript{280} ibid; World Health Organization, 'Situation Report: Zika Virus, Microcephaly and Guillain-Barré Syndrome' (Apps.who.int, 2016) available at <http://apps.who.int/iris/bitstream/10665/247197/1/zikasitrep4Aug2016-eng.pdf?ua=1> accessed 7 August 2016. (The WHO (World Health Organization) declared Zika virus infections as a public-health emergency in February 2016, after Zika virus had been reported transmitted to humans in sixty-two countries worldwide.)

\textsuperscript{281} World Health Organization, 'Zika Virus' (World Health Organization 2016) <http://www.who.int/mediacentre/factsheets/zika/en/> accessed 7 August 2016. (The Zika virus is transmitted through the bite of an infected Aedes specie mosquito (Ae.aegypti and Ae.albopictus. The virus causes serious brain defects in children that are born to women who are infected with it.)

growing body of literature points to the failure of the patent-based incentive to facilitate the availability of adequate medicines, particularly for diseases afflicting poorer parts of developing countries. For example, The WHO’s Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) explains that ‘[w]here the market has very limited purchasing power, as is the case for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating and bringing new products to market.’

Assessing this economic reality further, the CIPIH concludes that [f]or developing countries, where the demand is weak — but not the need— there is little incentive to develop new or modified interventions appropriate to the disease burden and conditions of the country.

The Special Rapporteur on human rights to health in his mission statement to the WTO further wrote:

The commercial motivation of intellectual property rights encourages research, first and foremost, towards ‘profitable’ diseases, while diseases that predominantly affect people in poor countries—such as river blindness—remain under-researched.

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285 ibid 23.

The lack of research into specific diseases or appropriate medicines affecting women, with specific requirements such as reproductive or sexual health, has also been noted.\textsuperscript{287} Drawing a similar observation as CIPIH, Oxfam stated that even the existing health treatments may not be appropriate for particular groups of patients such as women and children with special needs.\textsuperscript{288} For example, little research has been directed to the effects of antiretrovirals on women who are pregnant or lactating.\textsuperscript{289} Thus there is another issue of R&D of drugs to cater for the particular needs of women.

A pertinent factor in the unavailability of treatments for NTDs is the role of the TRIPS Agreement as a means of encouraging innovation into diseases. Commonly argued, the extension of patent rights for pharmaceuticals in TRIPS has failed to boost research for drugs that satisfy the health needs of developing countries.\textsuperscript{290} Considering the current challenges for the availability and accessibility of drugs for neglected diseases, several authors and organisations have called into question the relevance of patents in the TRIPS Agreement on pharmaceutical R&D and global health.\textsuperscript{291} In 2006, CIPIH concluded that there was ‘no evidence that implementation of the TRIPS Agreement in developing countries will significantly boost R&D in pharmaceuticals’ and ‘insufficient market incentives’ in developing countries are

\begin{itemize}
\item\textsuperscript{287} Malpani, Heineke and Kamal-Yanni (n 229) 16.
\item\textsuperscript{288} Ibid 1, 16.
\item\textsuperscript{289} Ibid 7.
\end{itemize}
identified as factors for this conundrum.\textsuperscript{292} El Said and Kapczynski further argue that the world’s pharmaceutical market share in developing countries is low for increased marginal value resulting from stronger patent protection; hence the benefit of a patent is unlikely to outweigh the impact on access.\textsuperscript{293} While it would be overstating the importance of a patent to expect that is the only factor that can spur the degree of necessary investment in R&D to address the disease problems of developing countries, the argument, as above, holds that it offers incentive for researchers and pharmaceutical companies to undertake important drug discovery ventures. Indeed, as noted in the Chapter II,\textsuperscript{294} there were reasons to believe that the introduction of patent law in developing countries would facilitate FDI, lead to an increase in innovation for the pharmaceutical companies and enlarge the incentive to undertake important research.\textsuperscript{295} The success of innovative efforts is thus greater when inventions are protected. However, the dearth of investment in products to tackle diseases predominately affecting people in developing countries calls into question the justification of the incentive argument for patent rights in developing countries. The current situation leads some scholars to argue that the welfare benefits of introducing a global regime of minimum patent law through the instrumentality of the TRIPS Agreement is negative or yet to materialise.\textsuperscript{296} It also begs the question as to why developed countries and pharmaceutical companies strongly lobbied to ensure that patent rights were made available to pharmaceutical processes and products in developing countries. Hestermeyer


\textsuperscript{294} See subsection 2.5, 2.5.1 and 2.5.2.

\textsuperscript{295} Hestermeyer (n 206) 162; Carlos Primo Braga and Carsten Fink, ‘Reforming Intellectual Property Rights Regimes: Challenges for Developing Countries’ (1998) 1 Journal of International Economic Law 538.

\textsuperscript{296} Hestermeyer (n 206) 163.
pondered on this and suggests that, as a market strategy, the pharmaceutical industry wanted to prevent low ‘price leakage’ from developing countries to the markets of other developed countries through parallel imports.\(^{297}\) Also, as indicated in Chapter II, developed countries and their industries wanted to limit the imitation, ‘free-riding’ and generic re-engineering of their products and a global IP system appears to be the most appropriate mechanism.\(^{298}\)

While it is an undisputed fact that pharmaceutical companies are first and foremost, profit-making ventures with financial responsibilities to shareholders, they can facilitate the much needed availability of, and access to, medicines. Although the pharmaceutical industry is only one player in this scheme of research into NTDs (arguably, it is the government’s duty to ensure that there is investment in pharmaceutical R&D for the benefit of its people, particularly women), they could significantly contribute to the R&D of essential drugs including treatments for NTDs if more efforts are directed to address these diseases. For this reason, several proposals have been made for new, alternative or complementary mechanisms for directly incentivising and promoting the R&D of innovative treatments for NTDs.\(^{299}\)

In 2012, the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) examined proposals for new and innovative ways of financing and stimulating R&D, specifically for developing countries.\(^{300}\) They include amongst others: public-private partnerships (PPPs) to encourage private and public partnerships in drug

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\(^{297}\) Hestermeyer (n 206) 165.

\(^{298}\) See subsection 2.5.1.

\(^{299}\) These proposals are generally grouped under two categories of ‘push’ and ‘pull’ mechanisms. While push programmes aim to finance or support a specific R&D project by a particular innovator, research institute or pharmaceutical firm, the pull programme is based on a pledge to reward several competitors for a valuable pharmaceutical R&D innovation. Thomas Pogge, ‘The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices’ in Thomas Pogge, Mathew Rimmer and Kim Rubenstein (eds), Incentives for Global Public Health: Patent Law and Access to Essential Medicines (Cambridge University Press 2010) 147.

discovery, development or production programmes; Prize Funds for rewarding innovative R&D; Advanced Market Commitments (AMC) to assure pharmaceutical companies and researchers a return on their investment in R&D for treatments of diseases predominantly affecting developing countries; medicines patent pools for licensing of patents to members of a pool or third parties; patent buyout schemes and open source medicine initiatives. These avenues provide the means for pooling resources, data, and expertise to promote pharmaceutical R&D, licensing and drug production, towards the public health objectives of providing the necessary treatments, especially for populations afflicted by poverty. Importantly, these innovative approaches to promoting and incentivising R&D emphasise a network of collaboration and sharing of knowledge and data between various stakeholders such as governments, public sector, academia, scientists, donor groups, and international organisations as well as the pharmaceutical industry.

Scholars and several organisations also promote the exploration of these multi-sectoral collaborative innovation models to promote R&D and access to medicines in response to the problems of the patent system, such as its implication on the cost of drugs and neglected diseases of the developing world. Developing

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301 This list is in no way an exhaustive alternative or supplementary means to the current traditional patent law approach to incentivising innovation. Other schemes exist to stimulate innovation for the health needs of developing countries and promote access to medicines. They include the foreign filing approach, where patents right holders pledge not to enforce their rights in certain low-income countries, patent ‘buyouts’, international purchase agreements etc. For a general discussion on these, see WHO, *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights*, *Innovation and Public Health* (n 284) 66-91; Michael Kremer ‘Patent Buyouts: A Mechanism for Encouraging Innovation’ (1998) *The Quarterly Journal of Economics*.


countries such as Nigeria can explore these alternative/complementary collaborative methods of stimulating innovation for R&D of essential medicines and vaccines as additional health-related safeguards.

Recently, the scourge of the Ebola virus disease (EVD), and the effective response to treatment for the epidemic, is illustrative of how these collaborations and partnerships work to promote R&D for global health. To help combat the deadly Ebola virus in West Africa, several public-private partnerships and collaborative programmes were set up to support and significantly expedite the research, clinical testing, development, production and distribution of treatments for EVD. Through combined efforts, the clinical trial and research of treatments for EVD were undertaken with funding and technical expertise by the public and private sectors. For example, in 2014, the US Agency for International Development (USAID), the Broad Institute for MIT, and Harvard, and Illumina Inc, initiated a public-private partnership to train personnel, supply technological equipment and gather data that would expedite the development of diagnostic treatments, vaccines and medicines. The initial clinical study and manufacturing cost for the EVD Vaccine CAd3-ZEBOV was part financed by public bodies and research institutes. In 2014, Johnson and Johnson, in collaboration with the US-National Institute for Allergy and Infectious Diseases (NIAID), commenced research, development and clinical

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testing of vaccines for EVD. In 2015, Johnson and Johnson announced the formation of a consortium with other global research institutes and NGO’s to accelerate the R&D of EVD Vaccines. Funding for the project was supported by the Innovative Medicines Initiatives. Development of the vaccine ZMapp by Mapp Biopharmaceuticals received public funds from various government agencies and organisations. To fast-track research, trials, treatments and access to EVD vaccines and medicines, a consortium of government bodies, international NGOs and leading research institutions with a grant of $3.2 million from the Wellcome Trust was set up in 2014. Commendably, despite the low disease incidence (the recent outbreak was contained to a few countries) and obvious lack of financial incentive to research and develop treatments for EVD, there was a rapid response to combat the most recent Ebola outbreak from the onset. There was huge support from pharmaceutical companies in association with government and organisations who rallied together to share information, collaborate and mitigate the cost associated with the drug and vaccine R&D for EVD. Significantly, the traditional incentive argument of patents as an incentive was not relied on as a primary driver to stimulate the R&D.

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310 ibid
312 'Ebola Treatment Trials to be Fast-Tracker in West Africa' (Wellcome 2014) <http://www.wellcome.ac.uk/News/Media-office/Press-releases/2014/WTP057419.htm> accessed 13 May 2015. Partners include the International Severe Acute Respiratory and Emerging Infections Consortium (ISARIC), the University of Oxford, Médecins Sans Frontières (MSF), the World Health Organization (WHO), Institut Pasteur, Institut Pasteur de Dakar, Fondation Mérieux and the Global Health Network. A number of pharmaceutical companies including Mapp Biopharmaceutical, Sarepta and Tekmira are collaborating in the initiative and are providing key data on efficacy, safety and production abilities for a number of potential treatments.
313 PhRMA, 2016 Biopharmaceutical Research industry Profile (p 206) 40.
One of the biggest lessons to be learnt from the Ebola incident and subsequent coordinated attempt to diagnose, prevent, and find cures for the outbreak is that a more collaborative method of incentivising and promoting R&D also reshape the operational efficiency of medicinal R&D, particularly for NTDs. A convergence of interest and expertise from different parties may also lead to a better managed R&D performance and output; accelerate the discovery and development of effective and safe medicines and promote the availability and access to them.

It is worth mentioning that international and donor organisations, public institutions, charities and private individuals are also supporting and funding the R&D of pharmaceuticals and vaccines, especially for neglected diseases pertinent to developing countries.\textsuperscript{314} The Bill and Melinda Gates Foundation, the Rockefeller Foundation, the Wellcome Trust, the William J Clinton Foundation, and Doctors Without Borders (Médecins Sans Frontières) are a few examples of non-governmental organisations (NGOs) and philanthropic donors that actively fund and support the R&D of drugs for diseases towards enabling the availability and access to essential drugs for the needy.\textsuperscript{315} Other examples are PATH Malaria Vaccine Initiative (MVI), an initiative set up to facilitate and speed up the R&D of medicines and vaccines for malaria treatments;\textsuperscript{316} the Roll Back Malaria (RBM) Partnership, a collaborative network fighting malaria;\textsuperscript{317} and the Foundation for Innovative New Diagnostic (FIND), a non-profit organisation devoted to developing and providing new and affordable diagnostic tests and


\textsuperscript{315} It is pertinent to note that this list is merely symbolic of groups and organisations that actively seek alternative measures to encourage pharmaceutical innovation, R&D and availability of essential medicines.

\textsuperscript{316} More information about the organisation’s activities can be found at the official website <http://www.malariavaccine.org/>.

\textsuperscript{317} More information about the organisation’s activities can be found at the official website <http://www.rollbackmalaria.org/>.
other tools for poverty-related diseases such as sleeping sickness in developing countries.\textsuperscript{318}

From an IP perspective, this is not to say that patents are irrelevant to pharmaceutical R&D or should be discarded. Rather than work in isolation to incentivise the manufacturing and distribution of medicines based on financial remunerations and charging higher prices to recoup R&D investment cost, patent holders could also contribute to life-saving pharmaceutical R&D through partnership arrangements, collaborations, sharing of knowledge and many other ways. Pharmaceutical companies could also explore collaborative funding mechanisms to undertake the R&D of medicinal treatments for NTDs.

To be fair to pharmaceutical companies, some have made commendable efforts to scale up access to cheaper drugs through discounted prices or drug donations in partnership with donor groups or organisations. Other pharmaceutical corporations have committed themselves not to acquire or enforce their patent rights in some developing countries. In Zambia, for instance, Novartis offered a discounted price for Coartem, an effective but expensive drug for the treatment of malaria, at cost price through the WHO.\textsuperscript{319}

In Uganda, drug donations have provided immense benefits in the treatment of leprosy, lymphatic filariasis, onchocerciasis sleeping sickness and HIV.\textsuperscript{320} However, while drug donation is important to the affected communities, access through these means is at the discretion of the pharmaceutical companies or donor organisations that can elect to discontinue such discount/donor


More information about the organisation’s activities can be found at http://www.finddiagnostics.org/.


\textsuperscript{320} Ibid
programmes at will. Caines and Lush, for example, express concerns that the
discounts for drugs remain uncoordinated and fragmented, as companies
exercise different approaches in making their donations and discount prices
available.\textsuperscript{321} Another shortcoming of donation is that access to drugs may be
unreliable and inconsistent, donation programmes may be short-term, for
specific periods and reasons only. It is therefore argued that, for sustainable
health benefits, it is essential that there is a consistent and reliable channel for
the supply of effective drugs to meet the health challenges of developing
countries.

More recently, in 2016, GlaxoSmithKline announced their intention to facilitate
better access to medicines by not filing, or even dropping its patents, in poor
countries.\textsuperscript{322} GlaxoSmithKline made the decision not to file for patents in 50 low-
income countries.\textsuperscript{323} For lower-middle income countries, GlaxoSmithKline will
continue to file for patents but grant licences to generic manufacturers for a
‘s small royalty.’\textsuperscript{324} In richer countries, however, patents will still be filed. The
decision was made with the aim of allowing other independent manufacturers to
make and sell generic versions in developing countries and thereby increase
access to them.\textsuperscript{325}

This commendable move has been hailed as important for broadening access
to essential drugs, one which other major pharmaceutical companies can
emulate.\textsuperscript{326} Recognition of the effect that patents can have on accessibility, and
taking steps to curtail the interference of patent right with this access, by the

\begin{footnotesize}
\begin{itemize}
  \item \textsuperscript{321} ibid 37-38.
  \item \textsuperscript{322} BBC News, ‘Glaxosmithkline to "Drop Patents in Poor Countries for Better Drug Access”’ (BBC News 2016)
\texttt{<http://www.bbc.co.uk/news/health-35933692> accessed 24 May 2016.}
  \item \textsuperscript{323} ibid
  \item \textsuperscript{324} ibid
  \item \textsuperscript{325} ibid
  \item \textsuperscript{326} Professor Hill, a former president of the British Pharmacological Society in commending this move remarked that ‘[t]his is a
brave and positive step towards broadening the access important and new medicines in the developing world.’ ibid
\end{itemize}
\end{footnotesize}
pharmaceutical industry, will greatly improve access to and use of essential drugs by the poor in developing countries.

The contribution of this type of ‘corporate social responsibility’ may, however, remain modest if developing countries do not have the facilities and pharmaceutical manufacturing infrastructures to take advantage of such opportunities, especially if the original price set by the pharmaceutical companies on their patented drug is still high. Moreover, access to medicines through this channel remains at the discretion of pharmaceutical companies, who can take out a patent on a dependent drug (e.g. cocktail of ARVs needed at different stages of HIV/AIDS treatment) or seek patent protection in major generic manufacturing countries such as India. This may still affect developing countries with little manufacturing capacity that rely on these cheaper drugs. There is also the issue of how to enforce pharmaceutical companies’ patents pledges should they choose to renege on it. Nonetheless, the importance of this voluntary means of ensuring access is commendable and should not be underestimated.

Having considered the first aspect of the debate on the advantages and counter-arguments on the justification of patents, the consequential adverse effect on public health is further analysed.

3.7 ‘Tripping’ Women’s Health and Access to Medicines: The Case Against Patents in the TRIPS Agreement

Despite the foregoing analysis of the beneficial effects of patents on pharmaceutical innovation, patent rights could nevertheless limit the access to, and use of, the patented medicinal resources or effectively reduce the

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transformative potential (i.e. ability to build upon existing innovation) of the patented invention.\textsuperscript{328} Scholars have noted that, although patents can contribute to increased innovation by encouraging invention and creativity, the protection may incur a social welfare cost and in some cases, obstruct the use and development of the patented invention by others.\textsuperscript{329} This point echoes the two conflicting perspectives to patent rights: on the one hand, a patent is justified by the claim that it provides the necessary incentive to spur pharmaceutical R&D, facilitate FDI and technology transfer and makes available important medicines leading to access.\textsuperscript{330} On the other hand, patent rights might impede access to important resources such as life-saving medicines and thus obstruct development goals. In this manner, reservations about the development benefits of patent rights in the TRIPS Agreement are often contrasted with potentially adverse effects on the affordable accessibility and availability of pharmaceuticals.\textsuperscript{331} This case against patent rights is based upon the exclusive rights granted to inventors and the nature of the protection which could limit poor women’s access to available, affordable and preventive essential medicines and reproductive health supplies. This argument essentially centres on the effects of a patent’s monopoly right on public health and consequently, social welfare and development.

\textsuperscript{328} Pogge, ‘The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices’ (n 299) 137. I have coined the term ‘transformative’ to illustrate the implication of patents for further research and innovation around the existing invention.

\textsuperscript{329} Haiyang Zhang, ‘Rethinking the Patent System from the Perspective of Economics’ in Frederick M Abbott, Carlos M Correa and Peter Drahos (eds,) Emerging Markets and the World Patent Order (Edward Elgar Publishing 2013) 61.

\textsuperscript{330} As discussed earlier in 3.4.1.1.

Figure 3.3 Framework of the Debate and the Relationship between Patents, Access to Medicines and Development in the Context of the TRIPS Agreement.\footnote{This diagram is this thesis author’s representation of the debate. For a discussion of the conceptual framework in which the debate on patents, the TRIPS Agreement and access to medicines within the context of human rights is taking place, see Cullet (n 194) 180-170.}

3.7.1 Arguments on Patents’ Exclusive and Monopoly Rights and Access to Pharmaceuticals

It can be recalled\footnote{From subsection 2.2 in Chapter II.} that exclusivity and monopoly are inherent features of IP and patent law.\footnote{WR Cornish, Intellectual Property: Patents, Copyrights Trademarks and Allied rights (Sweet and Maxwell 1993) 47.} Under patent law, no one can use a patented idea without the
authorisation of the patent owner. It is this ‘monopoly rent to innovators’ that has generated controversy with regards to the effect of patents on the availability of, and access to, medicines. A study of the arguments against patents indicates that the exclusive right which fosters the monopoly and control of knowledge has been challenged by scholars and international organisations, particularly with regards to public health. Nobel laureate Joseph Stiglitz notes that: ‘the fundamental problem with the patent system is simple: it is based on restricting the use of knowledge.’ In other words, a patent’s exclusivity is grounded in the concept of restriction which ‘involves constructing higher walls around knowledge and controlling it tightly.’ When it comes to essential drugs, rights holders, who are usually pharmaceutical companies, can, through their IPRs, control who uses their patented inventions, when and in what circumstances.

With regards to follow-on medicinal R&D, critics have accused the patent system through patentees’ rights, of preventing the transformative use of a patented innovation by those who wish to leverage on the existing inventions. They claim that, while a patent aims to encourage scientific and pharmaceutical R&D, an associated problem is that it can reduce the utilisation of the invention by other inventors, scientists and researchers. Two of the most outspoken critics of IP monopoly rights, economists Boldrin and Levine, also argue that

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335 Boldrin and Levine (n 204) 8; Thomas Pogge, ‘The Health Impact Fund: Boosting Innovation Without Obstructing Free Access’ (n 204) 79.
337 ‘t Hoen, The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health (n 196) 79. (Stating that the temporal patent monopoly ‘comes at a cost to society.’)
340 ibid 18.
341 ibid
monopoly rights have an adverse effect on economic growth, science and technological progress.\textsuperscript{343}

Boldrin and Levine’s contention has some merit. Although, as discussed earlier\textsuperscript{344} a patent is essential to the pharmaceutical industry to encourage the creation of new medicines, it may affect the subsequent availability of, and access to, important follow-on products. Patent rights could act as a barrier to research and innovation when they preclude other pharmaceutical companies from either developing or commercialising new health products and drugs due to concerns over patent infringement or patent thickets. Edwin Cameron argues that patents paradoxically limit the ‘current use of existing inventions so as to increase the development and thus the future availability of new inventions.’\textsuperscript{345}

Thus the foremost objection to the justification of patent as an incentive-to-innovate is that the monopoly right it creates can endanger further use and incremental innovation around the existing invention, rather than promoting it.\textsuperscript{346}

Scholars, such as Posner and Landes, while accepting that IP is instrumental to investment in innovation, also make a case for second-comers who might wish to adapt and improve existing inventions.\textsuperscript{347}

It may be argued that subsequent inventors seeking to improve an invention can negotiate a licence with the rights owner. This argument appears simple in principle; in practice, however, obtaining a licence is not always straightforward.

\textsuperscript{343} They argue that:

\begin{quote}
Intellectual monopoly is not a cause of innovation, but rather an unwelcome consequence of it. In a young, dynamic industry full of ideas and creativity, intellectual monopoly does not play a useful role. It is when ideas run out and new competitors come in with fresher ideas that those bereft of them turn to government intervention – and intellectual "property" – to protect their lucrative old ways of doing business.
\end{quote}

Boldrin and Levine (n 204) 17.

\textsuperscript{344} In subsection 3.6.2.1


\textsuperscript{346} ibid

\textsuperscript{347} Williams M Lands and Richard A Posner ‘An Economic Analysis of Copyrights law’ (1989) 18 The Journal of Legal Studies 325. (While their argument is within the discourse of copyright, the general position on this relates to IP.)
or easy to negotiate. At the discretion of the originator, the request may be refused.\textsuperscript{348} Moreover, the royalty rate for pharmaceutical innovation tends to be high, especially in cases where multiple patent licences are required for R\&D.\textsuperscript{349} The higher cost of patent licences could, in turn, also increase the price of the product, resulting in limited access. The effect of the high cost of the product may be ameliorated where people are able and willing to pay the premium price for the products. But for poorer people, particularly women, in developing countries who cannot afford to pay the premium prices that ordinarily flow from patent exclusivity rights, access becomes a grave concern.\textsuperscript{350} With regards to this monopoly right, scholars and commentators have expressed mixed reactions to the suitability of patents for promoting scientific, technological and enhancing human development, especially in developing countries.\textsuperscript{351}

Another argument centres on the financial and welfare cost of obtaining the patented pharmaceutical products, especially for the poor in many parts of developing and in some cases, developed countries.\textsuperscript{352} This monopolistic effect of patents is more to do with the way it is used and implemented by rights holders within the legal privilege of patent law.\textsuperscript{353} While patents in theory only give the innovator a monopoly of rights to prevent others from practising the innovation, exercising this exclusionary right may, in many cases, control the actual access to the innovative resources. This results from the ‘right to exclude’

\footnotesize{\textsuperscript{348} Indeed, as will be examined in Chapter VI, many compulsory licences have been granted due to the refusal of patent holders to grant licences.  
\textsuperscript{349} Michael H Jester, Patents and Trademarks Plain & Simple (Career Press 200) 107 (Noting that, depending on the licencing arrangement, royalties charged for pharmaceuticals are as high as 20-60 percent.)  
\textsuperscript{350} Cameron (n 345) 442.  
\textsuperscript{353} Gold and others, Toward a New Era of Intellectual Property: From Confrontation to Negotiation: A Report from the International Expert Group on Biotechnology, Innovation and Intellectual Property (n 306) 13.}
monopoly right which provides an opportunity for patent holders to restrict
generic reproduction, control competition, and raise the prices of their
innovative products as they deem fit.\textsuperscript{354} This temporary market exclusivity
allows the rights owner discretion to set the price of the drugs, which they
usually set much higher than the production costs.\textsuperscript{355}

In a competitive market, multiple companies will produce the same product and
compete on price, thus driving the price down to a point near production cost.\textsuperscript{356}

However, during the subsistence of patents, patent holders (often large
pharmaceutical companies), have a monopoly right over the production,
distribution and price fixing of their patented products.\textsuperscript{357} This price control,
therefore, raises issues about its effect in limiting access to affordable drugs
required by people in developing countries to fight diseases and infections.\textsuperscript{358}

This is more so where one patent holder holds a patent right to an essential life-
saving drug with no therapeutic substitute, leaving consumers without a choice.


\textsuperscript{355} Joachim Henkel and Robert Lutte, ‘Synthetic Biology: Solving the Pharmaceutical Industry Innovation Problems?’ in Ifígo de Miguel Beriaín and Carlos María Romeo Casabona (eds), \textit{Synbio and Human Health: A Challenge to the Current IP Framework?} (Springer 2014) 36. Describing how market monopoly power works, Schulz adds:

[i]n a monopoly market, the sole producer of an item is free to set the price, in contrast to producers in competitive markets which have no individual influence in price and hence may be regarded as price takers rather than price setters. The monopolist has a considerable degree of market power, which will increase his profit as compared with that which he might expect to earn in a competitive market situation.


\textsuperscript{358} ibid 145. These problems are not inherent in patent law, rather, they are a result of the manner in which patent right owners utilise and enforce their rights. E Richard Gold and others, ‘Are Patents Impeding Medical Care and Innovation?’ (2010) 7 PLoS Med 1, 3.

\textsuperscript{357} Aida Caldera and Ziga Zarnic ‘Affordability of Pharmaceutical Drugs in Developing Countries’ Kiel Institute for World Economics Working paper No. 419. (Note, however, that even where drugs are patented, the patent owner only has monopoly rights over the chemical entities, and can only exclude others from making, selling, using or dealing with the patented invention. The right holder(s) still compete with other producers with therapeutic substitutes.) Carsten Fink ‘How Stronger Patent Protection in India Might Affect the Behavior of Transnational Pharmaceutical Industries’ (1999) Policy Research Working Papers, 3; Haochen Sun, ‘A Wider Access to Patented Drugs under the TRIPS Agreement’ (2003) 21 Boston University International Law Journal 101, 106.

Commentators have expressed differing opinions on the anti-competitive effect of patent monopoly on accessing essential drugs. Some argue that the problem of access to medicines has little to do with patents. Putting forth a similar argument, Professor Adewopo states that ‘patent law, though a factor in the dynamics of promoting public health, is neither a determinant for nor a barrier to access.’ Furthermore, it is argued, for example, that in countries with high rates of HIV/AIDS, patents for many antiretroviral are non-existent or rarely enforced. The basis of some of the contrary arguments is that patents do not confer sufficient monopoly control over ideas or market power to cause lack of access to medicines. This argument also hold the view that, actually, right holders in relation to pharmaceuticals have less than ten years to exclusively market their products as they wish, after which generic competitors can engage in price competition.

This argument is, however, insufficient considering that pharmaceutical companies can, and do, frustrate the generic availability of a drug by taking new patents to extend the life of pharmaceuticals through a process known as ‘evergreening.’ The effect of patents on price is further examined.

359 Jae Hun Park, Patents and Industry Standards (Edward Elgar Publishing 2010) 120. It is worth noting that the problem of access to medicines in developing countries is multifarious and not limited to patents alone. However, patent can be a factor. As a report indicated, The problem of access to essential medical products – diagnostics and vaccines as well as medicines – persists for reasons that are complex and often interlinked. They have to do with trade agreements, market size, drug pricing, intellectual property and competition within the pharmaceutical industry as well as with a progressively drying R&D pipeline, the financing of R&D and pharmaceutical production, procurement and supply issues, and the failures of health systems in many poor countries and regions. This complex situation calls for a comprehensive approach that will improve coherence among many players across different sectors.


361 Adewopo ibid 186.


363 Adewopo (n 360) 186-187.

364 Oxfam reports for example, that ‘[i]nstead of promoting true innovation, pharmaceutical companies, due in part to the perverse incentives created by IP rules, have instead sought extensions on pharmaceutical patents (ever-greening), to pursue only
3.7.1.1 Examining the Literature on Patent’s Effect on the Price of Medicines

So far, empirical evidence directly linking the prices of patented essential medicines to inaccessibility, and the degree to which patents specifically threaten access to new drugs, varies. Nonetheless, many empirical and scholarly investigations into several developing and developed countries make this connection by describing the effect of patents on prices, and then linking the increased price to the affordability of the products in association with other socio-economic, political and environmental factors.

In Nigeria, there have been no specific empirical studies associating problems of accessing essential medicines with patent rights. However, a 2006 study by the Federal Ministry of Health, in conjunction with organisations which include the World Health Organization (WHO) and Health Action International (HAI), offers empirical evidence on price differences between the originator (innovator brands) and cheaper generic medicines. The study found that innovator brands of medicines for all treatments cost more than the equivalent generic version. By way of example, the study revealed that, while it would cost a worker one point four days’ wages to pay for the cheapest hypertension generic drug, atenolol, it would require ten point four days’ wages to pay for the branded equivalent of atenolol. The study thus concludes that the innovator brand of the

blockbuster returns on medicines and to develop ‘me-too’ medicines in lieu of true innovation.’ Malpani, Heineke and Kamal-Yanni (n 229) 36. India and China who were the bulk suppliers of generic drugs are now subject to global regulation of patents under TRIPS. Thomas Faunce, ‘The Awful truth About Evergreening’ (2004) The Age. Available at <http://www.theage.com.au/articles/2004/08/06/1091732084185.html> accessed 15 June 2015. This point is further discussed in Chapter VI. For reasons of space and the scope of the study, this debate will not be sufficiently covered in this chapter.

365 For a more comprehensive description of the results of the study, see Federal Ministry of Health and others, Medicine Prices in Nigeria: Prices People Pay for Medicines in Nigeria (n 79).

366 ibid 27, 35-36. In comparison, this price ratio for medicines procurement in public facilities was above the international reference price and five times higher than seven other developing countries in Africa. Also, generics in Nigeria were comparatively 825% more expensive than seven other countries. ibid 6, 38.
drug atenolol cost seven point three times more than the lowest priced generic.\textsuperscript{367} Furthermore, although the study indicated the low availability of medicines in public facilities\textsuperscript{368} compared to private facilities, it showed that generics were more available and affordable in all sectors than the originator brands.\textsuperscript{369}

In 2011, the situation report by the Federal Ministry of Health and the World Health Organization also illustrates that the median ratio price\textsuperscript{370} for public procurement of originator drugs was four point zero one and three point twenty nine for the generic equivalent.\textsuperscript{371} In the public sector, the median price for originator drug was seven point four and three point five for the generic, while the private sector had a considerable difference of fourteen point six for originator brand and four point five for the generic.\textsuperscript{372}

\begin{table}[h]
\centering
\begin{tabular}{|c|c|c|c|}
\hline
 & Public procurement & Public patient & Private patient \\
\hline
\textbf{Availability} & & & \\
Median (%) & Originator & 1.2 & 14.8 \\
 & Lowest priced generic (LPG) & 21.4 & 30.7 \\
\hline
\textbf{Price} & & & \\
Mean Price Ratio & Originator & 4.01 & 7.4 & 14.6 \\
 & Lowest priced generic (LPG) & 3.29 & 3.5 & 4.5 \\
\hline
\textbf{Affordability} & & & \\
Number of days’ wages & Originator & 1.3 & 1.5 \\
 & Lowest priced generic (LPG) & 0.5 & 0.6 \\
\hline
\end{tabular}
\caption{Representations of the Availability, Affordability and Price Difference between the Originator and Lowest Priced Generic Medicines in Nigeria.\textsuperscript{373}}
\end{table}

\textsuperscript{367} ibid 5-6.
\textsuperscript{368} Only about 46\% of a basket of key medicines were found in facilities. ibid 11.
\textsuperscript{369} ibid 16, 22-25.
\textsuperscript{370} In the study, prices of medicines were compared with standard international reference prices and expressed as a ratio of the national price to the international price. The Median Price Ratio was selected to reflect the access to medicines situation in the country. For example, a price ratio of two will indicate that the price is twice the international reference price. Federal Ministry of Health and World Health Organization, \textit{Nigeria Pharmaceutical Country Profile} (n 108) 22.
\textsuperscript{371} ibid 22-23.
\textsuperscript{372} ibid
\textsuperscript{373} Adapted from Federal Ministry of Health and World Health Organization, \textit{Nigeria Pharmaceutical Country Profile} (n 108) 22.
What these statistics portray is that prices of the original medicines are higher than the prices of similar generic sources in Nigeria.

Other investigations in developing and developed countries have generated additional insight into the effect of a patent on price and access to medicines.\textsuperscript{374} Much of the evidence linking patent prices and access to medicines have been highlighted in the case of HIV/AIDS.\textsuperscript{375} For instance, the result of a comparative study of patented and generic price differences of HIV/AIDS medicines in Thailand from 2001-2004 found that the patented drugs were one point five to three times more expensive than the equivalent generic version in 2001.\textsuperscript{376} In another example, the price of an important antiretroviral HIV drug, 3TC (Lamivudine, Epivir), was marketed and sold by Glaxo in the US for US$3,271 while the generic version was sold for $190 and $98 by Cipla Ltd and Hetero Drugs Limited respectively.\textsuperscript{377} Furthermore, Schulz, citing examples of differences in the wholesale prices of several HIV drugs in three countries (South Africa, India and Thailand) under different patent regimes, illustrates a considerable price variation as follows:\textsuperscript{378}


\textsuperscript{377} Oh, ‘TRIPS, Patents and Access to Medicines: Proposals for Clarification and Reform’ (n 374)

\textsuperscript{378} Schulz (n 355) 147.
Comparatively, the study shows that the prices of generic drugs in India and Thailand were considerably less than their patented equivalents in South Africa. The study indicates that the reason for considerable price variation in Thailand and India is the difference in patent protection. While the patent law in South Africa offers considerable patent protection, India and Thailand, until recently, did not offer protection to pharmaceutical products.

This point is further illustrated by MSF in a report on the wholesale price difference between the patented and generic versions of the ARV fluconazole in 2000. MSF observed that, while the original drug sold by Pfizer cost US$11.84 in Guatemala, $10.50 in Kenya, and $8.25 in South Africa, the generic version by Cipla sold for $0.64 in India and $0.28 in Thailand. MSF estimated that, if South Africa imported the generic version from Thailand, it would reduce the cost of one year’s treatment from $2970 to $104, thereby increasing access to the medicine.

Figure 3.5 An illustration of the Price Variation of a Drug in South Africa, India and Thailand.

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Chemists pay in South Africa</th>
<th>Thailand/India</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole</td>
<td>R 80.24</td>
<td>R 1.78</td>
<td>150 mg capsule</td>
</tr>
<tr>
<td>Combivir (AZT/3TC)</td>
<td>R 20.00</td>
<td>R 5.43</td>
<td>300 mg + 150 mg</td>
</tr>
<tr>
<td>AAZT</td>
<td>R 5.54</td>
<td>R 2.38</td>
<td>100 mg capsule</td>
</tr>
<tr>
<td>3TC</td>
<td>R 22.80</td>
<td>R 16.30</td>
<td>150 mg capsule</td>
</tr>
<tr>
<td>Nevirapine</td>
<td>R 31.75</td>
<td>R 12.00</td>
<td>200 mg capsule</td>
</tr>
<tr>
<td>DDI</td>
<td>R 10.90</td>
<td>R 6.00</td>
<td>150 mg capsule</td>
</tr>
<tr>
<td>D4T</td>
<td>R 26.00</td>
<td>R 2.75</td>
<td>40 mg capsule</td>
</tr>
</tbody>
</table>

Source: Treatment Action Campaign, South Africa. Cape Times 18.10.00.
1 Rand ≈ USD 0.133.
and others on the determinants of sources price of antiretroviral (ARV) drugs between 1998 and 2002 in Brazil and thirteen developing countries, including Nigeria,\textsuperscript{385} observes that patent policy can be linked to the price increases in drugs for HIV/AIDS treatment.\textsuperscript{386} In one of the cited examples, the study found a considerable price difference between the branded drugs Zidovudine 300mg, and lamivudine 150 mg, and the cheapest generic equivalent:\textsuperscript{387}

\begin{figure}[h]
\centering
\includegraphics[width=0.5\textwidth]{price_difference.png}
\caption{An illustration of the Price Difference between Branded Drugs and Generic Equivalents\textsuperscript{388}}
\end{figure}

In another example, a review of international and national empirical evidence of the impact of patents in Thailand in 2006, indicated that 200mg (100 capsules) of originator efavirenz HIV treatment cost 3,192 baht per bottle, while the generic version sold for 1,292 baht.\textsuperscript{389} The point being made here should not be lost on the reader. What these data reveal is that the prices of patented or branded medicinal treatments are prohibitive compared to the prices of similar generics sources or alternative medicines.

\textsuperscript{385} The data in the study was collected between 1996 and 2002, and the African countries considered include: Botswana, Congo, Gabon, Kenya, Nigeria and Senegal to ensure a good mix of varying purchasing powers and HIV rates. See Stephane Lucchini and others, ‘Decrease in Prices of Antiretroviral Drugs for Developing Countries: From Political “Philanthropy” to Regulated Markets?’ in IP Moatti, and others (eds), Economics of AIDS and Access to HIV/AIDS Care in Developing Countries: Issues and Challenges (ANRS 2003).

\textsuperscript{386} Ibid 169–211. (Although the study observed that pharmaceutical companies adopt different pricing strategies in developing countries.) Ibid 201.

\textsuperscript{387} Ibid 198.

\textsuperscript{388} Adapted from ibid.

\textsuperscript{389} Yamabhai and Smith (n 376) 2.
Several other studies have focused on the difference between the price of patented medicines and generic versions after the expiration of the patent.\textsuperscript{390} Many of these studies indicate that drug prices are lower amongst multiple competitors.\textsuperscript{391} For example, Suh and others studied the effect of generic drugs entry on the price of thirty-five chemical entities after the expiration of patents between the periods of 1984 and 1987 in the US.\textsuperscript{392} The study demonstrates the benefits of generics by indicating that, while the price of the original patented drug increased after patent expiration, the price had declined by the fourth year after patent expiration due to the availability of competing generic substitutes. The study, therefore, concludes that `\textit{consumers as a whole can gain from the entry of multiple-source drugs because the average price of the market continually declines after patent expiration.}'\textsuperscript{393} Building on this perspective, in 2005, Boersma and others studied the price difference of three medicines: Enalapril, Fluoxetine and Ranitidine prior, to and after patents expiration from 1996 to 2001 in the Netherlands.\textsuperscript{394} Results of the study indicate a decrease in the cost of drugs after patent expiration.\textsuperscript{395}

In other instances, the introduction of generics through compulsory licences successfully reduced the price of essential drugs. The case of Thailand offers a


\textsuperscript{391} It has been indicated however that the presence of multiple local generic competitors does not necessary translate into lower prices of local drugs. Jayashree Watal, `Workshop on Differential Pricing and Financing of Essential Drugs' [2001] available at https://www.wto.org/english/tratop_e/trips_e/wto_background_e.pdf> accessed 15 June 2015.

\textsuperscript{392} Suh and others (n 390) 529.

\textsuperscript{393} ibid 529, 543.


\textsuperscript{395} ibid 195. Enalapril 61%, Fluoxetine 51%, and Ranitidine 65%. (The study noted that the reduced rate was due to availability of generic substitutes and competition.) Conversely, Grabowski and Vernon illustrate that the price of generics might actually increase when introduced after the expiration of the patented version Through a regression analysis, the study observed an increase in prices of original products one or two years after the introduction of generics. Henry G Grabowski and John M Vernon, `Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act' (1992) 35 The Journal of Law and Economics 339-341. (According to Borell, competition has the beneficial effect of reducing price discrimination in no-patent regime.) Borrell (n 375) 506.
good example. A study by Yamabhai and others assessed the effect of compulsory licensing in facilitating the availability of cheaper generic medicines in Thailand. The licences granted for seven drugs showed a positive result in access to drugs and public benefits. The study estimated that an extra 84,158 patients had access to the seven cheaper generic drugs over a period of five years after the compulsory licences were granted.

In contrast to the submission that the pricing of patented pharmaceuticals is a contributory factor to the inaccessibility of new and efficacious drugs, a study by Amir Attaran argues that other socio-economic factors, especially poverty and infrastructural incapacity, not patent policies, are responsible for the problems of access to medicines. Through surveys and statistical analysis, Attaran studied the relationship between patents and access to drugs by examining the status of essential medicines, as defined by the WHO Model List of Essential Medicines, and the frequency of patenting in sixty-five low and middle-income countries. The study showed that only seventeen out of the total 319 essential medicines on the WHO Essential Medicines list were patented. He concluded that patenting of essential medicines is rare in developing countries; hence patents are not a significant threat to the accessibility of relevant essential medicines in the developing world.

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396 For a review of the literature and price difference between generics and patented health products, see Yamabhai and Smith (n 376) 1-18.
398 Yamabhai and others (n 376) 1, 6-7.
399 Borrell (n 375) 506.
400 Amir Attaran, ‘How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?’ (2004) 23(3) Health Affairs 156, 163. (The author further states that the market in developing countries does not offer significant incentives for investment.)
401 This thesis is mindful of the fact that the study published in 2004 is rather old. However, it is cited in this thesis to illustrate an objective view of the debate on the effect of patent on access to medicines and since the study is empirical, it offers a strong basis for one side of the debate.)
402 ibid 155.
403 ibid 159.
study further suggests that patents are not a hindrance because they do not exist ninety-eight point six percent of the time in many developing countries.\footnote{ibid 159. It is worth noting that the study is based on medicines on the WHO Essential Model List. Since the cost effectiveness and affordability of overall treatment is a criterion for selecting essential medicines on the list, this may account for the absence of some expensive drugs under patents; hence the results of analysis may be limited. See selection criteria at Who 'Essential medicines' at <http://www.who.int/medicines/services/essmedicines_def/en/> accessed 15 September 2015. (Although as Attaran stated, there is no evidence to suggest that expensive patented medicines were deliberately excluded.)} While the study stated that ‘patents are infrequent determinants of access to essential medicines,’\footnote{Attaran (n 400) 164.} it is noted that it did not report a zero frequency for patenting. With pharmaceuticals and essential medicines being fundamental to the life of an individual, the one point four percent patent incidence is significant enough and worth taking into account where patents threaten access to the means of treatment for survival.\footnote{According to the study, patents exist for one point four percent of essential medicines - that is ‘300 instances out of 20,735 combinations of essential medicine and countries.’ ibid 158.} With little or no insurance provision and payment for medicines out-of-pocket in many developing countries, even a minor increase in the price of medicines can be prohibitive for many; thus the adverse effects of patenting, no matter how little, could constitute a life and death issue. Therefore, the role patents play in contributing to the problem of accessibility, however slight, is worth a policy response in making medicines more accessible to the poor in developing countries.

In one way, the study by Attaran, which linked problems of access to inadequate economic, social and regulatory factors, supports the position taken in this thesis that, due to additional existing socio-economic, cultural practices and traditional factors, any incremental challenge to accessing medicines will escalate and entrench the problems for people, especially women, in Nigeria and other developing countries. Thus it is not to say that other factors cannot hinder access to medicines. Yet, the problems associated with patent monopoly and pricing control on accessibility to life-saving drugs should not be
discounted. Currently, some important HIV medicines that can maintain and reduce viral loads in HIV patients are under patent protection in some countries. Important second-line or third-line ARV treatment regimen recommended by the WHO such as etravirine, Lopinavir, rilpivirine and raltegravir are presently under patent protection in the national and regional patent laws of developed and developing countries. MSF made the observation that, because of patent barriers, there are no generic equivalents to the ARV treatments and the company discounted prices are not affordable to many in developing countries.

As mentioned earlier, poverty is prevalent in many parts of the developing world. The World Bank, for example, reports that extreme poverty in sub-Saharan Africa was around forty seven percent and that an estimated three-fifths of the world’s extreme poor are concentrated in just five countries which

406 See more on patent status for ARV treatments at Esteban Burrone and Karin Timmermans, "Patents and Licences on Antiretrovirals: A Snapshot" (World Health Organization 2014).

407 The compound patent on the third-line ARV treatment, etravirine, is set to expire in 2019. Patent is available for the treatment in Argentina, ARIPRO member countries, Brazil, China, EAPO member countries, India, Malaysia, Mexico, OAPI member countries, Philippines, South Africa, Sri Lanka, Turkey, Ukraine and Vietnam. As of 2014, patents were pending in Indonesia and Pakistan. Also, patents on novel forms of etravirine expected to expire in 2026 are available in Albania, Mexico and Turkey and are pending in Brazil, China and India. Burrone and Timmermans (n 406) 14.

408 Lopinavir, a second line treatment, whose patent is set to expire in 2017, is protected in Argentina, China, Colombia, Mexico, Philippines, South Africa and Thailand. ibid 16.

409 The compound patent for rilpivirine, another second line treatment has the due date to expire in 2022 in many countries. The patent is available in Albania, Argentina, ARIPRO member countries, China, EAPO member countries, India, Mexico, OAPI member countries, Panama, Philippines, South Africa, Sri Lanka, Turkey and Ukraine. As of 2014, patent application was pending in Brazil, Egypt, Jordan, Malaysia, Pakistan, Venezuela and Vietnam. A patent on the salt form, expiring in 2025, is also available in ARIPRO member countries, Philippines, South Africa, Turkey and Ukraine. ibid 20.

410 The compound patent on raltegravir, a third-line treatment, is set to expire in or around 2022 in developing countries. A review of patent status information by Esteban Burrone and Karin Timmermans indicates that patent has been granted in Albania, China, Colombia, Georgia, India, Mexico, Montenegro, Philippines, South Africa, Turkey, Ukraine, Uzbekistan and Vietnam, and is pending in Brazil as at 2014. The patent on the potassium salt which is expected to expire in 2025, is available in some developing countries including South Africa. ibid 19.

411 ibid; Médecins Sans Frontières (MSF), Untangling the Web of Antiretroviral Price Reductions (14th edn, Médecins Sans Frontières' 2011).

412 ibid

413 See subsections 3.3 and 3.4.3.
include Nigeria. The high cost of drugs in these countries means that many do not have access to medicines. Consequently, the problem of high prices for newer and more effective essential drugs under patent protection may be particularly disturbing for people in Nigeria and other developing countries because of the economic and financial burden it imposes on individuals who cannot afford to purchase these medicines. With women forming the bulk of poor people in most developing countries, this challenge poses a bigger threat to their general health well-being. In the UK, for example, the National Health Service (NHS) provides publicly funded healthcare services and hospital treatments for all UK residents. Unfortunately, such effective public healthcare services, treatments or health insurance do not exist or are ineffective in Nigeria and many developing countries. With access to health care treatments, as stated previously, dependent on out-of-pocket expenses, the high cost of patented medicines can be dire and debilitating to public health.

3.7.2 Revisiting the Debate on the TRIPS Agreement: Patent Rights, Price and Access to Medicines

Although the impact of patents on access to affordable medicines predated the TRIPS Agreement, the introduction and requirements of the international IP system have generated controversy around the implications for price and access to essential medicines. As with the discussion above, the Agreement is considered a determining factor in the challenge of access to medicines

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416 With the exceptions of some services and charges including prescriptions, optical and dental services. NHS, 'About the National Health Service (NHS) in England' (Nhs.uk) <http://www.nhs.uk/NHSEngland/thenhs/about/Pages/overview.aspx> accessed 12 May 2016.
417 In subsections 3.2 and 3.3.
because it introduced the same minimum standard of patent rules for all WTO members to adopt and implement.\textsuperscript{418} Thus the Agreement has added impetus to the concern that the patent protection of processes and products can restrict generic competition and raise the transaction cost of accessing medicines which, in turn, limits the ability of users to purchase the product at a competitive price.\textsuperscript{419} Consequently, patent rights in the TRIPS Agreement, to the extent that it has broadened and lengthened the scope of the protection thereby increasing the market power conferred by patents, is seen to contribute to the problem of accessibility.\textsuperscript{420}

Before TRIPS came into being, some developing countries were able to avoid paying the high prices charged by pharmaceutical companies for purchasing branded medicines by acquiring the generic equivalents at a lower price from other countries whose patent laws did not cover pharmaceutical products, such as India.\textsuperscript{421} These generic medicines had the advantage of being less expensive when compared to patented equivalents because they did not have all the risks and costs associated with R&D for manufacturing new medicines.\textsuperscript{422}

With the introduction of the TRIPS Agreement, however, generic reproduction or imitation of patented drugs amounts to infringement in all WTO member


\textsuperscript{420} Sampath (n 157) 257.

\textsuperscript{421} 't Hoen, The Global Politics of Pharmaceutical Monopoly Power Drugs Access, Innovation and the Application of the WTO Doha Declaration on TRIPS AND Public Health (n 196) 5-6.

\textsuperscript{422} Fink (n 357) 2.

Generic companies essentially focus on the reproduction of existing compounds when patent protection has expired rather than developing new medicines. Countries such as India which was the biggest supplier of cheap generic medicines to developing countries (with sixty seven of its exports going to the developing world) had to comply with the TRIPS.
countries, unless produced under the safeguard and flexibilities in TRIPS or produced under licence from the patent holder.\textsuperscript{423}

These structural conditions and mandate imposed by global patent law have reconfigured the landscape of countries that were prominent generic drug producers. For example, generic producing industries in Brazil and India had to conform to the mandatory twenty year term for product patents which was previously not part of their patent law.\textsuperscript{424} With many developing countries including Nigeria relying on cheaper generics from these countries for several reasons, including the inadequate or insufficient manufacturing capacity and expertise, the concern has been raised that patents for pharmaceuticals will affect the supply, availability and accessibility of the less expensive generics.\textsuperscript{425}

In spite of the access problems associated with the monopolistic and exclusive control of drugs, the TRIPS Agreement contains some flexible safeguards which members can incorporate into national law and take advantage of, in the interest of public health.\textsuperscript{426} These flexible exceptions are the focus of Chapter VI of this thesis.

3.8 Conclusion: Making a Case for Women’s Access to Medicines in TRIPS

Trade regulations are generally perceived as gender-neutral.\textsuperscript{427} Nevertheless, Professors Elson, Cagatay and other foremost economists observe that seemingly neutral trading relations, market systems, economic policies and

\textsuperscript{423} Sampath (n 157) 260. (This is applicable where the national laws of a country so provides in accordance with the minimum standards of the TRIPS Agreement.)

\textsuperscript{424} Before the current IP Law (No. 9.279 of May 14, 1996 (Industrial Property Law) which took effect in 1997), pharmaceutical patents could not be patented in Brazil. Brazil subsequently signed and incorporated the TRIPS Agreement into the national legal system, thus allowing patent protection for pharmaceuticals. World Bank, Innovation Policy: A Guide for Developing Countries (World Bank 2010) 113.


\textsuperscript{426} These flexibilities provide members with optional measures to foster competition, control prices and ensure equitable access to medicines. The flexibilities are discussed further in Chapter V of this thesis.

programmes can bolster existing socio-economic inequalities and social biases.\textsuperscript{428} In the same vein, although the WTO trade rules, agreements and annexes make provisions via national laws that apply to men and women equally, the concern is that these trade arrangements may occasion adverse consequences for women.\textsuperscript{429} Within the ambit of TRIPS, gender issues are identified and traced to women’s access to healthcare and products that will improve their health.\textsuperscript{430} In assessing the impact of trade liberalisation on women’s reproductive health, Grown argues that ‘it can potentially compromise women’s access to affordable and quality reproductive care.’\textsuperscript{431} Specifically, she noted that the TRIPS Agreement is likely to lead to an increase in prices and limit women’s access to affordable reproductive health products.\textsuperscript{432} In addition to the already mentioned effect of a patent right on access to medicines which would affect everyone, the effect may be greater on women as a result of other underlying factors, such as women’s vulnerable situations, roles in society, as well as their economic and social circumstances.\textsuperscript{433} In the case of Nigeria, because poverty increases or is especially prevalent among women, additional policies and laws that have adverse health implications mean that women will have little or no access to quality healthcare. Given that the higher cost implications of beneficial patented medicines affects those with less income and financial means, it is also likely that the high price of medicines will


\textsuperscript{429} Sampath (n 157) 255-256. (Arguing that the effect of the trade rules in the TRIPS agreement could have greater adverse effect on women than men because of their vulnerable positions, especially, in many developing and least developed countries.)

\textsuperscript{430} Doyal (n 415) 233–250.


\textsuperscript{432} ibid 33.

\textsuperscript{433} Sampath (n 157) 256.
be more severe on women.\footnote{Doyal (n 415) 242. (Arguing that, while men and women are affected by the effect of the TRIPS Agreement, ‘there are good reasons for assuming that the impact on women might be especially severe. In the first place, the high cost of potentially beneficial drugs will hit those with the fewest resources and the lowest social status hardest. In many situations this is likely to be women.’)} Therefore, to the extent that patent protection can result in changes that lead to price increases of drugs available to the poor, it can significantly reduce women’s access to medicines and pose a bigger threat to their general health, well-being and human development. This situation may be particularly daunting for pregnant women, resulting in incidental problems to babies and young children under women’s maternal care. The adverse cost effect of medicines on women in many poor countries is also likely to be substantially heavier on women that commonly take care of children, the sick and, at the same time, undertake primary responsibility for the provision of food and other basic household needs.\footnote{Majaraj and Roberts (n 155) 218.} This is more so in cases where the male head of the household is also sick or incapacitated.\footnote{Ibid 218.} Consequently, while every person is subject to the same limitations and disproportionate access to health care services in developing countries, nonetheless, having unequal access to drugs and medicines based on several other factors may be an additional burden for most women in developing countries.\footnote{Note that the use of the term ‘more’ is cautious in this instance. There is no empirical study to indicate that women suffer more in accessing medicines under patents and this thesis has not conducted any empirical study sufficient to draw this conclusion. However, the analogy in this study argues that compared to men, women may suffer the effect of inaccessibility more due to excessive increase in prices of medicines under patents. Other scholars make a similar point with regards to trade agreements and treaties. See Cottingham and Berer (n 20) 69-84; See also Gammage and others (n 427); Sampath (n 157) 256.} For these reasons, this thesis makes a case for women’s access to medicines in subsequent chapters. This is not to say that men are not taken into account in the analysis. In the end, this study is structured to influence policy-making in a way that benefits both men and women. However, from a women’s perspective, this thesis urges the Nigerian policy makers to ensure that patent rights do not interfere with access to medicines and when it does, to effectively take out
necessary measures to ameliorate the situation. In this manner, it argues for more proactive measures, including the use of the TRIPS-compliant flexibilities, to facilitate accessibility to life-saving drugs.

Taking a human rights stance, the next chapter makes a moral and legal claim for women’s access to life-saving drugs as a human right. It also argues that there is no human rights basis for a patent right’s interference with access to medicines.
CHAPTER IV: ACCESS TO MEDICINES TO GUARANTEE WOMEN’S RIGHTS TO HEALTH IN NIGERIA: THE PHARMACEUTICAL PATENTS CONNECTION

The state’s obligation with regard to the right to health […] encompasses not only the positive duty to ensure that its citizens have access to health care services and medication but must also encompass the negative duty not to do anything that would in any way affect access to such health care services and essential medicines. Any legislation that would render the cost of essential drugs unaffordable to citizens would thus be in violation of the state’s obligations […]\(^1\)

4.1 Introduction

The preceding chapter discussed the proposition that the patent protection of pharmaceuticals and the exercise of this patent right raises concerns for health, particularly, access to medicines. In this chapter, access to medicines is identified as a fundamental human right to health, given that the right to health cannot be achieved without access to essential medicines for effective treatment of ailments and diseases. Health as a human right is enumerated in several human rights instruments. Article 25 of the United Nations Declaration of Human Rights identifies that: ‘[e]veryone has the right to a standard of living adequate for the health and wellbeing of himself and of his family, including food, clothing, housing and medical care and necessary social services.’ The 1979 Convention on the Elimination of All Forms of Discrimination against Women (CEDAW) in Article 12(1) makes provisions for the consideration and protection of women’s right to health. In addition, health, and the importance of

\(^1\) Patricia Asero Ochieng, Maurine Atieno, Joseph Munyi, and AIDS Law Project v Attorney General Petition No. 409 of 2009 (High Court of Kenya) paragraph 66.
accessing essential medicines for adequate healthcare, are identified as significant to an adequate standard of living and connected to other human rights such as the rights to life, human dignity, education, development and the participation in civil and political life of society.

It is against this background that this chapter situates the ongoing debate about pharmaceutical patents, access to medicines and public health within the framework of human rights. The chapter argues that the exercise and implementation of patent rights can raise human rights issues in the context of human health and access to essential and affordable life-saving pharmaceuticals. More specifically, human rights principles provide a strong moral support and useful framework within which this thesis argues for a consideration of women’s access to medicines in Nigeria, in view of the adverse impact of international and national patent law on public health. The chapter consequently argues for the consideration, interpretation, and implementation of patent rights to respond to the right to health and access to medicines.

This chapter comprises three sections. The first examines the legal commitment to the rights of women to health in international legal instruments. It starts by examining the right to health and its medicinal component; implications for specific individuals or groups (women specifically); the obligation on states in respect of the right; and its connection to the accessibility of medicines. It also provides a brief introduction to the responsibilities of pharmaceutical companies to the right to health.

The second part examines the intersection between patent rights and human rights, particularly the right to health and access to medicines. The last part makes a case for women’s access to medicines as a basic human right to health, specifically in Nigeria. As Nigeria has committed itself to protect,
safeguard and fulfil this right, the chapter argues that the state has a legal obligation to safeguard the health and wellbeing of everyone, including women, in the context of patent protection and its effect on access to life-saving treatments as discussed in the foregoing chapter.

PART I: THE RELATIONSHIP BETWEEN ACCESS TO MEDICINES AND HUMAN RIGHTS: THE BASIC FRAMEWORK

3.2.1 The Nature of Human Rights

Before delving into the relationship between, and the normative content of the right to health and access to medicines, it is pertinent to ask: what is a human right?

James Nickel identified human rights as:

[Basic moral guarantees that people in all countries and cultures allegedly have simply because they are people. Calling these guarantees ‘rights’ suggests that they attach to particular individuals who can invoke them, that they are of high priority, and that compliance with them is mandatory rather than discretionary. Human rights are frequently held to be universal in the sense that all people have and should enjoy them, and independent in the sense that they exist and are available as standards of justification and criticism whether or not they are recognized and implemented by the legal system or officials of a country.]

This definition sums up the basic tenets as: natural and universal entitlements accruable to all humans; and moral or ethical rights and legal claims. The dualistic nature of human rights as both moral and legal claim means that they

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can exist outside of, or prior to, a legal recognition and at the same time exist within a defined positive law.3

Human rights are frequently held to be universal, inalienable, equal and non-discriminatory, indivisible and interdependent.4 As a universal right, a human right is a prerogative that is held by every human being solely by reason of their very existence. The United Nations5 in 1987 for example, defined human rights as ‘those rights which are inherent in our nature and without which we cannot function as human beings.’6 The concept of human rights is embedded in the notion that ‘human beings are born equal in dignity and respect. [Therefore], [t]hese rights are moral claims that are inalienable and inherent in all human individuals by virtue of humanity alone.’7

The constitutive character of human rights is unassignable; it cannot be bought, sold or inherited; and it is indivisible, whether political, civil, cultural, social or economic.8 All human rights are interdependent and interrelated as such; each human right safeguards, guarantees and contributes to the fulfilment and actualisation of other human rights.9 Being a justifiable entitlement, a human right is not a gift or mere privilege.10 Human rights so construed find legal and moral expression in several international, regional and national human rights

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3 Roger Brownsword and Morag Goodwin, Law and the Technologies of the Twenty-First Century: Text and Materials (Cambridge University Press 2012) 230. For example, Amartya Sen argues that human rights are principally ethical demands, that can and ‘often do, inspire legislation [but] this is [not] a constitutive characteristic of human rights.’ See Michael DA Freeman, Lloyd’s Introduction to Jurisprudence (9th edn, Sweet & Maxwell 2014) 1289.
5 On 10th December, 1948, the General Assembly of the UN adopted the Universal Declaration of Human Rights (UDHR). The UDHR is the basic statement of the inalienable and inviolable rights of the human family and it contains general principles and standards of human rights. Article 1 of the UDHR lays down the philosophy upon which the declaration is based and asserts that ‘[a]ll human beings are born free and equal in dignity and right […].’
9 Koch ibid.
10 Freeman (n 3) 1287.
laws, conventions and legal instruments that impose a degree of enforceable commitment on states and duty bearers to guarantee, safeguard, enforce and protect.

Generally, scholars offer some philosophical theorisation of the nature of human rights as: a) ‘wills,’ or ‘choices’; and b) ‘entitlements,’ ‘interests,’ ‘benefits,’ ‘claims to goods and services.’\(^{11}\) The first approach, ‘wills’ or ‘choices’ emphasises an individual’s personal liberty, freedom of choice and actions.\(^{12}\) The ‘wills’ right advocates hold the view that the purpose of law is to give individuals the broadest possible means to assert and express themselves.\(^{13}\) Essentially, this rights perspective is defined by people’s freedom to be and do something. Thus Hart the philosopher, speaks of rights as equal liberty of ‘all men to be free’\(^{14}\) and advances the concept of rights that are based on will, freedom and the capacity for autonomy.\(^{15}\)

The second approach views human rights as entitlements to have and to enjoy various freedoms, opportunities and benefits.\(^{16}\) Proponents of this right perspective argue that a right aims to protect and promote people’s interests to secure certain benefits.\(^{17}\) This ‘interests’ theory places an emphasis on the welfare and wellbeing of the right holder.\(^{18}\) Human Rights advocates further argue that rights regulate the way people relate to each other or impose an obligation on states to fulfil human being’s certain essential interest and needs.\(^{19}\) Professor Finnis argues, for example, that human rights are

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\(^{11}\) ibid 335.

\(^{12}\) ibid

\(^{13}\) ibid

\(^{14}\) HLA Hart, ‘Are There Any Natural Rights?’ (1955) 64 The Philosophical Review 175.

\(^{15}\) Hart, ‘Are There Any Natural Rights?’ ibid 175; Freeman (n 3) 1305.

\(^{16}\) Freeman (n 3) 335.

\(^{17}\) Freeman (n 3) 336.


instrumental in securing the basic values and interest of human beings to live good lives.\textsuperscript{20} Within the context of social rights, Eide puts it thus, ‘the enjoyment of […] right requires, at a minimum, that everyone shall enjoy the necessary subsistence rights — adequate food, and nutrition rights, clothing, housing and the necessary conditions of care.’\textsuperscript{21} There are, however, difficulties with this ‘interests’ view. Because human needs are boundless, the ‘interests’ theory raises questions as to whether there is a limit to the obligation on a state to fulfil this right.\textsuperscript{22} Nevertheless, the ‘interests’ approach provides a philosophical basis for the recognition and protection of economic, social and cultural human rights.\textsuperscript{23} As well as recognising a human’s basic ‘liberties,’ or ‘freedoms,’ these socio-economic and cultural rights such as the right to education, housing, an adequate standard of living, health and many others, are essential to the overall enjoyment of human rights.

In sum, a human right is significant not only because it seeks to guarantee the moral and legal freedoms and entitlements of every individual, human rights also protect and promote the realisation of certain rights—usually in relation to the responsibilities of states to uphold and implement.

\textbf{4.2.2 Health and the Right to Health}

Good health is one of the many aspects of human wellbeing that is necessary for the enjoyment of human rights. Health,—a person’s state of physical and mental condition and wellbeing—also plays a pivotal role in empowering people

\textsuperscript{20} John Finnis, \textit{Natural Law and Natural Rights} (Clarendon Press 1980) 81-92. (These basic human goods include life and its capacity for development; the acquisition of knowledge, as an end in itself; play and the capacity for recreation; aesthetic expression; sociability and friendship; practical reasonableness; the capacity for intelligent and reasonable thought process; religion or the capacity for spiritual experience and marriage. Finnis identified these interests or ‘basic forms of human good’ as essential factors for human well-being.)


\textsuperscript{23} Nonetheless, for the purpose of this thesis, no distinction is drawn between the ‘interests’ and ‘wills’ theories of rights.
to pursue other activities that will enhance their welfare.\textsuperscript{24} For example, a person who is healthy is in a better position to practically engage in activities he or she find useful, improve their living standards, increase their life chances and also enjoy other human rights.\textsuperscript{25} Thus, as an essential state of wellbeing, health is also a means by which people can undertake social, economic and cultural activities as well partake in civil and political activities, and, as a basic human right, health is an essential, fundamental and indispensable state of wellbeing.\textsuperscript{26} In this sense, health is both a human right in itself and an essential means for the realisation of other human rights.\textsuperscript{27} Consequently, the right to health is one of the cornerstones for the enhancement and improvement of overall social, cultural, economic and human development. The right to health, as with all human rights, contains ‘freedoms’ and ‘entitlements’.\textsuperscript{28} Freedom includes the right to make decisions and control one’s own health and body such as sexual and reproductive rights, while the entitlement aspect of the right to health pertains to the equal rights and opportunity for everyone to access an adequate healthcare system including health services, facilities and drugs.\textsuperscript{29} These guarantees and articulation of human rights to health are acknowledged in several human rights laws and instruments.\textsuperscript{30} Significantly, Nigeria is a signatory to several of these international instruments that establish the right to

\textsuperscript{24} The WHO identified health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. However, the scope of this thesis focuses on health as a physical and mental condition.
\textsuperscript{25} See the introduction of this chapter.
\textsuperscript{26} Freeman (n 3) 1294.
\textsuperscript{27} See Article 1, UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant) (Adopted at the Twenty-second Session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000 E/C.12/2000/4)
\textsuperscript{29} Ibid
\textsuperscript{30} The convergence of these human rights laws indicates that every human being has a fundamental claim to the protection and enjoyment of their rights to an adequate state of health
health, thus the obligation to fulfil the human right to health may be binding on the government under certain conditions.

4.2.3 International Legal Commitments to the Right to Health

The earliest articulation of health as a basic right is in the 1946 Constitution of the World Health organization (WHO) which states that ‘the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being [...]’. This highest standard of physical and mental health as a right of individuals and a duty of the state is also accorded recognition in a number of human rights declarations and treaties. Implicit in the objective of the UN to ‘promote social progress’ and ‘better standards of life’ is the recognition that health is a right worth protecting, and a responsibility of states to recognise, enforce and safeguard in Article 25(1) of the UDHR. To emphasise the commitment to social security and other socio-economic and cultural rights, including the right to health, Article 22 of the UDHR requires State Parties to expend available resources and take steps individually and

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33 Nigeria is a signatory to, and has ratified, several human rights international instruments such as the International Covenant on Civil and Political Rights (ICCPR), Ratified October, 29 1993; The International Covenant on Economic, Social and Cultural Rights (ICESCR), Ratified October 29, 1993. The International Convention on the Elimination of All Forms of Racial Discrimination (the ICERD) Ratified January 4, 1969; The Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT) Ratified July 28, 2001; The Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW) Ratified July 13, 1985; and the Convention on the Rights of the Child (CRC) Ratified April 19, 1991. Nigeria has also signed the two optional protocols related to this Convention: The Optional Protocol to the Convention on the Rights of the Child on the involvement of Children in Armed Conflict and the Optional Protocol to the Convention on the Rights of the Child on the Sale of Children, Child Prostitution and Child Pornography, both signed on September 8, 2000. (The implementation conditions and binding status of these human rights instruments in Nigeria are further examined in the final section of this chapter.)

34 The extent of Nigeria’s obligation to the right to health is further examined in the last section of this chapter.


37 For instance, the fifth recital of the Preamble to the Universal Declaration of Human Rights (UDHR) of 1948 states that ‘...the peoples of the United Nations have in the Charter reaffirmed their faith in fundamental human rights, in the dignity and worth of the human person and in the equal rights of men and women and have determined to promote social progress and better standards of life in larger freedom. Article 25(1) further provides that Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.'
through international and national cooperation, to facilitate the realisation of the rights of all citizens to ‘economic, social and cultural rights indispensable for his dignity [...].’

Being a United Nations declaration rather than a treaty, the authority, legal and binding status of the Declaration on the state’s commitment to secure human rights, has been questioned. Nonetheless, the United Nations International Conference on Human Rights in 1968 established that the Declaration ‘constitutes an obligation for the members of the international community.’ Its provisions have influenced a significant number of national and international laws, treaties, conventions and judicial decisions.

The right to health is also acknowledged in other significant human rights frameworks such as Article 5 (e)(iv) of the 1965 International Convention on the Elimination of All Forms of Racial Discrimination; mentioned in Articles 3, 6, 17, 23 and explicitly outlined in Article 24 of the Convention on the Rights of the Child. These conventions recognise the fundamental right of everyone to medical care, health facilities and access to treatments as constitutive

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39 ibid 4-5. For example, although not explicitly stated, the international Court of Justice touched upon the binding status of the UDHR in the context of state obligation in the Tehran Hostages Case. The Court considered the principles enshrined in the Declaration when examining the responsibility of Iran towards the United States for the detention of US diplomats and consular staff in Tehran and stated thus:

Wrongfully to deprive human beings of their freedom and to subject them to physical constraint in conditions of hardship is in itself manifestly incompatible with the principles of the Charter of the United Nations, as well as the fundamental principles enunciated in the Universal Declaration of Human Rights [UDHR].

40 The Article imposes an obligation on State Parties

[t]o prohibit and to eliminate racial discrimination in all its forms and to guarantee the right of everyone [...] to public health, medical care, social security and social services.

41 The Convention was adopted and opened for signature, ratification and accession by General Assembly resolution 44/25 of 20 November 1989. The Convention entered into force on September 1990.

The Convention in Article 24(1) states as follows:

States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.
components of the right to the ‘highest standard’ of health. Specifically, the expansive provisions on the right to health in Article 24 of the Convention on Rights of the Child aim to address and reduce child mortality and ensure that every child is provided with, and has access to adequate healthcare services and facilities. It also includes the obligation on states to provide the necessary medical care and facilities for the reproductive, prenatal and postnatal care of mothers.

The right to health, as an indispensable right to the enjoyment of the highest attainable state of physical and mental health and social wellbeing, is also contained in several regional legal instruments and national laws. For instance, the right to the highest possible standard and protection of health is recognised and promoted in Article 11 of the 1996 European Social Charter (Revised).\textsuperscript{42} The African Charter on Human and People’s Rights of 1981 (African Charter) in Article 16(1) also provides that every person is entitled to the ‘best attainable state of physical and mental health.’\textsuperscript{43} The Article obligates states to take expedient measures to protect the health of their citizens and respond to their medical needs.\textsuperscript{44} The effect of the right to health in the African Charter was established in \textit{Purohit and Another v The Gambia}.\textsuperscript{45}

In this case, the applicants alleged, amongst other things, that the legislative regime in The Gambia for mental health patients violated the right to enjoy the best attainable state of physical and mental health (Article 16) and the right of the disabled to special measures of protection in keeping with their physical and


\textsuperscript{44} Article 16 (2), African Charter of 1981.

\textsuperscript{45} (2003) AHRLR 96.
moral needs. Holding that The Gambia fell short of satisfying the requirements of Articles 16 and 18(4) of the African Charter, the African Commission stated that the enjoyment of the right to health is crucial to the realisation of other fundamental rights and freedoms and includes the right of all to health facilities, as well as access to goods and services, without discrimination of any kind. The right to health is also recognised as important and promoted in the 1993 Vienna Declaration and Programme of Action.\textsuperscript{46} In Article 31, states are required to refrain from taking ‘any unilateral measure’ that impedes the full enjoyment of human rights, particularly, ‘the right of everyone to a standard of living adequate for their health and wellbeing’ including access to medical healthcare.\textsuperscript{47} Reiterating the same commitment, Article 41 specifically recognises the importance of women’s physical and mental health and reaffirms the obligation on states to promote their equal access to adequate healthcare and reproductive health services.

\textbf{4.2.4 The Right to Health in the International Covenant on Economic, Social and Cultural Rights (ICESCR)}

The ICESCR provides the most comprehensive provision on human rights to health as part of the socio-cultural and economic aspect of human rights. The right in Article 12(1) is in two parts as follows: the first gives a general recognition of the rights of everyone to ‘the highest attainable standard of physical and mental health.’ Having reaffirmed the rights of everyone to health, the second aspect of the right in Article 12(2) exhorts a duty on State Parties such as Nigeria, to take the necessary steps to guarantee and ensure the full

\textsuperscript{46} See Articles 18, 24, 31 and 41 of the Vienna Declaration and Programme of Action of 1993. (Adopted by the World Conference on Human Rights in Vienna on 25 June 1993)

\textsuperscript{47} Ibid
realisation of the rights by providing the necessary health-related resources (medicines), facilities, environment, information and conditions. 48

4.2.5 Approaching Women’s Health as a Human Right

In addition to the above stated general entitlement of every person to the right to health and healthcare, the specific rights of women to health is recognised in several human rights instruments. The Protocol to the African Charter on Human and People’s Rights of Women in Africa is a significant human rights instrument that re-affirms and promotes women’s health and reproductive rights in Article 14. 49 The Article particularly pays attention to the guarantee, protection and promotion of women’s reproductive health. Article 14(2)(a) requires the states, such as Nigeria, to undertake all necessary actions to ensure women’s access to adequate, affordable and accessible health services which will also include medicines. In addition, the 1995 Beijing Declaration and Platform for Action 50 explicitly recognise women’s reproductive rights and also, the entitlement of all women to healthcare and access to adequate medicinal treatments as essential to their sustainable development and empowerment. 51

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48 The necessary steps to be taken include:
(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
(b) The improvement of all aspects of environmental and industrial hygiene;
(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.


49 Article 13(i) also guarantees adequate and paid pre- and post-natal maternity leave in both the private and public sectors.

50 The Beijing Declaration and Platform of Action was adopted at the Fourth World Conference on Women, convened by the UN in Beijing, China, in 1995. The Declaration and Platform of action is a commitment by governments and a global framework of action and blueprint for advancing women’s rights, promoting gender equality, and opportunities for the empowerment of all women. The Declaration and Platform of Action, reinforces the human rights provisions in CEDAW although the commitments and promises are not legally binding. See more at UN Women, Beijing Declaration and Platform for Action: Beijing+5 Political Declaration and Outcome (UN Women 2014).

Furthermore, the Beijing Declaration obliges states to ‘[g]ive higher priority to women’s health and develop mechanisms for coordinating and implementing the health objectives of the Platform for Action and relevant international agreements to ensure progress.’

CEDAW is one of the most significant legal instrument guaranteeing women’s right to health. CEDAW is an international treaty that particularly set out to affirm the principles of fundamental human rights and equality for all women, including girls, around the world. Principally, CEDAW is concerned with promoting and protecting women’s rights by putting women’s issues at the centre of human rights. The Preamble to the Convention, having recognised that ‘in situations of poverty women have the least access to food, health, education, training and opportunities for employment and other needs,’ makes provisions for the guarantee and realisation of women’s fundamental rights including their rights to health.

The protection of women’s human right to health in CEDAW is characterised in two aspects: the first addresses gender discrimination and equality between men and women; while the second part promotes the realisation of the specific, collective and individual rights of women in all areas of their lives including their rights to health and access to basic healthcare services and medicinal treatments in the interests of their human rights.
The recognition of women’s rights, including the right to health, in CEDAW, starts with their rights to be free from all forms of discriminations thus:

[...] any distinction, exclusion or restriction made on the basis of sex which has the effect or purpose of impairing or nullifying the recognition, enjoyment or exercise by women, irrespective of their marital status, on a basis of equality of men and women, of human rights and fundamental freedoms in the political, economic, social, cultural, civil or any other field.\textsuperscript{57}

Implicit in this definition is the recognition that any ‘distinction, exclusion or restriction’ that compromises women’s rights—including their rights to healthcare systems and products—constitutes discrimination. Most importantly, it can be said that this provision aims to ensure their equal access to opportunities, health systems, medicinal products and facilities, and emphatically prohibits health-related violence against them.\textsuperscript{58} As further clarified by CEDAW General Recommendation No. 24 on Article 12 of the Convention (Women and Health), the elimination of discrimination against women requires the guarantee of their health, wellbeing and access to healthcare services to ensure the ‘attainment of highest standard of health.’\textsuperscript{59}

In recognising the important connection between women’s health and their developmental wellbeing, Article 12 of CEDAW specifically emphasises women’s right of access to adequate levels of healthcare systems in connection with their general, and specific reproductive and maternal health.

Article 12 (1) explicitly directs as follows:

\textsuperscript{57} CEDAW 1979, Article 1.


\textsuperscript{59} ibid
States Parties shall take all appropriate measures to eliminate discrimination against
women in the field of health care in order to ensure, on a basis of equality of men and
women, access to health care services, including those related to family planning.60
This provision fundamentally reiterates the right of women to the enjoyment of
the highest attainable standard of physical and mental health as set out in
UDHR and ICECSR. However, while it is generally acknowledged that everyone
has an equal right to health, CEDAW goes further, recognising that women may
face additional challenges in accessing the relevant health-related goods,
services and facilities, as considered in the preceding chapter.61 Thus
specifically for women, the right to healthcare is linked to the elimination of
discrimination.62
It can be said that the provisions in CEDAW reflect the importance of health and
the health system to women’s human rights and wellbeing by linking the issue
of discrimination as another reason to ensure equal access healthcare. Indeed,
one author, in noting the force of discrimination, argues that ‘discrimination is
the most comprehensive, systematic and severe deprivation of human rights.’63
Accordingly, women’s right to health is more than a requirement to guarantee
their access to healthcare systems, resources and facilities, it is broadly
construed as an ‘entitlement to an effective and integrated health system’64
which also entails the removal of all forms of barriers and discriminations to
accessibility.

60 Also, in the place of employment in Articles 11 (1) (f) of CEDAW 1979.
61 See the analyses in the subsections of 3.4 in Chapter III.
62 According to paragraph 13 of the CEDAW General Recommendation No 24,
The duty of States parties to ensure, on a basis of equality of men and women, access to health-care services,
information and education implies an obligation to respect, protect and fulfil women’s rights to health care.
States parties have the responsibility to ensure that legislation and executive action and policy comply with these
three obligations. They must also put in place a system that ensures effective judicial action. Failure to do so will
constitute a violation of article 12.
64 United Nations General Assembly, ‘The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and
The normative framework, the nature of the human rights to health and the obligations on states to guarantee the enjoyment of the right, is further examined. This subsection also explains the significance of accessing medicines, including patented pharmaceuticals, as a component of the right to health and the states’ duty to ensure affordable access to pharmaceuticals in this respect.

4.3 Analysing the Theoretical Perspective and Normative Content of the Human Right to Health and Medicines

The content and conditions necessary for the fulfilment of the right to health have been authoritatively expounded by the United Nation’s Committee on Economic, Social and Cultural Rights (CECSR). This is captured in General Comment No 14 on the Right to Health. The conceptual interpretation of the right to health in Article 12(1) of the ICESCR by the CECSR offers a useful clarification of the nature and scope of the right as well as the corresponding duty on states, including Nigeria, to realise the enjoyment of the right.

4.3.1 The Content and Objectives of the Right to Health

The entitlement to the right to health under human rights law is narrowed down to two health objectives: the right to healthcare and the right to healthy conditions.⁶⁵

The right to healthcare aims to guarantee the availability of and access to an adequate system of healthcare. Inherent in this right is the assumption that everyone should have the means, facilities, products or drugs and services necessary for the realisation of the right to health in a timely and appropriate

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⁶⁵ Freeman (n 3) 1295.
manner.\textsuperscript{66} The CESCR has emphasised the role of states in providing the amenities, supplies, medical services and products necessary for the enjoyment of the right to health.\textsuperscript{67}

The right to healthy conditions places an obligation on states to provide reasonable conditions to enable people to attain and maintain good health such as a healthy working and living environment, and housing (essentially health-related human rights).\textsuperscript{68} It also includes the underlying determinants of health such as nutrition, food, safe and potable water and sanitary conditions, and access to health-related information.\textsuperscript{69} This holistic approach to health includes the right to participate in all health-related decision-making in the community, and at national and international level.\textsuperscript{70} The right to healthcare and healthy conditions are also broadly conceived to include socio-economic factors, such as resource distribution, sensitivity to gender differences, and other traditional and cultural environments including socially-related events such as armed conflicts and violence which are so damaging to health.\textsuperscript{71} HIV/AIDS and other deadly diseases such as cancer are identified by the CECSR as diseases that require specific consideration in the right to health.

It is worth noting that with regards to the duty of the state towards the right to health, the CESCR clarifies that the right to health is not synonymous with the unconditional right to be ‘healthy,’ in that being healthy is determined by several factors including unhealthy lifestyles, biological, genetic and physiological

\begin{flushleft}
\textsuperscript{66} ibid
\textsuperscript{68} Stephen P Marks, ‘The Emergence and Scope of the Human Right to Health’ in Jose M Zuniga, Stephen P Marks and Lawrence O Gottin (eds), Advancing The Human Right To Health (Oxford University Press 2013) 9.
\textsuperscript{69} CECSR, General Comment No. 14, paragraphs 11, 15.
\textsuperscript{70} ibid
\textsuperscript{71} Freeman (n 3) 1296.
\end{flushleft}
dispositions. The state is not expected to safeguard the good health of its citizens against all possible cases of sickness or every cause of ill-health and disability, rather the right to health embraces a wide range of factors necessary to lead a good life. Notwithstanding, the state is expected to take into account biological factors and socio-economic circumstances of individuals in addition to the available resources of the state in providing for the highest attainable health standards. Consequently, the CESCR reiterates that the right to health is conceived within the terms of the right to the enjoyment of medical care including ‘a variety of facilities, goods, services and conditions’ conducive to a standard of living adequate for basic health.

4.3.1.1 The Key Standards of the Right to Health

The CECSR identifies that the realisation of the right to health and its usefulness in contributing to the enjoyment of other human rights broadly embodies four interrelated dimensions: Availability, Accessibility, Acceptability, and Quality.

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73 Paragraph 4, CECSR, General Comment No. 14, Marks (n 68) 9.
74 CECSR, General Comment No. 14, paragraph 9.
1) **Availability** in sufficient quantities: Availability includes adequate and functioning healthcare facilities (such as hospitals, medical professionals), goods (e.g. medicines, vaccines and medical equipment), services (primary care, maternal and reproductive services, physical and mental care) and health-related programmes, as well as underlying healthy conditions (e.g. safe environment, food, water). The healthcare facilities, supplies and conditions must be physically available when and where needed (for example, in both the rural and urban areas).

2) **Accessibility** to everyone without discrimination: the health infrastructures, medicines services and conditions must be equally accessible in a non-discriminatory manner in accordance with the general principles of human rights. Accessibility encompasses three aspects - physically accessible in safe reach for everyone; financially affordable; and with accessible health-related information in a clear and meaningful format. As will be discussed below, this accessibility is most relevant to the discussion on access to medicines in this chapter. Specifically, economic accessibility is important to the study as it touches upon the issue of drug pricing and pharmaceutical patent rights.

3) **Acceptable** in the sense of respect for medical ethics and customs: the healthcare institutions, goods, medicines and services must be provided

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75 Adapted from World Health Organisation 'Right to Health Fact Sheet' available at http://www.searo.who.int/entity/human_rights/Right_to_health-factsheet.pdf?ua=1
76 CECSR, General Comment No. 14, paragraph 12(a).
77 CECSR, General Comment No. 14, paragraph 12(b).
with regard to human dignity and medical ethics, in a culturally appropriate and acceptable manner.\textsuperscript{78}

4) ) Of good quality and scientifically appropriate: all healthcare delivery, services and drugs must be timely, of high standard that is medically and scientifically appropriate, efficacious and safe.\textsuperscript{79}

These key dimensions provide the basic framework of the interventions to achieve the objective of the right to health. These core standards generally refer to the idea that the enjoyment of the equal right of everyone to health should encompass all these dimensions. As a result, Nigeria and other State Parties to human rights laws must bear in mind these dimensions and standards in identifying and responding to the obligation to the right to health and the healthcare needs of their populations, including instances of negotiating multilateral and bilateral trade agreements, and formulating or interpreting patent rights.

4.3.1.2 The Additional Framework of Women’s Right to Health

Generally, the framework of the interventions necessary to guarantee the right to health in the human rights instruments including the ICESCR and the corresponding General Comment No 14, can be applied \textit{pari passu} in the context of women’s right to health in CEDAW and the Protocol to the African Charter on Human and People’s Rights of Women. However, in addition to the above, specific health consideration is given to women. For this purpose, the General Recommendation to CEDAW makes detailed requirements for the provision of healthcare services, goods (medicines) and facilities necessary for the prevention and treatment of women’s specific and general health conditions in a

\textsuperscript{78} CECSR, General Comment No. 14, paragraph 12(c).
\textsuperscript{79} CECSR, General Comment No. 14, paragraph 12(d).
non-discriminatory and cost effective manner.\textsuperscript{80} In the interests of women’s right to health, this duty is reiterated in paragraph 21 of the General Comment No 14 on women’s right to health. Accordingly, states such as Nigeria are required to provide healthcare in the following manner:

a) Physical and financial accessibility: the CEDAW Committee, in noting that cultural, socio-economic barriers, including those of physical access, and the high cost of healthcare services can influence the decision of women to seek healthcare interventions, requires states to ensure that there is timely and affordable access to healthcare.\textsuperscript{81} The Committee further imposes a dual duty on states to promote access to healthcare systems and information, and also to remove every hindrance women encounter in accessing these basic healthcare facilities, services and goods including essential pharmaceuticals.\textsuperscript{82} Health service must be financially accessible to everyone within a reasonable and safe distance in a gender-sensitive manner that also takes into account the vulnerable, the old, children, the disabled and women.\textsuperscript{83}

b) Reliable and available healthcare: Special attention is given to the health interventions that can prevent, detect and treat specific women’s diseases, or conditions that affect women differently from men.\textsuperscript{84}

c) Acceptable: the healthcare measures must be sensitive to women’s rights, dignity, interests and cultures of minorities and indigenous

\textsuperscript{80}CEDAW, \textit{General Recommendation No. 24}, paragraph 9.
\textsuperscript{81}CEDAW, \textit{General Recommendation No. 24}, paragraph 21. The Committee adds that physical and economic access to health services is also part of this obligation on states in paragraphs 7 and 17.
\textsuperscript{82}CEDAW, \textit{General Recommendation No. 24}, paragraph 11 and 21.
\textsuperscript{83}CECSR, \textit{General Comment No. 14}, paragraph 12(b); Joo-Young Lee and Paul Hunt, ‘Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines’ (2012) 40 The Journal of Law, Medicine & Ethics 220, 225. (The authors write extensively on the responsibilities and obligations of pharmaceutical companies to the right to health and access to medicines.)
\textsuperscript{84}CEDAW, \textit{General Recommendation No. 24}, paragraphs 10, 11 and 12.
women, also taking into account the disadvantaged, vulnerable and disabled women.85

d) Quality: the healthcare services and conditions must be of good and safe quality, tailored to meet the distinct features of women’s physiological and biological condition.86

Thus, women are guaranteed the right to health in all facets of their lives. This right includes access to adequate healthcare facilities, services, goods, and living conditions necessary for the enhancement of their health and wellbeing.

4.4 The Human Right to Medicines

Medicine is a significant means for the realisation of the right to health. Where there are no drugs for essential medical treatments, it is hard to conceive the guarantee of the highest attainable standard of health, as it is a powerful resource for the realisation of the good health and wellbeing of humans. This opinion is shared by the UN Human Rights Council, reaffirming that access to medicines is ‘one of the fundamental elements in achieving progressively the full realisation’ of the right to the highest standard of health.87 For this reason, the right to medicines requires that medicinal resources are sufficiently available, accessible, culturally acceptable and of good quality and for women, without discrimination. With regards to affordability, the WHO further states that accessibility implies that the medicines are available at an affordable rate to all.88 This position coincides with the reasoning of other resolutions of the UN

85 CEDAW, General Recommendation No. 24, paragraph 22.
86 CEDAW, General Recommendation No. 24, paragraph 22.
and treaty monitoring bodies.\textsuperscript{89} The UN Office of the High Commissioner for Human Rights writes that ‘[f]rom a human rights perspective, access to medicines is intrinsically linked with the principles of equality and non-discrimination, transparency, participation, and accountability.’\textsuperscript{90} While all medicines are important to health, the General Comment No 14 expressly acknowledges accessibility to health-related goods and essential medicines as defined by the WHO Action Programme on Essential Drugs as a central component of the right to health.\textsuperscript{91} The WHO identified essential medicines as ‘those that satisfy the priority healthcare needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.’\textsuperscript{92}

The link between access to medicines and human rights to health is significant to the argument in this thesis that it is the duty of the Nigerian state to improve and guarantee women’s access to essential medicines within the purview of patent rights. Accordingly, accessing good quality, affordable pharmaceuticals in a timely manner is not only significant to women’s health, development and wellbeing, there is an incumbent duty on Nigerian government as the primary duty bearer to protect, promote and sustain this access and remove of all obstacles to accessibility, including patent rights that could interfere with this access. The obligations on states with regards to accessing medicines, as a


\textsuperscript{91} CECSR, General Comment No. 14, paragraph 12(a) and paragraph 43(d).

\textsuperscript{92} ‘WHO Essential Medicines’ (Who.int). Available at <http://www.who.int/topics/essential_medicines/en/> accessed 6 May 2016. The WHO regularly reviews and updates the list of essential medicines.
human right entitlement have been examined by scholars and human rights advocates.93 For example, Yamin argues from a human rights perspective that access to medicines is not only a necessary component of health, but as a legal right, it emphasises the role that government, third parties and international organisations can play in facilitating and ensuring access.94 Consequently, accessing medicines as a human rights issue delineates the process, normative framework, policies and laws necessary for ensuring access and guarantying of the right.95 In this respect, it imposes a responsibility on duty-bearers to do all they can to ensure women’s access to the medicines in a manner commensurate with the right to health.

Access to medicines from a human rights perspective implies several other obligations. First, it imposes a moral and humanitarian responsibility to undertake the necessary steps to ensure women’s access to medicinal and health treatments as will be further explored below.96 Secondly, there is a legal obligation to ensure women’s access to medication as a national legislative and policy priority which should be reflected in the health system including ‘competition, pricing, licensing and other laws.’97 Thus, states are obliged to facilitate and enhance the means to accessing pharmaceuticals and drugs as a matter of human rights in their legislative and policy considerations. For example, since Article 8 of the TRIPS Agreement grants WTO members the flexible authority to ‘adopt necessary measures’ compatible with the general provisions of the Agreement to safeguard public health and promote the

94 Yamin (n 93) 329.
95 Ibid
96 Ibid 327.
97 Ibid 327.
interests of the public, states such as Nigeria, can adapt their IP regimes to take into account the accessibility of its people to adequate medicines, as a human right. Also, the human right to access medicines can be recognised as legitimate grounds for the design and implementation of the exceptions to TRIPS’ obligations and flexibilities regarding patents. Hestermeyer examines access to medicines as a human right within the framework of the WTO system and the TRIPS Agreement. His study indicates that access to medicines as a human right is essential to the interpretation of the objective and purpose of the Agreement within the context of public health. The study likewise illustrates that access to medicines as a right allows WTO members more discretion to take appropriate measures to guarantee accessibility.

Third, the legal responsibility of states to the right to medicines requires an accountability obligation to enhance accessibility. This will also include measures to ensure that accessing medicines as a right is not interfered with. Thus, accessing drugs as a central component of the right to health, should guide Nigeria’s actions and policies both at the international and national levels.

A number of judicial decisions have shed more light on the central role of medicines as a prerequisite to the realisation of human rights in general and the right to health in particular. In Costa Rica, the applicant in International Ms Vera Salazar Navarro vs Caja Costarricense de Seguro instituted an action against the Social Security Institution for refusing to repay the cost of prescribed

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99 ibid 207-224.
100 ibid 229-254.
101 Yamin (n 93) 327.
patented drugs. Instead the applicant alleged that she was offered a cheaper generic drug for her multiple sclerosis.\textsuperscript{103} The applicant therefore claimed that refusal to reimburse the branded drugs violated her right to health. The court held in favour of the applicant and ruled that the social security institution had a constitutional and internationally binding obligation to provide the exact patented drugs prescribed by her doctor and not the cheaper substitute on the Social Institutions Scheme. In that context, the court found that a denial of access to a certain drug can constitute a violation of the right to health.\textsuperscript{104}

Similarly the Costa Rican Supreme Court in \textit{Mr William García Álvarez vs Caja Costarricense de Seguro},\textsuperscript{105} ruled in favour of the plaintiff, an HIV-positive person who was refused antiretroviral treatment by the social security institution. Because the medicines were not considered essential at that time, they were not on the official national drugs list and thus were not freely available in public facilities.\textsuperscript{106} The plaintiffs argued that the treatments were expensive in the private sector and so refusal to provide them by the institution and inaccessibility was a violation of the right to life and health.\textsuperscript{107} The judge, in the ruling in favour of the plaintiff, decided that:

\begin{quote}
If the right to life is especially protected in each modern State and with the right to health, any economic criteria that pretends to deny the exercise of those rights, has to be of second importance [...] without right to life, all the remaining rights would be useless.\textsuperscript{108}
\end{quote}

\textsuperscript{103} The defendant’s main argument was that the effects and composition of the generic drugs were the same as the branded ones.

\textsuperscript{104} For a comprehensive discussion on other similar cases, see Hogerzeil, Samson and Casanova (n 102) 27.


\textsuperscript{106} ibid

\textsuperscript{107} ibid

\textsuperscript{108} ibid (As interpreted and cited in Hogerzeil, Samson and Casanova (n 102) 27).
Most importantly, although the court considered the economic rationale of not providing the necessary treatment, the court recognised the significance of accessing medicines as a part of the right to life and health. This progressive judicial interpretation of the right to access medicines as an intrinsic aspect of human right is worth emulation in Nigeria.

It is important to note that Costa Rica, similarly to Nigeria, does not expressly recognise the right to health in its Constitution. However, there are provisions that seek to guarantee and safeguard the health of the citizens.\textsuperscript{109} For example, under the social rights and guarantees, Article 50 of the Costa Rican Constitution, recognises the right of every person to a healthy environment.\textsuperscript{110} Article 73 provides for the establishment of a social security system for the protection of the citizens against illnesses to be managed by an institution known as the Caja Costarricense de Seguro Social (Costa Rican Social Security Administration) to offer health services.\textsuperscript{111} Costa Rica like Nigeria had also ratified a number of international human rights instruments and had even taken further steps by establishing institutions to give practical enforcement in the event of violations of the rights, such as the Constitutional Court and Ombudsman’s Office.\textsuperscript{112} The Constitutional Court has held in a number of cases that access to medicines plays an important role as an essential component of the rights to health and life.\textsuperscript{113}

\textsuperscript{109} For more details on the Costa Rican provision on health, see María del Rocío Sáenz, Juan Luis Bermúdez and Mónica Acosta, ‘Universal Coverage in a Middle Income Country: Costa Rica’ (World Health Organization 2010).
\textsuperscript{110} Political Constitution of the Republic of Costa Rica 1949 (as amended).
\textsuperscript{111} ibid
\textsuperscript{112} In making this comparison, it is important to acknowledge the constitutional and legislative variation in both countries as well as the international status of human rights law in their various domestic legal systems. In Nigeria, health is not a justiciable right under the Constitution. The Nigerian judicial authorities are also reluctant to cite international treaties and laws as the basis for their decision on human rights based on Section 12 of the Constitution as will be discussed.
\textsuperscript{113} See for example the decision in Mrs Sidonia Vargas v Hospital San Juan de Dios Constitutional Court [1994] File 2390- C- 94. In this case, a woman suffering from acute leukaemia and diabetes was denied access to the necessary medication to self-administer at home. The reasons given for the refusal to provide the medicines were safety and administrative related. Also, the hospital alleged that its own query to the National Health system to allow the reimbursement of this sort of arrangement was refused. The
Another good example of a case where a state has been made accountable for its obligation to provide medicines in realisation of the right to health is a South African case by Treatment Action Campaign. The case of Treatment Action Campaign and others v Minister of Health and others\(^{114}\) and subsequent appeal to the Constitutional Court (Minister of Health and others v Treatment Action Campaign and others),\(^{115}\) illustrates the binding obligation of the state to provide essential medication as a right to health and life. At the time this case was decided in 2001, HIV/AIDS was a national epidemic in the country, with a high prevalence rate for women, particularly among pregnant women in rural areas.\(^{116}\) Approximately 70,000 children were infected through mother-to-child-transmission (MTCT).\(^{117}\) The WHO reports that about 1,600 infants were exposed to the infection through birth every day, while others contracted the virus through pregnancy or breastfeeding, with many more children at risk.\(^{118}\) AZT or nevirapine were considered significant in reducing chances of MTCT.\(^{119}\) It is against this backdrop that some civil society groups and national health advocacy NGO’s challenged the decision of the South African government to

plaintiff challenged the refusal on the grounds that it violates her rights to life and health respectively. The Constitutional court relied on the importance of upholding the constitutional provision on the right to life to rule that the rule on compulsory administration of such drugs in the hospital permits such an exception. The court linked the right to life with the right to health in its decision. Significantly, this case also illustrates the importance of having access to medicines as a constituent of human right. As interpreted and cited in Hogerzeil, Samson and Casanova (n 108) 25-26.


117 Minister of Health v Treatment Action Campaign (n 115) paragraph 19.


119 Ibid
restrict the procurement and use of nevirapine, an effective drug for the prevention of mother-to-child HIV transmission, to specific pilot sites, through its Protocol Programme.

Most vocal in this case was an NGO, the Treatment Action Campaign (TAC), an HIV/AIDS campaign, lobbyist and advocacy group. The group and its allies claimed that the restriction by the South African government was a fundamental violation of women and children’s constitutional rights to health and equal access to medicines as guaranteed in section 27(1)(a) and 28(1) of the South African Bill of Rights, as well as the right to life and human dignity. Furthermore, the absence of a programme to promote the use of the drug was a breach of its constitutional duty under section 27(2), and its international binding human rights obligations. The central argument was that the government’s programme affected the rights of mothers and their babies who cannot afford to access the private healthcare, research and training sites, hence it restricts their access to the medicine. The Ministry of Health counter-argued that the preventive efficacy and safety of the drug has not been conclusively proved,

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120 Boehringer Ingelheim offered to supply the drug free of charge for five years but the offer was turned down by the government.
121 The Protocol for Providing a Comprehensive Package of Care for the Prevention of Mother to Child Transmission of HIV in South Africa imposes restrictions on the availability of nevirapine in the public health sector to pilot sites in each of the Provinces. For more discussion and analyses of the case and role of the NGO’s, see Duncan Matthews, Intellectual Property, Human Rights and Development: The Role of NGOs and Social Movements (Edward Elgar 2011) 95-112.
122 Section 27 provides that
Everyone has the right to have access to –
(a) health care services, including reproductive health care;
(b) sufficient food and water; and
(c) social security, including, if they are unable to support themselves and their dependents, appropriate social assistance.
(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
123 Section 28(1) reads:
Every child has the right – [...] (c) to basic nutrition, shelter, basic health care services and social services
124 Chapter Two of the Constitution of South Africa contains the Bill of Rights, a human rights charter that protects the civil, political and socio-economic rights of all people in South Africa.
125 Minister of Health v Treatment Action Campaign (n 115) paragraph 44.
126 ibid
127 ibid paragraph 17.
and the state did not have sufficient resources to provide the relevant counselling and monitoring facilities and trained personnel to administer the treatment programme.\textsuperscript{128}

The court after a careful consideration of both arguments held that nevirapine was an efficacious drug that could significantly combat MTCT of HIV and the restrictive programme failed to take into account the need to provide access to the necessary health services to mothers and children who do not have access to the sites ‘particularly for those who cannot afford to pay for medical services.’\textsuperscript{129} The court held that, for children, the primary burden on the state to provide this access is irrespective of parental or family care.\textsuperscript{130} The court concluded that the cost of providing access to the drug was within the resources of the state and ‘it was not reasonable to restrict the use of nevirapine to the research and training sites.’\textsuperscript{131} The court therefore ordered the government and health authorities to progressively make the medicines accessible in all public health facilities and set up a programme to promote the use of nevirapine.\textsuperscript{132}

This South African case significantly establishes the conceptual and remedial framework for the provision and enforcement of the right to access medicine as a right to health. It points to the need to consider access to essential medicines within the broader context of the state’s obligation to respect and promote human rights. The court took the time to consider the legal obligation of the state to enforce socio-economic rights and stressed that the state is under a constitutional duty to take all necessary and reasonable actions to comply with the provision of the right to health. In this regard, the court decided that, while it

\textsuperscript{128} ibid paragraphs 48-57, 65.
\textsuperscript{129} ibid paragraph 57, 60 and 67.
\textsuperscript{130} ibid paragraph 79.
\textsuperscript{131} ibid paragraph 71 and 95. (The court made orders for extensive access to nevirapine necessary to prevent MCT transmission of HIV in the pilot sites of all the health centres in the country.)
\textsuperscript{132} ibid paragraph 135.
is practically impossible to give everyone access to a ‘care service immediately’ (according to the minimum core obligation), the state is under a duty to reasonably provide access to socio-economic rights on a progressive basis.\textsuperscript{133}

Although the delineation of this reasonable standard was not clearly defined by the court, it stated that that government is required to undertake all reasonable measures to eliminate or reduce the condition and ‘large areas of severe deprivation that afflict our society.’\textsuperscript{134} Notably the Court relied on international treaties (ICECSR) to interpret the state’s obligation to adopt ‘reasonable measures’ to implement the right to health.\textsuperscript{135}

All the aforementioned cases have one thing in common: the recognition that access to essential life-saving medicines is an important aspect of human rights, particularly life and health. Understanding the interpretation of access to medicines as a constituent of human rights leads to thinking about its centrality in the guarantee of all human rights. Since access to medicines as a human right is dependent on several factors, including affordability, availability and an efficient healthcare system, it is argued that the Nigerian government for example, has a duty to take proactive positive steps to strengthen its healthcare systems, prevent interference with the right to access medicines and generally fulfil the obligation to provide affordable, safe and timely access to treatments for the practical enjoyment of human rights.

\footnote{ibid paragraph 35.}
\footnote{ibid paragraph 36.}

The court considered the argument of the defendants as to whether section 27(1) (a) conferred a right to health care that was different from the content of the obligation of the state in section 27(2) and found that the two sections cannot be separately interpreted, accordingly, ‘section 27(1) of the Constitution does not give rise to a self-standing and independent positive right enforceable irrespective of the considerations mentioned in section 27(2).’ The court further concludes that Sections 27(1) and 27(2) must be read together as defining the scope of the positive rights that everyone has and the corresponding obligations on the state to “respect, protect, promote and fulfil” such rights. The rights conferred by sections 26(1) and 27(1) are to have “access” to the services that the state is obliged to provide in terms of sections 26(2) and 27(2).

\footnote{paragraph 39 ibid.}

\footnote{ibid paragraph 26. (The court considered the minimum obligation of states in the General Comment No. 3: The Nature of States Parties’ Obligations (Art. 2, Paragraph. 1, of the Covenant.)}

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4.4.1 Linking Access to Medicines and the Human Right to Life

As well as being quintessential to the right to health, accessibility to medicines is also an integral component of the right to life.\textsuperscript{136} As mentioned earlier,\textsuperscript{137} the right to health, is also interlinked with all human rights including the rights to life, development, social justice and human dignity.\textsuperscript{138} Access to medicines as a right to health is also paramount to the enjoyment of other basic human rights such as liberty, freedom, etc., since health is indispensable to living a meaningful and fulfilling life in dignity.\textsuperscript{139} Without access to essential life-saving medicines, the right to health, and indeed life, can be compromised.

The right to life as a non-derogable right is enshrined in Articles 6 and 4 of the International Covenant on Civil and Political Rights (ICCPR).\textsuperscript{140} It is described as the ‘most basic, the most fundamental, the most primordial and supreme rights which human beings are entitled to have and without which the protection of all other human rights becomes either meaningless or less effective.’\textsuperscript{141} F Menghistu identifies two aspects of the deprivation of the human right to life as (a) execution, murder, torture and (b) ‘lack of fulfilment of basic needs such as

\textsuperscript{136} Lee (n 93) 122, 132.
\textsuperscript{137} In subsection 4.1 of this chapter.
\textsuperscript{139} CECSR, General Comment No. 14, paragraph 1; Lee (n 93) 135.
The Nigerian Constitution in Sections 33(1), 34 and 35 explicitly recognises the right of everyone to life, human dignity and liberty respectively.
\textsuperscript{140} Article 6(1) states:

\begin{quote}
Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.
\end{quote}


Article 3 of the UDHR also states that

\begin{quote}
Everyone has the right to life, liberty and security of person.
\end{quote}

The right to life is also enshrined in numerous regional human rights instruments such as: Article 4 of the African Charter; Article 2 of the European Convention on Human Rights (ECHR); and Article 4 of the American Convention on Human Rights (ACHR). The right to life is also non-derogable under Article 4 of the ICCPR and Article 15 of the ECHR.

\textsuperscript{141} F Menghistu, ‘The Satisfaction of Survival Requirements’ in Bertrand Ramcharan (ed), The Right to Life in International Law (Martinus Nijhoff 1985) 63.
food, basic health facilities and medical care’. Accordingly, the right to life is narrowly construed to include direct actions that cause death, and also broadly understood to include other aspects of human preservation that are necessary for nourishment, existence and human survival.

In the same vein, the Human Rights Committee, writing on Article 6 of ICCPR, states that

[...] the right to life has often been narrowly interpreted. The expression “inherent right to life” cannot properly be understood in a restrictive manner, and the protection of this right requires that States adopt positive measures. In this connection, the Committee considers it would be desirable for States parties to take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics.

Thus, the right to life imposes a duty on states to refrain from unlawfully or intentionally taking life, and also, a positive obligation to undertake appropriate actions to safeguard the right to life, which includes the provision of ‘adequate and appropriate’ healthcare facilities and treatments.

In *Tavares v France*, the European Commission on Human Rights (ECHR) reiterated this broad interpretation of right to life. In that case, the complainant instituted the action on behalf of a woman who died in childbirth, alleging that the death was a violation of the deceased’s right to life as contained in Article 2 of the European Convention (EC) on human rights. The case was subsequently dismissed on a legal technicality; however the court found that the right to life under the EC includes a duty on the state to take all
necessary steps in preventing unintentional loss of life. By application of this judicial reasoning, it can be said that guaranteeing the right to life includes the duty to provide health-related goods, services and facilities including drugs that will prevent the unintentional deprivation of life. This extensive understanding of the right to life to ‘include necessary measures to protect and preserve the right to life’ was reaffirmed by the Inter-American Court of Human Rights in *Villagran Morales v Guatemala*. The court clarified that the right to life also includes a right that a person ‘[…] will not be prevented from having access to the conditions that guarantee a dignified existence.’

These judicial cases accentuate the interrelatedness, interconnectivity and indivisibility of the rights to life and right to health and the role of healthcare facilities, services, and goods including medicines in fulfilling the practical application of these rights. As the human rights scholar Lee also argues, access to essential medicines fundamentally constitutes a part of the minimum conditions necessary for survival and is thus a part of the right to life.

Following this line of argument, this thesis argues that Nigeria has a positive duty to ensure women’s equal access to medicines as a necessary condition and requirement of the right to life. This also entails a consideration of the ways which patents can interfere with this access to medicines. For without access to medicines, the rights to health, life and improving the quality of standards of living in Nigeria remains an illusion and a mere aspirational provision. A more

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148 *Villagran-Morales et al. v Guatemala* (Street Children Case) [1999] Inter-American Court of Human Rights (IACrtHR), Joint Concurring Opinion of Judges in Paragraph 139. Also available at http://www.corteidh.or.cr/docs/casos/articulos/serie_c_63_ing.pdf, last accessed 11 April 2014. In this case, the Court was called upon to determine the kidnapping, torture and unlawful killing of Villagran and four others including minors by the Guatemalan National Police.

149 ibid paragraph 144.

150 Durojaiye, ‘Children and Adolescents Access to Reproductive and Sexual Healthcare’ (n 147) 161.

151 Lee (n 93) 134.
detailed analysis of the duties of Nigeria and other human rights signatory states to the human right to access medicines, particularly in the context of patent law is further considered.

4.5 The Obligation on States to Protect, Fulfil and Promote Human Rights to Health and Access to Medicines

The right to health and medicines like other human rights imposes certain enforceable responsibilities on states. These obligations range from taking steps to facilitate the various means that will satisfy the right to health (active duty) and also refraining from interfering or violating the right to health (passive duty). Asbjørn Eide, the former Special Rapporteur to the UN Sub-commission identified three levels of obligations: to respect, protect and fulfil. In reiterating these obligations, the CESCR further clarified that ‘such steps must be deliberate, concrete and targeted towards the realisation of the right to health.’

The duties of states include:

**Respect:** The obligation to respect human rights to health places a binding responsibility on all governments and its organs and duty bearers to desist from interfering directly or indirectly with the socio-cultural and economic rights of all citizens, including the right to access medicines and safe healthy conditions. This obligation extends to the duty to refrain from entrenching any discriminatory, prejudicial and health practices that affect women’s health and

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153 This is also contained in the CESCR, General Comment No. 14 Paragraph 33. States obligation towards human rights was earlier introduced by Henry Shue who wrote about the duty of states to ‘avoid depriving’, ‘to protect from deprivation’ and ‘to aid the deprived.’ Henry Shue, Basic Rights (2nd edn, Princeton University Press 1996) 52.
154 See more cases and discussions of instances where the court has held states and their authorities accountable to the right to health and life at Hogerzeil, Samson and Casanova (n 102) 5-42.
155 CESCR, General Comment No. 14, paragraph 2.
156 Ida Elisabeth Koch, 'Dichotomies, Trichotomies or Waves of Duties?' (n 152) 81, 82; Hoferzeil, Samson and Casanova (n 102) 10-11.
limit or deny them access to medicines.\textsuperscript{156} In particular, this would require Nigeria to abstain from limiting women’s right to reproductive, sexual and contraceptive health products and health-related information.\textsuperscript{157} Likewise, there is an additional duty to guarantee this right in a non-discriminatory and equal manner for women.\textsuperscript{158}

The state is also mandated to address the cultural impediments, social, infrastructural, economic and other challenges to women’s access to healthcare services, drugs and facilities. Article 3 of CEDAW for example, specifically prohibits discrimination against women in political, civil, economic, social and cultural context.\textsuperscript{159} This obligation is important because it focuses on crucial factors such as traditions, social norms, customs and cultural practices, including economic factors that impair the enjoyment of fundamental human rights including the right to health.\textsuperscript{160} This includes the harmful biases, practices and stereotypes at the root of women’s adverse health conditions such as Female Genital Mutilation (FGM).\textsuperscript{161} Women are therefore guaranteed a right to health and access to the healthcare services within the context of their social, cultural and economic circumstances. This way, the obligation on State Parties to CEDAW extends beyond the responsibility to respect, promote and fulfil the rights to health of women; it also implies that the provision of adequate healthcare systems, information, education and facilities, including medicines, is part of the measures and a state’s duty to eliminate discrimination and biases against women, on the basis of their equal rights.\textsuperscript{162}

\textsuperscript{156} CESC\textsuperscript{a}, General Comment No. 14, paragraph 34.  
\textsuperscript{157} Ibid paragraph 34.  
\textsuperscript{158} Ibid paragraph 34.  
\textsuperscript{159} It provides: ‘[t]o modify the social and cultural patterns of conduct of men and women, with a view to achieving the elimination of prejudices and customary and all other practices including stereotypes. Further, Article 5(a) obligates states to eliminate traditional and cultural practices and prejudice against women.  
\textsuperscript{160} See the Preamble to CEDAW 1979.  
\textsuperscript{161} See the discussion in subsection 3.4.1 of Chapter III.  
\textsuperscript{162} Article 10(h) and 14 (b) of CEDAW 1979.
It is also imperative to note that CEDAW explicitly prohibits actions by states and affiliated agencies that perpetuate direct and indirect discriminatory practices against women.\textsuperscript{163} Accordingly, countries that ratify or accede to the CEDAW not only commit themselves to taking measure towards ending women’s discrimination; they also are bound by an obligation to ensure that the fulfilment of the right is not impaired by national legislation or executive action or policy responsibility.\textsuperscript{164} Consequently, a state’s trade policies, laws and programmes must align with the human rights provisions to secure their enjoyment of the right to health. For example, this would include laws that could limit access to health facilities and medicines, whether directly or indirectly, such as patent laws. As the CESCR affirmed, it is a duty on states including Nigeria, to ensure that the right to health, including access to medicines, is not violated in a policy consideration context. This includes, for instance, the adoption of legislation or policies that are ‘manifestly incompatible with pre-existing domestic or international legal obligations with regards to the right to health.’\textsuperscript{165} It follows that the obligation to respect the right to access medicines will be violated if the Nigerian state does not take into account its people’s rights to access medicines when signing and adopting bilateral or multilateral agreements and treaties such as the TRIPS Agreement.\textsuperscript{166} The CESCR specifically emphasises that any IP regime that encumbers and makes it difficult for states to comply with their core duties in relation to health as set out in the

\textsuperscript{163} For instance, Article 2(f) mandates the state ‘(t)o take all appropriate measures, including legislation, to modify or abolish existing laws, regulations, customs and practices which constitute discrimination against women.’

\textsuperscript{164} Article 2 (a)-(h) CEDAW 1979.

\textsuperscript{165} CESCR, \textit{General Comment No. 14}, paragraph 48.

\textsuperscript{166} Several international organisations and human rights Committees have reported and highlighted that the IPR provisions of the TRIPS Agreement can have a profound effect on human rights, particularly, the right to health, life and guarantee of access to medicines. See for example, World Health Organization, \textit{Network for Monitoring the Impact of Globalization and TRIPS on Access to Medicines} (Meeting Report, 19–21 February 2001 Chulalongkorn University Bangkok, Thailand 2002) 20-21; World Health Organization, ‘Globalization, TRIPS and Access to Pharmaceuticals’ (WHO Policy Perspectives on Medicines, No 3, 2001) (It was highlighted that accessing essential medicines is a human right and that patent protection, although an effective incentive for R&D, could likely affect accessibility, especially for the poor. The use of the TRIPS safeguards was promoted as an effective means for improving access.)
Covenant (ICESCR), is incompatible with the legally binding obligations of states. This understanding of the general provision of women’s right to health is important to the articulation in this thesis because it would require the Nigerian state to be aware of any health consequences in all its legislation and to ensure that laws or policies, agreements and treaties do not obstruct its obligation to guarantee and the enjoyment of the right to health.

Protect: To protect obligates two duties: to facilitate and enhance; and to prevent any obstruction to accessing healthcare facilities, services and medicines by third parties. This obligation not only requires states to protect and safeguard human rights to health, it mandates the state to facilitate access by preventing medical care providers (private and public) and third parties e.g. pharmaceutical companies, from violating the right to health. In Nigeria, this duty obliges the state to ensure that the rights granted to third parties, or private service providers in the provision of healthcare, do not interfere with the availability, acceptability and accessibility of high quality, affordable healthcare systems, services and medicinal resources.


168 Koch, ‘Dichotomies, Trichotomies or Waves of Duties?’ (n 152) 88-89.


170 CESCR, General Comment No. 14, paragraph 35.

171 CESCR, General Comment No. 14, paragraph 42.
The significance of this obligation is relevant to the consideration of access to medicines in this thesis. As the CESCR expatiates, states are to ‘control the marketing of medical equipment and medicines by third parties’ and ensure that privatisation of the health sector does not threaten the right to health, provision of healthcare and access to medicines. The UN Norms for Corporations and Businesses further indicates that states have a general duty to ensure that corporations and business enterprises respect and promote human rights. Likewise, State parties are required to prevent violations of women’s rights, including the right to health, by third parties, organisations and enterprises operating within the rights granted by states. It can, therefore, be argued that this responsibility places a duty on the Nigerian state to ensure that national patent legislation and patent rights granted to inventors do not constitute a hindrance to the availability and affordability of essential medicines, an important component of the right to health. Bearing this in mind, it is argued that this duty on states can be achieved by preventing pharmaceutical companies from introducing high prices for medicines, unreasonably restricting competition and follow – on R&D, thus limiting access, or by ensuring that the prices of patented medicines are at least affordable to the poor. In addition to other measures such as price control, the TRIPS flexibilities can be instrumental in this regard.

**Fulfil:** Under this duty, the government is obligated to take appropriate legislative, regulatory, budgetary, administrative, judicial, and other necessary

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172 CESCR, *General Comment No. 14*, paragraph 35.

Article 2(e) reads: 
‘...to take all appropriate measures to eliminate discrimination against women by any person, organization or enterprise.'
measures to progressively fulfill and ensure access to medicines and healthcare facilities for the realisation of the right to health. These measures are designed to guarantee the availability of, and equal access to, health facilities, healthy conditions and products for everyone. Specifically, signatories to the ICESCR are obliged to create the necessary conditions for health by providing ‘equal and timely access to basic preventive, curative, rehabilitative health services […] and appropriate treatment of prevalent diseases, illnesses, injuries and disabilities, […] [including] the provision of essential drugs; and appropriate mental health treatment and care.’ states, including Nigeria, are therefore required to ensure that the appropriate legislative and policy actions comply with the basic objectives of women’s right to health in line with the obligation. While Nigeria can be constrained from providing the necessary healthcare system due to limited resources, there is still a responsibility on the government to use the available resources progressively to give the fullest attainable expression to the realisation of the rights to the highest standard of health and living for women and indeed, everyone in Nigeria.

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176 It is within this context that the CESCR expatiates that:
The obligation to fulfil requires States parties, inter alia, to give sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation, and to adopt a national health policy with a detailed plan for realizing the right to health.

For this purpose also,
States must ensure provision of health care [...].

CESCR, General Comment No 14, paragraph 36. The framework of the legislation necessary for implementing the right to health at the national level is contained in paragraphs 53-16 of General Comment No. 14.

177 CESCR, General Comment No. 14, paragraph 17.

178 See generally CEDAW, General Recommendation No.24, paragraphs 13-17.

4.6 Is there a Duty on Pharmaceutical Companies in Relation to the Rights to Health and Access to Medicines?

While it is the duty of states to adopt all reasonable measures to realise the right to health, including the prevention of third parties from interfering with the right, a question that is receiving increasing attention is whether third persons or non-state actors and corporations have a duty towards the rights to health and access to medicines? Another question in this respect is whether states, as principal duty bearers, can compel third parties or corporations to protect and promote the right to health and enhance access to medicines.

Within the specific sphere of pharmaceutical companies’ activities and influence, it has been suggested that they are obligated to respect and contribute to promoting human rights including the right to health.\textsuperscript{180} Accordingly, within the scope of their business operations, business enterprises and corporations, and medical healthcare providers should respect, protect, fulfil and support the human rights of everyone.\textsuperscript{181} In this manner, the UN Norms for corporations in 2003 recognised the responsibilities of corporations and business enterprises to respect, promote and secure human rights including the right to health.\textsuperscript{182} The UN Norms make provisions covering a wide range of areas for corporations and businesses with regard to their human rights responsibilities in the exercise of their activities and influence.\textsuperscript{183} Specifically concerning health, the UN Norms emphasise that transnational corporations and business enterprises should respect and contribute to the

\textsuperscript{180} Lee and Hunt (n 83) 231, 227.
\textsuperscript{181} Jernej Letnarić Cernic, ‘Corporate Obligations under the Right to a Healthy Living Environment’ (2012) 3 Danube Law and Economics Review 21, 22, 31-34.
\textsuperscript{183} Accordingly, ‘within their respective spheres of activity and influence, transnational corporations and other business enterprises have the obligation to promote, secure the fulfilment of, respect, ensure respect of and protect human rights recognized in international as well as national law, including the rights and interests of indigenous peoples and other vulnerable groups.’ ibid paragraph A(1).
realisation of the ‘highest standard of physical and mental health’ and also refrain from any action which limits or obstructs the realisation of the right.¹⁸⁴

In more recent times, the human rights responsibilities of third parties and corporations such as pharmaceutical companies have heightened. In 2011, the UN Human Rights Council adopted the human rights Guiding Principles for Businesses and Transnational Corporations on the Report of the Special Representative of the Secretary-General, John Ruggie. The Ruggie Report presented the Guiding Principles to clarify and differentiate the human rights responsibilities of states, business enterprises and transnational corporations.¹⁸⁵ The ‘Protect, Respect and Remedy’ Framework centred on three core principles: (a) States’ existing obligations to respect, protect and fulfil human rights and fundamental freedoms; (b) the role of business enterprises as specialised organs of society performing specialised functions, required to comply with all applicable laws and to respect human rights; and (c) the need for rights and obligations to be matched to appropriate and effective remedies when breached.¹⁸⁶ Significantly, the Guiding Principles reaffirmed the primary duty of states to protect human rights, provide effective remedies for abuses and also prevent third persons and non-state actors from abusing or impeding human rights. The guidelines add that business corporations and companies also have a duty to human rights.¹⁸⁷ In the Guidelines, the corporate

¹⁸⁴ ibid paragraph E(12).
¹⁸⁷ Ruggie Report ibid
responsibilities of businesses centre on the duty to respect human rights. Ruggie expounds that the duty ‘[t]o respect rights essentially means not to infringe on the rights of others — put simply, to do no harm.’ The UN Guiding Principle on Businesses and Human Rights also reaffirms that businesses and corporations are mandated to ‘respect human rights which mean they should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved.’ This duty exists irrespective of the state’s ability and willingness to fulfil its own human rights responsibility. What does this right to health duty of corporations imply for the pharmaceutical industry?

This duty to respect — ‘does no harm to’ — human rights is relevant to the discussion on the duties of pharmaceutical companies towards access to medicines as a central component of human rights. This obligation to respect the right to medicines as an aspect of health, suggests that pharmaceutical companies are obligated to refrain from doing anything that will interfere with the enjoyment of the right to health, including access to life-saving drugs. In this regard, the UN’s Interpretive Guide on ‘The Corporate Responsibility to Respect Human Rights’ emphasises that ‘[f]or pharmaceutical companies, the right to health will be particularly salient.’ For this purpose, it entails the responsibility to avoid and mitigate any adverse human rights impact that their business activities may cause or contribute to, and is linked to their operations,

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188 Ruggie Report ibid paragraph 51-81.
189 Ruggie Report ibid paragraph 21.
191 ibid 14.
192 Cernic (n 181) 31-33.
products (including medicines) or services.\(^\text{194}\) Because access to medicines is one of the means to the realisation of the right to health, this duty implies that pharmaceutical corporations should ensure that their corporate activity does not violate or impair the realisation of the human right to health.

In respect to the availability of, and accessibility of affordable medicines, it can be argued that pharmaceutical companies and their activities could positively and negatively impact access to medicines and the right to health.\(^\text{195}\) Negatively, the monopoly and marketing practices of patent holding pharmaceutical companies can impact on accessing medicines.\(^\text{196}\) Hence the obligation on states to ensure that the right granted to pharmaceutical companies as patent holders does not interfere with the right to access medicines. Positively however, pharmaceutical companies can support the state to fulfil, respect and protect the right to health by providing the means for the realisation of the right to health.\(^\text{197}\) Through their pharmaceutical R&D and production undertakings, the drugs they produce can facilitate the availability of drugs for the realisation of the right to health. It is further argued, however, that their contribution to the human right to health goes beyond providing the

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\(^{196}\) See the discussion in subsection 3.7.1 of Chapter III. Paul Hunt, the first Special Rapporteur on the right to health, for instance, noted that the practices (pricing, research priority, marketing etc.) and policies of the pharmaceutical industry could hinder the state’s obligation to implement and fulfill the right to the highest standard of health. UN Human Rights Council, \textit{Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health}, Paul Hunt, annex: Mission to GlaxoSmithKline, (A/HRC/11/12/Add.2, 18 May 2009) paragraphs 4, 24. Also available at <http://www.who.int/medicines/areas/human_rights/A_HRC_11_12_Add_2.pdf> accessed 17 August 2015.

\(^{197}\) Geralyn S Ritter, ‘Are Drug Companies Living Up to their Human Rights Responsibilities? The Merck Perspective’ (2010) 7 PLoS Med, 1. Analysing the special responsibility of pharmaceutical companies to the right to health, Hunt notes: Whether characterised as contract, licence or trust, the company holds the patent on express and implied terms. Society has legitimate expectations of a company holding the patent on a life-saving medicine. In relation to such a patent, the right-to-health framework helps to clarify what these terms, and expectations, are. Because of its critical social function, a patent on a life-saving medicine places important right-to-health responsibilities on the patent holder. These responsibilities are reinforced when the patented life-saving medicine benefited from research and development undertaken in publicly funded laboratories.

\(^{ibid}\) paragraph 36.
facilities and goods (medicines) necessary for the enjoyment of this right. This responsibility extends to refraining from any act or policy that will obstruct access to affordable and available medicines, given that their business and marketing practices could limit this access as discussed in Chapter III. Whether they actually owe this responsibility as an enforceable legal duty and how to measure the responsibility of pharmaceutical companies in this regard may vary considerably, depending on where they operate and whether national laws imposes this duty on them. The UN Guidelines and reports are authoritative standards guiding the responsibilities of pharmaceutical companies and interested parties to human rights and are not binding on them. However, since states have the primary duty to enhance access to medicines through every necessary means, they could compel a binding legal duty to respect and remedy human rights on pharmaceutical companies and patent holders who are domiciled or registered within the territory of their states.

From an international human rights perspective, scholars have also argued that pharmaceutical companies indeed owe a duty to the right to health and access to medicines. Within the context of patent rights and access to drugs, scholars and experts have analysed the corporate responsibilities of pharmaceutical companies to the right to health. Lee and Hunt for example, argue that pharmaceutical companies may have certain additional ‘public function’ responsibilities beyond the duty to simply respect human rights. In view of

198 See subsection 3.7.1.
199 The significant shared responsibility of pharmaceutical companies towards the right to access medicines recognised in the Millennium Development Goals (MDGs). The MDG goal 8.E is a target to provide access to affordable essential drugs in developing countries, in collaboration with pharmaceutical companies. 'Official Millennium Indicators' (Mdgs.un.org) <http://mdgs.un.org/unsd/mdg/Host.aspx?Content=Indicators/OfficialList.htm> accessed 11 August 2016.
200 See for example, Lee and Hunt (n 83). (The authors argued that human rights can shape and influence the policies of pharmaceutical companies. Also, human rights provide a framework to hold pharmaceutical companies liable for human rights.) See also, Lisa Forman and Jillian Clare Kohler, Access to Medicines as a Human Right: Implications for Pharmaceutical Industry Responsibility (University of Toronto Press 2012).
201 Lee and Hunt (n 83) 225. The argument mirrors Paul Hunt’s Report on the right to health framework of pharmaceutical companies, and the human rights guidelines for pharmaceutical companies. See Paul Hunt, Human Rights Guidelines for
pharmaceutical companies’ right-to-health obligations, Lee and Hunt argue that pharmaceutical companies should take reasonable actions to ensure that medicines are sufficiently available in countries where they are needed, including taking measures to address the issue of R&D of neglected diseases.\textsuperscript{202} They also suggest, for instance, that pharmaceutical companies ‘should either provide in-house research and development for neglected diseases, or support external research and development for such diseases.’\textsuperscript{203}

In closing, the foregoing discussion argues that states (Nigeria) have an obligation to facilitate and make available affordably, safe and good quality medicines, in an acceptable manner. Pharmaceutical companies and patent owners can have a human right to health responsibility within the sphere of their business operations. This responsibility would pertain to the pricing of their drugs, testing and clinical trials, R&D, provision of safe and good quality medicines and the duty to ensure that their practices do not constitute an obstacle, especially to women’s enjoyment of human rights, and their right to medicines. Notwithstanding the obligations of pharmaceutical companies to the right to access medicines, states are ultimately the duty bearers accountable for the guarantees, and prevention of the violations of the rights to access medicines. It is their duty to monitor and also ensure that pharmaceutical firms do not impede the enjoyment of the right to health. Hence, if women’s access to

\textit{Pharmaceutical Companies in Relation to Access to Medicines}\textsuperscript{1} (n 195). In the Guidelines, Paul Hunt stresses that the pharmaceutical sector, especially patent holding companies besides their responsibilities to shareholders, has a commitment to contribute to the promotion of access to medicines and R&D of neglected diseases. Ibid paragraph 23-25. See also, UN Human Rights Council, \textit{Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Health, Paul Hunt, Annex: Mission to GlaxoSmithKline} (n 196). (Reporting that the goal of enhancing access to medicines is a shared responsibility and pharmaceutical companies play a huge role in meeting this responsibility. The Report emphasises that while it is the core duty of the State to promote access to medicines and the right to health, pharmaceutical companies can equally play a supporting role in the quality production, acceptability, availability, and accessibility of medicines.)


\textsuperscript{203} Lee and Hunt (n 83) 225. In addition to making drugs available, they argue further that pharmaceutical companies have a human rights duty to ensure that the medicines are of good quality, acceptable, accessible and affordable and in this respect, the prices should be reasonably affordable to as many individuals and communities as possible. Ibid 225-226.
medicines is to be enhanced, the Nigerian state must provide medicines and also guarantee the sustainable availability and accessibility of drugs through every avenue.

Having examined the obligations and responsibilities to women’s rights to health and access to medicines, the next part focuses on the relationship between patent rights and the right to access drugs.

**PART II: RE-EVALUATING THE RELATIONSHIP BETWEEN PATENT RIGHTS AND HUMAN RIGHTS**

4.7 Patent Rights and Human Rights

While the foregoing section analysed the link between the right to health and access to medicines, this part essentially analyses the relationship between patent rights and human rights with a view to making a case for broader access to medicines as a right to health. From a human rights perspective, this segment points to the issues and conflict that arise between patent and human rights. It is argued that patent rights in national laws and the TRIPS Agreement do not exist in a socio-economic and cultural vacuum; instead, they should be enforced and interpreted with regards to public interest and human rights. It is also argued that human rights to health, as expounded in the preceding part, provide a significant socio-economic and cultural framework for the consideration of patent rights and its effect on the right to access medicines. As such, there is a need to consider the effect of patent rights on the right of access to medicines and the state’s duty in this respect, particularly for Nigeria.
4.7.1 Is There Interconnectivity Between Patent Right and Human Rights?

In recent years, scholars, courts and international organisations have devoted increasing attention to the connectivity between human rights and IP. As Professor Helfer remarks, ‘[h]uman rights and intellectual property, two bodies of law that were once strangers, are becoming increasingly intimate bedfellows.’\textsuperscript{204} The question that arises in this regard for the purpose of analysis in this chapter are: what is the exact nature of the relationship between a proprietary patent right and human rights? Does this relationship conflict or mutually coexist in a way that can reinforce each other for the common good of society? Are patent property rights human rights? If so, how far, and subject to what laws and limits, can human rights be relied upon by patent right holders?

These questions are relevant to the examination of the impact of patent rights provisions in the TRIPS Agreement on access to medicines as a component of the right to health.

4.7.1.1 Revisiting the Issue: Is a Patent a Property Right?

Traditionally, a patent, as analysed in the last chapter,\textsuperscript{205} is viewed as an intangible private property right that is granted and protected by the state in exchange for a disclosure of an invention.\textsuperscript{206} However, the articulation of patents or intellectual property rights (IPRs) generally as ‘property rights’ has been the subject of heated debate, with some scholars arguing that ‘the expression of ‘intellectual property’ is actually a misnomer and that patents are

\textsuperscript{205} See subsection 2.3.2 of Chapter II.
just privileges that have no claim to the full dignity of ordinary property rights\textsuperscript{207} or indeed human rights.\textsuperscript{208} Analysts frequently point to the difference between the general characteristics of IP in contrast to physical tangible properties.\textsuperscript{209} For example, a patent right protects the intangible capital and expression of the innovation, not the tangible medium in which it is itself expressed. On the other hand, rights in physical properties are conferred in the tangible property itself.\textsuperscript{210}

Secondly, the duration of a patent right is limited to the legal term granted by the state and, on that score, is a limited monopoly right to restrict others from exploiting it,\textsuperscript{211} unlike many real property rights, for example, which are perpetual in nature.\textsuperscript{212} Thirdly, because the right is granted by the state on behalf of society in exchange for a disclosure, the character of the right has an element of public good and the state can override a patent right in the public interest.\textsuperscript{213} Fourthly, a patent right is territorial in nature, hence, the property right is limited to the jurisdiction within which it is granted.\textsuperscript{214} Nevertheless, sharing similar attributes to physical property, patent rights allow the owner to share, assign, license, use, sell, transfer and exclude others from


\textsuperscript{211} Minimum of 20 years in the TRIPS Agreement.

\textsuperscript{212} Vaver (n 209) 160. (In some jurisdictions).

\textsuperscript{213} Through compulsory licensing for example. Pierre Régisbeau and Katharine Rockett, 'The Relationship between Intellectual Property Law and Competition Law: An Economic Approach' in Steven D Anderman (ed), \textit{The Interface between Intellectual Property Rights and Competition Policy} (Cambridge University Press 2007) 507. Note that in some jurisdictions, such as Nigeria, the state has powers to compulsorily acquire private properties such as land for the common good and developmental needs of society, even without the voluntary consent of the owner or occupant, subject to the payment of remuneration. Adefi M Olong, \textit{Land Law in Nigeria} (2nd edn, African Books Collective 2012) 122-123.

doing these things. Therefore, to the extent which a patent grants control over an invention or product of innovation, and confers exclusive rights to prevent others from having unlicensed access to the products, patents can be regarded as a form of ‘property right.’ However, the idea that all forms of intellectual proprietary rights, including a patent, should be viewed as a right within the realm of human rights may not find support from all scholars. The nature of the relationship between patent rights and human rights – including the right to health and medicines, is further analysed below.

4.7.2 Examining the Relationship between a Patent Right and Human Rights

The exact relationship between patent rights and human rights is the subject of diverse scholarly debate. Gold summarises the current views on the relationship between patent and human rights thus: the ‘subjugation approach,’ the ‘coexistence approach’ and the ‘integrated approach.’

The ‘subjugation approach’ makes the point that patents, sometimes, come into conflict with human rights. Analysing the subjugation approach, Helfer observes that IPRs — patent protection — are seen to be incompatible with human rights, by undermining the enjoyment and realisation of a broad

216 The US Court in the case of Panduit Corp. v Stahlin Bros. Fibre Works, Inc., [1978] 575 F.2d 1152 6th Cir. attributed the status of human rights to patent, as a property right. Judge Markey was of the opinion that:

> Patents must by law be given "the attributes of personal property." The right to exclude others is the essence of the human right called "property." The right to exclude others from free use of an invention protected by a valid patent does not differ from the right to exclude others from free use of one's automobile, crops, or other items of personal property. Every human right, including that in an invention, is subject to challenge under appropriate circumstances. That one human property right may be challenged by trespass, another by theft, and another by infringement, does not affect the fundamental indicium of all "property," i.e., the right to exclude others.

spectrum of human rights, especially socio-economic and cultural rights.\textsuperscript{220} Where this conflict arises, scholars argue that human rights should be given priority and trump patent rights.\textsuperscript{221} One commentator in arguing that human rights considerations should prevail over rights granted to authors and inventions, writes that ‘[i]ntellectual property rights should be limited when necessary to protect the public health and to the degree necessary to guarantee the general welfare.’\textsuperscript{222} As will be further discussed shortly, this thesis is more inclined to analysing the relationship between patent rights and access to drugs within this context.

With regards to the ‘coexistence approach,’ advocates assert that patent law and human rights law are two distinct areas of law; although they share the same fundamental goal of contributing to the common good and improvement of human welfare.\textsuperscript{223} Principally, this school of thought argues that rather than viewing patents and human rights laws as conflicting, they are compatible, mutually supporting each other to promote innovation and access.\textsuperscript{224} In his description of this approach, Helfer notes that the school of thought,

\begin{quote}
[s]eees both areas of law as concerned with the same fundamental question: defining the appropriate scope of private monopoly power that gives authors and inventors a sufficient incentive to create and innovate, while ensuring that the consuming public has adequate access to the fruits of their effort.\textsuperscript{225}
\end{quote}

\textsuperscript{220} Helfer, ‘Human Rights and Intellectual Property: Conflict or Coexistence?’ (n 208) 48.
\textsuperscript{222} Zita Lazzarini, ‘Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the Case of Brazil’ (2003) 6(1) Yale Human Rights and Development Law Journal 103, 123; Tobin (n 175) 365.
\textsuperscript{223} Gold (n 218) 188-189; Helfer ‘Human Rights and Intellectual Property: Conflict or Coexistence?’ (n 208) 48-49.
\textsuperscript{224} Helfer, ‘Human Rights and Intellectual Property: Conflict or Coexistence?’ (n 208) 48-49; Gold (n 218) 188-189.
\textsuperscript{225} Helfer, ‘Human Rights and Intellectual Property: Conflict or Coexistence?’ (n 208) 48.
Proponents of this approach point to a number of human rights provisions that seek to assure creators and inventors a protection of their moral and material interest.\textsuperscript{226} This view may be totally hard to sustain in view of the effect of a patent right on the right to medicines. As recalled in Chapters III,\textsuperscript{227} a patent right can interfere with the right to access medicines under human rights law, thus the question is how to strike a balance between the incentive to innovate on the one hand and access on the other.\textsuperscript{228}

The ‘integrated approach’ views patents and other IPRs as human rights, with emphasis on property rights and the individual inventor’s rights under human rights instruments.\textsuperscript{229} Advocates of this approach argue that the provisions of tangible property rights should be extended to cover IPRs by assimilating the rights into human rights frameworks.\textsuperscript{230}

The conceptualisation of intellectual proprietary rights as a natural human right was articulated after the French Revolution.\textsuperscript{231} Article 17 of the 1789 Declaration recognised property rights as an ‘inviolable and sacred right, no one shall be deprived thereof, except where public necessity, legally determined, shall clearly demand it.’\textsuperscript{232} This articulation of property rights sought to attach a sense of morality, equity and fairness to the right as an inherent human

\textsuperscript{226} Gold (n 218) 189.
\textsuperscript{227} This was examined in Chapters III, subsection 3.7.1.
\textsuperscript{228} ibid; Helfer ‘Human Rights and Intellectual Property: Conflict or Coexistence?’ (n 208) 48-49.
\textsuperscript{229} Matthews (n 121) 205.
\textsuperscript{230} Matthews (n 121) 206.
\textsuperscript{232} Sprankling (n 231) 7.
entitlement.\textsuperscript{233} From this proprietary rights assertion, it has been argued that all IP rights are sacred and inviolable human rights entitlements, as set forth in Articles 2 and 17 of the Declaration.\textsuperscript{234} In this view, a patent right is perceived to extend beyond a mere licence or privilege granted by the state; it is seen to possess characteristics grounded in legal, social and ethical human rights entitlement.\textsuperscript{235}

Proponents of patents-as-human rights also rely on the rights to property in regional instruments such as the American Declaration of the Rights and Duties of Man\textsuperscript{236} and the EU Charter of Fundamental Rights to argue for the recognition of IP rights as property rights.\textsuperscript{237} The argument that IPRs as property rights are human rights finds some support in the judicial decisions of the European Commission of Human Right’s (ECHR). In \textit{Anheuser Busch Inc. v Portugal},\textsuperscript{238} for example, one of the main issues before the ECHR was whether the provision of Article 1 (1) of the Protocol No. 1 of ECHR was applicable to IP.\textsuperscript{239} In the instant case, the applicant alleged an infringement of its right to peaceful enjoyment of ‘possession’ of a trade mark.\textsuperscript{240} Accordingly, its trade mark constitutes ‘possession’ within the meaning of Article 1 (1) of the Protocol,
and a deprivation of the right to the ‘possession’ of the trade mark was clearly in breach of its human rights. Although the ECHR ruled that there was no violation of the trade mark and the applicants could only have relied on this right after registering the trade mark, the ECHR established that the provision of Article 1 of Protocol 1 is definitively applicable to IP as such.\textsuperscript{241} Thus a trade mark was held to constitute a ‘possession’ within the human rights provisions of Article 1.\textsuperscript{242} In this connection, the ECHR noted that ‘possession’ within the meaning of the Article 1 (1) of Protocol No. 1 is not limited to physical properties: certain rights and interest constituting assets, including IP can validly come within the purview of that Article.\textsuperscript{243}

The ECHR came to the same judicial conclusion namely, that a patent property right is a human right, in the case of \textit{Smith Kline and French Laboratories Ltd v Netherlands}.\textsuperscript{244} In deciding whether there was an interference with the patent right of the applicant in the case, the Commission ruled that ‘that a patent accordingly falls within the scope of the term “possessions” in Article 1 (1) Protocol No. 1 (P1-1).’\textsuperscript{245}

Interestingly, both natural and legal persons are recognised as having the right to this ‘possession.’ This means that pharmaceutical corporations can lay a claim to their ‘human rights’. Viewed from this perspective, it would seem justifiable that pharmaceutical firms or innovators and researchers would want to draw on this ‘natural human right,’ commercially to capitalise on the fruits of

\textsuperscript{241} Paragraph 73. See also in paragraph 83 of the decision. The Grand Chamber also held that the main issues in Anheuser-Busch Inc’s complaint was a ‘challenge to the interpretation and application of Portugal’s law in its case by its national Courts; and the Strasbourg Court’s settled practice is not to question the decisions of national Courts unless they are arbitrary or manifestly unreasonable.’ See more analysis of the case at ‘Anheuser’ (Opil.ouplaw.com). <http://opil.ouplaw.com/view/10.1093/law:ihrl/3436echr07.case.1/law-ihrl-3436echr07#law-ihrl-3436echr07-divN-72> accessed 5 May 2016.

\textsuperscript{242} Paragraph 72 of the decision.

\textsuperscript{243} Paragraph 63 of the decision.

\textsuperscript{244} Application 12633/87, (1990) ECHR Decision and Reports.

\textsuperscript{245} ibid

\textsuperscript{245} ibid
their labour through patents. Nonetheless, the question remains, are patent rights human rights within the purview of international human rights law? Put in another way, can the interference of patents with the right to access drugs be justified under human rights law?

4.7.3 Human Rights Protection of an Inventor’s Moral and Material Interest

It appears that the arguments that patent rights are human rights might find some support in human rights instruments such as the UDHR and ICECSR. Article 27(1) of the UDHR acknowledges the right of everyone to take part in the ‘cultural life of the community.’ Furthermore, the right to benefit from a creative work as a moral and material legal entitlement is accorded recognition in Article 27(2) of the UDHR which provides that ‘everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.’ This provision corresponds with the linguistic articulation and objectives of Article 15(1)(c) and 15(2) of the ICESCR, which obligates the state to recognise an author’s rights to ‘benefit from the protection of the material and moral interest resulting from any scientific, literary or artistic production.’

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246 Article reads:

Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.

247 Article 15(1)(c) ICESCR. (Emphasis added.)

Article 15 states:

1. The States Parties to the present Covenant recognize the right of everyone:
   (a) To take part in cultural life;
   (b) To enjoy the benefits of scientific progress and its applications;
   (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.
These provisions are commonly identified as the basis for the right to the protection of creators and inventor’s interests in intellectual creations.\textsuperscript{248} It can be said that Article 27(2) of the UDHR and Article 15(1)(c) of the ICESCR underscore the protection of the interests of authors (or inventors or creators, as the case may be) and the result of their intellectual efforts. This protection is not only for the broader advantage of the public to enjoy the benefit of scientific progress and its application in Article 15(1)(b) of the ICESCR, but also because the creative interests and moral rights of the inventors are recognised as worthy of such protection.

These human rights provisions raise questions relevant to the present discussion on the relationship between patent rights and human rights to health and life, particularly with regards to women’s access to medicines. Can it be said then that a patent as a proprietary right to the intellectual interest of inventors is a human right within the contemplation of UDHR and ICESR?

\textbf{4.7.3.1 The Moral and Material Rights of Creators/Inventors}

From the foregoing, the wording of Articles 15(1)(c) of the ICESCR and Article 27(2) of the UDHR expressly seek the protection of an author’s ‘moral’ and ‘material’ interest in his or her intellectual creation. The ‘moral interest’ in an invention, resonates with the natural rights postulations of the property rights argument.\textsuperscript{249} This right recognises that a person’s ingenious labour and effort to scientifically, artistically or literarily create a thing is to be protected. Moral rights, which are more relevant to the debate for authors of literary and copyrighted works, recognise and protect the non-material interest arising from


\textsuperscript{249} The Natural Law and Labour Rights school of thought as discussed in Chapter II of this thesis (subsection 2.3.1).
the intimate connections of an author to his/her work. Essentially, the Articles, by recognising moral interests, seek to protect the intrinsic personal character of an invention or creation of the human mind, including the integrity of an author or creator’s work.250 A moral right also acknowledges the right of an inventor to be so named and recognised as the ‘author’ of the invention.251

The ‘material interest’ of inventors, on the other hand, protects his or her rights to deal with, enjoy, transact, and commercially utilise, reap and receive adequate remuneration from the fruit of their inventive labour and intellectual creations.252 It is often the material interest of the inventor that raises a number of questions on the interference of the right of patent holders to earn a living from their inventions and its effect on the right to access medicines.

4.7.3.2 Is a Patent Right a Human Right?

A first reading of the human rights provisions in ICECSR and UDHR may suggest that they equate IPRs with other types of human rights.253 This leads some authors, such as Stephen Marks, to argue that they provide a human rights justification for patent rights, as well as other forms of human rights.254 That is, the recognition of the inherent human rights interests of creators in their inventions broadly extends to patent rights. Other IP scholars are, however, sceptical of this approach. Schermers argues, for example, that IPRs cannot be rightly categorised as fundamental rights since human rights are ‘of such importance that their international protection includes the right, perhaps even

250 CECSR, General Comment No. 17, Paragraph 12; Hestermeyer (n 98) 157.
251 Hestermeyer (n 98) 157.
252 Ibid 157.
253 Oke (n 219) 95.
254 Stephen P Marks, ‘Access to Essential Medicines as a Component of the Right to Health’ in Andrew Clapham and Mary Robinson (eds), Realizing the right to health (Rüfer & Rub 2009) 89-90.
the obligation, of international enforcement. Schermers’ argument is premised on the fact that IPRs do not command the sort of protection and enforcement as other types of human rights which are so imperative to humans that ‘no legislative organ may lawfully take these rights away from the citizens.’

This thesis shares the opinion that a patent right arising from statute law is not a fundamental human right within the purview of human rights laws. By its very nature, a patent is a statutory creation, whereas other categories of human rights, such as the right to health, are derived from the inherent nature, dignity and worth of all human beings. A further distinction can be drawn from the regulatory structure of patent rights. The state, in recognising the rights of patent holders under a national statute, can withdraw or override that right in the interest of the public. The rights under the UDHR and ICESCR, however, accrue to inventors as inherent rights; hence they are independent of the state’s recognition and grant of exclusivity rights. Most importantly, patent rights exist within a fixed length of time, unlike human rights which are perpetually vested in human beings. Similarly, patent rights, being statutory creations, are assignable, transferable and revocable, an attribute that is not shared by any human right. The inherent nature of human rights, one that recognises the inalienable interdependence and indivisibility of all human rights to all human beings.

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256 Schermers (n 255) 565-580.
257 CECSCR, General Comment No 17, paragraph 1. See also Poku Adusei, Patenting of Pharmaceuticals and Development in Sub-Saharan Africa: Laws, Institutions, Practices, and Politics (Springer 2013) 205; Hestermeyer (n 98) 154.
258 Hestermeyer (n 98) 154.
beings, is, in short, fundamentally absent in patent rights.\textsuperscript{259} PN Bhagwati, in describing the character of human rights, maintains that they are:

Not ephemeral, not alterable […] not the product of philosophical whim or political fashion. They have their origin in the fact of the human condition and because of this origin, they are fundamental […] constitutions, conventions or governments do not confer them. These are the instruments, the testaments of their recognition […] they do not give rise to human rights. Human rights were born not of humans but with humans.\textsuperscript{260}

Sganga, commenting on the assignable rights of IP, also observes that ‘IPRs belong to the realm of national policies and international trade, as proven by the fact that, contrary to human rights, they are limited in time, limited in scope and—with the exception of moral rights—revocable, forfeitable, licensable and assignable.’\textsuperscript{261} Stretching this argument further, the right to health is universal, whereas patent rights, as stated previously are territorial in character.\textsuperscript{262}

This opinion finds support in the clarification by the CECSR in paragraph 3 of the General Comment No 17 which categorically states that IPRs are not to be equated with the human rights provisions of Articles 15(1)(c). The CECSR stresses the point that the human rights recognised in Article 15 (1)(c) solely ‘safeguards the personal link between authors and their creations […] as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living.’ IPR regimes, on the other hand, ‘primarily protect

\begin{thebibliography}{9}
\bibitem{Bhagwati} PN Bhagwati ‘Creating a Judiciary Culture to Promote the Enforcement of Women’s Human Rights’ in Andrew Byrnes, Jane Frances Connors and Lum Bik (eds), \textit{Advancing the Human Rights of Women: Using International Human Rights Standards in Domestic Litigation} (Commonwealth Secretariat 1997) 21.
\bibitem{subsection} In subsection 4.2.2.
\end{thebibliography}
business and corporate interests and investments. In other words, a patent right is not coterminous with human rights. To further underscore this point, the CECSR in paragraph 1 of the General Comment 17, clarifies that

Human rights are fundamental as they are inherent to the human person as such, whereas intellectual property rights are first and foremost means by which States seek to provide incentives for inventiveness and creativity, encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific, literary, and artistic productions for the benefit of society as a whole.

In terms of structure, patents for pharmaceuticals, by way of an example, are more concerned with the protection of the investors’ right than the right of inventors who, in most cases, are scientists and researchers whose laborious efforts lead to the intellectual production. In the case of a pharmaceutical patent, many people, and in some cases institutions, are involved in the research and production. In some cases, employees undertake the research, yet the ownership rights’ may be vested in an individual(s) or an institution who may not be the actual inventors. Indeed, patents, as has been discussed at length in Chapter II, are mainly used as economic and utilitarian instruments to advance the policy of the rights-owners. This character of patents is unlike the provisions on human rights which are more concerned with the inventor as a person.

263 CECSR, General Comment No 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Paragraph. 1 (c) of the Covenant) (Hereafter CECSR, General Comment No 17) paragraph 2.
264 CECSR, General Comment No 17.
266 See subsection 2.5.2 of Chapter II.
267 Hestermeyer (n 98) 157.
268 Ibid
Moreover, human rights are applicable to individuals as humans and cannot be vested in legal entities.\textsuperscript{269} Patent rights on the other hand can be owned by companies, in fact, the bulk of pharmaceutical patents are actually owned by corporations.\textsuperscript{270} The CESCR has made it clear that the language of ICESCR is addressed to a natural person; hence the beneficiaries addressed are humans.\textsuperscript{271} To clarify this further, the CESCR adds that under the ‘existing international treaty protection regimes, legal entities are included among the holders of intellectual property rights. However, [...] their entitlements, because of their different nature, are not protected at the level of human rights.’\textsuperscript{272} What this means is that legal personalities cannot derive benefits from the protection of their moral and material interest in an invention under the ICESCR.\textsuperscript{273}

Still on this point, some commentators argue that there is a conceptual difference between IP rights and the moral and material interest of the inventors under ICESCR and UDHR.\textsuperscript{274} The scope of IPRs, according to Hestermeyer, extends beyond the material and moral interest of the ‘author’ or inventor.\textsuperscript{275} He argues that, although the overall objective of patent protection is to serve a larger development goal for society’s benefit and thus shares a similar goal to human rights values, it is an instrumental right rather than a ‘fundamental’

\textsuperscript{269} CECSR, General Comment No. 17 paragraph 7. See also Abbe Brown and Charlotte Waelde, ‘Human Rights, Persons with Disabilities and Copyright’ in Christophe Geiger (eds), Research Handbook on Human Rights and Intellectual Property (Edward Elgar Publishing 2015) 592. Although some Human Rights laws such as the ECHR allow legal personalities to rely on them when it relates to property rights. Hestermeyer (n 98) 155.
\textsuperscript{270} Adusei (n 257) 204.
\textsuperscript{271} CECSR, General Comment No. 17, paragraph 7.
\textsuperscript{272} ibid
\textsuperscript{273} Hestermeyer (n 98) 155.
\textsuperscript{274} ibid 154-155.
\textsuperscript{275} ibid 154-155.
right.\textsuperscript{276} This is indicative in the temporal nature and transferable character of patent rights.\textsuperscript{277}

Perhaps a hybrid approach to the relationship between patent rights and human rights may be to argue that a patent right, one that necessarily prevents others from unlawfully appropriating or free riding on a patented invention in order to recoup the cost of investment in the inventive enterprise, recognises the human right i.e material interest of the inventor. From this IP-human rights dimension, the patent rights of inventors, and the moral and material interests of right-holders in human rights law could overlap. That is, a patent holder’s rights under patent law can, at the same time, have human rights characteristics. The patent rights-holders can, within the specific limit of his proprietary interest in the creation, rely on the rights conferred in the human rights instruments to claim the moral and material ownership and benefit of an invention. Likewise, creators/inventors could rely on the patents right protection under statutory law to seek legal protection and draw material benefit from the invention.

However, it is possible for one of the rights to exist without the other. Therefore, even when the patent term has elapsed, the right holder’s moral and material interest as a creator in the invention is not extinguished. In other words, it is possible to have a human rights entitlement to the protection of a scientific and material interest without a corresponding grant of patent right protection. In this manner, a patent protection is also an important medium through which the

\textsuperscript{276} Ibid; Dreyfuss (n 208) 79.

\textsuperscript{277} Ibid. Dreyfuss also argues in this respect that the main objectives of IP in the TRIPS Agreement, unlike human rights, are expressed in utilitarian terms; that is the rights contained in the Agreement ‘must be balanced against social welfare concerns.’ Dreyfuss (n 208) 79.
government can promote the human rights of an inventor as contained in the ICESCR and UDHR.278

This argument should, however, be treated with caution as human rights within the contemplation of the ICECSR and UDHR are clearly not to be equated with patent rights. Thus, to the extent that a patent under the law is a statutory instrument granted by the state within specific boundaries and conditions, it is erroneous to say that it is a human right in its entirety. In this respect a patent protection as a legal instrument under patent law, cannot be said to be a human right in itself. What this indicates is that an inventor’s right in a patent cannot be expected to carry the same weight of enforcement as other fundamental human rights such as the right to health. Thus to answer the question asked at the start of this section, human rights offers little justification for patent holders, and certainly pharmaceutical companies, to interfere with the public interest and the human right to access to medicines.279

4.7.4 ‘Balancing’ the Rights of Inventors, and the Public’s Human Rights to Health and Access to Medicines

On the issue of the human rights protection of an inventor’s interest on the one hand and the public’s access to the invention such as medicines on the other, the UDHR280 and ICESCR attempt to strike a balance. This is indicative in the provision of Article 15(1)(a) and 15(1)(b) of the ICESCR which recognises the right of everyone to enjoy and take part in ‘cultural life’ and to enjoy ‘the benefit of scientific progress and its applications.’ Fundamentally, these rights provide a moral and legal claim for users to access the fruits of scientific and

278 Hestermeyer (n 98) 154-155.
279 See also SmithKline and French Laboratories Ltd v Netherlands (n 244).
280 In Article 27 (1), ‘[e]veryone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.’
technological innovations. In this sense, access to the benefits of scientific R&D is placed on an equal standing with the protection of the rights of inventors under Article 15(1)(c). Commenting on this, Professor Okediji argues that the ‘user’s interests are just as rights-based as the interests of owners.’

On her part, Chapman observes from a human rights perspective that benefiting from the products of science and technology presupposes that everyone will have access to them.

Along this line, the CESCR relates the public policy goals of protecting the moral and material interest of creators to the realisation of other economic, social, and cultural rights. In paragraph 2, the right to benefit from the protection of a ‘scientific, literary and artistic production’ is described in the General Comment No 17 as a means through which creators are encouraged to contribute to ‘arts and sciences and to the progress of a society as a whole.’

It may be argued that Article 15 of the ICESCR as a whole tries to strike a balance between the recognition of a creator’s right to control his/her intellectual capital and derive benefit from its innovative value and the public’s right to access the products of the invention. In this manner, the objective of the protection of the inventor’s interest is to serve a broader societal goal as the right is intrinsically linked with other rights of users in Article 15 to ‘enjoy the benefits of scientific progress.’ Other fundamental human rights, such as the right to access medicines, will also come under this public welfare benefit to society. Moreover, paragraph 35 of the General Comment No 17 emphasises

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283 CESCR, General Comment No. 17, paragraph 4.

284 Hestermeyer (n 98) 158.

285 CESCR, General Comment No. 17, Paragraph 2.
that the states’ obligation in the context of Article 15 has to take into account other rights recognised under the ICESCR. This mandate would require states, such as Nigeria, to strike a balance between protecting the private interests of inventors and promoting the larger socio-economic and cultural rights of society to have access to the products of creators. Accordingly,

In striking this balance, the private interests of authors should not be unduly favoured and the public interest in enjoying broad access to their productions should be given due consideration.\textsuperscript{286}

Although there is no delineation of this balance, the clarification that the rights should be balanced with the right to access offers a platform to bolster the argument for a broader reliance on human rights to promote access to medicines in Nigeria and elsewhere, within the context of patent rights.

This argument can best be understood within the context of the drafting background to Articles 15 of the ICECSR and 27 of the UDHR. A study of the original draft ESCR Covenant of 1954 reveals that Article 15(1)(c) was not included in the first draft.\textsuperscript{287} The original draft only contained provisions guaranteeing the rights of everyone to partake in cultural life and enjoy the fruits scientific progress (i.e Articles 15(1)(a)(b)).\textsuperscript{288} Likewise, in the original draft of Article 27 of the UDHR, Article 27(2) which seeks to protect the moral and material interest of authors and creators was not present.\textsuperscript{289} The Article only included provisions for participation in cultural development and enjoyment of

\begin{footnotesize}
\begin{itemize}
\item[286] CECSR, General Comment No. 17, Paragraph 35.
\item[288] Note that Article 15 of the current text was in Article 16 of the 1954 Covenant.
\item[289] ibid
\item[288] United Nations, Report of the Third Session of the Commission on Human Rights (UN Doc E/800 1948) 13. Article 27 of the current text was in Article 25 of the draft Declaration.
\end{itemize}
\end{footnotesize}
the benefits of scientific advances.\textsuperscript{290} It would therefore appear that Articles 15 of the ICECSR and 27 of the UDHR were drafted and construed from an ‘end-user’ perspective.\textsuperscript{291} This is to guarantee that users can derive benefits from scientific creations and inventions and also freely engage in the cultural development of the community. It follows that human rights values and places emphasis on social welfare and promotes society’s interest to have access to scientific developments.\textsuperscript{292} Thus the later addition of Article 15(1)(c) to the ICECSR cannot qualify the first two paragraphs of Article 15.\textsuperscript{293} With regards to IPRs and societal benefits (user’s rights), Professor Cullet argues that ‘[h]uman rights treaties require the balance to be attempted from the perspective of society at large.’\textsuperscript{294} In addition, the CECSR stresses that the recognition of inventor’s or creators’ interest should not be at the risk of the state’s core obligation towards the realisation of the rights to health and access to medicines ‘as well as to take part in cultural life and to enjoy the benefits of scientific progress and its applications.’ The CECSR goes on to emphasise that State Parties have a duty to ensure that the protection of inventor’s rights under IP law does not occasion ‘unreasonably high costs of access to medicines.’\textsuperscript{295} Furthermore, this rights-based approach also implies that the obligation on states extends to the implementation of patent rights in a way that does not conflict with the right to access the products of the inventor’s scientific progress.\textsuperscript{296} Therefore, the moral

\textsuperscript{290} ibid
\textsuperscript{292} ibid
\textsuperscript{293} ibid
\textsuperscript{294} ibid 152.
\textsuperscript{295} CECSR, General Comment No. 17, Paragraph 35.
\textsuperscript{296} ibid
and material interests of the inventors in patent law should not interfere with the right to access medicines. Moreover, Article 30 of the UDHR also stipulates that ‘[n]othing in this Declaration may be interpreted as implying for any state, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms set forth herein.’ Clearly, the right given to inventors in Article 27(2) should not affect the human right to health as stipulated in Article 25, which will include the right to access medicines. What this means is that inventors have very little ground in human rights to stand on as justification for encroaching on the right to access drugs. One author notes that, if any of the socio-economic rights is at risk from the protection of the creator’s interest, the ‘pendulum swings towards supporting diffusion and access to the benefit of the new technology.’

To sum up, the analysis above highlights the interrelationship between patent rights, inventors’ rights, human rights and the human rights of end users to access scientific advancements. It has been argued that the rights of inventors, particularly their patent rights, should not constitute a hindrance to the fundamental right to health. If the rights of inventors lead to a reduction in the quest of women to obtain cost-effective medicines for better health, it may be in violation of women’s fundamental human rights. In particular, the Nigeria has a duty to ensure that patent rights, as a means to protecting the human rights and moral and material interests of inventors, does not negatively impact on the quest of women to obtain medicines, and indeed, other follow-on inventors.

Having made the case for women’s access to medicines as a human right within the context of patent law, the next section specifically narrows down the

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297 Hestermeyer (n 98) 158-159.
study to Nigeria to examine its obligation to human rights. More specifically, the country’s commitment to provide healthcare and the legislative measures to guarantee the right to health, including access to essential drugs.

PART III: TOWARDS AN ENFORCEMENT OF WOMEN’S RIGHTS TO HEALTH AND ACCESS TO MEDICINES IN NIGERIA

4.8 Constitutional Recognition of Healthcare in Nigeria

In Nigeria, although the 1999 Constitution (as amended) does not expressly recognise the right to health, the country’s commitment to provide healthcare to its people is subsumed under the general provisions on health in the Fundamental Objectives and Directive Principles of State Policy in Chapter II of the Constitution. Section 17(3)(d) of the Constitution requires the state (Nigeria) to take appropriate measures and direct its policies towards ensuring an adequate standard of medical care for everyone, including the provision of medical and healthcare facilities. Under that section, the state shall also ensure that ‘the health, safety and welfare of all persons in employment are safeguarded and not endangered or abused.’ It can be said that these Fundamental Objectives and Principles consider it a primary duty of the state to improve the healthcare and welfare of Nigerians. For this reason, it imposes

298 It reads:
The State shall direct its policy towards ensuring that-
(d) there are adequate medical and health facilities for all persons.
The health and safety of people in the workplace are also accorded recognition in section 17(3)(c) of the Constitution.


300 In the case of Attorney-General of Ondo State v Attorney-General of the Federation (2002) FWLR (pt. 111) 1972, the Nigerian Supreme Court per Uwaise, JSC clarified that the word ‘state’ applies to all tiers of government, authorities and persons exercising legislative, executive or judicial powers with regards to the enforcement of the Fundamental Objectives and Directive Principles of State Policy under the Constitution.
a liability on the state to secure the necessary facilities for the promotion of health and wellbeing of all Nigerians.\textsuperscript{301}

While this blanket provision does not effectively address the issues of rights to health and access to adequate medical treatments in Nigeria, it could be argued that the Constitution’s reference to ‘adequate medical and health facilities’ accords recognition to the appropriate health services and medicines as necessary for the improvement of the health and health-related conditions of Nigerians. Thus, the Nigerian government has a duty to promote the welfare of every individual, including the guarantee of their healthcare-related interests such as accessibility to medicines as part of medical care. This fundamental obligation of the government is supported by Section 14(1)(2) of the Constitution which enjoins the state to promote social justice, including the security and welfare of Nigerians, as a matter of public good. It could be argued that the obligation to promote the welfare and wellbeing of Nigerians could be discharged by providing adequate healthcare services and drugs for effective treatments of diseases and illness. A broad interpretation of this obligation also extends to ensuring that patents do not obstruct access to medicines or interfere with healthcare provision.

4.8.1 Is Access to HealthCare and Medicines Legally Enforceable in Nigeria?

Notwithstanding the provisions of Sections 17(3)(b) and (c) of the Constitution, there are two identifiable problems with the categorisation of the healthcare provision in Chapter II of the Nigerian Constitution. First, it is unenforceable by the courts; and secondly, the provision is not a ‘human right.’

The categorisation of healthcare as a Fundamental Objective and Directive Principle as contained in Chapter II of the 1999 Constitution has been characterised as ‘an aspirational or hortatory goal’ with no legally binding claim.\(^\text{302}\) This is because the duty on the state to provide adequate healthcare facilities including medicines, in accordance with section 17(1)(c)(d) in Chapter II of the Constitution, falls under one of the judicially unenforceable categories of duties and responsibilities within the contemplation of Section 6(6)(c) of the Nigerian 1999 Constitution.

By virtue of Section 6(6)(c) of the Constitution, the courts lack jurisdiction to entertain issues emanating from the socio-economic and cultural aspirations and objectives in the Fundamental Objectives and Directive of Principles of State Policy in Chapter II of the Constitution. Under Section 6(6)(c), the judicial powers vested in accordance with the provisions of Chapter II in the Constitution,

\[\text{...} \] shall not except as otherwise provided by this Constitution, extend to any issue or question as to whether any act of omission by any authority or person or as to whether any law or any judicial decision is in conformity with the Fundamental Objectives and Directive Principles of State Policy set out in Chapter II of this Constitution.

Consequently, the justiciability of the socio-economic guarantees in the Constitution or any other law is clear.\(^\text{303}\) Accordingly, Section 6(6)(c) implies that an aggrieved person cannot take the government to court, or seek a judicial remedy for a violation of the provisions of Chapter II.\(^\text{304}\) As Section 17(1)(c)(d) falls within the provision of the Fundamental Directives in Chapter II, the restrictions on judicial enforceability apply to the duty to provide healthcare


\(^{304}\) ibid 43, 58.
facilities. In essence, a claim to medical and healthcare treatments in Nigeria has no judicial enforceable status under the Constitution. This means that in the Constitution, interference with access to healthcare services and medicines cannot be redressed through judicial channels by Nigerians. A further implication is that the government of Nigeria cannot legally be compelled to implement its obligations to provide medical and healthcare facilities under the Constitution.

Although the necessity of directing state policies towards facilitating access to medical and healthcare facilities to further the material wellbeing of Nigerians was promoted in the Constitution, the status of this provision as a non-justiciable entitlement robs the provisions of a judicial recourse to compel government compliance, action and enforcement. Thus as it stands, the provision is a mere political objective and goal, devoid of a concrete redress mechanism against the duty bearers to guarantee the enjoyment of these important provisions on health. This leads academicians and legal specialists to criticise the categorisation of the obligations to which the provision on healthcare in the Constitution belongs as a ‘toothless bulldog’ that barks but cannot bite because there are no concrete enforcement mechanisms attached to the health objective.\(^\text{305}\)

The Nigerian courts have generally adopted the same attitude to the non-justiciability of the socio-economic provisions in Chapter II and have upheld the unenforceability of its provisions. For instance, the Nigerian Court in *Archbishop Anthony Olubunmi Okogie (Trustee of Roman Catholic Schools) & Others vs Attorney General of Lagos State*,\(^\text{306}\) reaffirmed the challenge that Section

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\(^{305}\) Nnamuchi (n 302) 2.

\(^{306}\) (1981) 2 NCLR 350. The reasoning in the above decision was affirmed in the later case of Adewole v Jakande (1981) 1 N.C.L.R. 152. This is another case which arose over the abolition of private elementary schools in Lagos State.
6(6)(c) poses to the judicial application of the Chapter II provisions by the courts, thus raising the questions of how and whether the provisions are actually ‘fundamental’ since they cannot command judicial enforcement. In this case, the courts were invited to adjudicate on the question of the enforceability of the fundamental rights of the plaintiffs. The Lagos State Government issued circulars to abolish all private fee paying primary educational institutions. This was done ‘towards ensuring that there are equal and adequate educational opportunities at all levels’ as provided under Section 18 of the 1979 Constitution (a non-justiciable provision in the 1979 Constitution). The plaintiff claimed that the plan by the government to abolish private primary education was a threat to the freedom to hold and impart education under Section 36 of the Constitution. The Court of Appeal reaffirmed in its ruling pursuant to Section 6(6)(c), that the provisions of Chapter II were not enforceable in courts. The court proceeded on the general note that the provisions in Chapter II are not justiciable, and that ‘the arbiter for any breach of the Objectives and the Directive Principles of State policy is the legislature or the electorate.’

Delivering the ruling, Justice Mamman Nasir (as he then was) acknowledged that the directive principles are the ultimate objectives of the nation and are policies which are expected to be pursued in the nation’s interest to realise its welfare objectives. He explained further that,

[...] while Section 13 of the Constitution makes it a duty and responsibility of the judiciary among other organs of government, to conform to and apply the provisions of Chapter II, Section 6(6)(c) of the same Constitution makes it clear that no Court has jurisdiction to pronounce any decision as to whether any organ of government has acted or is acting in conformity with the Fundamental Objectives


Paragraphs 7-8.
and Directive Principles. It is clear that Section 13 has not made Chapter II justiciable.\textsuperscript{309}

Ruling in favour of the plaintiff’s fundamental rights, the court further held that no legislation, pursuant to Section 16 or 18 of the Constitution can validly override the constitutionally guaranteed rights in Chapter IV of the Constitution. Likewise in \textit{Uzoukwu v Ezeonu} II the Courts, per Nasir PCA, reiterated the non-justiciability of Chapter II thus:

\begin{quote}
There are other rights which may pertain to a person which are neither fundamental nor justiciable in the Court. These may include rights given by the Constitution under the Fundamental Objectives and Directive Principles of State Policy under Chapter II of the Constitution.\textsuperscript{310}
\end{quote}

In this case, the appellants sought the enforcement of their fundamental rights, as guaranteed by Sections 31 and 39 of the 1979 Constitution. They alleged that the respondents treated and regarded them as slaves, in violation of their Constitutional guaranteed rights. The court in its ruling clarified that while the fundamentally ascribed rights in Chapter IV are justiciable in courts, the rights given by the Constitution in Chapter II are not fundamental or justiciable in Courts.\textsuperscript{311} It is unfortunate that despite the importance of the socio-economic and cultural provisions in Chapter II, their practical enforceability has been undermined by the same Constitution that pledged to promote the welfare and wellbeing of all persons in Nigeria.

Another issue is that the provisions on health in the Constitution are not ‘human rights’; they are fundamental state objectives and principles which the Nigerian state aims to achieve for all its citizens. While the importance of protecting human rights in national constitutions is without doubt significant to

\begin{footnotes}
\textsuperscript{309} Paragraphs 1-2.
\textsuperscript{310} (1991) 6 NWLR (pt 2000) 761, paragraphs A-D.
\textsuperscript{311} ibid
\end{footnotes}
guaranteeing the enjoyment of the rights, the Nigerian Constitution has failed to accord the provisions in Chapter II with human rights status. Although the provisions embody socio-economic and cultural rights, the heading, focus, goals and procedural judicial embargo clearly indicate that the provisions are not guaranteed human rights. Indeed, while Chapter IV of the Constitution is entitled ‘Fundamental Rights, Chapter II has the heading ‘Fundamental Objectives and Directives of State Policy.’ If the intention of the legislature was to make the provisions in Chapter II human rights, it would have clearly stated so. Thus, despite the significance of access to medicines as a human right to health and the need to ensure that medical patents do not interfere with this access from a human rights perspective, the Constitution has failed to effectively reflect a human rights goal to the provision on health.

It is argued that there is a need to guarantee the provisions in Chapter II as legally enforceable human rights. Under international law as analysed above the provisions on human rights carry with them obligations for the state to respect, protect, fulfil and implement. This duty includes ensuring that policies and laws such as patents do not interfere with the enjoyment of the right. As justiciable human rights, the provisions on health would also avail Nigerians with the opportunity and legal recourse to measure the performance of the government, authorities and third parties who infringe on those rights. However, the failure to guarantee the provisions on health as human rights under the Constitution means that the provisions may not make full meaningful impact on all Nigerians, especially since the provisions are non-justiciable.

Moreover, it is argued that the extant legislative provision on healthcare in the Constitution is inadequate to capture all the dimensions of the right to health.

312 See subsection 4.5 above.
The provision in Section 16(3)(d) simply obliges the state to direct its resources towards providing ‘adequate medical and health facilities for all persons.’ This language of the law does not guarantee all the dimensions of the right to health as discussed above in the subsections of 4.3.1 above. From the lens of access to medicines perspective, the text of the law with regards to health does not appear to clearly guarantee the availability and accessibility of affordable drugs that are acceptable and of good quality, in a gender sensitive and non-discriminatory manner. Nevertheless, a broad interpretation of the measures to be undertaken to provide the medical and health facilities in the Constitution would require that health medicines are provided and any interference with accessing medicines is addressed by the Nigerian state. For the sake of brevity, however, the recognition of the provisions on adequate healthcare in the Constitution as human rights would ensure that all components of the right to health including access to medicines are guaranteed.

This suggestion is consistent with the preamble to the Constitution which pledges to promote the wellbeing of Nigerians. But without access to adequate healthcare and medicines, securing the wellbeing of the Nigerian women, and indeed all Nigerians will remain a pipe dream. Thus it is important that the healthcare of the citizens is given paramount importance as a matter of right in the country.
4.8.2 Making a Case for the Provision of Healthcare and Access to Medicines for Women under the Nigerian Constitution

The Drafting Committee of the 1979 Constitution characterised the ‘Fundamental Objectives’ as the ‘identification of the ultimate objective of the nation’. As such, they are the ‘ideals towards which the Nation is expected to strive’ to promote the security and welfare of the people. The ‘Directive Principles’, on the other hand, ‘lay down the policies which are expected to be pursued in the efforts of the Nation to realise the national ideals.’ In other words, the Principles are identified as the guidelines which lead to the realisation of state ideals or goals; hence the state is expected to direct its policies to achieve these ideals. For this purpose, Section 13 of the 1999 Constitution states:

> It shall be the duty and responsibility of all organs of government, and of all authorities and persons, exercising legislative, executive or judicial powers, to conform to, observe and apply the provisions of this Chapter [Chapter II].

This provision, however, leaves a myriad of questions open. Such as: what is the nature of duty and responsibility that the state is expected to adopt to comply with the requirement to fulfil the obligation to medical and healthcare facilities for women pursuant to Section 17(3)(c) and (d)? In other words, to what extent is the government expected to satisfy the duty to ‘conform to, observe and apply the provisions’ on guaranteeing their access to healthcare facilities including medicines? More specifically, if the state fails in its duty, how

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313 The precursor to the current 1999 Constitution. The Constitution was the first to categorise the Fundamental Objectives and Directive Principles on state policy provisions.
314 *Report of the Constitution Drafting Committee* Vol 1 (Government Printer 1976) v. Accordingly, the ‘Fundamental Objectives are ideals towards which the Nation is expected to strive whilst Directive Principles lay down the policies which are expected to be pursued in the efforts of the Nation to realise the national ideals.’
316 Emphasis added.
can it be compelled to meet its responsibility and duty to healthcare, considering
the fact that their recourse to a legal remedy has been foreclosed?

Where there is a duty, there is a corresponding obligation to fulfil that duty, and
a remedy mechanism to enforce compliance with that duty; yet Section 6(6)(c)
of the Constitution exempts this duty from judicial scrutiny. Can it be said then
that there is no actual duty on the state to implement the provision on access to
adequate medical care because it is not legally binding?

Neither Section 13 nor any other section in the Constitution gives a clear
answer to these questions. However, it is argued that, although the provision of
access to adequate healthcare cannot compel judicial legal recourse, it does
not affect the duty and responsibility of the Nigerian state to implement, apply
and observe the statutory provisions of Section 17(3)(c) and (d) with regards to
facilitating and protecting women’s access to adequate medical care. In other
words, the absence of a justiciable statute does not divest the state of a duty to
protect, promote and realise its duty to the provision of medical care. One
scholar, commenting on the nature of the government’s duty, argues that the
word ‘Directive’ in the title of Chapter II implies that this duty is mandatory and
the provisions create an obligation on the government to fulfil and comply with
the provisions on access to adequate health and medical facilities.\footnote{317}

Accordingly, the term ‘Directive’ in Chapter II suggests that it is an order or
command, meaning that the provisions of the Chapter are obligatory and create
commitments for the government to comply.\footnote{318} In agreement with the above
suggestion, it appears that the duty with respect to adequate medical and health
facilities, including access to medicines, is couched in an authoritative or
mandatory term which requires the state to achieve the intended outcome.

\footnote{317} Nnamuchi (n 302) 4.
\footnote{318} ibid
Clearly, Section 6(6) (c) only purports to exclude the legal enforcement of a claim on this duty or a violation of the Fundamental Directives by foreclosing the possibility of subjecting the positive realisation of the provisions in Chapter II to judicial scrutiny.

Notwithstanding this judicial bar, the state has a duty to direct its policies towards ensuring women’s access to adequate healthcare facilities and medical treatments. That is, the non-enforceability of the provision does not negate the fact that the state has a duty to ensure that its policies and laws guarantee women and indeed all Nigerians access to health facilities including medicines, even though this duty cannot command the force of law in a judicial proceeding. In addition, as Nwabueze observes, the provisions of Chapter II can be relied upon in the interpretation of constitutional debates.\(^{319}\) In this regard, it can be said that the provisions of Section 17(3)(c) can be relied upon to argue that the state direct its policies to ensuring that there is non-interference with women’s healthcare in view of patent rights, or utilise the patent-related flexibilities to guarantee their access to adequate medical care. India’s attitude to the constitutional provision on health offers a good example to support these arguments.

The Fundamental Objectives and Directives in Chapter II of the extant Nigerian Constitution (including the provision on health and medical care) is borrowed from the Indian Constitution (1948) and was first included in the 1979 Nigerian Constitution.\(^{320}\) India’s present constitutional provision on the rights to health and healthcare is, however, extensive and covers a wider range of conditions.

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for public health and wellbeing of everyone.\textsuperscript{321} For example, the state in Article 47 has a primary duty to secure the public health of the people by ‘raising the level of nutrition and standard of living […] and the improvement of public health […]’ including control of substances that affect health and human conditions of work. Notably, Article 42 recognises the importance of women’s health and makes provisions to secure ‘maternity reliefs’ and benefits as being integral to health.\textsuperscript{322} Similarly to Nigeria, the provisions on health are not legally enforceable by the courts in India.\textsuperscript{323} Notwithstanding, the Indian courts have broadly construed the constitutional provisions on health to enforce the state’s obligation to improve the health and rights of the people to affordable healthcare, especially medicines.\textsuperscript{324}

In \textit{Samity v State of Bengal}, for instance, access to timely healthcare necessary to preserve life was upheld by the Indian Supreme Court.\textsuperscript{325} Deciding on the basis of the right to life, the court held that the right includes an obligation to provide access to medical treatments to preserve human life as a ‘constitutional

\begin{itemize}
  \item \textsuperscript{321} The obligation on the state to ensure, create and sustain the necessary facilities and conditions congenial to good health is generally found in the Constitutional directives as contained in Articles 38, 39(e)(f), 41, 42, 47 and 48A in Part IV of the Constitution of India. For example, Article 41 states that the
  \begin{quote}
  \textit{State shall, within the limits of its economic capacity and development, make effective provision for securing the right to work, to [...] public assistance in cases of [...] old age, sickness and disablement [...].}
  \end{quote}

  \item \textsuperscript{322} Indrajit Khaneke, BH Tirpude and PN Murkey, ‘Right to Health Care’ (2012) 34 (2) Journal of Indian Academy of Forensic Medicine 160.

  \item \textsuperscript{323} Ebenezer Durojaiye, ‘Litigating the Right to Health in Nigeria: Challenges and Prospects’ in Magnus Killander (ed), \textit{International Law and Domestic Human Rights Litigation in Africa} (PULP 2010) 166. The provisions guaranteeing healthcare and health conditions in India are found under the Directive Principle of State policy which is not justiciable in India. Article 37 of the Constitution declares that the
  \begin{quote}
  \textit{[t]he provisions contained in this Part shall not be enforceable by any Court, but the principles therein laid down are nevertheless fundamental in the governance of the country and it shall be the duty of the State to apply these principles in making laws.}
  \end{quote}

  \item \textsuperscript{324} See discussions and cases on this in Mihir Desai and Dipi Chand, ‘Fundamental Right to Health and Public Health Care’ in Mihir Desai and Kamayani Bali Mahabal (eds), \textit{Health Care Case Law in India} (Centre for Enquiry into Health and Allied Themes (CEHAT) and India Centre for Human Rights & Law (ICHR) 2007) 17-35.

  \item \textsuperscript{325} \textit{Paschim Banga Khet Samity v State of West Bengal}, Case No. 169, Judgement of 6 May 1996 Writ Petn. (Civil) No. 796 of 1992 (SC Agrawal, GT Nanavati JJ) (1996). In this case, Samity fell off a train and suffered serious head injuries. The necessary health facilities (including vacant bed) to treat him were not available in six hospitals. The Court held that ‘failure on the part of the government to provide timely medical care to a person in need of such treatment results in a violation of his right to life guaranteed in Article 21 of the Constitution. See paragraph 9 of the judgement.}
\end{itemize}
obligation of the state to provide adequate medical services to the people.\textsuperscript{326} Perhaps, it is not out of place for Nigeria to follow this judicial activism and adopt a rights-based attitude to lay down the standards for the Nigerian state to comply with its obligations to women’s health.\textsuperscript{327} Still on the issue, how then can an aggrieved person compel the enforcement of the duty to comply, enforce and observe the provisions of access to healthcare? The answer to this question remains unclear. However, despite the non-enforceability and justiciability challenge of Chapter II, the Nigerian courts have begun to open up new windows to allow the enforcement of the constitutional provisions in Chapter II including the recognition of the health provisions as rights. The court generally relies on the justiciable fundamental rights in Chapter IV of the Constitution to interpret the non-justiciable provisions. For instance, in the case of \textit{Gbemre v Shell Petroleum Development Company Nigeria Limited and Others},\textsuperscript{328} the Nigerian Federal High Court delivered a landmark ruling for the protection of right to health and a healthy environment. In that case, the appellants sought an order to enforce their fundamental rights to life and dignity of person pursuant to Sections 33(1) and 34(1) of the Nigerian Constitution. The applicants supported their claim by relying on Articles 4, 16, and 24 of the African Charter.\textsuperscript{329} They claimed that the degradation of the environment by the respondents violated their human rights to a healthy environment. The respondents counter-argued that the African Charter and its provisions on health and healthy environment do not create justiciable and legally enforceable

\textsuperscript{326} Paragraphs 9, 15-16 ibid. Notably, the court held that this duty on the state is irrespective of financial and resource constraints and the state responsibility can be discharged in ‘whatever is necessary for this purpose.’ Paragraph 16 ibid.

\textsuperscript{327} It should be noted that Nigeria shares a similar constitutional law and legal system with India hence the comparative study of Nigeria and India. This suggestion is made not only because Nigeria and India share a similar constitutional provision with regards to healthcare, but more so that both countries share a comparable socio-economic condition and political landscape.

\textsuperscript{328} 152 (2005) AHRLR 151 (NgHC 2005).

\textsuperscript{329} Article 4 on the right to life, 16 on the right to health care and 24 on right to satisfactory environment in the African Charter. On the right to health provisions in African Charter, the appellant argued that they have a right to ‘enjoy the best attainable state of physical and mental health as well as a right to a general satisfactory environment favourable to their development.’
rights in regular Nigerian courts. The judge, Nwokorie J, rejected the arguments of the respondents and ruled that the provisions of the Charter are applicable in Nigeria.

The Courts further held that:

That section 3(2)(a) and (b) of the Associated Gas Re-Injection Act and section 1 of the Associated Gas Re-Injection (Continued Flaring of Gas) Regulations section 1.43 of 1984, under which gas flaring in Nigeria may be allowed are inconsistent with the applicant’s rights to life and/or dignity of human person enshrined in sections 33(1) and 34(1) of the Constitution of the Federal Republic of Nigeria, 1999 and articles 4, 16 and 24 of the African Charter on Human and Peoples’ Rights (Ratification and Enforcement) Act, cap A9, Vol 1, Laws of the Federation of Nigeria, 2004) and are therefore unconstitutional, null and void by virtue of section 1(3) of the same Constitution.\(^{330}\)

In this case, the judge relied on the guaranteed constitutional provisions on the rights to life and dignity of person and broadly construed the right to life as extending to the right to health and a healthy environment under the ratified African Charter.

This case is a significant improvement in the judicial attitude to human rights, especially socio-economic provisions, for the following reasons. Firstly, the case was the first time a Nigerian court had made a pronouncement on the right to health and a healthy environment. Importantly, the court linked the right to a healthy environment (non-justiciable under Chapter II) with the justiciable right to life and human dignity provision in the 1999 Constitution. The right to life was thus broadly interpreted to include congenital factors such as a healthy living environment. Secondly, although the case was not decided exclusively on the human rights provisions in the African Charter, the court significantly relied on the right to health and healthy environment in the Charter to enforce socio-

\(^{330}\) Paragraph 5(6).
economic rights in Nigeria. Thirdly, this case also illustrates the influence and application of human rights provisions in the African Charter to grant a human rights remedy.

It follows that another way to secure the litigation of the provisions on health and access to medicines in Nigeria is by linking the enforcement of the provisions in Chapter II to the justiciable rights such as the right to life, dignity and liberty. This way, an action for the violation of the rights to health which will face the challenge of justiciability under the constitution can be based on the right to life as discussed above. The argument can be made when asserting these claims that, although the access to adequate medical care including medicines in Chapter II may not be a legally guaranteed right, nonetheless, it is essential to the enjoyment of other guaranteed rights in the Constitution.

Most people would agree that the right to life in Section 33(1) of the Nigerian Constitution is more meaningful to a healthy person. Likewise, without essential medicines, it will be hard for the Nigerian government to guarantee health, life and other socio-economic objectives and political rights of Nigerian women and all its citizens. As stated above, access to essential medicines as a part of providing adequate medical and healthcare facilities has implications for the enjoyment and realisation of the civil and politically justiciable rights in the Constitution. In guaranteeing the right to life, therefore, the government has

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331 For example, in Archbishop Anthony Olubunmi Okogie & Ors v Attorney General of Lagos State, (n 306), although the courts held that the Fundamental Directives and State Policy were non-justiciable, at the same time, the Court of Appeal held that the implementation of Chapter II could not be done in such a way as to infringe on the fundamental rights enunciated in Chapter IV of the Constitution (the freedom to hold opinion, receive and impart ideas under Section 36(1) of the Constitution). The court further found in favour of the plaintiffs on the basis that Sections 16(1)(c) and 18 of the Constitution guarantee their rights to participate in the economy and hindering them would amount to a violation of their fundamental rights under Section 36 - freedom to hold, receive and impart ideas.

332 Durojaye (n 323) 166-167.

333 Nnamuchi (n 302) 8; Agbakoba and others (n 303) 42.

334 The Nigerian Constitution in Section 33(1), 34 and 35 explicitly recognises the right of everyone to life, human dignity and liberty.

335 In subsection 4.4.1 above.
a duty to take appropriate measures to the provision of adequate healthcare system and medicines for women and children and all Nigerians.

Other case studies also indicate that the non-justiciability status of Chapter II of the Constitution in Section 6(6)(c) of the Constitution may not be absolute and in some instances, the provisions in Chapter II can be made justiciable.336 The enforcement of Chapter II provisions is allowed where it is so provided under other sections of the Constitution. This argument is better explained in the case of Olafisoye v Federal Republic of Nigeria.337 In this case, the appellants were charged with offences under the Corrupt Practices and Other Related Offences Act, 2000. The Court was invited to determine the question of whether or not the National Assembly validly enacted the Corrupt Practices and Other Related Offences Act of 2000 in accordance with the powers conferred to the Government under Section 15(5)(2) of the Constitution. The Section, contained in Chapter II of the Constitution, grants powers to the National Assembly to make laws to prohibit and abolish corrupt practices and abuse of power. The Court in its ruling stated that Section 6(6)(c) does not completely foreclose the justiciability of Chapter II. In the words of Niki Tobi (JSC),

In my humble view section 6 (6) (c) of the Constitution is neither total nor sacrosanct as the subsection provides a leeway by the use of the words “except as otherwise provided by this Constitution.” This mean that if the Constitution otherwise provides in another section, which makes a section or sections of Chapter 11 justiciable, it will be so interpreted by the Courts.

The Supreme Court also based its decision on the provisions of Item 60(a) of the Exclusive legislative list of the Second Schedule to the Constitution which vests power in the National Assembly to promote and enforce the observance

Accordingly, the court ruled that the legislature validly exercised its rights in the exclusive list.

In view of the foregoing, it appears that while Chapter II is non-justiciable, there are other ways which the provisions can be made justiciable. Pursuant to Section 4(2) of the 1999 Constitution, the National Assembly has the exclusive power to make laws for the peace, order and good government of the Nigerian Federation with regards to any matter in the Exclusive List. Equally, under Item 60(a) of the Exclusive List of the Constitution, the legislature has the power to promote and enforce the realisation of the provisions of Chapter II (which contains provisions on Nigeria’s access to adequate healthcare facilities and medicines). This power extends to the establishment and regulation of the appropriate authorities for this purpose. The provisions of Section 4(2) and Item 60(a) essentially give teeth to the enforcement of Chapter II. As the matter of regulating Chapter II provisions falls under the Exclusive Legislative List, the National Assembly can make laws with respect to the implementation and enforcement of the provisions of Chapter II. Since the bar to the enforceability of Chapter II does not extend to matters in the Exclusive List, it can be argued that

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338 The sub-item provides:

The establishment and regulation of authorities for the Federation or any part thereof –
(a) To promote and enforce the observance of the Fundamental Objectives and Directive Principles contained in this Constitution.

339 Pursuant to Section 4(2) of the Constitution, the legislative power is vested in the National Assembly of the federal Republic of Nigeria, consisting of the Senate and Federal House of Representatives, with regards to matters in the Exclusive List.

340 For example, Justice Mohammed L Uwais CJN (as he then was) succinctly emphasised the importance of Item 60(a) thus:

Item 60 of the Exclusive Legislative List of the Constitution of the Federal Republic of Nigeria specifically empowers the National Assembly to establish and regulate authorities for the Federation to promote and enforce the observance of the Fundamental Objectives and Directive Principles, and to prescribe minimum standards of education at all levels, amongst others. The breath-taking possibilities created by this provision have sadly been obscured and negated by non-observance. This is definitely one avenue that could be meaningfully exploited by our legislature to assure the betterment of the lives of the masses of Nigerians, whose hope for survival and development in today’s Nigeria have remained bleak, and is continuously diminishing. The utilisation of this power would ensure the creation of requisite bodies to oversee the needs of the weak and often overlooked and neglected in our society. It would also provide a unique and potent opportunity to our legislators to monitor and regulate the functions of these bodies, where the Executive, for reasons best known to it, fails or neglects to prioritize and implement the provisions of Chapter II, and by extension, the welfare of all Nigerians.

the legislature in Nigeria can make laws that permit the enforceability of the provisions of Chapter II, notwithstanding the bar in Section 6(6)(c). In this connection, Obilade noted with respect to the duties of the state to abolish corrupt practices and the abuse of power that

[It is clear […] that although Section 15(5) [in Chapter II] of the Constitution is, generally not justiciable, as soon as the National Assembly exercised its powers under Section 4 of the Constitution with respect to Item 60(a) of the Exclusive Legislative List, the provisions of Section 15(5) of the Constitution becomes justiciable.341

This argument also finds support in the case of Attorney General of Ondo State v Attorney General of the Federation & Others.342 The Supreme Court adopted a liberal interpretation which suggests the likelihood of the justiciability of Chapter II through relevant federal legislation. One of the main issues before the court for determination in that case was the question of whether or not the National Assembly was competent to enact the Corrupt Practices and Other Related Offences Act of 2000 in relation to Section 15(5) (under Chapter II) as empowered under Item 60(a) of the Second Schedule to the Exclusive Legislative list.343 The court upheld and justified the enactment of the Act based on the legislative authority of the National Assembly under Items 60(a), 67 and 68 of the Exclusive Legislative List.344 On the non-justiciability of the

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342 (2002) 9 NWLR (Pt 772) 222.

343 The plaintiffs challenged the constitutionality and validity of the Corrupt Practices and Other Related Offences Act of 2000 establishing the Independent Corrupt Practices and Other Related Offences Commission to prosecute alleged offenders in relation to Section 15(5) (under Chapter II) on the federalism principle. One of the questions before the Court was whether the National Assembly is constitutionally empowered to make laws with respect to ‘all corrupt practices and abuse of power’ in Section 15(5) under Item 60(a) of the Second Schedule to the Exclusive Legislative list.

344 Similarly, in the case of Bamidele Aturu v Minister of Petroleum Resources and Others (2013) Suit No FHC/ABJ/CS/591/09, Aturu instituted an action challenging the incessant fuel price increases and the Nigerian government’s neo-liberal policy of deregulation of the downstream sector of the petroleum industry. He argued that the policy of deregulation was unconstitutional and illegal in view of Section 16(1) of the Constitution (under Chapter II) and Sections 6(1) and 4(1) of the Petroleum Act and the Price Control Act, respectively. The defendants counter-argued that the suit was not properly constituted on the grounds of locus standi and non-justiciability of section 16(1). On the substantive issue, the court ruled that the combined reading of the provisions of section 16(1) of the Nigerian Constitution and sections 6(1) and 4(1) of the Petroleum Act and the Price Control Act respectively obliged
Fundamental Objectives and Directives of State Policy, Uwaifo S (JSC)\textsuperscript{345} adds as follows:

While they remain mere declarations, they cannot be enforced by legal process but (it) would be seen as a failure of duty and responsibility of State organs if they acted in clear disregard of them […]. But the directive principles (or some of them) can be made justiciable by legislation.

Uwaifo further expounded on this thus:

The Constitution itself has placed the entire Chapter II [on Directive Principles] under the Exclusive Legislative List. By this, it simply means that all the Directive Principles need not remain mere or pious declarations. It is for the Executive and National Assembly, working together; to give expression to anyone of them through appropriate enactment as occasion may demand.\textsuperscript{346}

This view of the judge gives credence to the opinion in this thesis that provision of healthcare including medicines and the regulatory measures to ensure that women’s access to healthcare is not impeded is an obligation and possibly an enforceable duty on the Nigerian government. These judicial pronouncements significantly suggest that there are alternative and indirect means by which the provisions of Chapter II can be made justiciable by means of enacting and executing legislation to this effect.\textsuperscript{347} Thus it is possible that the provisions on access to adequate healthcare can be made justiciable through legislative provisions to bolster the effect of the provisions in Chapter II of the

\textsuperscript{345} Not the leading judge in the case.
\textsuperscript{346} Uwaifo S (JSC) 391 paragraph(s) G–H, 410 paragraph G.
\textsuperscript{347} Nwabueze (n 219) 382. See also the case of Federal Republic of Nigeria v Anache and 3 ors. (2004) 17 NSCQR 140 where the court adopted the opinion that the phrase ‘save as otherwise provided by this constitution’ does not absolutely exclude matters in Chapter II from justiciability in the Constitution.
However, the legislature has to make provisions to give applicability to them.  

4.8.3 Current Measures to Promote the Right to Health in Nigeria

Towards the promotion of the health and welfare of Nigerians, the National Health Act was signed into law in December 2014. The Act provides a policy framework for the enhancement, regulation and management of the national health system. Notably, it provides a framework to ‘protect, promote, and fulfil the rights of the people of Nigeria to have access to healthcare service.’ Part of the healthcare services in the Act includes the duty to ‘promote availability of good quality, safe and affordable essential drugs, medical commodities, hygienic food and water.’ It regulates both the private and public health service sectors and also creates a Basic Health Care Provision Fund to ensure access of every Nigerian citizen to healthcare services. The use of the word ‘right’ to denote the entitlements of Nigerians to a healthcare system is illustrative of the legislators’ recognition of healthcare as an essential human right. It could be said that the Act imposes a human rights obligation on the state to provide healthcare to its citizens. Although not expressly stated in the

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348 See for example, the National Health Act which recognises Nigerians to a right to healthcare and services.
349 In a related manner, in the 1999 Constitution, health is listed in Schedule II, Part II, Item 17(a) of the Concurrent list; however the wording of the Item indicates that the National Assembly is charged with the responsibility of making laws with respect to matters and issues relating to health. Schedule II, Part II, Item 17(a) provides as follows that the National Assembly may make laws for the Federation or any part thereof with respect to: ‘[t]he health, safety and welfare of persons employed to work in factories, offices or other premises or in inter-State transportation and commerce including the training, supervision and qualification of such persons.’ Under Schedule IV, Item 2(c), one of the functions of a local government authority (municipal) is to facilitate ‘provision and maintenance of health services’ in section 2(c).
350 Emphasis added. Section 1(1) (e) of the National Health Act 2014. The Act provides a framework for the regulation, development and management of a national health system and sets standards for rendering health services in the federation.
351 Section 2(1) (i) of the National Health Act. This duty is vested in the Ministry of Justice.
352 Section 4(1) of the Constitution provides that ‘[t]he legislative powers of the Federal Republic of Nigeria shall be vested in a National Assembly for the Federation, which shall consist of a Senate and a House of Representatives.’ Under section 4(4)(a), the National Assembly shall have power to make laws with respect ‘any matter in the Concurrent Legislative List set out in the first column of Part II of the Second Schedule to this Constitution to the extent prescribed in the second column opposite thereto.’ What this provision seems to suggest is that the National Assembly can make laws with regards to issues relating to health as stated in Schedule II, Part II, Item 17(a). It can be argued that the National Assembly has exercised its right under the Constitution to make access to healthcare a matter of rights as opposed to merely stating that healthcare is an aspirational objective and directive principle of the Nigerian government.
Act, the obligation to provide healthcare and medicinal treatments will require
the state to guarantee that its laws and policies, such as patent laws and the
rights conferred on inventors do not hinder access to medicines or its duty as
considered in the preceding parts of this chapter. The Act is still at its nascent
stage; it remains to be seen if it will live up to its objective of promoting access
to quality healthcare for women and everyone in Nigeria.

4.9 Nigeria’s International Obligation to International Human Right
Provisions Guaranteeing Rights to Health and Access to Medicines

Nigeria, as mentioned in subsection 4.2.2, has committed itself to protect the
rights to health and life under several international human rights instruments.
This commitment to human rights imposes a duty on the state to fulfil its
contractual obligation to respect, protect, enforce and promote the actualisation
of human rights provisions including women’s right to health, life and access to
medicines as earlier enumerated. Nonetheless, the applicability of human
rights provisions in international laws and instruments is not absolute. The
binding obligation on the state to give practical expressions to the right to health
and access to medicines as a constituent of the right in the international human
rights instrument raises numerous enforcement issues particularly with regards
to Section 12(1) of the Nigerian Constitution. Nigeria is a dualistic state; thus
treaties and laws do not automatically carry the force of law. The reason for this
is that Section 12(1) of the Constitution expressly provides that before a treaty
can be recognised as law in Nigeria, it must be incorporated into national law by
the National Assembly for domestic validity.

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353 See the analyses in subsections 4.2.3, 4.2.4, 4.2.5, 4.3 and 4.4 of this chapter.
354 Section 12(1) provides that
[n]o treaty between the Federation and any other country shall have the force of law to the extent to which any
such treaty has been enacted into law by the National Assembly.
ICECSR and other international laws which contain significant human rights to health provision have not been enacted into the national laws of Nigeria. They will require domestication by the National Assembly to bear practical applicability and direct enforcement in Nigeria. The only binding human rights provision in Nigeria is the African Charter, which has been ratified and domesticated accordingly.

4.9.1 Nigeria’s Commitment and Obligation to the Right to Health in the African Charter

At the regional level, Nigeria is a State Party to the African Charter. The Nigerian National Assembly in March 1983 formally incorporated the African Charter (Ratification and Enforcement) Act into the domestic laws of Nigeria. Section 1 of the Act states that the Charter shall have the force of law in Nigeria and shall be given full recognition and effort and be applied by all authorities. Thus the Act directly incorporates all the human rights provisions of the African Charter including the right to health. Furthermore, Article 18(3) of the Act specifically requires the state to take action to eliminate discrimination against women and ensure the protection of their rights as enumerated in international law.

What this means is that international law does not exist as law unless it is explicitly incorporated into national law as well. Section 12(2)(3) of the Constitution further provides that where the subject matter of a treaty falls outside the Exclusive Legislative List, a bill for an Act of the National Assembly to give the treaty the force of law must be ratified by a majority of all the Houses of Assembly in the federation before it is enacted and assented to by the President. Hence, until a treaty has been domesticated in Nigeria, it cannot be applied within the country.

This Charter is part of the Nigerian law in Chapter 10 Laws of the Federation 1990. (It is worth noting that, although the National Assembly enacted the Act in 1983, the president was entrusted with the power to set the commencement date for the Act. Before the date was set, the military Administration took over. Consequently, the Revised Edition of the Laws of the Federation of Nigeria backdates the Act and its commencement to 17 March 1983.)

By virtue of Article 16 of the African Charter on Human and Peoples’ Rights (Ratification and Enforcement) Act Chapter A9 which states that:

Every individual shall have the right to enjoy the best attainable state of physical and mental health.
Declarations and Conventions including CEDAW. By virtue of the Act, all human rights provisions in the African Charter are recognised in Nigeria, hence the right to health in the Charter constitutes a part of the domestic laws of Nigeria. The policy makers, judiciary and legislature are therefore duty bound to enforce and safeguard the rights of every Nigerian to health. In this regard, Nigeria has an obligation to undertake all reasonable measures to guarantee the enjoyment of all human rights including the right to access medicines.

4.9.1.1 What does this Human Rights Commitment mean for Women’s Access to Medicines as a Right to Health in Nigeria?

The explicit recognition of women’s fundamental right to health imposes a duty on the Nigerian state to give serious considerations to women’s state of health in Nigeria and also to promote, protect, and provide adequate, affordable medicines in this respect. The state has a duty to guarantee that there is no impediment to this access, including ensuring that its activities or those of third parties, laws and treaty obligations are not inconsistent with its human rights duties to health. The failure of the Nigerian state to promote, respect and fulfil its obligations to women’s rights means that it is in breach of its duty. The African Charter has played an important role in imposing a human rights responsibility on the Nigerian government to respect the right to health and provide medical care to its citizens. In Media Rights Agenda & Others v Nigeria, the Commission took the view that the denial of an incarcerated suspect’s

358 Furthermore, in Order 1 (2) of the Fundamental Rights (Enforcement Procedure) Rules, 2009 ‘Fundamental Right’ is defined as ‘any of the rights provided for in Chapter IV of the Constitution, and includes any of the rights stipulated in the African Charter on Human and Peoples’ Rights (Ratification and Enforcement) Act.’
access to medical care while his health was deteriorating is a clear violation of the right to health under Article 16 of the Charter.\textsuperscript{359}

With specific regard to international human rights instruments such as ICESCR and CEDAW, containing important human rights obligations to health, the interpretative authority of the CECSR remains unclear since Nigeria is yet to incorporate the Covenants.\textsuperscript{360} Interestingly however, Article 60 of the African Charter provides that the Commission ‘shall draw inspiration from international law on human rights and people’s rights,’ including the provisions of ICESCR on rights to healthcare, and ‘specialised agencies of the United Nations’ such as the CECSR which has clearly stated that access to medicines is a constituent component of the right to health.\textsuperscript{361} In light of this provision, it appears that the provisions of the ICESCR and the accompanying General Comments and recommendations on the right to health can provide a conceptual interpretation and also guide the courts in the adjudication of rights of women and every Nigerian citizen’s to access medicines as a fundamental human right. Likewise General Comment No 2 on Article 14(1)(a)(b)(c) and (f) and Article 14(2)(a) and (c) of the Protocol to the African Charter on Human and Peoples’ Rights on the Rights of Women in Africa provides similar principles in relation to the right to health and the analogous state obligations as contained in CEDAW General Recommendation on Women’s Right to Health.\textsuperscript{362} It can be said, therefore, that

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\textsuperscript{360} Nonetheless, the provisions of the African Charter and Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa with respect to their right to health can be legitimately enforced by the courts in Nigeria.

\textsuperscript{361} As articulated in subsection 4.2.4.

\textsuperscript{362} And also, African Commission on Human and Peoples’ Rights, General Comment No. 3 on the African Charter on Human and Peoples’ Rights: The Right to Life (Article 4) (Adopted during the 57th Ordinary Session of the African Commission on Human and Peoples’ Rights held from 4 to 18 November 2015 in Banjul, The Gambia) Paragraphs 3, 42 and 43 where state’s obligation to the right to life is broadly construed to include adequate healthcare. In paragraph 42, the state has an obligation to prevent maternal mortality ‘by establishing functioning health systems and eliminating discriminatory laws and practices which impact on individuals’ and groups’ ability to seek health care.’
\end{flushright}
attaining the best standards of health of women in Nigeria will require access to medicines to overcome illnesses and restore health. This also requires the state to address violations and safeguard against interference by patent right holders and pharmaceutical companies. Section 16(2) of the African Charter (Ratification and Enforcement) Act specifically mandates the state to protect the health of the people and ensure access to medical care. Access in this regard presupposes that the Nigerian government should take all necessary actions, including the use of patents exceptions and TRIPS-complaint flexibilities safeguards to provide essential medicines and also ensure that accessibility to the medicine is not hindered.\footnote{\textsuperscript{363}}

A question with regards to the African Charter, however, is whether it has domestic application in terms of the enforcement of its provisions by the courts in Nigeria. In a number of cases, the courts have held that the African Charter and all its provisions are indeed directly enforceable in Nigeria. In \textit{Ogugu \& others v State},\footnote{\textsuperscript{364}} the Supreme Court held \textit{per} Bello (CJN) that the African Charter is a part of Nigeria’s domestic law as ‘[…] the Charter has become part of our domestic laws, the enforcement of its provisions like our laws fall within the judicial powers of the Court as provided by the Constitution and all other laws relating thereto.’\footnote{\textsuperscript{365}} Accordingly, the rights in the African Charter are ‘[…] enforceable by the several High Courts depending on the circumstances of each case and in accordance with the rules, practice and procedure of each

\footnote{\textsuperscript{363} Within the context of promoting the right to health, scholars have pointed out that compulsory licence and other public health exemptions are valuable tools for this purpose. See Lazzarini (n 222) 125; Haochen Sun, ‘A Wider Access to Patented Drugs under the TRIPS Agreement’ (2003) 21 Boston University International Law Journal 101. (Sun argues for the implementation and interpretation of the TRIPS flexibilities, Doha Declaration and the Paragraph 6 Solution in light of public policies and the right to health, particularly, accessibility, availability and affordability in a non-discriminatory manner, to secure access to medicines.) ibid 112-113.}

\footnote{\textsuperscript{364} \textit{Ogudu v State} (1994) 9 NWLR (Pt.366) 1. (The case is also reported as \textit{Peter Nemi v A.G of Lagos} [1994]1LRC 376 in some reports.) In this case, the 3rd appellant and four other persons were convicted of conspiracy to commit armed robbery and sentenced to death on 28th February 1986. In their appeal, they invoked the provisions of the African Charter and invited the court to assume jurisdiction in a question of complaint of “cruel, inhuman or degrading punishment and treatment” contrary to Article 5 of the African Charter on Human and Peoples Right.}

\footnote{\textsuperscript{365} ibid 26-27, paragraph G-G ibid.}
Thus all human rights provisions including the right to health in the African Charter are justiciable and applicable in all courts of law in the same manner as the Fundamental Rights in Chapter IV of the Constitution. This opinion is supported by Cui who notes that the Nigerians can rely on the African Charter as an enforceable legal instrument, to seek redress for their human rights. This position is also reiterated by the Supreme Court in *General Sani Abacha & 3 others v Gani Fawehinmi*. The Supreme Court held that the African Charter is a part of Nigerian laws and the provisions are enforceable by the courts as other laws in Nigeria. It follows that the right to the ‘best attainable standard of mental and physical health’ including access to medicines in the Charter can be enforced by the courts in Nigeria. Importantly therefore, the right to health in the African Charter complements the absence of an enforceable right to health in the Constitution.

This argument finds support in the seminal ruling by the African Commission on Human and People’s Rights in *Social and Economic Rights Action Centre (SERAC) and another v Nigeria*. The Commission broadly interpreted the African Charter to enforce the right to health provisions amongst others, and

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268 27, paragraph G-G ibid.
269 What this signifies is that all the provisions of the Charter will have similar effects to the Fundamental Rights under the Constitution. Olouw (n 307) 173. Although this was decided based on the enforcement of a civil and political right, undoubtedly, the application of the Court’s decision extends to the socio-economic rights in the Charter.
271 (2000) Volume 4 Federation Weekly Law Reports 533. In this case, the respondents challenged their detention by the military government on the grounds that it violated their fundamental human rights under the Nigerian Constitution and Article 4, 5, 6, 12 of the African Charter.
272 Per Ogundare JSC (ibid 31-32, paragraph F-G). Notwithstanding this, the court held that the Constitution is supreme and overrides any other law or binding international treaties; hence in the event of a contravening provision in the Charter, the Constitution will prevail.
273 In *Socio-Economic Rights and Accountability Project (SERAP) v Federal Republic of Nigeria and Universal Basic Education Commission* (2012) No. ECW/CC/APP/0808, the Economic Community of West African States (ECOWAS) Community Court of Justice also upheld the justiciability of the African Charter as a part of the domestic laws in Nigeria. In a case involving the right to education, the court held that it has the jurisdiction to entertain matters under the African Charter notwithstanding the fact that the educational objective in the Constitution of Nigeria is unenforceable by the court. The court ruled that ‘under article 9 (4) of the Supplementary Protocol, the Court clearly has jurisdiction to adjudicate on applications concerning the violation of human rights that occur in Member States of ECOWAS and that it ‘has jurisdiction over human rights enshrined in the African Charter and the fact that these rights are domesticated in the municipal law of Nigeria cannot oust the jurisdiction of the Court.’
found that the Federal Republic of Nigeria was in violation of Articles 2, 4, 14, 16, 18 (1), 21 and 24 of the African Charter on Human and Peoples' Rights by allowing multi-national companies to carry out oil exploration operations that affected the environment and health of the people in that region. The Commission imposed a responsibility on the Nigerian government to respect the health and environmental rights of the people of Ogoniland, even though it was a non-justiciable right under the Nigerian Constitution. This decision opened up another avenue for the enforcement of the right to health in Nigeria. Fundamentally, this was a decision against acts committed by a corporation but the court held the Nigerian government liable for the acts of the third parties. Applying the current understanding of the obligations of pharmaceutical corporations to respect and promote rights to health and access to medicines, there is no reason barring the application of the court’s rationale in this case to determine the liabilities and responsibilities of pharmaceutical companies in cases on pharmaceutical patents and access to medicines.

Nevertheless, Section 12(1) of the 1999 Constitution remains in force; hence CEDAW, ICECSR and UDHR which contain significant human rights to health provisions, will require domestication to bear meaningful practical applicability in Nigeria. In the meanwhile, the binding duty of responsibility on the Nigerian government to give reference to the provision of adequate healthcare and medicines in the African Charter and Constitution is sufficient to compel a binding duty. As Article 5(3) of the Protocol to the African Charter allows relevant NGO’s with observers status and Individuals to institute cases directly to the African Commission with regards to their human rights, Nigerians and NGO’s on their behalf can institute actions to mandate the government to foster

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See ibid paragraph 70.
better access to medicines as a part of the people's legitimate human rights entitlements. Nigerians can also seek to compel the government to take into account the human rights aspirations and interests of the people in the negotiations, implementation and enforcement of its international trade obligations such as TRIPS. More specifically, the government can be mandated to consider the citizens' rights to health when designing, structuring and enforcing the rights and exceptions contained in its patent law.

4.9.2 Adopting a Rights-Based Approach to Patent Right to Promote Women’s Right to Access Medicines in Nigeria

The sum total of the arguments and analysis in this chapter indicates that human rights relate to health and that access to medicines is germane to the enjoyment of the right to health as well as the right to life. In this manner, human rights provide the basis to argue for the alleviation of problems inhibiting women's access to healthcare in Nigeria. This rights approach to the issue of accessing medicine is relevant because it provides a guiding standard for national policies, laws and programmes to achieve the goal of fulfilling, protecting, respecting and generally securing their right to health.

To secure women’s right to health and ensure that they can fully enjoy their human rights, it is submitted that there is a need to promote their access to affordable medicines. The preceding chapter highlighted the concern that the patent protection of pharmaceuticals could result in high prices or stifle incremental innovation which could have the effect of impeding the availability of and women’s access to affordable drugs for serious medical needs. In this event, one of the ways in which the Nigerian state can meet its obligation, as to

374 See the debate in subsection 3.7 and its sub-subsections in Chapter III.
the right to health is to make sure that pharmaceutical patents do not constitute an obstruction to the enjoyment of the rights of women to better healthcare.

From a health perspective, however, patents cannot be discounted. As noted in the previous chapter,\textsuperscript{375} patent, as has been argued, could promote public health by facilitating increased medicinal R&D. Thus the human rights perspective in this thesis does not reject the importance of protecting the interests of the pharmaceuticals industry and patent right owners with regards to their pharmaceutical patent rights. However, there is a need for the Nigerian state to balance its responsibilities to women’s human rights and promoting scientific and medicinal R&D. One way of so doing is to limit the impact of patent rights on human rights in national laws. The state can do this by relying on public interest measures and flexibilities in the TRIPS Agreement to broadly give effect to the right to health and access to essential drugs.\textsuperscript{376} The right of WTO members to determine their appropriate level of protection in a given situation has been recognised by the WTO appellant body.\textsuperscript{377}

Another possibility open to the Nigerian government and the national courts is to strike a balance between the human rights-related interest of inventors on the one hand and promoting society’s welfare (which includes women’s rights) to access the fruits of pharmaceuticals R&D on the other. The need to strike a balance between the rights of the creators and the human right to access the products of technological innovation such as medicines also mirrors the debate about the balance of patent holders’ rights and user’s rights in IP systems.\textsuperscript{378} As

\textsuperscript{375} In subsection 3.6.2.1 of Chapter III.

\textsuperscript{376} See the case of Novartis AG v Union of India. IPAB Order No 100/2009 available at <http://www.ipab.tn.nic.in/Orders/100-2009.htm> accessed 22 October 2013; see also SC Civil Appeal Nos. 2706-2716 of 2013, paragraph 168.

\textsuperscript{377} Accordingly, ‘WTO Members have a right to determine the level of protection of health that they consider appropriate in a given situation’. European Communities - Measures Affecting Asbestos and Asbestos-Containing Products: Appellate Body Report (WT/DS135/AB/R April 5 2001) 168.

\textsuperscript{378} See subsection 2.5.4 of Chapter II.
identified in Chapters II and III, it is commonly argued that an objective of patent protection is to promote long-term public interest and social welfare by means of providing exclusive rights to right holders for a limited duration. 379 During the term of protection, there is potential for conflict between these private and public rights considerations, which can also mirror the differences between the interests of right holders and end users under human rights law. The challenge for national and international lawmakers is to find the optimal balance between the various competing interests with a view to maximising the benefit of the invention to the public, whilst also meeting the private interests of inventors. 380

One way in which this can be done is by properly delineating the nature and scope of public and private rights. For patents, the patentable subject matter, scope, limitations and term of protection, can be clearly defined and balanced against the socio-economic and cultural rights such as rights to health. Also, a way of finding this balance might be to clearly map out the purpose of patents, which is the promotion of technological and social development, and state that where private rights interfere with this goal, the fundamental human rights to health should prevail in the public interest. Human rights law does not provide a clear indication on how to strike the right balance between protecting the interests of inventors and promoting access to the products of intellectual activities, neither do international IP agreements offer an ideal balance. However, within the context of patent law, states can clearly delineate a way of addressing these two interests when they conflict. There is no Nigerian jurisprudence to support this point, however, by way of example, the case of Smith Kline and French Laboratories Ltd v Netherlands buttressed the point that public interest is given paramount importance where there is a conflict of

379 See subsections 2.3.2 and 2.3.3 of Chapter II and subsection 3.6.2.1 of Chapter III.
380 As discussed in subsection 4.7.4 of this chapter.
interests.\textsuperscript{381} The ECHR stated that the granting of compulsory licensing for a patented drug was not an interference with the human rights entitlement under Article 1 of Protocol No 1 of the ECHR.\textsuperscript{382} Even when the patent holder’s right was recognised as a human right, the court gave primacy to the public interest.

In that case, the applicant, a proprietor of a patented medicine cimetidine (for the treatment of gastric and duodenal ulcer), appealed against the granting of a compulsory license to a drug company, Centrafarm Bv, to use and work whose patented invention. Among other things, the applicant claimed that the compulsory licence was a violation of its right to peaceful enjoyment of its ‘possession’ contrary to Article 1(1) Protocol 1, and that the licence interfered with the exclusive right to exploit the patented invention.\textsuperscript{383} The ECHR in its ruling found that, although the compulsory license ‘constitutes a control of the use of property,’ the grant was lawful in accordance with the general interest of the public.\textsuperscript{384} Notably, the general public interest was adopted as a yardstick by the courts to test whether the interference with the use and enjoyment of the proprietor’s right was lawful. In the end, the ECHR came to the conclusion that, ‘the grant of the compulsory licence was lawful and pursued a legitimate aim of encouraging technological and economic development.’\textsuperscript{385} Since the applicant’s invention prevented the working of a patent that that was beneficial to society, the ECHR considered the long-term interest of the public to benefit from technological and scientific progress to decide in favour of the compulsory licence.

\textsuperscript{381} SmithKline and French Laboratories Ltd v Netherlands (n 244).
\textsuperscript{382} ibid
\textsuperscript{383} ibid paragraph 2.
\textsuperscript{384} ibid
\textsuperscript{385} ibid
It could be said that the interests of the patentee, in this case, were recognised; hence the ECHR found that the decision of the patent office to grant the licence constituted an interference with the inventor’s rights and use of its property. Yet, the ECHR took into account the broader development goal of the public (the dependent patent in this case) to access and use the patented invention since it was clear that the applicant’s patent limited the use and working of Centrafarm Bv’s invention. The ECHR attempted to strike a balance between two competing interests (SmithKline and French Laboratories Ltd and Centrafarm Bv) by recognising the overall objective of encouraging technological and economic development as a yardstick to measure their various interests.

In another example, the Indian Supreme Court in 2014, dismissed a petition by Bayer to set aside the compulsory license on the anti-cancer drug ‘Sorafenib Tosylate’, otherwise marketed as ‘Nexavar’. In that case, Nacto Pharma Ltd., a pharmaceutical drug producer, made a request for a voluntary licence to Bayer which was denied. Natco subsequently made an application for, and was granted, a compulsory licence to manufacture and market the patented drug in 2011. On appeal by Bayer against the decision to grant the compulsory licence, Natco argued in defence that Sorafenib tosylate, a crucial drug for patients living with kidney and liver cancer, was unreasonably expensive and unaffordable to patients in India. Moreover, Bayer had not worked its drug, Nexavar, in the territory of India. Bayer contended these claims, but the Controller General of Patents ruled in favour of Natco. In 2013, the

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387 This case was briefly mentioned in footnote of subsection 6.8. (See footnote 287).

388 See decision of the Controller at Natco Pharma Ltd v Bayer Corporation – Application for Compulsory License under Section 84(1) of the Patents Act 1970 in respect of Patent No 215758 Controller General of Patents, Mumbai, CLA No 1 of 2011
Intellectual Property Appellate Board (IPAB) considered whether the licence can be granted to the applicant on the grounds that the drug was not ‘available to the public at a reasonable price’ in accordance with Section 84(1)(b) of Indian Patents Act. The IPAB after a careful deliberation, dismissed the appeal filed by Bayer and confirmed the compulsory licence given to Natco.\(^{389}\) The IPAB based its decision on the yardstick of the public in ruling that ‘[s]ection 84 […] is only concerned with the price at which the drug is made to the public.’\(^{390}\) Significantly, the IPAB approached the appeal from the perspective of the public interest within the context of the right to life as guaranteed under Article 21 of the Constitution of India, 1950. Accordingly,

\[
\text{[I]there we are not concerned with the interest of the compulsory licence applicant,}
\]
\[
\text{but only the public interest. The grant of compulsory licence is not to favour the}
\]
\[
\text{applicant, but only because the applicant has demonstrated that the invention has}
\]
\[
\text{not reached the public in the manner envisaged under Section 84.}^{391}\]

The ruling in this case upheld the primary importance of public health over private monopoly rights and gave impetus for the Indian Government to grant more compulsory licences in the interest of access to medicines.

Commentators have also pointed to the persuasive effect of human rights rhetoric as a means to balance the rights in IP laws, mitigating the adverse impact of IP rights or adjusting IPRs to respond to essential human rights.

\(^{389}\) Bayer Corporation v Natco Pharma Ltd, Order No. 45/2013 (Intellectual Property Appellate Board, Chennai).
\(^{390}\) ibid paragraph 42.
\(^{391}\) ibid paragraph 43.
needs.\footnote{392} For example, Professor Correa points out the variety of ways that Human Rights Impacts Assessments (HRIAS) have been used to assess the direct and indirect impacts of agreements, treaties, and actions which affect the right to health.\footnote{393} Likewise, he examined the role and use of human rights principles by the courts to mitigate the excessive effect of IP on access to medicines and rights to health and concludes that human rights values, when incorporated into national legal systems, can ‘provide national Courts with grounds for effectively circumscribing the substantive procedural rights conferred under different modalities of IPR.’\footnote{394} Also, that there is ‘a lot of promise for the potential of human right [to health] arguments to play a key role in judicial decision-making.’\footnote{395}

Furthermore, it is submitted that the courts can adopt a rights-based approach to interpret and enforce matters bordering on patents and rights to health, life and the dignity of the human person. In recent times, a number of national court decisions in other jurisdictions have provided clear reference points on the impact of, and relationship between access to medicines, human rights and IPRs in general. For example, adopting a rights-based approach, the Kenyan Courts recognised the precedence of public health and basics human health over private IP rights in \textit{Patricia Asero Ochieng, Maurine Atieno, Joseph Munyi, and AIDS Law Project v. Attorney General}.\footnote{396} The court stated that the ‘right to
life, dignity and health of the petitioners must take precedence over the intellectual property rights of patent holders.'

In that case, a group of individuals living with HIV/AIDS instituted an action, challenging the Kenya Anti-Counterfeit Act on the grounds that the counterfeit provisions which included essential generic medications as counterfeit goods, violated their ability to access affordable and generic medicines and, therefore, their rights to health. The court, in ruling that IPRs should not override essential rights to life and health, found that the sections would negatively impact on the rights of the petitioners and others living with HIV and [AIDS] to access essential medicines. Thus, the Act was in ‘violation of their rights under the [Kenyan] constitution.’

Although the public policy objective of the Act was to prohibit counterfeit goods, the court took into account the effect of the provisions on the petitioners’ access to available and affordable essential medicines, including generic drugs. Importantly, this case supports the position adopted in this thesis that the right to access affordable essential medicines is greater and more critical than the enforcement of IP rights.

The Indian case of F. Hoffmann-La Roche Ltd. and Anr. v Cipla Ltd, further illustrates the point that litigation can effectively be used to give consideration to the rights to access affordable essential life-saving drugs where patent rights adversely impact on rights to medicines. In this case, the plaintiff brought an

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397 Paragraph 85 of the court’s decision ibid.
398 Sections 2, (definition of counterfeiting) section 32 (offences) and section 34 (powers of commissioner to seize suspected counterfeit goods).
401 Paragraph 52 of the decision.
402 Paragraph 85 of the decision.
action against the generic producer, Cipla Ltd, to prevent the infringement of its patent rights to the cancer drug erlotinib hydrochloride (‘Tarceva’). In a landmark decision, the court, in refusing the interim order sought by the plaintiff, also based its decision on broader public interest, health and the right to access life-saving medicines.\(^{404}\) In this connection, the court ruled that although, 

> India entered into the TRIPS regime, and amended her laws to fulfil her international obligations, […] the Court cannot be unmindful of the right of the general public to access lifesaving drugs which are available and for which such access would be denied if the injunction were granted. The degree of harm in such eventuality is absolute; the chances of improvement of life expectancy; even chances of recovery in some cases would be snuffed out altogether, if injunction were granted.\(^{405}\)

It is worth noting that the patent protected version of the drug in this case cost three times the price of the generic version by Cipla.\(^{406}\) Deciding in favour of the defendant meant that general public interest had a greater weight than private proprietary interest. In the end, the judicial decision was useful to safeguard the rights of the public to access essential drugs.\(^{407}\)

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\(^{404}\) Similarly, in the 2013 copyright related case of Ediciones de la Flor SA v. Fontanarrosa Franco s. Acción Mere Declarativa, file no. 1420/08, the Court of First Instance on Civil and Commercial Matters No. 12 of Rosario, the co-heir of a deceased author, Roberto Fontanarrosa, opposed the publication of the deceased’s unpublished works (a moral right specifically recognized to the author) arguing subsidiary moral rights as co-heir. The Argentinian Court of First Instance in Civil and Commercial Matters (No. 12 of Rosario) held that the rights of the public or community interest to have access to the unpublished work will prevail over authorial economic and moral interest, thus ensuring that social interests superseded individual private IP rights. In its decision, the court relied on Article 21(1) of the American Convention of Human Rights (which states that ‘[e]veryone has the right to the use and enjoyment of his property. The law may subordinate such use and enjoyment to the interest of society.’), and Article 15(1)(a) of the International Covenant on Economic, Social and Cultural Rights. See the translated report in Maximiliano Marzetti, ‘Comments on Ediciones De La Flor v Fontanarrosa Franco’ (2013) 44(7) International Review of Industrial Property and Copyright Law.

\(^{405}\) Paragraph 85 of the decision. An appeal against this decision found that there was no infringement.

\(^{406}\) Correa (n 393) 212.

\(^{407}\) The obligation of the state to protect rights to health and life was also reiterated in the case of Eli Lilly and Company v Laboratorios Lel, S.A.V. y otra s/ Infracción de derechos (patente) (2011) Circunscripción Judicial de Caracas, Venezuela,Jugado Superior Octavo en lo Civil, Mercantil, Tránsito y Bancario. [Judicial Circuit of Caracas, Venezuela, Eight High Tribunal on Civil, Commercial, Transit and Banking]. In that case, the defendant alleged that the act of granting marketing approval of the medicine raloxifen hydrochlorid, before the expiration of its patented term was an infringement of patent rights. The court stated that ‘the right to health as an integral part of the right to life, in keeping with the high aim of the Andean integration, represents an obligation for the state.’ (As interpreted and quoted in Correa (n 393) 214.)
The cases above lend credence to the point that national courts can adopt standards of interpretation to give significant effect to human rights to health in view of the public interest and welfare. To fully implement the right to health, and particularly women’s rights to access medicines with regards to patent rights, the Nigerian courts can play a major role. In actions bordering on health and access to medicines, the courts can interpret and lay down similar human rights standards for the guarantee and enforcement of health provisions. It has been argued that national courts can play a role in giving practical effect to human rights by preventing violation and interference. The courts can also encourage and where necessary, compel the fulfilment and realisation of human rights. Since human rights are part of the legal framework of Nigeria as per the African Charter, the courts could develop appropriate standards for enforcing the right to health and life, particularly where the issues concern the conflict between public health and patent rights. The principles of human rights and key dimensions of the right to health provide a fundamental jurisprudence to guide the court in this duty to enhance women’s rights to health in Nigeria.

4.10 Conclusion: Making Human Rights Central to Promoting Women’s Access to Medicines within the Context of Patent Rights in Nigeria

Indubitably, everyone is entitled to the right to a standard of health. While women’s rights to health and life are clearly established in legal instruments, having these laws without the fulfilling them will not serve the people they are meant to safeguard. For this reason, this chapter argues that the right to health and life includes the right to an effective access to available, good quality, safe,
and effective medicines that are equally affordable to everyone. It is also submitted that ensuring this access to a choice of essential medicines at an affordable price requires the state to ensure that the granting of patent rights to inventors and pharmaceutical companies does not hinder access to essential drugs.

More specifically, the argument based on human rights principles in this chapter is a consideration of women’s health needs in Nigerian regulations and policies to fulfil their demands of healthcare. Although the current effect of international human rights laws in Nigeria with regards to Section 12 of the 1999 Nigerian Constitution leaves many of questions open, the government is not absolved of its socio-economic and cultural obligations to promote, respect and fulfil the rights of women to have equal access to affordable, safe and effective medicines. This positive step in the right direction includes implementing the TRIPS Agreement in a manner that supports women’s rights to health. Such a trade agreement should be balanced against the right to health, especially where its patent rights interfere with health of women whether directly or indirectly.410

To add to the justification for a consideration of women’s access to medicines within the context of patents, the next chapter also makes a case for access from a human development perspective.

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410 As stated previously, Nigeria has not incorporated the Agreement as required under Section 12 of the Constitution. Chapter VI of this thesis suggests ways in which the Nigerian Government and legislators could promote innovation and the public interest in implementing the Agreement. It is worth noting that the human rights framework for implementing TRIPS offers only one of the many policy arguments for making health a focal point in foreign trade policy and patent rights. In essence, it complements other policy approaches geared at improving people’s welfare and wellbeing including economic and human development, and security. See Michelle I Gagnon and Ronald Labonte ‘Human Rights in Global Health Diplomacy: A Critical Assessment’ (2011) 10 Journal of Human Rights 189,189–213.
CHAPTER V: RECONCEPTUALISING PATENTS AS TOOLS FOR HEALTH AND HUMAN DEVELOPMENT: ENHANCING ACCESS TO MEDICINES IN NIGERIA

The ends and means of development require examination and scrutiny for a fuller understanding of the development process; it is simply not adequate to take as our basic objective just the maximization of income or wealth, which is, as Aristotle noted, ‘merely useful and for the sake of something else.’ For the same reason, economic growth cannot sensibly be treated as an end in itself. Development has to be more concerned with enhancing the lives we lead and the freedoms we enjoy.1

5.1 Introduction

As the analysis in the previous chapters reveal, the patent system underlies public policy and welfare objectives.2 From a development perspective, a patent is widely considered as integral to human well-being and economic growth. As demonstrated in Chapter II3 it is generally argued that the grant of patent rights to innovators, and protection of new and substantially useful innovations are instrumental in bringing about technological and scientific progress and consequently, economic, social and technological development. In many ways, a patent is also assumed to give rise to development by promoting medicinal research and development (R&D), and facilitating technological innovation for public benefit.4 Patents are also considered important policy instruments for technology transfer (TT), foreign direct investment (FDI), and the dissemination of technological knowledge and the results of innovation, which in turn, lead to

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2 See subsection 2.4 and 2.5.6.
3 See subsection 2.3 and sub subsections 2.3.2, 2.3.3, 2.3.4, 2.5.1 and 2.5.2 Chapter II.
economic growth and other developmental advantages to the public.\(^5\) Furthermore, this development policy in the interest of IP owners and users is a principal objective in Article 7 of the TRIPS Agreement.\(^6\)

From a health perspective, human development is construed as the yardstick for measuring the development objective of patents to the public. It is argued that the development objectives in TRIPS and the patent system in itself, cannot give rise to development if it is not properly positioned to enhance vital areas of human well-being such as health. In this regard, this chapter argues that the development element of patents should extend beyond the traditional analysis of patents as a conduit for promoting the availability of innovative products and prospects for economic growth. Particularly, this chapter explores the human-centred dimension of patents by analysing the ways in which patents could potentially hinder women’s access to important medicines and consequently, human development; or confer benefits to their human development by enhancing their capabilities to be in good health.

It has been acknowledged that there is an inextricable link between enhancing the basic health of individuals and improving their prospects for development.\(^7\) As noted in Chapter IV, on human rights,\(^8\) the state of a person’s health is instrumental to their prospects for economic and human development. As such, there is a nexus between the right to health, as identified in the preceding chapter and women’s human development. The recognition of health as a human right which requires state action, therefore, entails the government and policy makers to take into account the importance of health to their people’s

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\(^5\) Wong (n 4) 3.

\(^6\) See the Preamble, Articles 7 and 8 of the TRIPS Agreement. This was discussed Chapter II of this thesis, subsection 2.5.6.


\(^8\) See subsection 4.2.2.
human development and the factors that can influence this development outcome. The Organisation for Economic Co-Operation and Development and World Health Organization (WHO) has shown that ill-health, particularly among the poor, significantly undermines development. Thus, improving the health of the people is a prerequisite for governments to meet national development goals. Indeed, one of the key aspirational objectives of the United Nation’s Sustainable Development Goals (SDG’s) is the improvement of health and well-being of everyone, including access to effective, safe quality and affordable essential medicines and vaccines. This development agenda affirms the intricate relationship between health and development.

In light of the above considerations, this chapter, using the capabilities approach, presents a critical analysis of the benefit or adverse effects of patents on women’s health and the consequential effects on their prospects for development with special focus on their access to medicines as a constituent component of the right to health. As the analyses in Chapter III subsection 3.7 of this thesis have demonstrated, patent rights could impact on accessibility to medicines by limiting the options to accessing affordable medicines to enhance health outcomes and therefore prospects for human development. Set within

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11 Goal 3.b pledges to [s]upport the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.
the context of patent law and women’s right to health, this chapter relies on the concepts of human development and capabilities approach as expounded by Amartya Sen and Martha Nussbaum to characterise access to patented medicines as a means through which women can enhance their opportunities for human development, build their health capabilities, and achieve their potential to live long, normal and sustainable lives. The capabilities approach in the context of human development essentially focuses on the development of women’s quality of life – what they are actually able to do and be.\textsuperscript{12} It is also argued that the inability to access quality and affordable medicines can constitute a challenge to women’s human development.

Questions raised in this chapter are: does the development goal of patent law extend further than the availability and production of innovative goods and the consequential technological/scientific and economic development outcome? If so, can the development objective extend to the development of human capabilities for sustainable human development? With these questions in mind, the welfare benefit of patents to health is analysed with a view to bringing out the relevance of the protection to human development in the context of the rights to health and access to medicines in Nigeria. Furthermore, the discussions in this chapter provide an additional basis to argue for the broad interpretation and implementation of the patent-related flexibilities to improve women’s access to medicines in Nigeria.

To achieve this purpose, the first section of this chapter starts with an overview of the understanding of development, particularly, human development. The

\textsuperscript{12} Sandrine Berges, ‘Why the Capability Approach is Justified’ (2007) 24 Journal of Applied Philosophy 16, 16-7. According to Ingrid Robeyns, the capabilities approach is a people-centred evaluative framework that focuses on removing obstacles to people’s lives so ‘that they have the freedom to live the kind of lives, upon reflection, they find valuable.’ Ingrid Robeyns, ‘The Capability Approach: A Theoretical Survey’ (2005) 6(1) Journal of Human Development. 93, 94-95.
second part underscores the importance of health to development from a right to development and health perspective. The last part makes a case for access to patented drugs in Nigeria as a means to the expansion and human development of basic capabilities such as the capability to be healthy.

5.2 Advocating for a Human Development-Oriented Patent System

This section argues for a pro-human development patent system that would take into account the public health and development needs of users.

To analyse the correlation between IP and human development, it is expedient to discuss the definition of the term ‘development,’ to place the understanding of development in this chapter within a meaningful context.

5.2.1 The Concept of Human Development

Development for the purposes of this thesis is construed in the context of a people – focused human development paradigm. Specifically, it is an exploration of the connection between the protection of pharmaceutical patents and access to essential medicines for the enhancement of human development and capabilities. The concept of development is examines in the following.

5.2.3 The Normative Framework of Human Development

An understanding of development in the wider context of expanding people’s human capabilities has been advocated by scholars such as Sen, Nussbaum, ul Haq, Alkire and adopted by the United Nations (UN). The 1990 United Nations Development Programme (UNDP) Human Development Report
provides a clear and fundamental definition of human development.13 The first chapter of the report reads:

Human development is a process of enlarging people’s choices. The most critical ones are to lead a long and healthy life, to be educated and to enjoy a decent standard of living. Additional choices include political freedom, guaranteed human rights and self-respect […].14

The 1990 report further identifies that the fundamental objective of development is to:

[…] create an enabling environment for people to live long healthy and creative lives. This is a simple truth, but it is often forgotten in the immediate concern with the accumulation of commodities and financial wealth.15

Human development analysis essentially centres on three main aspects viz.: people, opportunity and choice.16 According to the 2015 report, human

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16 ibid; Alkire, 'Human Development: Definitions, Critiques, and Related Concepts' (n 13) 4. Mahbub ul Haq 'The Human Development Paradigm' in Sakiko Fukuda-Parr and AK Shiva Kuma [eds], Readings in Human Development: Concepts, Measures
development is fundamentally about people; it emphasises that the main concern or central goals of development should not be income or resources but enhancing people’s capabilities, freedoms and opportunities to improve their quality of lives.\textsuperscript{17} Principally, human development ‘emphasizes the importance of putting people – their needs, their aspirations, their choices – at the centre of the development effort.’\textsuperscript{18} Human development is therefore a people-focused measure of evaluating an individual’s quality of life and well-being; hence, the end objective of human development is the expansion of people’s welfare and their well-being.\textsuperscript{19}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{dimensions_of_human_development.png}
\caption{The Dimensions of Human Development.\textsuperscript{20}}
\end{figure}

Human development in this view is concerned with expanding the choices, opportunities and full potential of people to live quality lives.\textsuperscript{21}

\begin{flushright}
\textsuperscript{21} ibid
\end{flushright}
As a lens to assessing development, human development basically focuses on the state of people’s welfare.\(^{22}\) Consequently, apart from focusing on an individual’s freedom to live the lives he or she finds valuable, the human development paradigm also draws attention to social, economic and welfare factors in evaluating the impact of policies on people’s lives.\(^{23}\)

The human development paradigm is significant in directing the aims of development-oriented policies and laws because it covers all aspects of a human’s life – whether economic, political, social or cultural – as long as the development goals centre on improving people’s lives.\(^{24}\) Within the human development structure, the economic system is also important because it is a medium for the production and distribution of commodities that can improve and enhance the standards of human lives.\(^{25}\) The resources and products of the economic system can create the economic opportunities and facilitate the means to expanding people’s capability, as well as extending to people a variety of choices to use the products or resources to advance their own well-being.\(^{26}\) However, economic growth focuses on external structures and economic progress to bring about developmental changes, thus it is only one of the means of ensuring human development,–albeit a very important one,–rather than an end in itself.\(^{27}\)

\(^{22}\) Tzen Wong adds that development in this sense is about giving people the opportunities to live the lives they value, and enabling them to become actors in their own destinies. Wong (n 4) 27.
\(^{23}\) Alkire and Deneulin (n 19) 19; Graham Dutfield and Uma Suthersanen, ‘Innovation and Development’ in Uma Suthersanen, Graham Dutfield and Kit Boey Chow (eds), Innovation Without Patents: Harnessing the Creative Spirit in a Diverse World (Edward Elgar P.ublishing 2007) 3.
\(^{24}\) Alkire and Deneulin (n 19) 27
\(^{26}\) ibid 21-22.
The focus on individuals, as opposed to income or commodities as central subjects of development, is grounded in the rationale that ‘people are the real wealth of a nation.’

Thus, ‘the expansion of output and wealth is only a means’ to achieving development. As will be discussed, although improved economic conditions and increased innovative products are necessary for development, product output and economic growth may not necessarily lead to a rise in the actual standard and conditions of individual’s lives.

With this understanding of human development in mind, this chapter and thesis advocates for the human development goal of expanding the provision of Nigerian’s basic health needs, to enhance their health capabilities and potential to live long, normal and healthy lives. This thesis engages the language of capabilities and freedom analysis to emphasise the welfare dimension of patents on human development, in line with the development objectives of patents, as also elaborated in Article 7 and 8 of the TRIPS Agreement. For this purpose a brief outline of the capabilities approach to human development, as expounded by Amartya Sen and Martha Nussbaum and other scholars is described in order to situate the arguments for access to medicines as a means to expanding the opportunities for people to enhance their health capabilities.

### 5.2.4 The Capabilities Approach to Human Development

Amartya Sen and Martha Nussbaum’s theoretical approach to development, which emphasises the enhancement of capabilities and people’s freedoms, choices and opportunities, has informed the insight into the concept of

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28 The 1993 Report essentially made a case for people’s participation in the development process. According to the report, the participatory nature of development means that ‘people are closely involved in the economic, social, cultural and political processes that affect their lives.’ United Nations Development Programme (UNDP), Human Development Report 1993’ (n 13) 21.


30 In subsection 5.3.1.1 and 5.6 below.

31 The account of human development adopted in this chapter is brief, merely intended to highlight the relevant aspect of the approach within the context of access to patented medicines.
development by the UNDP in its Human Development Report.\textsuperscript{32} Similar to the earlier mentioned conceptualisation of development in the UNDP reports,\textsuperscript{33} the capabilities approach views the expansion of people’s freedoms or human capabilities as the primary goal of development.\textsuperscript{34} According to Sen, development should be seen ‘[…] as the process of expanding the real freedoms that people enjoy.’\textsuperscript{35} Sen’s model of development as freedom further recommends the enhancement of people’s capabilities through the provision of basic means to meet human needs such as education and healthcare.\textsuperscript{36} In his writing, Sen makes reference to the social opportunities and the health facilities necessary to promote an individual’s substantive freedom and opportunity to live a better life.\textsuperscript{37} In particular, Sen identifies five distinct instrumental freedoms ‘that contribute, directly or indirectly, to the overall freedom people have to live the way they would like to live.’\textsuperscript{38} Among these are social ‘arrangements that society makes for education, health care and so on, which influence the individual’s substantive freedom to live better.’\textsuperscript{39} Accordingly, freedom or capability is dependent on socio-economic arrangements including the provisions of services and healthcare facilities, to allow human beings to function and live fuller lives.\textsuperscript{40} In this regard, the provision of some basic needs such as education and healthcare are elementary means to the development of

\begin{itemize}
  \item \textsuperscript{33} See subsection 5.2.3 above.
  \item \textsuperscript{34} Nussbaum, ‘Capabilities and Human Rights’ (n 32) 288; Sen, \textit{Development as Freedom} (n 1) 1.
  \item \textsuperscript{35} Sen, \textit{Development as Freedom} (n 1) 1. Sen argues that:
    \begin{quote}
      Development requires the removal of major sources of unfreedoms: poverty […] poor economic opportunities as well as systematic social deprivations, neglect of public facilities.
    \end{quote}
  \item \textsuperscript{36} Ibid 3-4, 17-20.
  \item \textsuperscript{37} Ibid 11. He argued that ‘[s]ometimes the lack of substantive freedoms relates directly to economic poverty, which robs people of the freedom to satisfy hunger, or achieve sufficient nutrition, or obtain remedies for treatable illnesses.’ Ibid 3-4, 17-20.
  \item \textsuperscript{38} Ibid 39.
  \item \textsuperscript{39} Ibid 38.
  \item \textsuperscript{40} Ibid 39. Sen also highlights the vital role of economic, social and political institutions and organisations in enhancing people’s capabilities or eliminating ‘unfreedoms’ and obstacles to development. Ibid 3-4, 17-20
\end{itemize}
These health facilities and systems can constitute an instrumental means for enabling an individual to exercise his or her health capabilities and choices.

Similarly to Sen, Martha Nussbaum espouses a human development paradigm that views the expansion of capabilities as an important goal of government, constitutional principles and development policies. This approach, fundamentally takes ‘each person as an end, asking not just about the total or average well-being but the opportunities available to each person.’ The arguments of Sen and Nussbaum adopt the capabilities approach as a normative evaluation framework to measure people’s well-being, standard of living, social arrangements, development policies and proposals for social change in society.

The capabilities approach has influenced several development and public policy analyses and increasingly, the approach has been applied to the analysis of IP and health. IP scholars have employed the human development and capabilities approach as an alternative way to analyse and evaluate the relationship and consequential effect of IP on development. In his consideration of patents and human development in sub-Saharan Africa for

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41 Ibid 17-18.
42 Martha Craven Nussbaum, Women and Human Development (Cambridge University Press 2000) 5, 12.
44 Robeyns (n 12) 94. (This thesis does not dwell on the distinction between Sen’s capability approach and Nussbaum’s work in its application of the capabilities approach. This thesis relies on both approaches of the scholars and uses their arguments interchangeably in this study.)
example, Poku Adusei makes suggestions for the integration of human development norms into the activities and agenda of the national patent policies and WTO and TRIPS to promote access to medicines. This chapter adds to the debate on access to medicines by examining the extent to which the capabilities approach can provide a lens to view the benefit of patent law to human development by enhancing the capabilities of individual persons in Nigeria and women in particular, to be healthy. It also highlights that patent rights could interfere with women’s quest for human development hence the Nigerian government must be proactive in safeguarding the right to health of women, particularly, by incorporating, designing and using the TRIPS-compliant flexibilities.

5.3 The Importance of Development in the Context of International Intellectual Property Law

‘Development’ in the sphere of IP discussions has, at its epicentre multiple issues of how IP influences prospects of development: as a means to improving technological progress; trading relations; knowledge disclosure; and stimulation of innovation (medicinal R&D) for public health. At the international trade fora, IP is also seen as having the potential to facilitate development, as well as the enhancement of trade prospects, economic progress and distribution of wealth.

Within the province of the World Trade Organization (WTO), development is a central component of the IP regime in the TRIPS Agreement. The Preamble of

47 Adusei (n 45) 261.
48 It is worth noting that this thesis adopts the capabilities approach within a restricted context of health to boost the argument for access to medicines within IP and TRIPS context. It lays no claim to all aspects of health capabilities.
49 Wong (n 4) 1.
the TRIPS Agreement, as discussed in Chapter II, mirrors a development objective by setting up a socio-economic and technological development priority for IPR protection. Article 7 of the TRIPS Agreement echoes this objective in stating that the objective of TRIPS is to ensure that protection and enforcement of IP rights contributes to technological innovation, dissemination and progress, by recognising private rights interest of IP producers in a manner that also takes into account, socio-economic welfare of consumers. With this developmental objective in view, Article 8(1) of the TRIPS Agreement further allows Members to formulate their IP legal systems to protect social well-being ‘in sectors of vital importance to their socio-economic and technological development,’ including public health. It can be said that these provisions delineate a fundamental development-oriented objective and the principle of the TRIPS Agreement.

Although the Agreement is silent as to how the development objective can be achieved, the basic assumption is that IP is a factor for development; hence the TRIPS Agreement aims to strike a balance by promoting innovation while also underscoring the social and economic welfare objective of IP to society.

It will be recalled from the argument in Chapter II, that the underlying objective of the patent system is public welfare-driven. The development for the public good flowing from a patent generally encompasses the dissemination of

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51 See subsection 2.5.6.
52 This recognition of development objectives corresponds with the development goal of the WTO, as identified in the Preamble of the Marrakesh Agreement Establishing the World Trade Organization, recognising that ‘trade and economic endeavour should be conducted with a view to raising standards of living, [...] while allowing for the optimal use of the world’s resources in accordance with the objective of sustainable development [...]’ Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, the Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 4 (1999), 1867 UNTS 154, 33 ILM 1144 (1994) (Hereinafter The WTO Agreement).
53 Emphasis added. The Preamble of the Agreement also made reference to ‘the special needs of the least-developed countries members in respect of maximum flexibility in the domestic implementation laws.’ See Preamble to The TRIPS Agreement.
55 See subsection 2.4.
innovative, increased technology from follow-on innovation, improvement of social welfare such as healthcare and knowledge through the availability of innovative results, and a long-term guarantee of access to the technology after the expiration of the patent term.\textsuperscript{56} From a development perspective therefore, it can be said that the TRIPS Agreement acknowledges the need to implement IPRs in a manner that promotes social welfare and human development. In this thesis, it is submitted that the full enjoyment of the human development opportunities that TRIPS aims to facilitate depends upon whether people are actually able to access and use the innovative technologies and products. It can be said therefore, that the health safeguards which gives countries greater flexibility in the implementation of patents in their national laws, recognise the need for states to take into account their people’s human development interests in the protection and implementation of IPRs, especially with regards to patent rights and access to medicines.\textsuperscript{57} The flexibilities in the Agreement and clarification thereof in the Doha Declaration\textsuperscript{58} adds credence to this development dimension of IP in TRIPS.\textsuperscript{59}

One issue that arises with regard to the significance of the development objective in the TRIPS Agreement, is the weight to be attached to Articles 7 and 8 which reference the development goals of the Agreement. The fact that the Articles are not within the main body of the treaty has led commentators to

\textsuperscript{56} Simon Walker, \textit{The TRIPS Agreement, Sustainable Development and the Public Interest: Discussion Paper} (IUCN 2001) 4. According to the United Nations Development Commission on Development Policy, for example, intellectual property rules and practices have a direct impact on health, education and access to knowledge, food security and rural livelihoods, the role of SMEs (including job creation and gender empowerment), international competitiveness and economic diversification. Committee for Development Policy, \textit{The United Nations Development Strategy Beyond 2015} (United Nations publication) 51.

\textsuperscript{57} Chon ‘Intellectual Property and the Development Divide’ (n 32) 2834-2835; Owoeye (n 54) 82.

\textsuperscript{58} (The Doha Declaration is discussed extensively in the next chapter.) Moreover, the Doha Ministerial Declaration specifically mentioned the development dimension of Articles 7 and 8 of the TRIPS Agreement as being particularly important in Paragraph 19. The paragraph provides that

In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.

\textsuperscript{59} Chon ‘Intellectual Property and the Development Divide’ (n 32) 2834-2835.
argue that the provisions of Article 7 and 8 are hortatory, rather than mandatory.\textsuperscript{60} Another issue in this regard is the language of Article 7 which states that IP ‘should’ contribute to development, as opposed to ‘shall’ provisions in other articles.\textsuperscript{61} Others, however, argue that the position of the Articles of the Agreement and its importance should not be ignored, particularly its interpretative significance.\textsuperscript{62} The Vienna Convention on the Law of Treaties is also clear on this issue. Article 31(1) states that ‘[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of the object and purpose.’\textsuperscript{63} Paragraph 5(a) of the Doha Declaration reiterates that the provisions of TRIPS shall be considered with regards to the objectives and principles of the Agreement. The language referencing Articles 7 and 8 clearly state that the provisions are the objectives and principles of the TRIPS Agreement, hence, the development objectives contained therein are significant to the consideration and interpretation of IPRs. Moreover, in relying on Article 31 of the Vienna Convention, the WTO Appellant Body in the \textit{United States, Standards for Reformulated and Conventional Gasoline}, emphasises that treaty interpreters should ‘take adequate account of the words actually used by [the treaty].’\textsuperscript{64} Thus the importance of the development objectives of TRIPS in Articles 7 and 8 should not be undermined; after all, the provisions are contained in the body of the Agreement not the Preamble.\textsuperscript{65} It follows that

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{60} ibid 2835; Owoeye \textsuperscript{(n 54)} 82.
\item \textsuperscript{61} Gervais, \textit{The TRIPS Agreement: Drafting History and Analysis} (n 58) 203, 207; Peter Yu ‘The Objectives and Principles of the TRIPS Agreement’ (2009) 46 Houston Law Review 978, 1003.
\item \textsuperscript{62} ibid. As Gervais argues, ‘[t]he fact that a provision of this nature is contained in the body of the Agreement and not in the preamble, would seem to heighten the status, as does the reference to this article [Article 7] and art.8 in the 2001 Doha Declaration.’ Gervais, \textit{The TRIPS Agreement: Drafting History and Analysis} (n 58) 203.
\item \textsuperscript{65} Yu (n 61) 1004.
\end{itemize}
\end{footnotesize}
Nigeria and other developing countries can rely on the development objective of the TRIPS Agreement, in particular, Articles 7 and 8, to improve women’s access to medicines and enhance their human development opportunities, particularly through the use of the flexibilities.

5.3.1 Conceptualising the Development Paradigms of IP

A study of the scholarship on IP and development indicates that, while commentators and studies generally identify IP as an important means to development and a tool for promoting human welfare, they differ in their articulations of how IP fosters development. Their approaches are divided along the lines of IP as a means of stimulating innovation and creativity efficiency for the public benefit, and its potential for facilitating economic growth to nations through TT and FDI on the one hand, and the social welfare benefits of IP law as a means to expand human capabilities and development on the other.

As an instrument for economic growth and innovation, a patent is seen to foster the transfer of innovations, and therefore increases the availability of the inventive product which, in turn, drives economic growth as a whole. Within this context, patent rights and similar IPRs, by stimulating economic growth through an increase in the supply of creative and innovative goods, FDI and TR, substantially contribute to overall economic performance and increase Gross

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67 Chon, ‘Intellectual Property and the Development Divide’ (n 32) 2859-2860. This chapter is concerned with the latter; however, the former is mentioned for analytical convenience. It is worth stating here that it is beyond the scope of this chapter to consider in detail all the arguments concerning whether IP actually leads to economic development or not.

68 CIPR (n 66) 11-12; Tú Thanh Nguyễn, *Competition Law, Technology Transfer and the TRIPS Agreement* (Edward Elgar 2010) 13; Commission on IP, Business Action to Stop Counterfeiting and Piracy (BASCAP) and Commission on Intellectual Property (ICC), *Intellectual Property: Powerhouse for Innovation and Economic Growth* (Business Action to Stop Counterfeiting and Piracy (BASCAP) and Commission on Intellectual Property (ICC)) 3-5. See subsections 2.5.2 and 2.5.3 of Chapter II.
National Products (GDP) which leads to sustainable development in developing as well as developed countries. Primary attention is therefore paid to the ways in which patent rights and IPR in general, play a role in bringing about development through their contribution to economic growth and the facilitation of technological progress. Kamal Idris, the former director of WIPO, for example, emphasises that the recognition and award of IPRs is instrumental in incentivising creativity and inventive activities which in turn, stimulate economic growth. In this regard, the forms of IP—patent, trade marks, copyright etc. are often portrayed as ‘power tools’ and ‘engines’ for economic growth, leading to development.

While these economic development perspectives are important in describing the role that a patent as an IP plays in facilitating development, it is argued that this

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71 Kamil Idris, Intellectual Property: A Power Tool for Economic Growth: (2nd edn, WIPO, 2003) 2; de Beer (n 70) 3. This discussion was mentioned in Chapter II (subsection 2.5.2).

This economic growth development rhetoric also dominates the development aspect of the TRIPS Agreement. Professor Daniel Gervais observes that the TRIPS Agreement was seen as a ‘poster child’ for development. Daniel Gervais, ‘Current Issues in International Intellectual Property Norm-Making’ in Josef Drexl, Henning Grosse Ruse-Khan and Souheir Nadde-Phlix (eds), EU Bilateral Trade Agreements and Intellectual Property: For Better or Worse? (Springer-Verlag 2014) 5. See also Carsten Fink and Carlos A Primo Braga, ‘How Stronger Protection of Intellectual Property Rights Affects International Trade Flows’ in Carsten Fink and Keith E Maskus (eds), Intellectual Property and Development Lessons from Recent Economic Research (World Bank and Oxford University Press 2005) 19-34; Carlos Correa, ‘Review of the TRIPS Agreement: Fostering the Transfer of Technology to Developing Countries’ (2005) 2(6) The Journal of World Intellectual Property 939. (Pointing out that the concept of IP is grounded in the rationale that high standards of protection lead to Foreign Direct Investment and technology transfer that would stimulate local innovation.)

72 Kamil Idris (n 71) 5. The UK Commission on IP strikes a similar picture of the relationship between IP protection and its economic development benefit argument to developing countries thus:

The contemporary evidence suggests that, because developing countries are large net importers of technology from the developed world, the globalisation of IP protection will result in very substantial additional net transfers from developing to developed countries. The benefits to developing countries from IP protection would have to come from an offsetting dynamic stimulus to trade, the development of technology, investment, and growth.

view mirrors only a partial picture of the development advantages of IP and should not be the only focus of IP’s development paradigm.

5.3.1.1 Reconceptualising the Relationship between Patents and Development

It is clear from the discussion above that the perception of IP, including patents, in terms of economic utility and development, has shaped the understanding of its development function as the conduit for technological innovation, economic growth and development. While this may be true in some circumstances, the development focus is on the role that patents play in increasing innovation for societal benefit rather than the actual development benefit of the resources to human lives. The focus of development on the growth-oriented economic angle of patents may not capture the social welfare and human dimension development because it stresses commodity output, as opposed to people, as the fundamental subject of development. It can be argued that, while patents can contribute to overall human development through the availability of goods which it stimulates, the growth and efficiency focus could also ignore the fact that the economic and product benefits generated as a result of patent rights do not necessarily mean that people can actually gain access to the innovative technologies and products. In other words, focusing on the innovation or R&D incentives conferred by patent rights as a measure for assessing development may not capture the central aspect of human development which is people-

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73 While it is often argued that patents encourage inventions when the socio-economic environment is conducive and the system is suited to innovations, the extent to which patents actually promotes innovation is still debatable and subject to varying analysis. (Note that this is however, not the focus of this chapter. It is not the intention of this study to analyse the economic argument and benefit of IP.)

74 Carlos M Correa, 'Pro-Competitive Measures under the TRIPS Agreement to Promote Technology Diffusion in Developing Countries' in Peter Drahos and Ruth Mayne (eds), Global Intellectual Property Rights: Knowledge, Access and Development (Palgrave Macmillan 2002) 42.
oriented.\textsuperscript{75} This observation coincides with the one drawn by the UNDP that ‘the recent decades show all too clearly that there is no automatic link between growth and human development.’\textsuperscript{76} The report concludes that while economic growth can enrich people’s lives, ‘more attention must go to the structure and quality of that growth—to ensure that it is directed to supporting human development.’\textsuperscript{77}

Consequently, it is argued that the economic development and productivity aspects of patents are not the only relevant factors when considering the development benefits of IP. Sunder observes for IP generally that:

\begin{quote}
The traditional utilitarian understanding of intellectual property focuses on incentivizing the creation of more knowledge goods. Public-domain advocates would preserve a rich public domain in order to promote this goal. But utilitarianism does not ask who makes the goods or whether the goods are fairly distributed to all who need them.\textsuperscript{78}
\end{quote}

Sunder further recommends a wider understanding of IP beyond the importance of producing more knowledge goods.\textsuperscript{79} To capture the instrumentality of patent to development, it is argued that there is a need to consider the other ways in which patent rights can enhance people’s human development, as an instrumental means to improving healthy well-being. In particular, access to patented medicines to treat life-threatening diseases is identified as a means of improving people’s health capabilities and as a corollary, promoting human development. Approaching development in IP from the human development

\textsuperscript{75} Dutfield and Suthersanen (n 23) 4.
\textsuperscript{77} ibid.
\textsuperscript{79} ibid.
paradigm in this thesis, finds support in a similar articulation by other scholars. Professor Margaret Chon and other IP scholars argue that IP should not only be considered in the narrow sense of technological efficiency, wealth maximisation, and economic growth or through a development paradigm that focuses on simple utilitarian measures of social welfare; rather, IP should be considered through the broader view of expanding human capabilities and freedom. In contrast to the economic growth or utility maximisation perspective of development in IP, Chon endorses a more comprehensive understanding of the human welfare and distributional-driven aspect and effect of IP on development. Approaching development in patent law from a human development perspective therefore, goes further to examine how individuals can actually benefit from the patent system and how it helps to build their capabilities. In corollary, approaching patents from a human development paradigm draws attention to the effect that patent rights could have on human wellbeing.

It is noteworthy that the aim of this thesis is not to critique the economic growth and efficiency argument of patent rights. Indeed, it is acknowledged that techno-

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80 Sunder ‘Intellectual Property and Development as Freedom’ (n 78) 470 (arguing that intellectual property law is essential to development, not just in the narrow sense of efficiency but in this broader view of expanding capability for central freedoms); Chon, ‘Intellectual Property and the Development Divide’ (n 32) 2815, 2869-2870; Barbosa, von Hase and Chon (n 46) 77. Margaret Chon inclines to an understanding of development as a freedom model in contrast to the economic growth analysis. Her study essentially takes a human development-oriented goal analysis of IP within international intellectual property regimes through a substantive equality principle. See Margaret Chon ‘Substantive Equality in International Intellectual Property Norm-Setting and Interpretation’ in Daniel Gervais (eds), Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in a TRIPS-Plus Era (OUP Oxford 2007) 476. Likewise, Barbosa, Chon and Moncayo von Hase, make the case for the principles of substantive equality within the World Intellectual Property Organization (WIPO) to link IP and innovation to human development. Barbosa, von Hase and Chon (n 46) 73. See also Wong (n 4) 22-26. (Making the argument that the social impact of IP should be approached and evaluated more systematically through the human development and capabilities context. He also argues for example that ‘[w]hile conventional IP policies tend to approach IP-protected intangible works in terms of markets and commodities to which public access needs to be balanced with private proprietary rights, what matters for human development is whether such access is provided in a way that enhances human capabilities.’) ibid 26.
81 Chon, ‘Intellectual Property and the Development Divide’ (n 32) 2823-2825, 2831. (Within the realm of development and IP, Chon challenges the assumption that wealth and utility maximisation, and economic growth are the ideal measures for social welfare and development. Instead, she contends that the normative goals and principles of global IP should also be measured by its distributional effects ‘—one that is responsive to development paradigms that have moved far beyond simple utilitarian measures of social welfare.’) ibid 2815, 2824-2825.
economic progress could be an instrumental means to enhance the capabilities approach adopted in this thesis. However this chapter draws attention to the less considered aspect of the development effect of patents on human development particularly, the improvement of human welfare and capabilities. In other words, although the importance of the economic growth development approach to patents in TRIPS cannot be disregarded since achieving economic growth has the potential to enhance people’s welfare and create the opportunities to expand their human capabilities, such a limited view may not capture all aspects of the development objectives in the Agreement. The expression ‘social development’ in Article 7 of the TRIPS Agreement is a useful reminder not to view patents only in terms of technological advancement or economic terms. With particular regards to women’s human development, a consideration of the advantages of patents through the human development paradigm— as ‘a process of expanding the real freedoms that people enjoy’— is necessary to direct a focus to ways which individuals can enhance their human development potential through access to medicines.

Before making a case for access to patented medicines as a means to the enhancement of health well-being and human development, an overview of the right to development is made to highlight the importance of development from a people-centred human rights perspective.

**5.4 Approaching Access to Essential Drugs as a Right to Development**

Development is not only central to general human well-being; it is recognised as a human right entitlement in international human rights instruments.\(^\text{83}\) Article 1

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\(^82\) Sen, *Development as Freedom* (n 1) 3.

\(^83\) In the 1993 Vienna Declaration and Programme of Action, the right to development is described as ‘[..] a universal and inalienable right and an integral part of fundamental human rights.’ Vienna Declaration and Programme of Action of 1993

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of the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognises the rights of everyone to self-determination. This right to self-determination is linked to people’s development thus Article 1 adds that ‘[b]y virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development.’\textsuperscript{84} The right to social, economic and cultural development is also articulated in Article 22 (1) of the 1981 African Charter on Human and People’s Rights (African Charter), with regards to people’s ‘freedom and identity and in the equal enjoyment of the common heritage of mankind.’\textsuperscript{85} Of equal importance is the reaffirmation of the right to development in the Vienna Convention as an integral part of human rights.\textsuperscript{86} The duty of Contracting States with respect to this right to development is to collectively and individually guarantee the exercise of the right to development.\textsuperscript{87} 

Likewise, development as a component of human rights is acknowledged by the United Nations Declaration on the Right to Development (hereafter UNDRD).\textsuperscript{88} Article 1 states that:

\begin{quote}
(Adopted by the World Conference on Human Rights in Vienna on 25 June 1993) Article 10. The Vienna Declaration adds that the right ‘should be fulfilled so as to meet equitably the developmental […] needs of present and future generations.’ ibid. It is worth noting that there are several debates on whether the development should be recognised as an international human right and how to implement the right. For more discourse on the categorisation of the right to development, political debate and objection, and challenges to the realisation of the right, see Stephen P Marks, ‘The Human Right to Development: Between Rhetoric and Reality Obstacles to the Realization of the RTD’ (2004) 17 Harvard Human Rights Journal 137–168.
\end{quote}

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The Preamble to the African Charter gives special emphasis to the right to development and duty of states thus: Considering that the enjoyment of rights and freedoms also implies the performance of duties on the part of everyone; convinced that it is henceforth essential to pay a particular attention to the right to development and that civil and political rights cannot be dissociated from economic, social and cultural rights in their conception as well as universality and that the satisfaction of economic, social and cultural rights is a guarantee for the enjoyment of civil and political rights.
\end{quote}


\textsuperscript{84} Articles 10 and 11, Vienna Declaration and Programme of Action (n 83).

\textsuperscript{85} Article 22 (1) of the 1981 African Charter.

The right to development is an inalienable human right by virtue of which every human person and all peoples are entitled to participate in, contribute to, and enjoy economic, social, cultural and political development, in which all human rights and fundamental freedoms can be fully realized.\(^{89}\)

Although the UNDRD, as a UN resolution, has no binding legal status under international law, the provisions are significant in explaining the importance and obligations to the right to development identified in the above mentioned binding human rights instruments (ICECSR and African Charter) in signatory states.\(^{90}\) Moreover, the provisions are persuasive in compelling a duty on states towards their citizen’s right to development.\(^{91}\)

The UNDRD, in Article 8, expatiates that the State is obliged to undertake all necessary measures for the realisation of the right to development including ‘inter alia, equality of opportunity for all in their access to basic resources, education, health services, food, housing, employment and the fair distribution of income.’\(^{92}\) Consequently, this provision confirms that effective means for development require that the state should undertake the necessary measures to ensure that every individual has access to medicines as a way of enhancing development.\(^{93}\) Moreover, and just as importantly, Article 8 of the Declaration specifically spells out a woman’s right to development and places a duty on the

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\(^{89}\) ibid


\(^{91}\) ibid 5.

\(^{92}\) Article 8 (emphasis added).

\(^{93}\) The Preamble of the Declaration on the Right to Development states that ‘[d]evelopment is a comprehensive economic, social, cultural and political process, which aims at the constant improvement of the well-being of the entire population and of all individuals on the basis of their active, free and meaningful participation in development and in the fair distribution of benefits resulting therefrom.’ Article 8 of UNDRD.
State to effectively ensure that every woman has an active role in the development process.94

The articulation of development as a human right is significant in enriching the argument for access to essential medicines as a human right to health in this thesis. Since all human rights are universal, interrelated, interdependent, and indivisible as stated in Paragraph 5 of the Vienna Declaration and Programme of Action,95 it can be said that the right to health and the right to development are related and both rights underlie a similar objective.96 This common objective is to promote the improvement of quality of life, create opportunities and enhance everyone’s standard of living, as a matter of right. The Preamble of the Universal Declaration of Human Rights (UDHR) which recognises that the peoples of the United Nations have reaffirmed ‘[…] the equal rights of men and women and have determined to promote social progress and better standards of life in larger freedom,’ supports this argument.97 The right to health, as discussed previously in Chapter III,98 mandates the state to guarantee, safeguard, respect, and enforce. For this reason, the right to development, like the right to health, requires State Parties to strive to improve their people’s human welfare, provide the resources and to create the necessary enabling environments for development.99 Given that health is linked to a person’s development prospects,100 it can be argued that the right to development would require the state to take all feasible measures to guarantee access to the

94 Consequently, ‘[a]ppropriate economic and social reforms should be carried out with a view to eradicating all social injustices.’ Article 8 of UNDRD.
95 The paragraph provides that
All human rights are universal, indivisible and interdependent and interrelated. The international community must treat human rights globally in a fair and equal manner, on the same footing, and with the same emphasis.
This was also discussed earlier in Chapter III subsection 3.2.1.
96 Office of the High Commissioner for Human Rights (n 90) 2.
97 See Preamble to the UDHR.
98 In subsection 4.5.
99 Office of the High Commissioner for Human Rights (n 90) 10.
100 Owoeye (n 54) 93.
important healthcare facilities, services and resources such as medicines, to achieve the full realisation of the right.

Furthermore, the reflection that the right to development includes the right of individuals to have access to basic resources, as well as equal opportunities for development, would also entail the removal of obstacles to achieving this development objective. It goes without saying that multilateral trading commitment in multilateral or bilateral agreements or treaties, and patent rights should not be allowed or implemented in a manner that limits the ability of people to enjoy the right to development and health. This important duty of the state to eliminate obstacles to development is emphasised in Article 3(1) of the UNDRD.\(^{101}\) To reiterate this point, the UN Intergovernmental Working Group on the Right to Development observed that, whilst IP is pivotal to development by stimulating innovative R&D and TR, the protection of IP should not limit the enjoyment of the right to health or undermine access to essential medicines.\(^{102}\) On this point, the utilisation of the TRIPS flexibilities, as reaffirmed in the Doha Declaration, is significant as states can utilise the health-related safeguards to address the access issues that arise from the application of pharmaceutical patent rights in the context of the right to development.\(^{103}\)

The UNDRD further directs states to create favourable international and national conditions for the realisation of the right to development.\(^{104}\) The duty to realise the right to development also requires that the state formulates appropriate national development policies aimed at constantly improving the

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\(^{101}\) Article 3(3) of UNDRD.

\(^{102}\) UN General Assembly, The Right to Development: Report of the Secretary General (UN Doc A/66/216, 1 August 2011) paragraphs 51, 58 and 59. Also available at http://www.ohchr.org/Documents/Issues/Development/A.66.216_en.pdf. (The Working Group was created to oversee the implementation of the right to development.)

\(^{103}\) Paragraph 58 ibid.

\(^{104}\) Article 3(1) of UNDRD.
well-being of the entire population and every individual, including the promotion of its citizens’ freedom to participate meaningfully in development processes and ‘the fair distribution of the benefits resulting therefrom.’

It stands to reason that the right to development also recognises the rights of individual inventors to legitimately pursue their innovative and research related activities according to their developmental goals: in like manner, patent law and policy can improve the capacity for participating in the ‘processes of knowledge creation.’ However, approaching the patent system and law from a human development paradigm requires not only enhancing the inventor’s rights and facilitating the process of producing innovative products and medicines but also promoting access to the benefits of these innovative products.

Significantly, Article 2(2) of the UNDRD places the responsibility for development on all human beings to ‘promote and protect an appropriate political, social and economic order for development.’ This responsibility is individually and collectively shared by every person and every organ of society, including civil society and private actors. As the United Nation Office of the High Commissioner for Human Rights, elaborates, businesses and corporations, which includes pharmaceutical companies, also have a responsibility to respect the right to development in accordance with their

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105 Preamble, Articles 1 and 2(2) of UNDRD.
106 Sunder, ‘Intellectual Property and Development as Freedom’, (n 78) 470. See also Article 1 of UNDRD. It can also be argued that this development objective is recognised in Article 7 of the TRIPS Agreement. This Inventor’s right to development argument corresponds with the recognition of the rights of inventors and creators’ right to participate in cultural life and derive benefits from the protection of their moral and material interest resulting from any scientific, literary or artistic production in Article 27 UDHR and Article 15(1) (a) and (c) of the ICECSR. For example, Madvi made the case for a broader understanding of IP to recognise the importance of producing more knowledge goods as well as participation in the process of knowledge creation. This view is however, not the central subject of this chapter.

It is doubtful whether companies and firms can enjoy this right to development privilege as the human person is the central subject of the right to development. Article 2(1) UNDRD.

107 It is noteworthy that the focus of this thesis is not on the development aspect of an inventor’s right within the context of patent hence it will not be analysed in detail. It is merely highlighted for analytical purposes.
108 Office of the High Commissioner for Human Rights (n 90) 4. See the previous discussion on the responsibilities of pharmaceutical companies in subsection 4.6.

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human rights obligations in the Guiding Principles on Business and Human Rights.\textsuperscript{109} Accordingly, non-state actors, namely, the private sector and individuals, can also contribute to the realisation of the right to development by creating favourable conditions.\textsuperscript{110} Linking this to the earlier discussion in the last chapter,\textsuperscript{111} pharmaceutical companies and patent holders can promote and facilitate the practical realisation of the right to development through the availability of medicines.

5.4.1 The Right to Development and Access to Life-saving Medicines and Patents

The right to development relates to the debate on patent protection of pharmaceuticals and access to essential medicines in a number of ways. As examined in Chapter III,\textsuperscript{112} the first issue is the widespread concern that patents can pose a barrier to accessing life-saving drugs for life-threatening sicknesses such as HIV/AIDS, malaria and other diseases, particularly in developing countries.\textsuperscript{113} Besides the human cost, HIV/AIDS epidemics for example, significantly disrupt the smooth functioning of economic and social systems in ways that also affect sustainable growth and human development, especially in sub-Saharan Africa.\textsuperscript{114} To address the development concerns that the health epidemic raises, there is the need for people to have access to newer antiretroviral treatments. As novel and more effective antiretroviral treatments

\textsuperscript{109} ibid
\textsuperscript{110} ibid 4-5.
\textsuperscript{111} See the discussion on the responsibilities of pharmaceutical companies in Chapter III, subsection 4.6
\textsuperscript{112} In subsection 3.7.
are more likely to be patented in developing countries,\textsuperscript{115} it is necessary for states to think more carefully about the delivery of and access to essential drugs in the regulation of their national patent law. This is because achieving the right to development as mentioned in subsection 5.4.1, entails the state taking proactive steps to improve the well-being of every individual including the provision of health care facilities, services and medicines as a matter of guaranteeing the right. Arguing in support, Adusei, highlights that guaranteeing the right to development requires that the state pursues ‘a comprehensive social, economic, legal, cultural and political process’ and policy.\textsuperscript{116}

The recognition of development as a human right in the African Charter is also significant to the arguments in this chapter. Accordingly, Nigeria, having ratified and incorporated the African Charter as noted in the last chapter,\textsuperscript{117} is bound by its treaty obligation to fulfil, respect and promote the right of every woman in Nigeria to be developed. The decision of the African Commission on Human and People’s rights in the case of Centre for Minority Rights Development (Kenya) and Minority Rights Group International on behalf of Endorois Welfare Council v Kenya (Endorois case) is illustrative of the duty of states to the right to development. In this case, the African Commission found that the state (Kenya) has a duty to create conditions favourable to the people’s development.\textsuperscript{118} In 1973 and 1978, the Kenyan government dispossessed the Endorois Community of their lands to create Lake Hannington Game Reserve and Lake Bogoria Game Reserve.\textsuperscript{119} The Endorois community, an indigenous people, alleged that

\begin{footnotes}
\item[116] Adusei (n 45) 240.
\item[117] Subsection 4.9.1.
\item[119] ibid paragraph 1-12.
\end{footnotes}
the government violated their rights to development as contained in the African Charter by forcibly removing them from their ancestral home, failing to compensate them for the loss of their properties, not involving them in the decision-making in the development process and the disregard for their well-being and continued development.\textsuperscript{120} The Endorois people also argued that the eviction from the game reserve limited the choices and capabilities open to them and affected their livelihoods as their cattle died from lack of access to the lake, usual pastures and salt licks.\textsuperscript{121} The African Commission, making reference to the right to development in the African Charter, took the view that the dispossession and disruption of the community’s pastoral enterprise was a violation of their human rights to development, contrary to Article 22 of the African Charter.\textsuperscript{122} According to the Commission on the state’s duty, ‘[t]he result of development should be empowerment of the Endorois community. [...] The capabilities and choices of the Endorois must improve in order for the right to development to be realised.’\textsuperscript{123} This case is significantly an example of the nature of the duty that states are expected to adhere to, or refrain from to realise the right to development.

On the basis of the Nigerian government’s duty to women’s right to development, it is argued that the state should aim at constantly improving their living standards and well-being. Since improved health is a central component of development and women’s well-being, the Nigerian authorities and policy makers have an obligation to provide the necessary healthcare facilities along with access to necessary medicines and services to improve or maintain women’s health including the promotion of public health in its laws. The state’s

\textsuperscript{120} ibid
\textsuperscript{121} ibid paragraph 126.
\textsuperscript{122} ibid paragraph 297-298.
\textsuperscript{123} ibid paragraph 283.
duty to fulfil the right to development implies, like the right to health, that measures should be taken to prevent direct or indirect interference with the right by third parties including multinational corporations.\textsuperscript{124} It is therefore important that the Nigerian government adopts a people-driven development approach to its patent law and policy to guarantee women and everyone in Nigeria access to affordable essential medicines.

It will be recalled\textsuperscript{125} that an important feature of the right to development is that it emphasises that every human being is a central subject of development.\textsuperscript{126} The identification of humans as the central subjects of development in the Article 2(1) of the UNDRD corresponds to the definition of development by the UNDP as a ‘process of enhancing human capabilities—to expand choices and opportunities so that each person can lead a life of respect and value.’\textsuperscript{127} This view, applied to patent law, captures the development-enhancing aspect of a patent policy and system, not only in the narrow sense of promoting technological innovation and pharmaceutical R&D, but also viewing the public benefit of patents as an important instrument for human development by enhancing basic human health capabilities.\textsuperscript{128} It is in light of this understanding that this chapter makes a case that wider access to patented medicines will expand and improve the health capabilities of women and every individual in Nigeria.

The second related issue is to do with the international obligation of Nigeria to implement a minimum standard of patents in the TRIPS Agreement under its

\textsuperscript{124} Office of the High Commissioner for Human Rights (n 90) 4.
\textsuperscript{125} From the discussion in subsection 5.2.3 and 5.2.4.
\textsuperscript{126} Article 2(1) of UNDRD.
\textsuperscript{127} United Nations Development Programme (UNDP), Human Development Report 2000: Human Rights and Human Development (United Nations Development Programme (UNDP) 2000) 2. Relating human development to human rights, the UNDP notes that ‘[w]hen human development and human rights advance together, they reinforce one another—expanding people’s capabilities and protecting their rights and fundamental freedoms.’ ibid
\textsuperscript{128} Adusei (n 45) 240; Sunder, ‘Intellectual Property and Development as Freedom’ (n 78) 470.
domestic law. In the light of the potential effect of patent rules on access to affordable essential medicines and adverse consequences for the availability of medicinal treatment, the issue for the state and lawmakers to consider is how Nigeria can meet the WTO international obligation and also safeguard the health and well-being of its people in the interests of their rights to development. While the TRIPS Agreement and Doha Declaration confirmed that countries can interpret and implement national patent laws and flexibilities to protect public health by taking into account its population’s socio-economic welfare, a related issue to consider is whether the country can exercise a greater policy space to enhance the citizens’ development needs and expand their capabilities in light of patent rights and the protection of pharmaceuticals. These issues will be further considered in the following sections. But first, the importance of the health capabilities for this purpose is highlighted.

5.5 The Human Capabilities Approach to Health: An Evaluative Framework

In analysing the significance of health to general welfare and well-being, Henry Sigerist writes:

A healthy individual is a man [woman] who is well balanced bodily and mentally, and well adjusted to his physical and social environment. He is in full control of his physical and mental faculties, can adapt to environmental changes, so long as they do not exceed normal limits, and contributes to the welfare of society according to his ability. Health therefore is not simply the absence of disease; it is something positive, a joyful attitude towards life, and a cheerful acceptance of the responsibilities that life puts upon the individual.\textsuperscript{129}

\textsuperscript{129} Henry E Sigerist, \textit{Medicine and Human Welfare} (Yale University press 1941) 100. The WHO also depicts health as a complete welfare condition besides the absence of diseases, and infirmity.
This depiction of health draws attention to the importance of health as an essential aspect of a human’s well-being and life. Sen observes that ‘health is among the most important conditions of human life and a critically significant constituent of human capabilities which we have reason to value’. From a health perspective, the human development framework and health capabilities approach draws focus to ‘the process of generating health’. In this vein, the capabilities approach offers a method for assessing whether individuals have the capability to be healthy. Therefore, Jennifer Prah Ruger describes health capabilities thus: [h]ealth capability constitutes a person’s ability to be healthy; it includes health functioning and health agency. In conceptualising health capability, Ruger adds that health capability creates an understanding of the conditions and barriers that could hamper health and the ability to make health choices.

Health plays a special role in the promotion of well-being within the capabilities approach framework. This is because health is not only intrinsically important to personal well-being; it can affect the mental and physical capability to achieve other development goals. Better health is a tool for other development prospects; the health capability of an individual to a large extent determines the level of opportunities, freedoms and choices to develop their capabilities in other areas of their lives. As such an individual’s health capability is fundamental in securing the viability of other capabilities. When individuals are

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132 Ruger, ‘Health, Capability, and Justice: Toward a New Paradigm of Health Ethics, Policy and Law’ (n 45) 106. Ruger writes that ‘[a]gency is important for public policy because it supports individuals’ direct participation in “economic, social and political actions” and enables individuals to make decisions” as active agents of change.’ ibid 158.
133 Jennifer Prah Ruger, ‘Health Capability; Conceptualization and Operationalization’ (2010) 100 American Journal of Public Health 42. From the same point of view, Venkatapuram highlights that an individual’s health capabilities include the ‘ability to achieve a basic cluster of beings and doings-or having the overarching capability, a meta-capability, to achieve a set of basic inter-related capabilities and functionings.’ Venkatapuram, Health Justice: An Argument from the Capabilities Approach (n 45) 20; Sridhar S Venkatapuram, ‘Health, Vital Goals, and Central Human Capabilities’ (2013) 27(5) Bioethics 271, 279.
in good health, they contribute effectively to the development of themselves and society at large. Gostin and Wiley, on the significance of health to the empowerment of populations and their socio-economic development, observe:

[...] health is also essential for the functioning of populations. Without minimum levels of health, people cannot fully engage in social interactions, participate in the political process, exercise rights of citizenship, generate wealth, create art, and provide for the common security. A safe and healthy population provides the basis for a country’s government structures, social organizations, cultural endowment, economic prosperity, and national defense. Population health becomes a transcendent value because a certain level of human functioning is a prerequisite for activities that are critical to the public’s welfare--social, political, and economic.134

In addition, the current 2015 UNDP Report stresses that an individual’s capability to live a long and healthy life is not only central to enhancing their overall capabilities; it is also fundamental to creating the necessary conditions to achieve other aspects of development.135 It follows that the capability to be healthy is also a nucleus of development in itself and a means to the development of other capabilities. In retrospect, a healthy person is better placed to develop society and also enjoy the technological and developmental benefits conferred by patent law to users as espoused in the TRIPS Agreement.

As Ariana and Naveed point out, it is important to recognise that the health of an individual is a multi-dimensional phenomenon that cannot be assessed by a single indicator.136 In this sense, while there are several factors that influence the ability of an individual to be in good health, including a person’s biological make-up, physical environment, social-economic conditions and personal

135 UNDP, Human Development Report 2015: Work for Human Development (n 17) 3. The WHO in a 2013 report also reiterates the importance of good health by stating that health is ‘a critical contributor to and outcome of sustainable development and human well-being’ World Health Organization, Health in the post-2015 development agenda: Report by the Secretariat (n 9) paragraph 18.
136 Ariana and Naveed ‘Health’ (n 131) 228, 230.
choices, from a capabilities perspective, an individual should also have the freedom, opportunities and choice to achieve a valued state of better health and well-being. Central to Nussbaum’s capabilities approach for example, is the idea that people should have the freedoms, choices and opportunities to live a life that is worthy of human dignity which they value. Nussbaum’s version of capabilities also analyses the choices and opportunities that an individual has to undertake a capability action based on their political, social and economic circumstances and further notes that it is the duty of the state or society to build and promote these basic human capabilities.

It can be said that a way of enhancing or supporting the development of health capabilities can be through access to health care services and sufficient, affordable and safe medicines for treatment of illnesses and diseases. Since health is central to a person’s capabilities, Nigerian authorities can strive improve the health capabilities of all its citizens by facilitating access to medicines, in a manner that takes into account everyone’s level of access—men, women and children. By making available the necessary medicines and providing the avenues through which individuals can have the opportunity to increase and sustain their health capabilities, the state can support, protect and guarantee the basic capabilities of individuals ‘to be and do what they have reasons to value.’ Applying this reasoning to the patent system, while innovation fostered by patent law may improve human well-being and/or

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137 Venkatapuram, Health Justice: An Argument from the Capabilities Approach (n 45) 18. (The biological and medical factors that influence health and well-being are not the focus of this thesis.)

138 Nussbaum, Creating Capabilities: the Human Development Approach (n 43) 21. According to Nussbaum, the concept of dignity has no precise definition and can be given different interpretations by people. Nonetheless, Nussbaum notes that human dignity that is closely related to the notion of a basic capability, ‘something inherent in the person that exerts a claim that it should be developed.’

139 ibid 31.

140 Martha Craven Nussbaum, Creating Capabilities: the Human Development Approach (n 43) 20-21.

140 Venkatapuram, Health Justice: An Argument from the Capabilities Approach (n 45) 115.
economic growth as argued by some scholars, from the capabilities approach, the issue is whether the products or R&D results as incentivised by patent, ultimately enhance the opportunities and choices that individuals have with regards to their health capabilities.\footnote{\textsuperscript{141}}

**5.5.1 Access to Medicines as a Right to Health: Enhancing Health Capabilities**

The argument for the enhancement of Nigerians’ health capabilities through access to medicines resonates with the right to health discussion in Chapter IV.\footnote{\textsuperscript{142}} As mentioned in the chapter,\footnote{\textsuperscript{143}} the normative objective and content of the right to health\footnote{\textsuperscript{144}} which recognise the inherent human entitlement, freedom and capability of a person to be able to attain a state of physical and mental well-being, also presupposes that it is the duty of the government to make available the necessary goods (medicines), health facilities and healthy conditions and environment for the realisation of the right to health.\footnote{\textsuperscript{145}} Thus, the enhancement of Nigerian's health capabilities is also a human rights obligation of the state. This obligation on the state corresponds with the capabilities approach, especially as propounded by Nussbaum, that it is constitutionally imperative for the state and society to provide certain basic social and human entitlements to every individual to enhance their human capabilities – in the case of health, the capability to be healthy.\footnote{\textsuperscript{146}} Medicines it is argued, can be a means through

\begin{itemize}
  \item Wong (n 4) 24.
  \item See PART I of Chapter IV.
  \item See subsection 4.3.
  \item In Article 12 of the ICESCR and in Article 25 (1) of the 1948 UDHR.
  \item Nussbaum argues for example that \cite{nussbaum}
\end{itemize}
which people can enhance their health capabilities thus accessing affordable medicines is significant in this regard. This duty on the Nigerian state is to create the opportunities and provide the health facilities for its citizens to exercise the choice to be in good health. Human rights therefore complement human development and capabilities by placing an obligation on states to account for the attainment of human development and building people’s capabilities to be healthy. In consequence, both human rights and the capabilities approach promote health and well-being, and reinforce each other by promoting the expansion of people’s capabilities as an objective of human rights – to be protected, respected and realised by the state.

Particularly to women in this study, human rights therefore serve as a legal basis to promote the development of their health capabilities and by extension, their human development through access to affordable life-saving drugs.

5.6 Towards a Human Development Paradigm of the Patent System in Nigeria

Patents intersect with human development and health capabilities on two levels: first, as a barrier to accessing medicines and consequently human development, and as a means to facilitating R&D which is significant to the enhancement of the capability to be healthy.

Martha C Nussbaum, ‘Human Capabilities, Female Human Beings’ in Martha C Nussbaum and Jonathan Glover (eds), Women, Culture, and Development: A Study of Human Capabilities (Oxford University Press 1995) 88. Nussbaum goes ahead to articulate a specific list of capabilities which includes the ‘[b]eing able to have good health, including reproductive health,’ and argues that the list is ‘the certain basic functional capabilities at which societies should aim for their citizens, and which quality of life measurements should measure.’ibid 82

Nussbaum also argues that the list provides the ‘philosophical underpinning for an account of basic constitutional principles that should be respected and implemented by the governments of all nations’ and the basis ‘for central constitutional principles’ that every citizen can demand from their governments as a matter of right.’ Nussbaum, Women and Human Development: The Capabilities Approach (n 42) 5, 12. See also Adusei (n 45) 258.
In the first instance, a potential drawback of patents is their effect on access to drugs and the consequential impact on the expansion of health capabilities. Discussed in Chapter III\textsuperscript{147} and stated earlier,\textsuperscript{148} a patent right could create a barrier to accessing the medicines needed to be in good health, which is important to the realisation of human development. Pointing out the effect of an IP owner’s right to freedoms, Gollin adds that the ‘the exclusivity of IP rights restricts the freedom of choice of those who seek access to an innovation.’\textsuperscript{149}

Through excessive pricing and other protectionist practices patent rights can diminish the capability of end users of the patented product to effectively access medicinal treatments for health purposes.\textsuperscript{150} In this light, patients who lack access to essential patented drugs would also lack the freedom and capability to use the drug as to ameliorate their health conditions as they wish. Given that patent protection grants monopoly rights that may have a significant effect on access to essential medicines, there is therefore a need to ensure that patent rights do not negatively impact on access. For access to pharmaceuticals therefore, it is the duty of the Nigerian authorities and policy makers to ensure that patent law does not hinder access to essential medicines, especially for women, as medicines are instrumental means to improve the capabilities to be

\textsuperscript{147} In subsection 3.7 and the sub subsections.

\textsuperscript{148} In subsection 5.4.1.


\textsuperscript{150} As discussed in Chapter III, subsection 3.7.1.1 and 3.7.2, the main barrier to ensuring that individuals with chronic diseases can access essential medications is pricing in many developing countries. Thus even if the developing country were to provide a healthcare system capable of supporting the procurement and provision of essential medicines, implementation may constitute a problem if the medicines are not affordably priced and the government cannot subsidise the medicine. With regards to the pricing policies of pharmaceutical companies, the high prices of patented medicines are described as a ‘gateway’ barrier for accessing pharmaceuticals. Brent Savoie, 'Thailand’s Test: Compulsory Licensing in an Era of Epidemiologic Transition' (2007) 48 Virginia Journal of International Law 211, 222.

In a similar regard, it is widely acknowledged that patent rights do not provide sufficient incentive to meet the need for the development of new products to fight diseases where the potential paying market is small or uncertain. World Health Organization, 'Intellectual Property and Access to Medicines: Papers and Perspectives' (World Health Organization 2010) 6.
healthy. Rather, patent law should be tailored to promote research and dissemination of knowledge, and used as a tool to facilitate R&D, alongside the relevant patent right exceptions through an appropriately designed policy and an efficient administration system.

In a related manner, within the patent system itself, it is recognised that patent law can serve as means to the availability of medicines by encouraging the research and production of drugs, thus promoting the means to human development and improving well-being in general. These medicines, as incentivised by patent rights, could in turn, create the opportunities and means to be healthy and further contribute to increasing people’s freedom to choose by enlarging their choices. In this vein, a patent can play a more positive role in expanding people’s choices and capabilities to be in good health. Chon succinctly captures the human development dimension of IP in general thus:

The model of development of freedom centres human capability through the provision of basic needs in the areas of education, health, and nutrition, because these lead to the ‘enhancement of human freedom, which is both the main object and the primary means of development’ (Sen 1999) [...] Simply put, the growth model of development prioritizes the innovation mandate of intellectual property, while the freedom model of development emphasizes its multi-dimensional aspects. In the latter paradigm, intellectual property not only stimulates innovation but also protects knowledge goods that enhance human capabilities, which in turn build national capacity for innovation.¹⁵¹

It is however argued that the development goals of patents in enhancing capabilities should not end with the availability of the products of innovation. There is a need to ensure that the actual societal benefits of the invention are

¹⁵¹ Chon, ‘Substantive Equality in International Intellectual Property Norm-Setting and Interpretation’ (n 80) 476; Barbosa, von Hase and Chon (n 46) 77.
realised. It is therefore important that the instrumental role of patents in guaranteeing the capability of users to be in a state of improved health is not merely focused on the R&D or incentive benefit of making the drugs available. To emphasise further, the technological innovation and economic development advantage of the patent system should not serve as an end to development; patent policy should also contribute substantially to sustainable human development. Patents are not only an incentive instrument for innovation, pharmaceutical R&D, or a ‘power tool’ for economic development, but also a means to improving the welfare of individuals in society. The human development paradigm is therefore important in assessing the development goal of patents to health through access to medicines, by drawing attention to the benefit of a patent system to humans (consumers), as well as the benefit resulting from innovation, economic growth and national GDP.

Approaching development in patent law from a human development perspective goes further in examining how individuals can actually benefit from patent protection and how it helps to build their capabilities. As Gollin remarks, ‘the IP system, in driving the innovation cycle, serves at least in part as an instrument of individual freedom and choice.’ Within the national context of Nigeria, it is argued that patent law should contribute to the overall function and development of humans, including public health. Thus, the Nigerian government, apart from promoting the availability of medicines by enacting a patent policy, also has an imperative duty to ensure that women and indeed every individual in Nigeria are guaranteed actual access to them.

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152 Gollin (n 149) 343.
Approaching the welfare benefits of having a patent system charged with enhancing the human development of women and all its people, can provide the Nigerian government and policy makers with considerable room to facilitate access to patented pharmaceuticals. One way is to ensure that the central development goal of enhancing the people’s human development and building human capabilities, informs the design and implementation of patent rights. As Chon argues, ‘focusing on capabilities helps us think about goals for the system as a whole. Should IP take into account health measures? education measures? […] in addition to or instead of pure innovation measures?’\textsuperscript{153}

While there may be several ways of enhancing health capabilities and improving human welfare, in this thesis, the flexibilities are identified as a significant means of providing opportunities for people to enhance their basic capabilities. The Nigerian government and the appropriate authorities can exercise greater flexibility in the use of the patents-related health safeguards and exceptions in accordance with the public health interest goals of facilitating access to medicines for human development reasons. The proactive use of the TRIPS flexibilities in the event that the excessive use of pharmaceutical patent rights poses a threat to accessing medicines is one of the many ways in which Nigeria can improve the quality of life for all its citizens as defined by their capabilities. The utilisation of the TRIPS flexibilities, as will be comprehensively discussed in the next chapter, are to; promote access to cheaper drug options (compulsory licensing or parallel imports); foster generic competition; or facilitate incremental pharmaceutical R&D through the research and experimental use exceptions and early working (Bolar) exemption,\textsuperscript{154} and also

\textsuperscript{153} As cited in Wong (n 4) 32.
\textsuperscript{154} Some of these flexibilities are further considered in the next chapter.
the use of internal controls such as price control mechanisms could in effect, counter-balance the adverse effects of patents on accessibility to affordable essential medicines.

Moreover, the human development and capabilities approach is a useful framework for considering the design and implementation of patent exceptions and flexibilities identified Chapter VI. As this human development paradigm views the expansion of human capabilities and opportunities to exercise genuine choices as important goals of development, the Nigerian authorities can create an environment in which people can fully develop their potential to expand their choices using TRIPS-compliant flexibilities. The authorities can seek to build the capability of women, and all Nigerians, to lead long and healthy lives, through having access to vital resources, such as medicines, that are needed to live healthy. This is through fully incorporating and adapting the flexibilities, proactively enforcing their use to promote health and curtailing the adverse effect of patent rights on access to medicines. It is therefore argued that approaching the incorporation and enforcement of the flexibilities from a human development and capability perspective, can be a justifiable reason to increase access to medicines in Nigeria. From the capabilities perspective, the goal of the government should be more than just to create an opportunity for people to have medicines by granting patents as incentives for incremental innovation. While these medicines can improve human wellbeing, approaching the patent system from a capabilities perspective should consider the relevance of the pharmaceuticals to enhancing human capabilities, and provide the most effective means of ensuring that patients who need the medicines can actually access them to build their health capabilities.
As Frishmann argues on the ways in which IP can be used to promote the capabilities, ‘[…] some social investments in capabilities are, or maybe or should be, made through legal structures that allocate freedoms to access and use resources that are necessary to participation in certain types of activities.’¹⁵⁵

In the context of promoting health capabilities of Nigerians, this observation highlights the need to ensure that the patent system is designed not only to protect IP and increase the development of innovative products, but also to take into account national development priorities and opportunities for people to access medicines, and use them to strengthen their health capabilities. The use of the flexibilities would ensure that the legal text of Nigerian’s patent regime is construed and applied in a way that caters not only to the interest of pharmaceuticals patent holders but also to the basic health needs of those who require access to essential medicines. The flexibilities can provide additional opportunities for Nigeria to broaden access to important and life-saving medicines and to promote development without the need to strip away the rights of patentees.¹⁵⁶

Equally important, the Nigerian courts and relevant authorities can interpret and enforce patent law in a manner that recognises the prominence of the human right to health and the right to development and the need to enhance health capabilities, in the event that the patent rights threaten access to medicines.¹⁵⁷

As argued in the preceding chapter,¹⁵⁸ the right to health and life to be healthy should be weighed against the patent holder’s rights and where there are exigent health implications, the right to health should trump patent rights. This

¹⁵⁶ Chon, ‘Intellectual Property and the Development Divide’ (n 32) 2880.
¹⁵⁷ See the Endorois case above in subsection 5.4.1.
¹⁵⁸ See subsection 4.7.4, 4.9.2 and 4.10 of Chapter III.
argument can also be approached from a capabilities, human development, and right to development perspective. Prioritising access to medicines to improve health capability can provide another moral justification and legal basis for Nigeria to limit the exercise of patent rights to cater to human development needs of all Nigerians.

The integration of human development considerations into the design, implementation and interpretation of patents has the value of ensuring that the Nigerian authorities take into account the development-related interests of Nigerians. The goal of any reform, redesign and repositioning of the patent system should be to guarantee that the people have opportunities to access medicines to enhance the quality of their lives. Likewise, strengthening patent exceptions and limitations should not be seen as a mere regulatory exercise of bringing the Nigerian laws into conformity with its TRIPS obligations. Rather, strengthening the flexibilities should be seen as a crucial way whereby health capabilities can be supported. Approaching it from this perspective will ensure that the system is designed to serve and promote this development objective.

To the best of this author’s knowledge, there is no judicial or WTO case on human development and IP rights. The argument to integrate human development principles into the norm-making and interpretation of patent policies, therefore, finds support in Paragraph 4 of the Doha Declaration which urges the interpretation and implementation of TRIPS in a manner that supports and promotes public health through access to medicines.

159 Also, the state can approach the issue of facilitating better access to patented pharmaceuticals to build the Nigerians human development potentials as part of its right to development duties to promote and protect health. See the discussion in subsection 5.4.
5.7 Conclusion: Enhancing Women’s Human Capabilities through Access to Medicines in Nigeria

It has been argued that pharmaceutical patents have significant implications for access to medicines and, by extension, human development. The reason for this is that access to affordable medicines is critical to the attainment of a good standard of life, which is fundamental to the realisation of a high level of human development. From a rights perspective, it is the duty of the Nigerian government to provide the necessary health care facilities and medicines to guarantee people the right to health. It can be said that providing a patent system to foster pharmaceutical research and production of drugs is one of the many ways in which Nigeria can facilitate the availability of health enhancing and medicinal resources. However, it is not enough that the patent right contributes to pharmaceutical innovation; there is a need to ensure that society can leverage these resources as a means of achieving social objectives, including the expansion of health capabilities. A fair balance between the private and social benefits of innovation requires the consideration of a development-oriented patent policy framework which ensures not only that new technologies are created but also that people are able to access them. In the context of patent rights as a barrier to accessibility to vital medicines, it is also the obligation of the Nigerian government to ensure that the patent law which should promote the R&D of pharmaceuticals does not obstruct specifically, women’s access, to the medicines and consequently, their potential for human development.

The nexus between the right to health, building human development through access to medicines for human capacity and development requires a renewed
approach to the consideration of patent law. It goes without saying therefore that, while patents can be essential to innovation, and that, within international IP fora, providing patent protection is seen to facilitate economic growth and development, approaching the issue of development in light of patents assesses whether the IPR is essential to development by evaluating the role it plays in the achievement of human development. From a human development and capabilities perspective, it is imperative that the Nigerian government and relevant authorities ensure that the results of innovation reach those who need them. Given the adverse effects of the marketing practices of pharmaceutical firms on access to medicines, it is advisable for Nigeria to control activities of the pharmaceutical companies and the marketing techniques that acerbate the problems of access to drugs. Specifically, thinking in terms of capabilities, the Nigerian government and policy makers can broadly utilise the TRIPS flexibilities to guarantee women and everyone in Nigeria, access to patented medicines and facilitate the availability of cheaper generic medicines. As will be discussed in the next chapter, this can be do by incorporating the necessary TRIPS flexibilities and utilising the patent law exemption in the interests of health and access to affordable, essential medicines thus enhancing women’s human development potential.
CHAPTER VI: TRANSLATING TRIPS AND ITS FLEXIBILITIES FOR ACCESS TO MEDICINES AND THE RIGHT TO HEALTH IN NIGERIA

6.1 Introduction

As discussed in Chapters III, IV and V of this thesis,\(^1\) patent rights could impact the ability to access to medicines, the right to health, and consequently, human development. To address some of the adverse effects of patent rights and the TRIPS Agreement on accessing affordable and essential medicines, members of the World trade Organization (WTO) can take advantage of the legal exceptions within the TRIPS Agreement to promote and facilitate the availability and access to cheaper medicines for their citizens.\(^2\) The aim of this chapter is to assess the extent to which the TRIPS-inherent flexibilities, as clarified by the Doha Declaration, could serve as effective measures for states, especially developing countries, to promote and improve the state of health of their people through access to affordable pharmaceuticals. The chapter starts therefore, with a critical analysis of the flexibilities in TRIPS as a policy tool for facilitating access to life-saving medicines and thereby promoting the realisation of the right to health and advancing human development. With a specific focus on Nigeria, this chapter examines the flexibilities with the view of recommending ways in which the Nigerian Government can utilise the flexibilities in the context of pharmaceutical patents to particularly enhance women’s access to affordable and essential medicines. In so doing the chapter also questions the

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\(^1\) See subsections 3.7, 4.5, 4.6 and 5.4 and 5.6 of Chapters III, IV and V respectively.
\(^2\) This was mentioned in subsection 3.7.2 of Chapter III.
effectiveness of the health-related safeguards in the TRIPS Agreement, especially for Nigerian society.

This chapter also generates insights into other developing and developed countries’ use of the flexibilities, the judicial authorities laid down by the courts and the WTO’s Dispute Resolution Panel to illustrate how a well-designed intellectual property (IP) policy and patent system can contribute to the performance of the flexibilities in a practical context. This chapter further examines how other WTO-member countries have handled their health crises using the flexibilities, including the challenges they encountered, to suggest how Nigeria can formulate its patent policy and system to expedite the availability of lower-priced medicines and also increase local production of pharmaceuticals whilst conforming to its international trade obligation.

In light of the foregoing aims, the first part of this chapter highlights the current implementation status of the TRIPS Agreement, including the flexibilities, in Nigeria and the practical measures undertaken so far to maximise their benefits. The second part analyses the legal framework of the flexibilities and also points to the issues and problems that have arisen with regards to their implementation in a practical context and the subsequent need for clarification at Doha in 2001. The third part analyses some of the flexibilities in greater detail, and also draws on practical examples from other states that have relied on the health-related patent exceptions in a practical context to facilitate access to medicines. Having provided the legal and moral justifications to promote women’s access to medicines in the preceding chapters, this part argues that the flexibilities provide important avenues for Nigeria to meet its human rights obligations to

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3 See Chapter III, IV and V of this thesis.
health and development and foster better access to drugs. It is argued, however, that effective use of the flexibilities in Nigeria depends upon its adaptation and interpretation in national laws in a manner that is better suited to the country’s national development and public health objectives.

Due to space constraints, the analytical focus in this chapter is on four flexibility provisions in the TRIPS Agreement: the patentability flexibility and exceptions in Article 27; the limits to a patent right in Article 30; and compulsory licensing and non-commercial (government use) flexibilities in Article 31.

PART I: AN OVERVIEW OF THE STATUS OF THE TRIPS AGREEMENT IN NIGERIA

6.2 The Introduction of the TRIPS Agreement for Patent Rights in Nigeria

As would be recalled from Chapter II, Nigeria became a signatory to TRIPS in 2005 but is yet to domesticate or implement the TRIPS Agreement into its national laws as required under Section 12(1) of the 1999 Nigerian Constitution. At the time of writing, the ratification process had been initiated by the Federal Executive Council (FEC), and now awaits ratification and implementation by the Nigerian National Assembly.

4 See subsection 2.6.3 of Chapter II.
5 Section 12 of the 1999 Nigerian Constitution states that all treaties must be passed into law and domesticated by the Nigerian National Assembly to have national effect. Hence the ratification process of the WTO TRIPS Agreement is subject to a national legislative act to be binding.
6 In 2013, 2014 and 2015, the author of this thesis visited the trade department of the Ministry of Trade and Investment (formerly the Ministry of Trade and Commerce) in Nigeria and was told that there is a bill on the floor of the NASS that seeks to update the Patent and Design Act of 1970 to reflect Nigeria’s WTO TRIPS obligation. I was able to view a draft copy of the ‘Request for Approval for the Ratification and Acceptance of the Protocol Amending the WTO Agreement on Trade-Related Aspect of Intellectual Property Rights (TRIPS), agreed at Geneva, Switzerland, on 6th December, 2005.’ Since the commencement of this research, I have visited the relevant departments responsible for this amendment and ratification on three different occasions in the span of three years (in 2013, 2014 and 2015) but I could not find the draft TRIPS ratification instrument itself. No one at the Ministry of Trade and Investment, legal drafting department of the Ministry of Justice (responsible for drafting bills in Nigeria), or
6.2.1 The Nigerian Intellectual Property Commission (NIPCOM) Draft Bill

The Nigerian IP regime is still under review and the legislative framework for a new consolidated IP legislation is at an advanced stage in Nigeria.\textsuperscript{7} Since 2002, attempts have been made to revise the IP laws in line with the international obligations of the TRIPS Agreement.\textsuperscript{8} Accordingly, the then Minister of Commerce (now the Minister of Trade and Investment) set up a committee to establish an administrative body to initiate this process.\textsuperscript{9} The Nigerian Intellectual Property Commission was, thereafter, inaugurated to administer IP laws.\textsuperscript{10} The Commission was charged with the responsibility for designing the necessary framework and fashioning the process for IP reform.\textsuperscript{11} The Committee in its report took into account the urgent need to comprehensively review and update substantive IP legislation in conformity to recent developments and the obligations and requirements of the TRIPS Agreement.\textsuperscript{12} The Committee made several recommendations for this purpose including the harmonisation of IP regulations and an institutional framework for a proposed Intellectual Property Commission and drafted the Nigerian Intellectual Property Commission (NIPCOM) Bill of 2007 to this effect.\textsuperscript{13}

\textsuperscript{9} ibid 26-27.
\textsuperscript{10} ibid
\textsuperscript{11} ibid
\textsuperscript{12} ibid 27.
\textsuperscript{13} ibid
The draft bill, compatible with the standards set out in the TRIPS Agreement, was presented to the Nigerian National Assembly as part of the intellectual property law reform process.\(^{14}\) It contains comprehensive provisions for the establishment of an administrative organ and harmonisation of all IP-related matters including patents and copyright.\(^{15}\) As such the bill contains detailed provisions on all the IP rights including copyright, trademarks, service marks, patent and designs, plant varieties, animal breeders’ and farmers’ rights. The bill also proposed to model the Nigerian IP system according to international standards and enhance domestic IP practices for the protection and administration of IP.\(^{16}\) The integration of the regulation and enforcement of IP under one administrative organ would reduce administrative costs, allow for better collaboration and ensure an efficient management of IP with fewer bureaucratic hurdles.\(^{17}\) Although the NIPCOM Bill was drafted before the ratification process to domesticate the TRIPS Agreement was initiated in Nigeria by the Federal Executive Council (FEC), the bill contains important provisions, including many of the TRIPS flexibilities options for enhancing access to medicines. The Draft Bill was the subject of an extensive review and consultation with various stakeholders; however, the bill has been before the legislative House of Assembly since 2007.\(^{18}\) Progress for enactment has been slow, partly due to lack of political and legislative will, administrative challenges

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\(^{16}\) ibid

\(^{17}\) Umahi (n 15) 9.

and changes in government.\textsuperscript{19} Within the context of patents and its related flexibilities, and access to medicines, the provisions in the current patents legislation in Nigeria,\textsuperscript{20} the Draft Bill, and TRIPS Agreement are further examined.

In summary, Nigeria is yet to adequately domesticate or implement the TRIPS Agreement to take advantage of some of the TRIPS-inherent flexibilities. From the perspectives of health, it is submitted that Nigeria should domesticate and broadly interpret the flexibilities to realise, fulfil, protect and promote women’s right to health and promote their human development in Nigeria. Since it is inevitable that the country, as a member of the WTO, has to adopt all the treaties and Agreements of the international trade system, including the TRIPS Agreement, Nigeria should effectively implement and adapt the Agreement and its flexibilities in the interests of its people’s health.

Against the background of the foregoing, the following section analyses the legal framework of the flexibilities guaranteed by the TRIPS Agreement and the Doha Declaration as measures for protecting public health and promoting access to medicines. This section will focus on the implementation challenges and the process leading up to the clarification at Doha.

\textsuperscript{19}ibid
PART II: REVISITING TRIPS FLEXIBILITIES AND SOLUTIONS FOR PUBLIC HEALTH

6.3 TRIPS Agreement and Flexibilities: Framing the Global Debate

As noted in Chapter III, the introduction of the TRIPS Agreement ushered in a new regime of global intellectual property (IP). In light of scientific and technological breakthroughs for life-threatening diseases in the pharmaceutical and medical sectors, a major concern was raised about the impact of patent protection contained in the TRIPS Agreement. Amidst millions dying each day from diseases that are treatable with existing medicines, the initial issue was how to make sure that the implementation of the TRIPS Agreement would not prevent the availability of, and access to, medicines for poor people in developing countries, but instead promote R&D. Consequently, the focus has shifted to the legal remedies contained in the Agreement that could be used by states to improve access to affordable patented medicines in the interests of the public.

6.3.2 The Flexibilities

The legal exceptions and patent-related flexibilities in the TRIPS Agreement are classified into two main categories: the time-based extension by way of

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21 This was mentioned in subsection 3.6.1 of Chapter III.
23 Sisule F Musungu, Susan Villanueva and Roxana Blasetti, Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks (South Centre 2004) 1-2. Problems arose due to the prohibitive cost of patented drugs, especially treatments for ARV and other opportunistic infections, as well as a lack of research into neglected diseases as discussed in previous chapters. Haochen Sun, 'The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health' (2004) 15 European Journal of International Law 123, 123-127.
transition periods for developing\footnote{Until 2005.} and least developed countries (LDC)\footnote{Until 2033.} to implement the Agreement; and the substantive patent rights exemptions and flexibilities that can be utilised for the promotion of public health and facilitation of access to medicines.\footnote{Musungu, Villanueva and Blasetti (n 23) 5.} The substantive flexibilities are further categorised into a) the objectives and principles of the TRIPS in Articles 7 and 8\footnote{The importance of the Articles to public health and human development was analysed in Chapter II, subsection 2.5.4, and Chapter V subsection and sub-subsections of 5.3.} which emphasises the balance of IP rights between the IP producers and users on the one hand, and promotes the social welfare and public health goals of IP on the other, and; b) specific exceptions to patent rights that WTO Member states can adopt to enhance access to medicines.

From the standpoint of health, the flexibilities with particular relevance to patents are contained in the following Articles of the TRIPS Agreement.\footnote{Some of the flexibilities are considered in detail in the next section of this chapter.} Article 1(1) which allows Members the discretion to adapt and determine the appropriate method for implementing the provisions of the Agreement in their domestic laws; Article 6 which gives considerable freedom for members to define their own appropriate exhaustion regimes, thus allowing a wide mandate for the legal use of parallel imports;\footnote{TK Mirabile, ‘AIDS, Africa and Access to Medicines’ (2002) 11 Michigan State University-DCL Journal of International Law 175, 212.} Article 8 which empowers members to formulate and amend their IP laws and regulations in a manner that takes into account public health, nutrition and other issues of public interest, including the adoption of necessary measures; and Article 27 which allows members to exclude certain inventions from patentability where preventing the invention from commercial exploitation where it is necessary to safeguard and protect humans, health, animals, plant life or the environment. Other flexibilities are found in Article 30.
which grants members the latitude to provide limited exceptions to the exclusive rights conferred by patents, provided such exceptions do not unreasonably conflict with the normal exploitation of the patent or prejudice the legitimate interests of the patent right holder; and Article 31 which provide for the grant and use of compulsory licences and government use or authorisation of a patented invention in certain circumstances including the promotion public health and control of anti-competitive practices. Some of these flexibilities were reaffirmed by the Doha Declaration in 2001, as will be examined shortly.

The flexibilities, as a means of fostering access to affordable drugs have gained support in several international policy regulations and fora. For example, in 2001, the World Health Organisation (WHO) expounded on the strategic use of compulsory licensing, differential pricing through parallel imports as well as price control as mechanisms to ensure affordable access to patented medicines. Furthermore, the WHO and WTO published a report describing the role of the flexibilities in health policies. Legal remedies as tools for public health were also stressed in the resolution of the World Health Assembly (WHA) and the Report of the Commission on Intellectual Property Rights, Innovation and Public Health. Specifically, Resolution WHA56.27 urged states to adapt their national laws and implement the full use of the flexibilities in the interests of public health. A trilateral study by the WHO, World Intellectual Property Organization (WIPO) and WTO in 2013, reiterated the importance of implementing and using

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32 See summary at Sisule F Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?* (South Centre 2006) xv-xxxiii.
33 See the next subsection 6.4 in this Chapter.
34 Jeffrey Sachs, ‘Macroeconomics and Health: Investing in Health for Economic Development’ (World Health Organization 2001) 87-91, 127. The WHO however, emphasised the use of voluntary licensing by countries, the pharmaceutical industry, generic producers and other donor organisations to negotiate pricing and licensing for drug production in developing countries. ibid 89.
35 World Health Organization (WHO) and World Trade Organization (WTO), *WTO Agreements and Public Health: A Joint Study by the WHO and WTO Secretariat* (World Health Organization and World Trade Organization 2002).
37 World Health Assembly (n 36).
the flexibilities as policy options for states to pursue public health objectives and enhance access to medicines.\(^{38}\) These resolutions and reports give significant impetus to developing countries to apply and enforce the IP exemptions and provisions limiting the exercise of patent rights to protect and to promote their people's public health interests.\(^{39}\)

6.4 Enhancing the Use of the Flexibilities: The Doha Declaration

Over the years, the exact scope and interpretation of the flexibilities in the TRIPS Agreement has been the subject of acrimonious debates over interpretation and application in practice.\(^{40}\) One of the most notable disputes relating to patent rights and access to medicines in developing countries leading up to the Doha Declaration was the challenge against the South African Medicines and Related Substance Control Amendment Act no 90 of 1997 (Medicines Act) by large multinational pharmaceutical corporations.\(^{41}\) Prior to this, South Africa, a member of the WTO, was experiencing a crippling scourge of HIV/AIDS.\(^{42}\) Many South Africans did not have access to essential


\(^{39}\) See also the World Health Organization, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (World Health Organization 2011). The Declaration's importance for clarification has been tested in the decisions of national Courts. In *Novartis Pharma AG c/ Monte Verde S.A. s/ varias propiedad industrial e intelectual Causa No. 5.619/05 (Arg.), Cámara Federal de Apelaciones [CFed.] [Federal Appeals Court], 1/2/2011*, the Argentinian Court of Appeal had to determine whether Argentine Law No 24,766 (the confidentiality Act) which regulates the protection of test data, did not offer an effective data protection and was thus inconsistent with the provisions of Article 39(3) of the TRIPS Agreement. Novartis argued that Article 39.3 mandates a data exclusivity protection with regards to its product Gleevec\(^{®}\). The court confirmed that the country's law and TRIPS implementation regime was consistent with the provisions of the TRIPS Agreement and that the granting of data exclusivity rights is disallowed. In its ruling, the court relied on the Doha Declaration as an interpretive tool and held that the Declaration allowed for a 'flexible interpretation of that provision.' The court further used the right to health as a balancing factor by noting that the 'WTO Members are not only obliged to comply with the TRIPS Agreement, but also to respect their commitment regarding human rights.' As interpreted and quoted in Christophe Geiger, *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar Publishing 2015) 212; Carlos Correa and Duncan Matthews, 'The Doha Declaration 10 Years on and its Impact on Access to Medicines and the Right to Health' (United Nations Development Programme 2011) 19. Also available at undp.org/content/dam/undp/library/hiv/aids/Discussion_Paper_Doha_Declaration_Public_Health.pdf accessed 16 January 2016.

\(^{40}\) International debate by developing countries and developed countries centred on the exact scope and utilisation of the flexibilities to address public health needs. Musungu, Villanueva and Blasetti (n 23) xii.


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antiretroviral (ARV) drugs and vaccines. This problem was aggravated by the pricing policies of the pharmaceutical companies who held patents on most of the ARV drugs. In consideration of the health crisis, the shortage of drugs and the high prices of essential medicines in the public sector, the government amended the Medicines and Related Substance Act of 1965 in 1997, to make medicines more available and affordable and improve the public health of its citizens. For this purpose, the Act, among other things, gave the government power to override patent rights in pharmaceuticals for public health reasons, issue compulsory licences and make provisions for the parallel importation of patented and cheaper medicines. In particular, the Act was amended to include a new Section 15C to make medicines cheaper and more available from other lower-priced options abroad, through parallel importation.

This legislative policy, particularly Section 15C, was strongly condemned by some interest groups, particularly, the pharmaceutical companies who sought to set aside the implementation of the amended Act on the grounds that the Act was unconstitutional. They also argued that its provisions sought to deprive the owners of their property rights without compensation, contrary to section 25 of the South African Constitution. They further argued that the amended Act was a violation of their rights as prescribed in Article 28 of the TRIPS Agreement.

43 Fisher III and Rigamonti (n 42) 2. With an estimated average annual income of $2,600, many South Africans could not afford to pay for the necessary treatment which was about $1,000 a month. ibid 2.
44 ibid 2-3.
45 Medicines and Related Substances Control Amendment Act, No. 90 of 1997 (Medicines Act).
49 Pharmaceutical Manufacturers’ Association of South Africa et al v President of the Republic of South Africa (1998) Case No 4183/98, Notice of Motion in the High Court of South Africa (Transvaal Provincial Division) Paragraphs 2-9.
The case received the backing of the United States (US) which threatened sanctions against South Africa unless the amended provisions were repealed.\(^{50}\) In May 2000, the case was voluntarily withdrawn by the pharmaceutical companies after it attracted considerable international criticism and concern about the effect of IP on access to medicines.\(^{51}\) The outcome of this significant case galvanised attention on the effect of IP rights on access to medicines, their impact on human survival in general and the actions of pharmaceutical companies in particular.\(^{52}\) According to Professor Fisher III and Rigamonti, the case ‘[…] touches upon the more fundamental question of to what extent WTO Member States – in this context, primarily developing countries – should be free to take legislative measures to deal with public health crises and to what extent the patent protection of pharmaceuticals required under TRIPS should limit the range of options available.’\(^{53}\) Importantly however, the outcome of this case helped to clarify the scope of the flexibilities that can be used by developing countries. Significantly, the strong opposition by the pharmaceutical industry to the legislative decision exposed some of the inadequacy of the flexibilities contained in TRIPS as a leveraging measure for access to medicines and the challenges inherent in implementing the flexibilities.\(^{54}\) The dispute around the practical implementation and utilisation of compulsory licensing and parallel imports as flexibility options also triggered a


\(^{51}\) Ellen FM ‘t Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Power Drugs Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public* (AMB Publishers 2009) 21-22. The withdrawal was largely a result of pressure, campaigning and public advocacy by several international NGO's including Médecins Sans Frontières (MSF), Oxfam, and Treatment Action Campaign (TAC) that raised awareness and brought global attention to the issues of access to medicines. The campaigns raised concerns about the role that patent on pharmaceuticals, and actions of patent holders can play in exacerbating the problems of access to medicines. For more discussion on the role of the NGO’s in this case and other access to medicines campaign, see Matthews, *Intellectual Property, Human Rights and Development: The Role of the NGO’S and Social Movements* (n 42) 99-100.


\(^{53}\) Fisher III and Rigamonti (n 42) 13.

\(^{54}\) Ibid
global debate on what should be allowed in the interpretation and application of the TRIPS flexibilities, to respond to health crises.\textsuperscript{55} The focal point of discussions in this regard was how to ensure an adequate balance of promoting public health through the flexibilities, while at the same time, preserving patents as important incentives for research and development (R&D) of pharmaceuticals.\textsuperscript{56}

In another instance, in 2000, the US brought an action before the WTO Dispute Settlement Body (DSB)\textsuperscript{57} against Brazil over Article 68 of the 1996 Brazilian Industrial Property Law which enumerates conditions for compulsory licensing.\textsuperscript{58} The legislative measure by Brazil was aimed at increasing the provision of, and access to medicines, especially for people living with HIV/AIDS, in light of the patent protection of pharmaceutical products.\textsuperscript{59} The US complaint to the DSB was on the grounds that the ‘local working’ requirement for local production in Brazil in Article 68, violated the exclusive rights conferred to patent owners in Articles 27(1) and 28(1) of the TRIPS Agreement.\textsuperscript{60} The US argued that Article 68 discriminated against, and curtailed the enjoyment of, the exclusive rights of US patent owners in Brazil whose products were not locally manufactured but imported into Brazil.\textsuperscript{61} Brazil, on the other hand, argued that the provision of the


\textsuperscript{56} Fisher III and Rigamonti (n 42) 14.

\textsuperscript{57} Brazil — Measures Affecting Patent Protection (WT/DS199/1 G/L/385 IP/D/23 8 June 2000 (00-2254).

\textsuperscript{58} Law No. 9,279 of May 14, 1996, effective May 1997 (Industrial Property Law Act).

\textsuperscript{59} Matthews, Intellectual Property, Human Rights and Development: The Role of the NGO’S and Social Movements (n 42) 130.


\textsuperscript{61} ibid. The said Article 68 of the Industrial Property Law, No. 9.279, of May 14, 1996 as amended by Law 10.196 of February 14, 2001 provides that:

\begin{quote}
The titleholder shall be subject to having the patent licensed on a compulsory basis if he exercises his rights derived therefrom in an abusive manner, or by means thereof engages in abuse of economic power, proven pursuant to law in an administrative or judicial decision.
\end{quote}

The Article further lists the conditions for compulsory licenses including non-exploitation of the object or working of the patent within the territory of Brazil for “failure to manufacture or incomplete manufacture of the product,” insufficient commercialisation
Act is TRIPS compliant and Article 27(1) should be considered in light of Article 2(1) of TRIPS which incorporates provisions of the Paris Convention permitting local working of patents.\(^62\) The US complaint was later withdrawn and the dispute mutually settled by a bilateral agreement between the two countries after Brazil agreed to furnish advance notice if a licence was to be issued under Article 68 for patents held by US companies and any dispute is subject to discussion through a ‘Consultative Mechanism.’\(^63\)

Similar to the South African situation, this US complaint attracted considerable criticism and discussions globally on the impact of patent on affordable medicines for people in developing countries and the challenge to efforts by governments to ensure cost-effective medicinal solutions to their health crises, especially HIV/AIDS.\(^64\) These conflicts generated further international debate on the interpretation, use and scope of the TRIPS flexibilities particularly with regard to access to affordable essential medicines.\(^65\)

In the run-up to the Fourth Session of the WTO Ministerial Conference held in Doha, Qatar in 2001, the African Group, supported by other developing countries and civil societies, requested the Council for TRIPS to reconsider the issue of IP protection and access to essential medicines especially for people in

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\(^{62}\) Article 5A Paris Convention. Matthews, *Intellectual Property, Human Rights and Development: The Role of the NGO’S and Social Movements* (n 42) 133-134; Brazil also argued that the requirement for local working conditions only applied to issuances where it was necessary to curtail the abuse of patent rights and economic dominant position and power. ibid 134.


\(^{64}\) Duncan Matthews writes extensively on the campaign and activism of several NGO’s and other interest groups in the outcome of this Dispute Complaint. See Matthews, *Intellectual Property, Human Rights and Development: The Role of the NGO’S and Social Movements* (n 42) 133-146.

\(^{65}\) ibid; Musungu and Oh (n 32) 1.
developing countries. In particular, the African Group, which includes Nigeria, made proposals for separate declarations with regards to access to essential medicines in the light of health crises such as AIDS in Africa. At the same time, there were various publicity campaigns for a solution to health problems within the context of IP rights by a large number of activist, international organisations and civil society’s around the globe.

To clarify the challenges that arose out of the impact of patent rules on affordable essential medicines, and the related use of the TRIPS flexibilities, the ‘Declaration on the TRIPS Agreement and Public Health’ (Doha Declaration), was adopted by WTO Members in 2001 to interpret and give credence to the exceptions contained in the TRIPS Agreement. Significantly, to reiterate the right of WTO members to use the flexibilities, the Doha Declaration recognised the deficiencies of TRIPS for health and subsequently

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66 Correa and Matthews (n 39) 7.
68 For example, Zimbabwe as head of the Africa Group stated:
   
   We propose that Members issue a special declaration on the TRIPS Agreement and access to medicines at the Ministerial Conference in Qatar, affirming that nothing in the TRIPS Agreement should prevent Members from taking measures to protect public health.


69 Fisher III and Rigamonti (n 42) 15; Matthews, Intellectual Property, Human Rights and Development: The Role of the NGO’S and Social Movements (n 42) 133-146.
68 For a detailed negotiating history of and commentary on the TRIPS Agreement including the process leading to the adoption of the Doha Declaration, see United Nations Conference on Trade and Development (UNCTAD) and International Centre for Trade and Sustainable Development (ICTSD), Resource Book on TRIPS and Development (Cambridge University Press 2005). (Hereafter UNCTAD and ICTSD).
70 WTO Ministerial Conference: The Declaration on the TRIPS Agreement and Public Health (Adopted on 14 November 2001 WT/MIN(01)/DEC/W/2) (Hereinafter called the Doha Declaration for brevity). It is important to note however that the Ministerial Declaration is principally an interpretative instrument of the obligations contained in TRIPS, thus its binding effect is persuasive to the provisions contained therein and any dispute arising out of the TRIPS Agreement. Alan O Sykes, ‘TRIPS, Pharmaceuticals, Developing Countries, and the Doha ‘Solution’ [2002] Chicago John M Olin Law & Economics Working Paper No. 140, (2D Series) 10.
sought to clarify the TRIPS health-related reliefs so that developing countries could effectively utilise them to improve their health situation.\textsuperscript{71}

The Doha Declaration did not aim to create new safeguard policies for public health but set out to confirm and expatiate the flexibility options that members could adopt and implement in the interests of public health and access to drugs.\textsuperscript{72} Accordingly, ‘[…] we affirm the right of the WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.’\textsuperscript{73} In this connection, the Declaration also affirms that the TRIPS Agreement should not prevent countries from promoting their public health objectives.\textsuperscript{74} Thus in recognising the gravity of the public health problems and diseases affecting developing and least-developed countries such as HIV/AIDS,\textsuperscript{75} the Doha Declaration acknowledged that developing countries could enforce the IP exceptions and flexibilities in TRIPS, as public health safeguards to promote access to medicinal treatments.\textsuperscript{76}

Furthermore, Paragraph 4 of the Doha Declaration makes reference to the ‘implementation’ and ‘interpretation’ of the Agreement. It establishes a standard for the interpretation of the Agreement in the light of public health so that, in the event of ambiguity, dispute resolution panels and the Appellant Body could interpret the implementation of the Agreement in a manner that gives support to WTO members’ right to protect their citizen’s health and enhance their


\textsuperscript{72} Correa and Matthews (n 39) 7; Haochen Sun, ‘A Wider Access to Patented Drugs under the TRIPS Agreement’ (2003) 21 Boston University International Law Journal 101, 104.

\textsuperscript{73} The Doha Declaration Paragraph 3.

\textsuperscript{74} This health consideration was declared as follows by the Ministers of the 142 Members of the WTO (at that time):

\textit{We agree that the TRIPS Agreement does and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted in a manner supportive of WTO Members right to protect public health in particular, access to medicines for all.}

\textsuperscript{75} The Doha Declaration Paragraph 4.

\textsuperscript{76} The Doha Declaration Paragraph 4.
accessibility to medicines. Although the Declaration is not a formal interpretative authority of the TRIPS Agreement from a legal point of view, its provisions explicate the use of the flexibilities in the interest of access to medicines.

More specifically, the Doha Declaration addresses the issues aforementioned by clarifying that each WTO Member has the right to issue and use compulsory licencing to improve access to medicines and, at each Member’s discretion, determine the grounds for the granting of the licences. Thus the Declaration leaves room for more flexibility in the determination of the justifications for the interpretation and implementation of compulsory licences. The Declaration also reaffirms that members are allowed the discretion to determine the scope of what constitutes ‘national emergency’ and ‘other circumstances of extreme urgency.’ Furthermore, it clarifies that ‘public health crises’ are understood to represent a ‘national emergency’ and ‘other circumstances of extreme urgency’, which could be a short or long term problem. To remove any doubt, HIV/AIDS, malaria and tuberculosis health crises are explicitly recognised as a case of such an emergency or urgency. Paragraphs 5(d) of the Declaration clarifies that members can adopt an appropriate principle of exhaustion of rights and are


in the case of disputes [e.g. in the context of WTO dispute settlement procedures] Members can avail themselves of the comfort provided by this Declaration. Panellists are likely to take account of the provisions of the TRIPS Agreement themselves as well as of this complementary Declaration, which, although it was not meant to affect Members’ rights and obligations, expresses the Members’ views and intentions. Hence, the Declaration is part of the context of the TRIPS Agreement, which, according to the rules of treaty interpretation, has to be taken into account when interpreting the Agreement.


78 Correa and Matthews (n 39) 18.
79 The Doha Declaration Paragraph 5(b).
80 The Doha Declaration Paragraph 5(c).
81 The Doha Declaration Paragraph 5(c).
82 ibid
free to determine the rules and regime for ‘such exhaustion without challenge.’ Likewise, the Doha Declaration acknowledges the difficulties that developing countries would face in using the compulsory licences with little or insufficient manufacturing capacity and therefore direct the Council for TRIPS to expedite a solution for access to generic medicines by poor countries with limited drug manufacturing capacity by 2002.83

Finally, the Declaration ‘reaffirmed the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country [LCD] Members pursuant to Article 66.2. […]’ and extended the transitional period for LCD under Articles 66.1 to implement and enforce sections 5 (patents) and 7 (test data) of part II of the TRIPS Agreement until 1 January 2016 ‘without prejudice to the right of least-developed country Members to seek’ further extensions.84

6.4.1 The Relevance of the Doha Declaration to the Rights to Health, Life and Accessibility of Medicines

The Doha Declaration significantly brought about some positive changes to the effort of developing countries to gain access to medicines.85

The adoption of the Doha Declaration signalled an important achievement for developing countries to safeguard their people’s human rights and ameliorate the impact of IP and patent protection of pharmaceuticals on access to affordable essential medicines and alleviate urgent disease burdens.86 More

83 The Doha Declaration Paragraph 6.
84 The Doha Declaration Paragraph 7.
importantly, the Doha Declaration has given additional support to Members of the WTO to facilitate the availability of cost-effective medicines under patents in the interest of the rights to health and life of their citizens as identified in Chapter III.\(^{87}\) Furthermore, the Doha Declaration has also helped to focus international attention on the problems of availability and access to medicines as a result of IP rights on essential medicines.\(^{88}\) Civil societies and NGO’s have relied on the principles and provisions of the Declaration to advocate for access to medicines and procure ARV for HIV/ADS treatment programmes.\(^{89}\)

The commitment to the principles and importance of the Doha Declaration is also referenced in bilateral and multilateral agreements. For instance, the EU-Colombia-Peru FTA, in making reference to the importance of the exceptions and flexibilities in TRIPS to guarantee access to medicines, emphasises that parties to the FTA can amend or formulate their laws to the allowed use of the flexibilities as clarified in the Declaration.\(^{90}\) A ten year plus report by the Joint United Nations Programme on HIV/AIDS (UNAIDS) also indicates that the Doha Declaration has been instrumental in influencing policy change at both international and national levels, and that significant success has been recorded

\(^{87}\) See the articulation of the rights to health and life in Chapter III. Although the Doha Declaration has significantly clarified the legal scope and rights of members to adapt and utilise the TRIPS flexibilities to protect public health, the solutions proffered are still the subject of scepticism as a result of implementation and administrative difficulties, external pressures to undermine the flexibilities and lack of manufacturing capacity to utilise the flexibilities. Another significant problem for some developing countries is the lack of legal expertise and appropriate specialist technical assistance or capacity to assess and enforce the TRIPS legal exceptions. See more at Sangeeta Shashikant, ‘More Countries Use Compulsory License, but New Problems Emerge’ (2005) Third World Network Info Service on Health Issues No 2. Also available at <http://www.twn.my/title2/health.info/twninfohealth004.htm> accessed 7 Sept 2015; Correa and Matthew (n 39)19-30; Musungu, Villanueva and Blasetti (n 23) 20-21; Peter Drahos, ‘Developing Countries and International Intellectual Property Standard-Setting’ (2005) 5 The Journal of World Intellectual Property 765, 776.

\(^{88}\) UNAIDS (n 86) 4.

\(^{89}\) UNAIDS (n 86) 4.

\(^{90}\) Accordingly, ‘[…] in interpreting and implementing the rights and obligations under this Title, the Parties shall ensure consistency with this Declaration.’ Article 197(1), Trade Agreement between the European Union and its Member States, of the One Part, and Colombia and Peru, of the Other Part (Official EN Journal of the European Union Volume 55 21 December 2012). Also available at <http://trade.ec.europa.eu/doclib/docs/2011/march/tradoc_147704.pdf> accessed 16 July 2016. The importance of Doha was also stated in Article 147(b) of the Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part (Official EN Journal of the European Union 30 October 2008)
in the use of the TRIPS flexibilities to facilitate access to essential drugs since
the Declaration. While the Declaration cannot authoritatively repudiate the
express provisions of the TRIPS Agreement, it helps in interpreting the
provisions of the Agreement, especially when there is an issue of ambiguity in
the TRIPS provisions.

The Doha Declaration holds promise for enhancing the accessibility to health
treatments in Nigeria. Fundamentally, the reaffirmed flexibility of the TRIPS
Agreement in the Doha Declaration is crucial to the realisation of women’s
access to medicines as a right to health and the expansion of their human
development prospects. However, to maximise the use of the flexibilities to
address public health issues with regards to patent rights in Nigeria, there must
also be a proactive effort to fully incorporate and adapt the flexibilities and the
willingness to utilise the flexibilities to satisfy public health needs. Other
countries have recognised and incorporated the flexibilities as measures to
promote public health. Within the context of legislative policy for example,
Cambodia, citing the Doha Declaration, implemented a new patent legislation
that excludes patents for pharmaceuticals until 2016. The European
Parliament endorsed a commitment to the Doha Declaration in its Resolution on
the TRIPS Agreement and access to medicines, and asked the European
Council to ‘support the developing countries which use the so-called flexibilities
built into the TRIPS Agreement and recognized by the Doha Declaration in order

91 UNAIDS (n 86) 3, 37.
92 Correa and Matthews (n 39) 23.
93 Correa and Matthews (n 39) 12; Daya Shanker, ‘Access to Medicines, Article 30 of TRIPS in the Doha Declaration and an
94 Article 136, Law on the Patents, Utility Model Certificates and Industrial Designs, Kingdom of Cambodia. In its preparation for its
accession to the WTO at Cancun, Cambodia started adapting its legislation to WTO requirements.
to be able to provide essential medicines at affordable prices under their domestic health programmes.\textsuperscript{96}

Developing countries, including Cameroon\textsuperscript{97} and Ghana, have explored the TRIPS flexibilities, as clarified by the Doha Declaration, to enhance access to the medicines to ameliorate their citizens' health.\textsuperscript{98} Zimbabwe was one of the first countries to issue compulsory licences in 2002 for ARV medications after the Doha Declaration.\textsuperscript{99} In 2002, the Zimbabwean Government issued a notice (General Notice No. 240 of 2002) to declare an HIV/AIDS crisis and authorise the exercise of statutory compulsory licensing option.\textsuperscript{100} The public health crisis was declared for an initial period of six months but was subsequently extended to 2008.\textsuperscript{101} Notably, the Zimbabwe's health declaration exceeded the grounds in Article 31 and broadly authorised the ‘making’ and ‘importation’ of drugs, hence also allowing parallel importation of generic HIV/AIDS medicines to effectively enable the government or third parties to source medicines from other countries.\textsuperscript{102} Following the declaration, a compulsory licence was issued to


\textsuperscript{97} According to MSF, Cameroon has been able to access the other affordable international prices for ARVs because its Ministry of Health has authorised the importation of generic versions of patented drugs available at lower prices than the originator brands. As a result, the national procurement agency paid about US$277 for its first-line treatment combination at one of the lowest prices available internationally at that time. MSF, One Step Forward, Two Steps Back?: Issues for the 5th WTO Ministerial Conference (n 85) 3.


\textsuperscript{99} Musungu and Oh (n 32) x-xvi, 38-41; UNAIDS (n 86) 17.


\textsuperscript{101} Mushayavanhu (n 100) 153; UNAIDS (n 86) 17. The extension was expedient in light of the realisation that a six months’ timeframe was not enough to curb the scourge of the HIV/AIDS epidemic in the country, and the fact that the necessary medicines could not be secured within the six months period. Ibid 153.

\textsuperscript{102} See Section 2(b) of the General Notice No. 240 of 2002 (ch 20:3).
Varichem Pharmaceuticals (Pvt) Ltd in 2003 to import and ‘produce antiretroviral or HIV/AIDS related drugs and supply three-quarters of its produced drugs to state-owned institutions.’

Zambia followed suit in 2004, making an emergency declaration with reference to the TRIPS and the Doha Declaration for public health emergencies to issue compulsory licences for its HIV/AIDS crises. Interestingly, however, Zambia’s declaration, unlike Zimbabwe’s, indicated that it would only locally produce the ARV’s and HIV-related drugs for the domestic market and also prohibited exports. Zambia later issued a compulsory licence to Pharmaco Ltd to manufacture the ARV’s locally. It is uncertain if the local production condition served its intended purpose since there were issues relating to manufacturing capacity.

It can be argued that the Doha Declaration sought to act as a balancing mechanism between promoting trade and development through patent rights at the same time as promoting public health, since the key provisions in TRIPS were nebulous in guaranteeing the use of the flexibilities in TRIPS as health safeguards. Consequently, the Doha Declaration reiterates the need to balance the protection of IP rights and the social welfare objective of the TRIPS

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103 UNAIDS (n 86) 17. Subsequently, other companies were also authorised to import antiretrovirals from India.
104 See Preamble to the Statutory Instrument 83 of 2004. In Zambia, the national state of emergency was declared in Statutory Instrument 83 of 2004 known as the ‘Patents (Manufacture of Patented Antiretroviral Drugs) (Authorization), Regulations, 2004’ Regulation 3; UNAIDS (n 86) 17.
105 See the Declaration pursuant to Statutory Instrument 83 of 2004. UNAIDS (n 86) 17; Mushayavanhu (n 100) 156.
106 Mozambique also relied on a similar local production condition in 2004 to issue a compulsory licence for HIV generic medications. The Ministry of Commerce, Trade and Industry on September 21 2004 issued compulsory license No. CL.01/2004 for the production of lamivudine, stavudine and nevirapine ARV. The licence was granted to Pharco Ltd., a local producer, to produce a triple fixed-dose combination of the ARVs. A maximum royalty rate of 2.5% applied to the compulsory license. The Consumer Project on Technology (CPTech), ‘Compulsory License For Antiretrovirals, Zambia’ (Cptech.org) <http://www.cptech.org/ip/health/c/zambia/zcl.html> accessed 28 January 2016.
107 Mushayavanhu (n 100) 156; Poku Adusei, Patenting of Pharmaceuticals and Development in Sub-Saharan Africa: Laws, Institutions, Practices, and Politics (Springer 2013) 142.
Agreement as prescribed in Article 7 of the Agreement,\textsuperscript{108} in the interests of public health through ‘access to essential medicines for all.’\textsuperscript{109} Some scholars further argue that the affirmations of the flexibilities in the Declaration significantly highlight the primacy of public health and access to medicines over the private interests of IP rights owners.\textsuperscript{110} Of equal significance is the role of the Doha Declaration in echoing the human development goal of patents and the TRIPS Agreement as discussed in Chapter V.\textsuperscript{111} Paragraph 5(a) of the Doha Declaration states that:

\begin{quote}
In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.\textsuperscript{112}
\end{quote}

From a human development standpoint, this provision affirms that members can interpret the TRIPS flexibilities in a manner that takes into cognisance the public welfare and development aspect of TRIPS, as enshrined in the objective and principles contained in Articles 7 and 8 of the Agreement. This point supports the earlier discussion in Chapter II that a patent has a social welfare purpose and also, the argument in Chapter V that the TRIPS Agreement underlies a development objective.\textsuperscript{113} In this vein, the flexibilities could serve as additional measures to ensure that the rights granted to patent holders, and the obligations to the WTO do not interfere with the Nigerian Government’s duty to the right to


\textsuperscript{109} The Doha Declaration, Paragraph 4. Correa and Matthews (n 39) 8.


\textsuperscript{111} See subsection 4.4 of Chapter V.

\textsuperscript{112} (Emphasis added.)

\textsuperscript{113} See subsections 2.4 and subsection 2.5.5 of Chapter II.
health and development. It is imperative that Nigeria effectively utilise the TRIPS flexibilities within the maximum limit allowed in the Doha Declaration to facilitate better access to affordable medicines, to enhance the women’s and all its people’s human capabilities to meet the obligation to the right to health with regards to the patent protection of pharmaceuticals. To utilise the flexibilities effectively however, they must be incorporated into the national law of the country.

6.4.1.1 The Importance of Adopting the TRIPS Flexibilities and the Doha Declaration in Nigeria

Nigeria, as stated above,\textsuperscript{114} has yet to incorporate all the flexibilities into national law in spite of the fact that their benefits can only be utilised if they are appropriately incorporated into domestic law.\textsuperscript{115} The country’s lackadaisical approach to the implementation of the flexibilities is surprising since it is part of the African Group that actively sought to place the discussion of the effect of IPRs on access to treatments for the needy in developing countries on the agenda for the WTO Ministerial Conference. This half-hearted approach to the incorporation of the flexibilities is in direct contradiction to the government’s duty to secure the enjoyment of human rights to health and development, including the guarantees of access to affordable medicines in Nigeria through every reasonably available means such as the flexibilities. While there may be many reasons why the TRIPS flexibilities have not yet been transposed in Nigeria, with the right political will and legislative approach, the government and legislative authorities can effectively incorporate the flexibilities. Although implementation of TRIPS and the flexibilities only requires the actions of the law-

\textsuperscript{114} See subsection 6.2 above.
\textsuperscript{115} Musungu, Villanueva and Blasetti (n 23) 24.
making body in Nigeria and the executive’s assent, the process of making the law would require the necessary legal and technical proficiency to tailor the flexibilities to the national circumstances and development public policy objectives of the country. Even if the local expertise and skilled capacity to assess, adapt and utilise the flexibility provisions are absent, the state could employ or train specialists in this area, after all, the country as previously stated, is one of the richest in Africa by GDP per capita.

Incorporating the flexibilities into the domestic laws of Nigeria is however, the first step towards guaranteeing women access to medicines in the country. In addition to making all the requisite TRIPS flexibilities available in Nigeria to take advantage of them, the government, law and policy makers have an obligation to ensure that the available opportunities to protect public health and promote accessibility to medicines are not curtailed in the future. This point needs emphasis in the light of bilateral agreements, regional Free Trade Agreements (FTAs) and multilateral treaties that could truncate the broader use of the flexibilities, impose onerous conditions for use, extend the terms of pharmaceutical patent rights or impose higher standards that exceed the minimum obligations required by the TRIPS Agreement.  

Often known as ‘TRIPS-plus’, these bilateral and multilateral treaties and agreements negotiated outside the purview of the WTO could in effect, also prevent, limit or undermine the effective use of the flexibilities as measures to facilitate better access to pharmaceuticals. Correa explains that ‘[t]hese new free trade agreements negotiated outside the World Trade Organisation (WTO),


117 Musungu, Villanueva and Biasetti (n 23) 3, 30.
require even higher levels of intellectual property protection for medicines than those mandated by the TRIPS Agreement, and in some cases go beyond that required in the developing countries that are promoting them.\textsuperscript{118} Although some TRIPS-Plus agreements and treaties permit the use of flexibilities such as compulsory licensing and non-commercial (government use), they deter member states from resorting to them freely or restrict their use to a limited number of situations.\textsuperscript{119}

Examples of TRIPS-plus provisions include the increase of patent terms beyond twenty years to make up for delays in the patent examination and application process.\textsuperscript{120} Instances can be found in regional and bilateral trade arrangements such as the Chile-USA FTA,\textsuperscript{121} US-Jordan FTA\textsuperscript{122} and the US-CAFTA\textsuperscript{123} that

\textsuperscript{118} Carlos Maria Correa, ‘Implications of Bilateral Free Trade Agreements on Access to Medicines’ (2006) 84 Bulletin of the World Health Organization 399. Carlos Correa writes that in 2006, the US had initiated over eleven bilateral and regional free trade Agreements with over twenty three countries with many more under negotiation. A common feature of these agreements is TRIPS-Plus standards that exceed IP protection beyond the terms allowed in TRIPS. These could reduce access to medicines in developing countries more than in developed countries. ibid 399-400.


\textsuperscript{121} For example, the Chile-US FTA expands the protection of pharmaceutical products and protection of test data and undisclosed information beyond the TRIPS provisions. ibid 1-2.

\textsuperscript{122} One of the many extensions of such arrangements outside the TRIPS Agreement negotiated between US and Jordan is under Article 4.23 (a) of the US–Jordan FTA which states that ‘[w]ith respect to pharmaceutical products that are subject to a patent: (a) Each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process.’ This provision is in contrast to Article 17 of the 1999 Jordanian Patent Law which provides that ‘the term of protection shall be twenty years beginning from the date of filing the application for registration pursuant to the provisions of this law.’ Mohammed El Said, Public Health Related TRIPS-Plus Provisions in Bilateral Trade Agreements: A Policy Guide for Negotiators and Implementers in the WHO Eastern Mediterranean Region (World Health Organization, Regional Office for the Eastern Mediterranean 2010) 144.

\textsuperscript{123} The United States (US) and Central America Free Trade Agreement (CAFTA) in Article 15.10 (a) and (b) of the Agreement contains prohibitions or limits grounds for reliance on data submitted for marketing approvals of drugs for a particular period. According to Article 15.10 (a) for example,

if a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided such information, to market a product on the basis of (1) such information or (2) the approval granted to the person who submitted such information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party.

And under Article 15.10 (b), third parties (e.g generic producers) shall not rely on data submitted for marketing approvals in ‘another territory.’ Frederick M Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements' (2004) Quaker United Nations Office, Occasional Paper 14, 6-7.
expand the terms of IP protection beyond TRIPS provisions or limit the grounds for use of the flexibilities. Jordan, Saudi Arabia and Oman joined the WTO with TRIPS-plus obligations attached to their accession process. Others prevent marketing approval for generic drugs when the patent is still in existence or provide data exclusivity for pharmaceutical test data which could delay the introduction of cheaper generic drugs; expand the subject matter of patentability and impose the grant of patent rights for second or new indications of pharmaceuticals. Some TRIPS-plus agreements prohibit parallel imports or the exports of drugs obtained under compulsory licence or impose stringent export rules. Such bilateral agreements and treaties take precedence over the intellectual property rights (IPRs) contained in TRIPS, or limit the scope of the Doha Declaration and benefits of the TRIPS flexibilities. An evaluation report by Oxfam in 2006 concludes that developed countries have reneged on their commitment to the Doha Declaration by circumventing, weakening or undermining the flexibility provisions through bilateral and regional trade treaties. The report also states that the Doha Declaration has not been interpreted in a favourable light by pharmaceutical companies. Accordingly, pharmaceutical companies, especially those in developed countries, have changed tactics, from lobbying to bullying, in a bid to pursue stronger IP rules

126 Correa and Matthews (n 39) 21; MSF, One Step forward, Two Steps Back? - Issues for the 5th WTO Ministerial Conference (n 85) 3.
128 Rohit Malpani and Mohga Kamal-Yanni, Patents Versus Patients Five Years After The Doha Declaration (Oxfam International 2006) 1-6,13-18.
129 Ibid 20.
that could effectively affect the accessibility to medicines.\textsuperscript{130} This they do by lobbying their governments to impose TRIPS-plus rules and sanctions to seek stringent IP protection, enforce their patent rights by relying on TRIPS-plus rules and challenging the use of the flexibilities as health safeguards.\textsuperscript{131}

Consequently, Nigerian policy makers should ensure that any treaty or agreement they enter into does not contradict the state’s duty to guarantee the realisation and enjoyment of women’s human rights, including the facilitation of access to affordable medicines. Increasingly, scholars and treaty monitoring committees of the UN have called on states to assess and consider the impact of their trade agreements and treaty obligations on the cost and access to medications, and their obligations to human rights laws, particularly the right to health.\textsuperscript{132} Accordingly, it is important that the Nigerian government considers its duty to the right to health when negotiating or implementing the TRIPS Agreement or TRIPS-plus IPRs provision to secure women’s rights to the attainment of the highest standard of physical and mental health and human development through access to cost-effective life-saving health treatments.

In addition, with respect to pharmaceutical reproduction through the use of the compulsory licence and other research-related exemptions, a robust and viable pharmaceutical sector (particularly generic producers) is vital for the effective

\begin{flushleft}
\textsuperscript{130} ibid 20-21.
\textsuperscript{131} ibid 21-22.
\end{flushleft}
use of the flexibilities. Several factors are essential to local pharmaceutical manufacturing and production. They include: the availability of skilled and technical personnel; access to capital and investment; adequate infrastructure and drugs production capacity; adequate regulatory environment; access to effective and relevant technologies; and the availability of active raw materials and input materials. Absence of any of these may constitute a barrier to local production of affordable medicines in Nigeria through the use of the flexibilities.

In sum, before Nigeria can take full advantage of the TRIPS exceptions to increase access to affordable medicines, these and many more issues need to be addressed for a substantial impact. Consequently, appropriate policies, considerable capital, sustainable public funds and technical assistance are needed to promote the growth of the pharmaceutical sector, increase medicines production capacity and address other manufacturing issues so that Nigerians can adequately benefit from the flexibilities.

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134 Frederick M Abbott, Trends in Local Production of Medicines and Related Technology Transfer (World Health Organization 2011) 2; Musungu, Villanueva and Blasetti (n 23) 26.
PART III: THE PUBLIC HEALTH EXCEPTIONS AND FLEXIBILITIES IN TRIPS: TRANSLATING THE PROVISIONS TO NIGERIA

6.5 Incorporating the Flexibilities in Nigeria

This part further examines some flexibilities in detail and recommends ways in which the Nigerian state can take advantage of the TRIPS-compliant exceptions to facilitate access to essential medicines for its people, particularly its women.

As we have seen,\textsuperscript{137} effective utilisation of the flexibilities is dependent on some conditions: a) the incorporation of the flexibilities options into domestic legislation as a \textit{sine qua non} condition to the utilisation of the safeguards; b) the availability of a viable domestic pharmaceutical manufacturing capacity;\textsuperscript{138} and c) supplementary policies and the political will to utilise the flexibilities in a nuanced manner to bring the provisions to fruition.\textsuperscript{139} This study examines the extent to which Nigeria has satisfied the above-mentioned conditions under the current national patents law, and the efforts made to incorporate some of the flexibilities in the NIPCOM draft Bill of 2007. Specifically, the relevant provisions of the Bill are comparatively analysed with the existing provisions of the current Patents and Designs Act of 1970 (PDA) in force, to determine the extent to which such measures effectively respond to the TRIPS flexibilities to address public health needs in Nigeria.

\textsuperscript{137} In subsection 6.4.1.

\textsuperscript{138} In the absence of an adequate domestic manufacturing sector, states have the option of importing from other countries; however the advantage of a vibrant and dynamic local pharmaceutical industry for generic reproduction outweighs the requisite conditions and risk of importing counterfeits and substandard pharmaceutical products.

\textsuperscript{139} Gopakumar (n 133) 327.
6.6 Patentability Standards and Limitations on the Grant of ‘New or Second Uses’ of Old Patents as Health Flexibilities

Article 27(1) of the TRIPS Agreement is a general provision applicable to the patentable subject matter before the grant of patents. The Article states that the ‘patents shall be available for any inventions, whether products or processes, in all fields of technology,’ on grounds of novelty, inventiveness and industrial application. While this provision does not provide a definition for inventions or specify what constitutes ‘new’, ‘inventiveness’ and ‘industrial applicability,’ WTO members have the flexibility to determine their domestic standard for patentability, and also interpret this provision in a manner that facilitates access to medicines to all and protects public health in accordance with the clarification in Paragraph 4 of the Doha Declaration. Scholars suggest that this deliberate patentability latitude is an opportunity for developing countries to determine the exact scope of what constitutes an invention and thus members can exclude new uses of old pharmaceuticals from patentability criteria under their domestic laws. A new pharmaceutical use is either a ‘first pharmaceutical use’ (another medical indication) or a ‘second pharmaceutical use’ (second medical indication). The former instance is a new pharmaceutical use of a known substance, e.g., a first pharmaceutical application for an existing patent (which had no prior pharmaceutical use), while the latter is a modified use of an existing pharmaceutical or further discovery of a new therapeutic value for a previously known drug.

140 Osewe, Nkrumah and Sackey (n 67) 12.
141 Musungu, Villanueva and Blasetti (n 23) 14; Osewe, Nkrumah and Sackey (n 67) 12.
142 Musungu, Villanueva and Blasetti (n 23) 14.
143 Musungu, Villanueva and Blasetti (n 23) 14; Musungu and Oh (n 32) 60.
In some jurisdictions, patents are granted for a new version of an old drug, often on the ground that it has improved the efficacy of the old drug.\(^{144}\) An example of this is AstraZeneca’s heartburn pill, Prilosec, which was extended by a slight modification of the chemical structure and subsequently renamed Nexium.\(^{145}\) Shortly before the patent for Prilosec expired, AstraZeneca applied for an extension to the US Food and Drug Agency (FDA) on the grounds that Nexium was more effective than Prilosec.\(^{146}\) In effect, Prilosec, now Nexium, maintained its exclusivity thereby thwarting generics and the availability of cheaper versions of the drug.\(^{147}\)

Opponents of the patent standard allowing the new or second use of an existing patented article, argue that it does not confer enough significant therapeutic advantage over generic versions to warrant the grant of a patent monopoly right.\(^{148}\) Accordingly, the problem with allowing the grant of patents for modified versions of old drugs is that it serves the anti-competitive purpose of stifling generic reproduction of the drugs and consequently delays their introduction after the expiration of the patent term. In other words, it is a mere guise to extend the period of protection, exclusivity and monopoly, block the entry of

\(^{144}\) Carlos M Correa Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options (Zed Books Ltd 1999) 228.


\(^{146}\) Some commentators, including Ronald Grisant, claim that there is not much difference between Nexium and Prilosec. Apparently, both are proton pump inhibitors (PPI). Grisant explains that, ‘Prilosec is the original proton pump inhibitor that functions by disabling the protein in your stomach that pumps hydrogen ions (H+ ions) into gastric juices. Basically the PPIs can increase the pH of the stomach from 1 to 5. That means acid production is effectively ceased by these drugs.’ Ronald Grisanti, ‘Nexium Prilosec Epiphany’ (Functional Medicine University) <http://www.functionalmedicineuniversity.com/public/888.cfm> accessed 25 January 2016.

\(^{147}\) Harris (n 145).

cheaper generics and hinder legitimate competition, which could in turn impact on accessibility to the medicines.\textsuperscript{149} Known as the practice of ‘evergreening,’ Gervais reiterates the criticism that,

\begin{quote}
[It has become the common practice in the pharmaceutical industry to repackaging molecule (active ingredient) with known salts, metabolites, etc., in some cases with little if any advantage, to claim a new patent, one of the forms of “Evergreening” (prolonging of rent from otherwise out-of-patent branded medications).\textsuperscript{150}
\end{quote}

Although patents for such new use medical purposes or subsequent indications may be useful as rewards for incremental ingenuity and the promotion of the economic interest of patent holders for the minor improvement, it may not serve the overarching purpose of incentivising or indeed, promoting genuine R&D of essential pharmaceuticals. With respect to public health, extending patent terms could also impact on accessibility to affordable drugs. As examined in Chapter III,\textsuperscript{151} a patent’s monopoly right could potentially affect accessibility to medicines, where an already existing patent is extended on the grounds that it is a new improvement or second medical use, it may not necessarily confer benefit to public health, and it could, in fact, reduce affordable accessibility in the long run. Thus, where the patentability standard is too lax, there is a high possibility that many patents will be issued for minor incremental medicinal modifications with monopoly implications for the generic availability of affordable drugs and access to medicines.\textsuperscript{152} Also, patentees could take advantage of lax patentability provisions to surreptitiously extend their patent terms. This is particularly problematic in countries that lack proper substantive examination.

\textsuperscript{149} Chaudhuri, Park and Gopakumar (n 148); Thomas A Faunce and Joel Lexchin, ‘Linkage’ Pharmaceutical Evergreening in Canada and Australia’ (2007) 4 Australia and New Zealand Health Policy 1-2.
\textsuperscript{150} Daniel Gervais, ‘Patentability Criteria as TRIPS Flexibilities, Examples of India and China’ in Ruth L Okediji and Margo A Bagley (eds), Patent Law in Global Perspective (Oxford University Press 2014) 562.
\textsuperscript{151} See subsection 3.7.1 of Chapter III.
\textsuperscript{152} Musungu and Oh (n 32) 59.
process or expertise to ensure that the purported second indication is actually novel and inventive, and in the case of medicines, capable of conferring an incremental therapeutic benefit.

The approaches to the issue of new uses or indications for known inventions vary across countries. The US, for example, favours the new use patent approach in 35 United States Code (U.S.Code) § 101 which permits the patentability of ‘new and useful improvements’ of useful process, machine, manufacture, or composition of matter.\[^\text{153}\] Also, U.S.Code § 156 permits the extension of patent terms on specific grounds.\[^\text{154}\] A research report indicates that this liberal standard may not facilitate the production of drugs that provide significant clinical benefit.\[^\text{155}\] For instance, out of a total of 1085 new drugs applications approved by US FDA between 1987 and 2000, only 361 were found to be new chemical entities (NCEs).\[^\text{156}\] Conversely, in accordance with Article 53(c) of the European Patent Convention (EPC) (2000), Article 54(4) and 54(5) provide exceptions to the general rule in that a patent can only be granted to (absolutely) novel product claims or substance for use in a method. Article 54(4) does not exclude from patentability any substance or composition for use in a method of treatment that is comprised in the state of art provided such use is not part of the state of the art.\[^\text{157}\] Also, a substance or composition for a known ‘first medical use’ or purpose-limited product claim is permitted for a second and

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\[^\text{153}\] Musungu and Oh (n 32) 60-61.
\[^\text{155}\] The National Institute for Health Care Management Research and Educational Foundation (NIHCM) (n 145) 3. The report demonstrated that the FDA approved 674 Medicines (sixty five percent) containing active ingredients that were already existing in the market. ibid 3.
\[^\text{156}\] Estimate for drugs approved by the Centre for Drug Evaluation and Research. ibid
\[^\text{157}\] Article 54(4) states:
Paragraphs 2 and 3 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c), provided that its use for any such method is not comprised in the state of the art.

Lee (n 50) 111.
subsequent medical use in a method according to Article 54(5), provided the indicated medical use satisfies the criteria of novelty and inventiveness and has not been disclosed in the prior art.\textsuperscript{158}

Although not specifically required by the TRIPS Agreement, very few developing countries have explicitly excluded the possibility of patenting new or subsequent improvements and medical uses of known processes or products in their national legislation.\textsuperscript{159} Studies in 2010 and 2011 reveal for example that, at least twelve developing countries have specifically placed a limit on the grant of a new use for known products, however, the patenting of second uses and indications of pharmaceutical products and methods are allowed under the national laws of at least forty five developing countries including Nigeria.\textsuperscript{160} Many patent laws in developing countries merely list the patentability criteria of novelty, industrial applicability and inventiveness, without specifying whether the patentability provisions exclude or extend to the availability of patents for new uses of known substances.\textsuperscript{161} This lack of clarification could effectively allow further use of known patents.\textsuperscript{162}

The measures undertaken by India when amending its national legislation in accordance with the TRIPS obligations are commendable in preventing the practice of ‘evergreening’. In line with its constitutional protection of the right to life and health objectives, Section 3(d) of the 1970 India Patents Act (as

\begin{footnotesize}
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\item[\textsuperscript{158}]
Article 54(5) states:
Paras 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.


\item[\textsuperscript{159}]
Deere (n 48) 78-79; Correa and Matthews (n 39) 20-21.

\item[\textsuperscript{160}]
Correa and Matthews (n 39) 20-21; Deere (n 48) 78-79.

\item[\textsuperscript{161}]
Musungu and Oh (n 32) 35; Deere (n 48) 79.

\item[\textsuperscript{162}]
Ibid
\end{itemize}
\end{footnotesize}
amended), when setting out specific criteria for the grant of a patent, excludes the new forms of known substances. The section states that there is no patentability for:

‘the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.’

For emphasis, the section further exempts sixteen categories of inventions from patentability because they are not considered inventions for the purpose of enhancing efficacy. From a public health perspective, India did not rely solely on the patentability criteria in TRIPS but provided a broad exemption which excludes new forms of known compounds and substances, or mere discoveries including new purposes for any known substance, thus limiting the scope of patents to novel efficacious medical treatments.

A recent ruling by the Indian Supreme Court in the case of Novartis’s application for a new version of the drug, Glivec (known as Gleevec in other countries) gave impetus to this provision and drew support from opponents of

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163 Section 3(d) of the Patents (Amendment) Act, 2005 (Act No. 15 of 2005). Studies of patenting trend in India however indicate that patent claims for compositions and formulations are for a new use of a known substance that are not patentable under section 3(d) of the India Patents Act and sometimes disguised to obtained patents. Chaudhuri, Park and Gopakumar (n 148) 100-102; Correa ‘Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing’ (n 148) 10-11. For example, study by Sudip Chaudhuri, Chan Park and KM Gopakumar in 2010 indicated that significant claims for patents (sixteen patents, or nineteen percent of the study sample) ‘of patents reviewed were formulated as composition claims but were in fact ‘new use’ or ‘method of treatment’ claims ‘in disguise.’’ Chaudhuri, Park and Gopakumar (n 148) 100.

164 The section provides that:

For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Gopakumar (n 133) 334.

165 KM Gopakumar points out that this exclusion is based on a known substance which does not result ‘in the enhancement of known efficacy’, hence novel forms of existing products may be patented as long as they are not “mere” discoveries. Gopakumar (n 133) 334.
new uses of existing drugs and modification of old versions.\textsuperscript{166} Novartis approached the court to challenge the India patent office's decision not to register a product patent for a specific compound, the beta crystalline form of 'imatinib mesylate' used to treat chronic myeloid leukaemia (CML), on the grounds that the refusal was discriminatory, unconstitutional and a violation of India's WTO commitment to the TRIPS Agreement.\textsuperscript{167} The high court of Madras upheld the decision by the patent office, rejected Novartis argument on the grounds of vagueness and arbitrariness\textsuperscript{168} and clarified that the meaning of efficacy under section 3(d) is understood as 'the therapeutic effect' of a drug in the pharmaceutical field.\textsuperscript{169} The high court, commenting on the issue of constitutionality with regards to section 3(d) of the Patent Act, explained that the amended provision was an '[…] inbuilt measure to guide the Statutory Authority

\begin{footnotesize}
\begin{enumerate}
\item Novartis AG v Union of India (UOI) and Ors (2007) A.I.R 24751 (Mandras H.C). In January 2006, the Indian Controller of patent and Designs examined the mailbox application for Glivec, (imatinib mesylate, a beta crystalline form of the free base imatinib, and rejected the application based on the fact that the claim by Novartis did not meet the required standard of novelty and inventiveness or improved efficacy under section 3(d) of the patent Act.)
\item Novartis AG v Union of India (UOI) and Ors, paragraph 12, 14, 168 Novartis AG v Union of India (UOI) and Ors, paragraph 13. The crystalline form of imatinib mesylate was already included in Novartis earlier US Patent on the free base imatinib (US patent No 5521184, 1993) hence it was considered a prior art, devoid of novelty and inventiveness.
\end{enumerate}
\end{footnotesize}
Novartis appealed and the Supreme Court in April 2013 also upheld the patent office’s decision in ruling that the beta crystalline failed the test of efficacy in Section 3(d) of the Patents Act. The court further clarified that ‘efficacy’ means therapeutic efficacy; i.e. a patent applicant must not only show that a new form of known compound is different from an old form but also that the modification will result in an improvement in the treatment of the patient. The patent claim by Novartis therefore, failed under the test of invention and patentability as provided in clauses (j), (ja) of section 2(1) and section 3(d) of the [patent office] in exercising its power under the Act. Reiterating the point that there is no vagueness in the provisions of Section 3(d), the court added that ‘[w]e have also found that the amended section does not suffer from the vice of vagueness, ambiguity and arbitrariness. The Statutory Authority would be definitely guided in deciding whether a discovery is an invention or not by the materials to be placed before him by the patent applicant.’ On the issue of compatibility with TRIPS, the High Court declined to rule on the issue and instead suggested that the WTO’s Dispute Settlement mechanism is the appropriate forum to entertain such an issue.

Novartis AG v Union of India (UOI) and Ors, paragraph 18.
Novartis AG v Union of India (UOI) and Ors, paragraph 14. The court also pointed out that the legislative aim of the section was to ‘prevent evergreening; to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens.’ ibid Paragraph 12, and 19.
Novartis AG v Union of India (UOI) and Ors paragraph 6; Lee (n 50) 300. See also Martin Adelman and others, Global Issues in Patent Law (West Academic 2010) 43-47.
Novartis AG v Union of India (UOI) and Ors Civil Appeal No. 2706-2716 of 2013, paragraphs 189, 190, 191 and 195.
Novartis argued that its invention showed thirty percent more biodiversity (the level at which the drug is available in the human body), but the supreme court ruled the invention was anticipated based on the grounds that it could not distinguish between its new salt form and its old salt form (which was marketed) in terms of enhanced bioavailability.

The court further clarified on the issue of incremental innovation in paragraph 191 that:

We have held that the subject product, the beta crystalline form of imatinib Mesylate, does not qualify the test of Section 3(d) of the Act but that is not to say that Section 3(d) bars patent protection for all incremental inventions of chemical and pharmaceutical substances. It will be a grave mistake to read this judgment to mean that section 3(d) was amended with the intent to undo the fundamental change brought in the patent regime by deletion of section 5 from the Parent Act. That is not said in this judgment.
The decision of the court importantly laid a precedent for the interpretation of the intricate aspects of Section 3(d) with regards to the therapeutic use of known substances. It can be said that this judgment gives consumers an opportunity to pay for expensive patented drugs only when they result from novel innovations that confer substantial efficacy benefit to health or are the genuine and significant therapeutic advancements of old versions in limited circumstances. The court also made allowance for the availability of cheaper generic options at the expiration of a patent term by barring any extension does not satisfy the criterion of Section 3(d) of the Patents Act. Significantly, the therapeutic benefit of medicines to the public’s interest was taken into account in this case.

The ruling highlights the need to strike a balance between promoting R&D on the one hand and innovation with affordability that will lead to cures rather than merely repackaging known compounds on the other. This case also demonstrates how India approached the issue of balancing the interest of patentee’s to promote innovation and the public health objective of facilitating access to medicines. The verdict came at a time when the price of the patented drug was vastly higher than that of the generic version; as news reports estimated that Gleevec (or Glivec) can cost up to $70,000 a year, while the

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175 India Patents Act. The cited paragraph refers to the interpretation of Section 3(d) of the Patents Act.
176 It can be noted that the judgment gives consumers an opportunity to pay for expensive patented drugs only when they result from novel innovations that confer substantial efficacy benefit to health or are the genuine and significant therapeutic advancements of old versions in limited circumstances.
177 The court also made allowance for the availability of cheaper generic options at the expiration of a patent term by barring any extension does not satisfy the criterion of Section 3(d) of the Patents Act. Significantly, the therapeutic benefit of medicines to the public’s interest was taken into account in this case.
178 The ruling highlights the need to strike a balance between promoting R&D on the one hand and innovation with affordability that will lead to cures rather than merely repackaging known compounds on the other. This case also demonstrates how India approached the issue of balancing the interest of patentee’s to promote innovation and the public health objective of facilitating access to medicines. The verdict came at a time when the price of the patented drug was vastly higher than that of the generic version; as news reports estimated that Gleevec (or Glivec) can cost up to $70,000 a year, while the
cheaper generic version cost about $2,500 a year.\textsuperscript{179} The court’s decision, therefore, gave support to India to continue making and supplying the medicines to other parts of the world which rely on the generic industry in India, thus facilitating access to affordable medicines to treat life-threatening diseases such as cancer, tuberculosis, HIV/AIDS and other opportunistic infections.

\textbf{6.6.1 New Use Patents Provision in Nigeria}

In Nigeria, Section 1(1)(a) of the Patents and Designs Act (PDA) of 1970 sets out the patentability standard in a threefold test.\textsuperscript{180} Specifically, these indispensable thresholds for the grant of patents are: novelty, utility or industrial applicability, and inventive step or non-obviousness.\textsuperscript{181} The monopoly and exclusive rights accruable from the patent are only granted if these predetermined objectives and standards are met. These criteria are consistent with the text in Article 27(1) of the TRIPS Agreement; however, the 1970 PDA further makes explicit provision for the patentability of new discoveries or improvements of an existing patented invention, provided the new invention satisfies the patentability requirements of novelty, inventiveness and industrial applicability. In this regard, Section 1(1) (b) of the PDA stipulates that patentability is allowed if an invention: ‘[…] constitutes an improvement upon a patented invention and also are new, results from inventive activity and is capable of industrial application.’

Similarly, the Nigerian Intellectual Property Commission (NIPCOM) Draft Bill of 2007 in Article 105 contains the same provision of ‘improvement’ and new uses


\textsuperscript{180} The Act states that patents will be granted to an invention ‘[…] if it is new, results from inventive activity and is capable of industrial application.’

for known patents and but does not specifically define the term and criterion of ‘improvement.’ What these provisions mean is that the improvement of an existing invention that is deemed novel, inventive, and capable of industrial application is another criterion that will be considered for patentability.\(^\text{182}\)

From a public health perspective, the patentability standard to which this provision applies does not indicate whether the improvement is for a new use of a known substance or a second indication of a patented product, but it appears to allow for modified versions of older drugs, thereby potentially permitting hindrance to the timely entry of cheaper generic medicines. Scholars such as Musungu and Oh support this view and raise the concern that patenting provisions for new use or second indications limit access to medicines when new combinations, formulations and new chemical entries are granted secondary patent protection and used for anti-competitive purposes to extend terms of patents.\(^\text{183}\) Moreover, the criterion of ‘improvement’ of a prior invention is too lax, not well-defined and the extent of such improvement, whether slight or significant, is not specified. All the law requires is that it is novel, of inventive standard and industrially applicable. In essence, patents could be granted to any modified drug in Nigeria, no matter how slight the modification, as long as the new improvement meets the patentability criteria of inventiveness or is capable of industrial application. This is also without a proper investigation of whether the improved product and new version will substantially enhance health outcomes. The significance of an improved drug is less sustainable when an old medicine is used to treat the same disease or sickness but administered through a different dosage or form.


\(^{183}\) Musungu and Oh (n 32) 62-63.
The problem of extending improvements on existing patents is not restricted to the aforementioned circumstances. The absence of a substantive examination process before granting patents is another problematic feature of the patent system in Nigeria. Section 4 of the PDA provides that the Registrar will only examine the form, not the subject matter, of patentability. In particular, the applications are also granted without a consideration of the prior grant of similar inventions or inquiry as to whether the description and claims in the patent application satisfy the patentability criteria of Section 1 of the PDA or standard of improvement of a known invention. This limited administrative capacity and practice is a worrisome gap that potentially affects the quality of patents granted. The absence of an examination process could in effect, expand the scope of patentability to admit any and every frivolous incremental modification of existing versions, which could consequently impact on access to essential, cost-effective, generic drugs. The Nigerian system is comparatively different from the substantive examination process adopted in most developed countries. In the UK for example, all patent applications are substantively examined to check whether the invention is new and inventive enough, and provides a useful application to merit the grant of a patent. The examination is also to ensure that the application is in line with other legal requirements including disclosure and enablement. The advantage of this latter system is that innovations

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184 Section 4(1) states that:

[i]he Registrar shall examine every patent application as to its conformity with section 3(1), (3) and (4) of this Act.

185 Section 4 (2) provides that:

Where the examination mentioned in subsection (1) of this subsection shows that a patent application satisfies the requirements of section 3(1) and (3) of this Act, the patent shall be granted as applied for without further examination and, in particular, without examination of the questions-

(a) whether the subject of the application is patentable under section 1 of this Act;
(b) whether the description and claims satisfy the requirements of section 3(2) of this Act; and (c) whether a prior application, or an application benefiting from a foreign priority, has been made in Nigeria in respect of the same invention, and whether a patent has been granted as a result of such an application.


187 Ibid
registered for patents are examined to ensure that they are truly novel, inventive, industrially relevant, and are adequately disclosed. The issue with the current system of patent registration in Nigeria is that it risks allowing the patenting of almost any invention, as long as it satisfies the formal requirements of the law. As pointed out by Yankey, the main problem of this registration system is that it secures the patenting of unmeritorious inventions.\textsuperscript{188} Thus inventions which may not confer the purported techno-economic and social benefits to society or unduly hinder follow-on innovations are protected.

Nonetheless, Section 4(4) of the PDA provides that the grant of a patent is ‘without guarantee of its validity,’ at the ‘risk of the patentee’ and may be set aside at any time. Furthermore, under Section 9 of the PDA, any person, including a public officer, can apply to the court to set aside patents on the grounds that the subject matter is not patentable; the description of the invention does not conform to the statutory criteria in Section 1(2) of the PDA; or there is an existing patent. It is argued however, that this provision unnecessarily shifts the duty of patent examination and the validity of patent claim onto an already overburdened judicial system. If a patent application was properly examined before it was issued it would save the time and cost of litigation. On that note, it is extremely important to examine patent applications before the grant. A proper examination could prevent the issuance of questionable and trivial patents that grant unwarranted market monopoly rights to inventors which would in turn, hamper competition and unduly increase costs.\textsuperscript{189} This assessment measure would not only ensure that truly innovative patents are given protection; it would also save potential inventors the substantial administrative processing cost of

\textsuperscript{188} G Sipa-Adjah Yankey, \textit{International Patents and Technology Transfer to Less Developed Countries: The Case of Ghana and Nigeria} (Avebury 1987) 249, 253.

filing for a patent and consequently the cost of conducting expensive litigation to assert their claims.

6.7 Making Patentability Exclusions, Public and Morality Exceptions to Encourage Access to Medicines

Most analyses of the effective utilisation of the flexibilities as a means to health have focused more on limiting the exclusive rights of the patent holder; less attention has been directed to the issue of grant in the first place.\textsuperscript{190} The TRIPS Agreement allows countries considerable discretion regarding their approach to the patenting of certain products or processes contrary to public order and policy or morality. The TRIPS Agreement allows members some flexibility as to what they can exclude on these grounds, thus the provision gives a certain amount of leeway for Nigeria to define and apply a patentability criteria in line with public health interest and priorities and also, achieving its human development objectives. In the context of promoting women’s right to health in Nigeria, this flexibility is particularly important to improving access to medicines. Consequently, the country could adapt this provision by excluding inventions or methods that can impact adversely on health or stifle further pharmaceutical research, such as the patentability of human genetic materials, with its implications for access to cost-effective treatments.

Article 27(2) of the TRIPS Agreement is subject to two conditions: first, the patentability of an invention may be excluded to prevent the commercial exploitation of the invention if it necessary to protect public order and morality. Since patent offices generally cannot prevent the commercialisation of a product, the non-patentability exemption may not necessarily prevent the

\textsuperscript{190} Musungu and Oh (n 32) 58.
commercialisation. Therefore, it appears that another competent authority may be required to prevent the commercialisation of the invention, even if it is not under a patent if the purpose is to protect morality and the public.\textsuperscript{191} The role of the patent officials, however, is to decline the issuance of patent protection in accordance with the patentability criteria.

The second condition prohibits exclusions which are not based on Article 27(2) merely because it is not permissible under national domestic laws.\textsuperscript{192} The WTO overview to some extent attempts to define this by stating that the provision is for inventions whose commercial exploitation is prohibited to protect human, animal and plant life and not because the national law excludes an exploitation of the invention.

These provisions for exclusion of patentability (\textit{ordre public} and morality) under TRIPS are rather ambiguous and raise questions of practical enforcement in light of global differences in moral principles and norms. According to Correa, ‘the notion of morality and \textit{ordre public} are vague and their content will be dependent on national perceptions by patent offices and judges.’\textsuperscript{193} In other words, the provisions are so nebulous that it risks being the subject of protectionist abuse where members unduly restrict patentability on the grounds of their perceived notions of morality and public order; hence its use may be susceptible to frequent challenge by other members.\textsuperscript{194} Nevertheless, It appears that the interpretation of what constitutes morality will depend on national policy.

\textsuperscript{191} Carlos M Correa, \textit{Intellectual Property Rights, the WTO and Developing Countries: The TRIPS and Policy Options} (Zed Books 2000) 63.

\textsuperscript{192} ibid 63.

\textsuperscript{193} ibid 62.

concerning what conduct will be contrary to the core values of a society.\textsuperscript{195} It is clear, however, that states have the authority to refuse patent registration on the grounds that it will encroach on public health and societal moral values.

The disputes that have arisen in the breast cancer field illuminate many of the issues around patenting in modern pharmaceutical science and its implications for public policy, especially women’s access to medicinal treatments.\textsuperscript{196} The patent conflict that has accompanied the development and dissemination of treatment and diagnostic methods for breast cancer clearly illustrates the nexus between patent rights and the objective of ensuring an effective health regime for women. These disputes centre on patent rights for specific molecules with medical significance for the prevention, diagnosis, and treatment of breast cancer.

A well-known controversy in this regard is the patenting of the human gene in the US case of \textit{Association for Molecular Pathology v Myriad Genetics Inc.}\textsuperscript{197} The dispute was over the validity of Myriad’s patents for the discovery of the location and sequencing of \textit{BRCA1}\textsuperscript{198} and \textit{BRCA2} genes relating to breast and ovarian cancer.\textsuperscript{199} Myriad had successfully isolated the DNA sequences and methods to diagnose a propensity for cancer which, in turn, enabled the company to conduct tests for the detection of the mutation and methods to

\textsuperscript{195} Correa \textit{Intellectual Property Rights, the WTO and Developing Countries: The TRIPS And Policy Options} (n 191) 62-63.


\textsuperscript{197} \textit{Association for Molecular Pathology et al v Myriad Genetics Inc. et al} (2013) 569 U.S. 12-398. In Europe, diagnostic patent right was granted to Myriad but the scope of the right was narrower than the patent granted in the USA. Similarly, the High Court of Australia (High Court) in 2015 unanimously revoked Myriad’s three patent claims on isolated \textit{BRCA1} DNA, although the court adopted a different reasoning for its decision. \textit{D’Arcy v Myriad Genetics Inc} (2015) HCA 35.

\textsuperscript{198} According to the National Cancer Institute, ‘\textit{BRCA1} and \textit{BRCA2} are human genes that produce tumor suppressor proteins. These proteins help repair damaged DNA and, therefore, play a role in ensuring the stability of the cell’s genetic material. When either of these genes is mutated, or altered, such that its protein product either is not made or does not function correctly, DNA damage may not be repaired properly. As a result, cells are more likely to develop additional genetic alterations that can lead to cancer.’ National Cancer Institute, ‘\textit{BRCA1 & BRCA2: Cancer Risk & Genetic Testing}’ (National Cancer Institute, 2016) <http://www.cancer.gov/about-cancer/causes-prevention/genetics/brca-fact-sheet#q1> accessed 21 February 2016.

\textsuperscript{199} Surya Mani Tripathi, Neeraj Parnami and Santosh Kumar Pati, ‘Biotechnology and Intellectual Property Rights (IPRs)’ in Chander Parkash Malik, Chitra Wadhwani and Bhavneet Kaur (eds), \textit{Crop breeding and biotechnology} (Pointer Publishers 2009) 250.
identify drugs using isolated DNA sequences.\textsuperscript{200} The patents by Myriad gave it exclusive rights to isolate an individual’s BRCA1 and BRCA2 genes, synthetically create BRCA cDNA and conduct the mutation test.\textsuperscript{201} Because of the exclusive right, Myriad charged up to US$250-500 to screen for the occurrence of the mutation.\textsuperscript{202} Myriad’s monopoly enabled it to own patent testing which could only take place in their labs\textsuperscript{203} and control the test process, which also deprived women of other cheaper alternatives. Myriad also challenged the test offered by other labs without its licence or where a licence was given, strict conditions were attached to it.\textsuperscript{204} The patent effectively limited other researchers from conducting research into other treatments and medicines for women using the process, thereby stifling incremental innovation.

In the case before the US Courts, the petitioners argued that the patents were essentially a monopoly over the laws of nature and approached the court to invalidate the patents on the grounds of 35 U. S. C. §101.\textsuperscript{205} On June 13, 2013, the US Supreme Court in a unanimous decision ruled that Myriad’s patents for naturally occurring DNA segments was a monopoly for a product of nature and,  

\begin{itemize}
\item Mutations in those genes can dramatically increase a woman’s chance of developing breast or ovarian cancer. Thereafter, Myriad introduced BRCAnalysis\textsuperscript{\textregistered} the first commercial genetic test to detect mutations in the breast cancer genes. Kane (n 196) 329.
\item Myriad’s enforcement of its patent rights requires any licensees to submit clinical samples directly to the Myriad laboratory for testing, a result that has been criticised on scientific grounds because it unduly limits the development of multiple technical approaches to genetic testing. Kane (n 196) 329.
\item Kane (n 196) 329. For example, it was reported that researchers at the University of Pennsylvania who offered BRCA testing received cease and desist letters from Myriad, threatening litigation unless they took out a license to the Myriad patents. Williams-Jones (n 202) 136.
\item Association for Molecular Pathology v Myriad Genetics (n 197) 1 (Slip Opinion).
\end{itemize}
therefore, invalid for patent protection even if it has been isolated from nature.\textsuperscript{206}

Delivering the majority judgement, Justice Clarence Thomas said:

Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent.

But the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad’s patents “were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach, […]”.\textsuperscript{207}

However, the court held the cDNA patent was eligible because it is not naturally occurring.\textsuperscript{208}

This case illustrates some of the issues that can arise with regards to granting patents for claims that could impact on public policy and morality. This case demonstrates some of the healthcare effects that an improvidently granted patent can create in limiting research into diseases affecting women and increasing the cost of access to health care.\textsuperscript{209} This problem supports the argument that patent monopoly could impact access to health care and the development of a competitive market; hence it is important that the TRIPS flexibility excluding patents for certain pharmaceutical methods, therapeutic and medical processes on a public policy basis is given maximum consideration by

\textsuperscript{206} ibid (Opinion of the Court) 8–18. In a similar US related case of Prometheus v Mayo Collaborative Services Prometheus holds patents for methods of determining the optimal dosages of two drugs used to treat irritable bowel disorders. Mayo had purchased and used Prometheus’s tests but later announced it would use and sell a test it had developed ‘in-house’. Prometheus then filed against Mayo for infringement. Mayo argued that Prometheus’s patents were invalid as they fail the “machine or transformation” test.

\textsuperscript{207} ibid (Opinion of the Court) 17.

\textsuperscript{208} Association for Molecular Pathology v Myriad Genetics (Opinion of the Court) 10–18. The cDNA patent is for synthetically created DNA known as complementary DNA (cDNA), which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins. ibid 1 (Opinion of the Court).

\textsuperscript{209} Kane (n 196) 329–335.
the Nigerian government, lawmakers and the judiciary to expedite access to affordable medicines and health care.\textsuperscript{210}

The exact provision and interpretation of public order and morality under the national laws of other WTO members varies according to their public values.\textsuperscript{211} For instance, Article 1(3) of the UK Patent Act 1977 states that ‘a patent shall not be granted […] for an invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour.’\textsuperscript{212} Under the Guidelines for Examination of the European Patent Office for example, \textit{ordre public} is linked to security considerations, such as riots or public disorder, and inventions which may lead to criminal or other generally offensive behaviour.\textsuperscript{213} In the European Patent Office (EPO), an application for a patent may be rejected on the grounds of morality or public order in some exceptional cases.\textsuperscript{214} Article 53 of the European Patent Convention (EPC) excludes the commercial exploitation of inventions which are contrary to ‘ordre public’ or morality.\textsuperscript{215}

\textsuperscript{210}This is especially imperative in the issue of patenting biological material and the human genome. (It is noteworthy that a comprehensive discussion of the broader policy implication of gene patenting or bio-scientific research is outside the scope of this thesis; however, it is touched upon because of the argument that patenting genes could block the downstream research on that particular DNA or gene sequence and its consequential impact on public health.) For more discussion, see Myles W Jackson, \textit{The Genealogy of a Gene: Patents, HIV/AIDS, and Race} (MIT Press 2015).


\textsuperscript{212}Paragraph 3(b) - 3(e) of Schedule A2 to the Patents Act 1977 also identifies types of inventions whose commercial exploitation would be contrary to public policy or morality and should not be granted a patent, similar to types of invention which are listed in the Biotech Directive. Essentially biological processes for the production of plants and animals which are not micro-biological or other technical processes are excluded from patentability by virtue of Paragraph 3(f) of Schedule A2 to the Patents Act 1977.

\textsuperscript{213}Part C Chapter IV, 3.1.

\textsuperscript{214}Correa, Intellectual Property Rights, the WTO and Developing Countries: The TRIPS and Policy Options (n 191) 63.

\textsuperscript{215}Article 53 states: European patents shall not be granted in respect of:

(a) inventions the commercial exploitation of which would be contrary to “ordre public” or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

See also ibid 63.
Likewise Article 6 of the EC Biotechnology Directive\textsuperscript{216} exempts from patentability, processes modifying the germ line genetic diversity, processes of cloning humans and uses of human embryos for industrial or commercial processes from patent protection based on *ordre public* or morality grounds.\textsuperscript{217}

The jurisprudence of the EPO offers illustration into the interpretation of the provisions of morality and public order, particularly in cases with implication for medical research.\textsuperscript{218} The opinion of public majority or public abhorrence test was given consideration in *Howard Florey/Relaxin*.\textsuperscript{219} A group challenged the validity of a patent for the hormone *Relaxin*. They argued that the isolation of mRNA from the tissue of a pregnant woman and patenting of the human gene which relieves the uterus during childbirth to reduce the need for caesarean section in difficult pregnancies and offends Article 53(a) of EPC on grounds of morality and human dignity and fail to satisfy the criteria of patentability.

The EPO often employs two methods of analysis: the ‘balancing of interest at stake’ test; and ‘the public opinion of a vast majority of people’ to assess cases bordering on morality and public interest. ibid

\textsuperscript{216} Article 6 asserts that

Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(a) processes for cloning human beings;
(b) processes for modifying the germ line genetic identity of human beings;
(c) uses of human embryos for industrial or commercial purposes;
(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

\textsuperscript{217} This list of exceptions to patentability is not exhaustive (Rule 28 EPC). See European Patent Office, ‘Patents on Biotechnology European Law and Practice’ (European Patent Office 2014). Li (n 202) 353.

\textsuperscript{218} In the EU’s Transgenic animals/\textit{Harvard ‘Oncomouse’ case} (T0019/90 (Oncomouse) of 3.10.1990.), the balancing of public interests approach was adopted by the EPO to consider the advantages of endangering genetically modified transgenic mice engineered to develop tumours, thereby subjecting them to excessive inconvenience. The EPO Technical Board of Appeal Board subsequently weighed the balance benefits to humans and animals by subjecting the animal to suffering and concluded that ‘a likelihood - but no more than a likelihood - that such suffering is necessary to "trigger" the operation of Rule 23 (d) EPC’ ([Harvard/ Oncomouse (2005) OJ/EPO, 229, T 0315/03 paragraph 6.2.) Therefore a substantial medical benefit had to be demonstrated if there is any likelihood that the animal will be subjected to such suffering. (Paragraphs 10.5, 10.6 and 10.9.) See more at Intellectual Property Office, ‘Examination Guidelines for Patent Applications Relating to Biotechnological Inventions in the Intellectual Property Office’ (Intellectual Property Office 2013) 39.

Although the EPO Opposition Division upheld the grant of the patent in question, it applied the public majority test ruled that the [p]atenting of the DNA would indeed be abhorrent to the overwhelming majority of the public if it were true that the invention involved the patenting of human life, an abuse of pregnant women, a return to slavery and the piecemeal sale of women to industry’ and in this case Relaxin was not. While the EPO allowed the patenting of the DNA, it however, affirmed that patents would not be granted to inventions that are regarded as universally outrageous, although it is not clear which inventions would be so regarded as outrageous. Though the public stands to benefit from the innovative advancement of genomic research and novel practice in the isolation of gene sequences, it is useful to provide clarity and limit the instances in which patents are granted for important genes and life forms, particularly where the commercial exploitation would negatively impact on pharmaceutical research, patient access and medical care. This is because patents on genomics imply

On the issue of the patent in question, the EPO Opposition Division pointed out that DNA is not ‘life’, but a chemical substance which carries genetic information and can be used as an intermediate in the production of proteins which may be medically useful. The patenting of a single human gene has nothing to do with the patenting of human life. Even if every gene in the human genome were cloned (and possibly patented), it would be impossible to reconstitute a human being from the sum of its genes. The opponents apparently do not object to the patenting and exploitation for medical purposes of other human substances such as proteins (even the H2-relaxin protein). However, no moral distinction can be seen in principle between the patenting of genes on the one hand and other human substances on the other, especially in view of the fact that only through gene cloning have many important human proteins (for example, erythropoietin and the interferons) become available in sufficient amounts to be medically applied.

The decision was upheld on appeal in Relaxin/Howard Florey Institute (Boards of Appeal, European Patent Office T0272/95, 23 October 2002).

In a 2008 landmark ruling on stem cell cultures, the Enlarged Board of Appeal (EBoA) in WARF/ Embryonic Stem Cell Patents (G0002/06 (Use of embryos/WARF) of 25.11.2008) came to the conclusion that under the EPC, a patent cannot be granted for an invention which involves the commercial use and destruction of human embryos. The EBoA also considered the exploitation of the invention within the context of Article 53(a) EPC which excludes inventions from patentability if their commercial exploitation is against ordre public or morality, Rule 28(c) and the TRIPS Agreement in ruling that, ‘this use involving destruction is thus an integral and essential part of the industrial or commercial exploitation of the claimed invention, and thus violates the prohibition of Rule 28(c) (formerly 23d(c)) EPC.’ ibid paragraph 29. The EBoA however stressed that the decision does not cover all questions of patenting human stem cell, accordingly, it is important to point out that it is not the fact of the patenting itself that is considered to be against ordre public or morality, but it is the performing of the invention, which includes a step (the use involving its destruction of a human embryo) that has to be considered to contravene those concepts. Similarly, the European Court of Justice in Oliver Brüstle v Greenpeace eV, (C-34/10) judgment of 18 October 2011 ruled that Article 6(2)(c) of the EU directive excludes from patentability, inventions which requires the destruction of human embryonic stem cells. The patent in question is a process for transforming hES cells (derived from an existing cell line) into nerve cells. Greenpeace sought to have the patent revoked on the grounds that the patent for the hES cells are excluded from patentability by virtue of the morality provision in the Article (6) and (2) of the Biotech Directive. The ECJ held that ‘on the same grounds as those set out in paragraphs 32 to 35 above, an invention must be regarded as unpatentable, even if the claims of the patent do not concern the use of human embryos, where the implementation of the invention requires the destruction of human embryos.’ paragraph 49.
that it is the property of the company and the monopoly could in effect, hinder further medicinal research and innovation.\textsuperscript{222} On the other hand, even if researchers negotiated licences for the patents, the royalty payments could increase the cost of R&D which shifts the burden to the public.\textsuperscript{223} A survey by Professor Merz found that many of the respondents claimed they abandoned their research because of gene patents.\textsuperscript{224} This leads scholars Heller and Eisenberg to call this the problem ‘tragedy of the anti-commons’ for biomedical research.\textsuperscript{225} Accordingly, while patents could attract further incentives for R&D, the exclusive IPR could paradoxically restrict the use of biomedical materials and data and further stifle the R&D of life-saving health products.\textsuperscript{226} With regards to licensing agreements, the scholars noted that deadlocks and delays in negotiations of licences to use research tools and information, plus the high transaction costs of bargaining for multiple licences, could block creative research, particularly, academic research.\textsuperscript{227} The result of this problem is either

\begin{itemize}
  \item \textsuperscript{222} Jon F Merz and others, ‘Diagnostic Testing Fails the Test: The Pitfalls of Patents are Illustrated by the Case of Hemochromatosis’ [2014] 415 Nature 577, 580.
  \item \textsuperscript{223} Mrinalini Gupta, ‘India: Are Gene Patents a Hindrance to Innovation?’ [2013] Mondaq. Available at
  \url{http://www.mondaq.com/india/x/247166/Life+Sciences+Biotechnology/Are+Gene+pat+ents+a+hindrance+to+Innovation>}
  \item \textsuperscript{224} Merz and others (n 222) 580; Li (n 202) 363. Other studies suggest however, that biomedical research in general may not significantly be affected by gene patents (with only 1% reporting having to delay a project, and none abandoning projects due to patents), Timothy Caulfield and others, ‘Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies’ (2006) 24 Nature Biotechnology 1-8; United States Patent and Trademark Office, ‘Report on Confirmatory Genetic Diagnostic Test Activity’ (United States Patent and Trademark Office 2015) 18. Other commentators are also sceptical of the argument that awarding patents to subject matters of biotechnology may be tantamount to granting a property right over life. Accordingly, a patent right only confers market monopoly right to exclude competitors and ‘ does not provide any means of curbing the way the invention might be exploited beyond limiting the impact or scope of the monopoly. A patent is not a means to regulate or control developments in science, medicines, or industry.’ Waelde and others (n 219) 519. While patent is indeed a right that only entitles holders to exclude others from unauthorised access, the exercise of that right by the patent holders could in effect, constitute a potential barrier to innovation and patient access, for example, through licensing and infringement claims. Such market exclusivity rights and monopolies could consequently limit patient access and increase prices. Peter Border, ‘Biomedical Patents’ (2012) Parliamentary Office of Science and Technology POSTNotes 401, 4. Available at
  \url{http://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN-401>}
  accessed 17 July 2016.
  \item \textsuperscript{225} Michael A Heller and Rebecca S Eisenberg, ‘Can Patents Deter Innovation? The Anticommons in Biomedical Research’ (1998) 280 Science 698.
  \item \textsuperscript{226} ibid 698.
  \item \textsuperscript{227} ibid 700-701. There are however, other mechanisms and flexibilities which can be used to ease the way and ensure cost effective licensing arrangements such as patent pool, a licensing arrangement where two or more patent holders offer a joint license for their patents to each other or third parties. Third parties can seek a compulsory licensing where the patent holder refused to negotiate the licence on reasonable terms or work the patent. Border (n224) 4; Waelde and others (n 219) 521.
\end{itemize}
less availability of health treatments or higher costs of the scarce end-product. Hence, the need to control and where possible, exempt certain important biological materials or inventions that could impact on the availability and accessibility of essential medicines and medical services.

Articles 27(3)(a)(b) TRIPS further exempts the patenting of plants, animals other than micro-organisms including diagnostic and therapeutic surgical methods from patentability. The objective behind the exclusion of medical, surgical and therapeutic processes from patentability itself is to protect methods of medical treatments to ensure that everyone gets adequate and proper healthcare by medical practitioners without limiting the means of providing it. An example is the BRCA1 and BRCA2 breast cancer treatment test and diagnostic patent monopoly by Myriad, aforementioned. While innovative medical instruments and diagnostic methods/processes could have positive effects on medical research and treatments, monopoly rights for them could impede the R&D of new medicines or increase licensing/royalty fees and 'cost of healthcare', and therefore, access. Further, given the medical value in plant-derived pharmaceuticals and chemical substances from plants, excluding patents for plants themselves becomes necessary to facilitate the development of new products based on plants and plant derivatives. It is worth noting that this

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228 Heller and Eisenberg (n 225) 700-701.
229 ibid
230 27(3) of the TRIPS Agreement states:
Members may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.
However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.
231 See subsection 6.7.
non-patentability exception does not however, extend to plant varieties, devices or products.234

6.7.1 Patentable Subject Matter Exclusions in Nigeria

The Patent and Designs Act (PDA) of 1970 in Section 1(4) extensively excludes from patentability, plants and animal varieties or, essentially, biological processes for the production of plants or animals, and other microbiological processes and their products.235 This protection conforms to the patentability criteria of Article 27(3)(b) TRIPS.236 Notably absent from this exclusion is a consideration of inventions that could affect humans and health, although Section 1(4)(b) of the PDA further prohibits the patenting of inventions that are by themselves contrary to public order or morality. In consonance with TRIPS, Section 1(5) of the PDA exempts principles and discoveries of a scientific nature from patentability. However, other permissible important patentability exclusions that are relevant to public health such as ‘diagnostic, therapeutic and surgical methods for treatment of humans and animals’ found in Article 27(2) of the TRIPS Agreement237 are not clearly included in the provisions of the Nigerian 1970 PDA. Also, Article 27(2) of TRIPS allows the exemption of inventions ‘to avoid serious prejudice to the environment,’ which is notably absent under the current Nigerian PDA.

234 Correa, Intellectual Property Rights, the WTO and Developing Countries: The TRIPS and Policy Options (n 191) 6.7.
235 Section 1 (4) PDA states that: Patents cannot be validly obtained in respect of-
   (a) plant or animal varieties, or essentially biological processes for the production of plants or animals (other than microbiological processes and their products); or (b) inventions the publication or exploitation of which would be contrary to public order or morality (it being understood for the purposes of this paragraph that the exploitation of an invention is not contrary to public order or morality merely because its exploitation is prohibited by law).
236 Article 27(2) allows Members to exclude
   [f]rom patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
237 Article 27(3) states:
   Members may also exclude from patentability:
   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals.
Likewise, there is no clarification or even an illustrative category of what would constitute *ordre* public and policy or morality, leaving the determination open to the patent registration authorities or the courts. Nigeria’s approach to issues of patentability is unlike India’s patent law which specifically excludes inventions that offend public order or morality or ‘[…] which causes serious prejudice to human, animal or plant life or health or to the environment’ in section 3(d) of the Patent Act. Conversely, since there is no definition of what constitutes morality or public order, the Nigerian courts in the interests of the right to health, can interpret the provisions of the 1970 PDA to secure the protection of public health and improve access to medicines, like the above stated case of *Myriad*.

On the other hand, the earlier mentioned NIPCOM Draft Bill 2007 in Article 105 Bill specifically excepts the publication and exploitation of inventions on morality, and public order grounds and the exemption patenting of human, animals, plant life, and protection of health or anything ‘which are likely to be seriously prejudicial to the environment’ under Article 105. Article 105(5)(6) further excludes ‘diagnostic, therapeutic and surgical methods for treatment of humans and animals’ and principles and discoveries from patentability respectively. If passed into law, this provision could exempt the patenting of pharmaceutical inventions and medical equipment which are detrimental to the physical and mental health of women in Nigeria on the grounds of public policy and morality.

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238 Section 3(b) excludes from patentability, an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment.

239 See subsection 6.2.1 above.

240 Furthermore, the bill explicitly states that computer programs which are of a scientific and mathematical nature may not be granted patent protection.
In comparison to other countries however, the provisions in the NIPCOM Bill are inadequate for this purpose. There are no clearly stated categories or instances where an invention could be considered injurious to human health on the grounds of morality or protection of public order, leaving the provision vague and ambiguous. Rule 28 on Exceptions to patentability under Article 53(a) of the EPC and India’s Manual of Patent Office Practice and Procedure provide examples of inventions that are excluded on grounds of public morality and order, including the protection of humans and health. In India, examples of inventions that are injurious to health include pesticides or methods of adulteration of food. Interestingly, India’s IPAB in the previously stated case of Novartis AG v Union of India (UOI) and Ors also considered the possible health consequences of the grant of a patent to Novartis’s drug on the grounds of securing public order before rejecting the application. In reasoning, the IPAD emphasised that

[...] we also observe that a grant of product patent on this application can create a havoc to the lives of poor people and their families affected with the cancer for which this drug is effective. This will have disastrous effect on the society as well. [...] we observe that the Appellant's alleged invention won’t be worthy of a reward of any product patent on the basis of its impugned application for not only for not satisfying the requirement of section 3(d) of the Act, but also for its possible disastrous consequences on such grant as stated above, which also is being attracted by the provisions of section 3(b) of the Act which prohibits grant of patent on inventions, exploitation of which could create public disorder among other things.


242 As cited in Novartis Ag vs Union Of India & Ors (2013) CIVIL APPEAL Nos. 2706-2716 of 2013 (Arising out of SLP(C) Nos. 20539-20549 OF 2009) paragraph 19.
These legislative and judicial activisms are worth emulating by lawmakers in Nigeria. This development is important to adequately secure Nigerians’ human rights to health and life and enhance their human development by safeguarding their public health interests. The fatal effect of the 1996 meningitis drug trial by Pfizer in Kano, Nigeria, is a useful reminder of the need to safeguard Nigerians health interests in all aspects. During a clinical trial, 1000 children were given an experimental new oral antibiotic trovafloxacin (Trovan), and another 100 were given a substandard anti-meningitis treatment ceftriaxone.\textsuperscript{243} Five children eventually died from Trovan complications and six from ceftriaxone.\textsuperscript{244} Although this is not a patent-related case, the disastrous consequences of that drug trial raise public policy, morality and health issues. Moreover, the absence of a substantive patent examination system may mean that a similarly disastrous drug with devastating consequences for human health might be granted patent protection. Although this thesis is on promoting women’s access to medicines, through the lens of human rights, it is imperative that these medicines are safe for consumption, in addition to being available and affordable.

Having analysed two flexibilities as to the methods of implementing the TRIPS obligations, two flexibilities with regards to the substantive standards of TRIPS are now examined.

\textbf{6.8 The Compulsory Licensing of Patented Pharmaceutical Inventions: Securing Accessibility to Affordable Medicines}

The use of Article 31 of the TRIPS Agreement as a means to addressing health challenges is one of the more common ways in which the TRIPS flexibilities have been utilised. The Article, which permits the state to use or approve the

\textsuperscript{244} ibid
use of an invention ‘without authorisation of the rights holder,’ is another way for the Nigerian authorities and third parties to circumvent a patent right, facilitate generic competition and exploit a patented medicine in the public interest.\textsuperscript{245} In many jurisdictions, the non-voluntary or compulsory licence is granted by the relevant administrative or judicial authority to a third party to use the patent without the voluntary consent of the patent rights holder.\textsuperscript{246} Consequently, the patent holder is informed of the licence and adequate remuneration is paid.\textsuperscript{247}

Compulsory licensing has the advantage of ensuring an alternative supply of patented medicines, often at a reduced and cheaper price.\textsuperscript{248} Particularly as regards the adverse effect of a patent’s monopoly on the right to accessibility to cheaper pharmaceuticals, compulsory licensing is an important mechanism for driving down the prices of drugs by facilitating competition in the market and creating an avenue for one or more generic producers to produce the same drug, thereby benefitting consumers, promoting social welfare and enhancing the enjoyment of the right to health.\textsuperscript{249} The grant of a licence to one or more third parties to use a patented method or product can also enhance access, which could lead to incremental R&D in the relevant field and enable the development of new follow-on innovations.\textsuperscript{250} Thus, in addition to expediting access to existing technology and drugs, compulsory licences can reduce the

\textsuperscript{245} Article 31 of TRIPS.
\textsuperscript{247} Osewe, Nkrumah and Sackey (n 67) 15.
\textsuperscript{248} Correa, Implications of the Doha Declaration on the TRIPS Agreement and Public Health (n 77) 15.
\textsuperscript{249} UNCTAD and ICTSD (n 69) 487-488; Carlos M Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (OUP 2007) 313; CIPR (n 136) 45.
\textsuperscript{250} Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (n 249) 313.

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adverse effect of a patent’s monopoly right and positively impact on R&D as well as ensuring the ‘future flow of innovations.’

A joint study by the WTO and WHO has identified this flexibility as a balancing mechanism by which the TRIPS Agreement aims to promote innovation, R&D of new drugs and also ensure the availability of lower priced medicines. WTO members have the discretion to determine the grounds for the utility of this licensing flexibility subject to some conditions in the TRIPS Agreement. Notably however, Article 31 lists some permissible illustrative grounds for compulsory licensing such as: the use to ameliorate health conditions, ensuring an adequate supply of medicines in the event of national health emergencies or other circumstances of extreme urgency and as a remedy for an anti-competitive practice. Other possible grounds for the issue of compulsory licences are when the rights holder has refused to deal or to grant a voluntary licence for a reasonable commercial arrangement by the applicant; where the working of a new invention is dependent on existing patents; and ensuring the working of a patent.

Significantly, as earlier discussed in subsection 6.4, the Doha Declaration has also reaffirmed the rights of members to adapt, interpret and fully utilise the flexibility options in the TRIPS Agreement to protect public health. Thus compulsory licensing can be broadly issued for the protection of the public

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251 ibid 314. (Carlos Correa notes that the US has issued more than a hundred licences for various reasons including promotion of research in a relevant technical field, access to research results, technology information or know-how to other industry members etc). ibid 317.


253 Osewe, Nkrumah and Sackey (n 67) 15; Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (n 249) 314.

254 Article 31(b) TRIPS of the Agreement.

255 The German Patent Law of 1996 in Section 24 (1) and the patent law of the Republic of China in Section 51 provide for the grant of compulsory licences on this basis.

256 Article 31(1) TRIPS Agreement.

257 See the Doha Declaration Paragraphs 4 and 5.
interest and enhancement of public health and nutrition.258 In this connection, Nigeria and other developing countries can incorporate, suitably adapt and utilise this flexibility to enhance their citizens’ human development and promote their rights to health, which includes the access to affordable life-saving medicines. Thus, the flexibility is relevant to enhancing women’s right to health and expanding their human development and capabilities opportunities in Nigeria.

Another significant authority for the broad use of this flexibility measure in the interests of women’s rights to health in Nigeria is the earlier discussed Article 8 of TRIPS,259 which allows states to adopt all means necessary for the protection of public health and nutrition. Furthermore, Nigeria and WTO Members can utilise this licencing procedure to advance development goals and the public and social welfare aspects of patents and the TRIPS Agreement as discussed in Chapter V.260 With particular reference to the grant of compulsory licensing, since the Doha Declaration in Paragraph 5(b) reaffirmed the unquestionable rights of members to grant licences and ‘freedom to determine the grounds upon which such licences are granted,’ Nigeria and other WTO Members could compulsorily use or permit the use of a patented invention to control market monopoly practices by pharmaceutical companies, which can directly result in price increase and reduction of accessibility.

In South Africa, for example, this avenue for health was exploited to address anti-competitive practices, with record success for access to affordable

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258 Article 31(b) of the TRIPS Agreement. Musungu and Oh (n 32) 28-31. An example of such provision is Article L.613-61 of the French Patent Law which permits the responsible minister to grant ex-officio licenses in the event of insufficient quality and quantity or high cost of medicines. See Law No. 92-597 of 1 July 1992 on the intellectual property code (legislative part); Osewe, Nkumah and Sackey (n 67) 15.

259 See subsection 6.2.2 above and subsections 2.5.3 and 2.5.4 in Chapter II.

260 See subsection 5.4 of Chapter V.
medicines.\textsuperscript{261} It is also relevant in preventing acts that could impact indirectly on accessibility to essential medicines, for example, anti-competitive practices and abuse of patent rights which unduly restrain trade and affect the transfer of important health-related technologies.\textsuperscript{262} In another instance, licences were issued for anti-competitive purposes after an investigation of anti-trust practices and abuse of dominant market position by the relevant competition authorities in Italy.\textsuperscript{263} In 2006, a compulsory licence was also granted for GlaxoSmithKline’s product sumatriptan succinate (for migraine headaches treatments), after an investigation into the refusal to licence and other anti-trust related grounds.\textsuperscript{264}

Where a compulsory licence is granted to remedy anti-competitive practices in an adjudicated judicial and administrative process, Article 31(k) can be relied

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The complaint was against the anti-competitive practices of charging excessive prices for ritonavir, lamivudine, lamivudine and nevirapine by the corporations. GSK and BI were subsequently found to have abused their dominant market positions in contravention of the Competition Act of 1998. On December 10, the Competition Commission reached a settlement with GSK, and the final terms of the settlement mandated the firms to:

1) extend the voluntary licence granted to Aspen Pharmacare in October 2001 in respect of the public sector to include the private sector;
2) grant up to three more voluntary licences on terms no less favourable than those granted to Aspen Pharmacare;
3) permit the licensees to export the ARVs to sub-Saharan African countries;
4) permit the importation of the drugs for distribution in South Africa if the licensee does not have manufacturing capability in South Africa;
5) permit licensees to combine the relevant ARV with other antiretroviral medicines; and
6) Charge royalties of no more than 5% of the net sales of the relevant ARVs.

See Love (n 63).


\textsuperscript{262} Article 31(b) TRIPS of the Agreement. Correa Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (n 249) 313.

\textsuperscript{263} Italian authorities Autorità garante della concorrenza e del mercato (the AGCM) have granted compulsory licenses in a number of anti-trust and anti-competition related cases. ‘T Hoen, The Global Politics of Pharmaceutical Monopoly Power Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health (n 51) 44; Love (n 63).

\textsuperscript{264} On 26 March 2007, the AGCM also issued a licence to Italian manufacturers to produce active pharmaceutical ingredients after an investigation of abuse of dominant position. Grounds for the compulsory licence include the refusal to grant a voluntary licence by Merck & Co. Inc; thus the AGCM requested that Merck ‘grant free licences to allow the manufacture and sale in Italy of the active ingredient Finasteride and related generic drugs two years before the 2009 expiration of the Complementary Protection Certificate.’ The licence further enables export to ‘other European countries.’ Love (n 63). See more at AGCM, ‘A364 - Merck - Active Ingredients (Conclusion of Investigation)’ (Agcm.it 2007) <http://www.agcm.it/en/newsroom/press-releases/1096-a364-merck-active-ingredients-conclusion-of-investigation.html> accessed 22 February 2016.
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upon to waive the condition of prior negotiation with the patent holder. It appears also that the state could employ the compulsory licence measure if the patent holder does not respond to voluntary negotiations within a reasonable time or the conditions for the voluntary licence are improperly restrictive. Since compulsory licences are issued for a particular purpose of exploiting a patented invention and addressing public health, the purpose of use can be weighed against the conditions offered by the patent holder and, when they are onerous, a compulsory licence may be the best option to utilise the invention. Arguably, what is required is that the negotiations are on reasonable terms.

The case of Brazil illustrates this point. After exhaustive unsuccessful attempts to negotiate with Roche Laboratories, the Brazilian Health Minister made an announcement on 22 August, 2001 that it would issue a compulsory licence for the manufacture of Nelfinavir, owned by Roche, for the treatment of AIDS, to Far Manguinhos, a Brazilian pharmaceutical producer. On August 31, the Government and Roche came to an understanding that Roche would sell the drug at an additional discount of forty percent and Brazil would not grant the compulsory licence. This approach also indicates the persuasive effect of the compulsory licence flexibility. The threat to issue the compulsory licence played an active part in ensuring access to affordable medicines. In another instance, in 2005, the Brazilian government issued a decree for compulsory licences of the ARV drug Kaletra on the grounds of public health, following failed attempts to negotiate a price reduction of the drug with Abbott. The government also gave Abbot an option of reducing the price to avert the compulsory licence within a

266 As per Article 31(b) of the TRIPS Agreement.
268 Carlos and Matthews (n 39) 24.
specified timeframe. Subsequently an agreement to waive the licence was agreed upon by the government and Abbott, on the condition that the company would supply the drugs at a lower price.

Studies also indicate that the degree of achievement, and the efficacy of the TRIPS flexibilities as a means of increasing access to medicines, is largely attributed to the grant of compulsory licences. Practical examples of the use of compulsory licensing in other countries demonstrate the extent to which the flexibility can play a part in sustaining increased access to cost-effective medicines in Nigeria, especially in times of health crises. In April 2005, Guinea issued a licence for the importation of drugs to treat HIV-AIDS from generic sources; on 8 June, 2005, Eritrea, an LDC, granted a licence for generic production of HIV-AIDS medicines for non-commercial purposes. Similarly, the compulsory licensing option has been proactively explored by Latin American countries. Examples include the grant of a compulsory licence by Brazil in 2007, for the patented drug efavirenz (Sustiva), an essential HIV medication. Countries such as Argentina, Chile, and Ecuador have also explored the compulsory licensing option in the interest of the public’s

269 ibid
270 ibid
271 Musungu and Oh (n 32) 18-26.
272 Nigerian Law Intellectual Property Watch (n 98).
276 The health Minister announced that the government would issue a compulsory licence for Tamiflu. It transpired that there was no patent for Tamiflu in Argentina. Love (n 63).
277 Essential Inventions made a request for a compulsory licence to supply Glivec to Chile in 2004. Love (n 63).
278 Acromax, a local manufacturer, petitioned the patent office to grant a compulsory licence for the fixed-dose combination of Lamivudine (3TC) and AZT (sold under the tradename Combivir by Glaxo) in 2003. The request was rejected; however, Glaxo subsequently granted Ecuador preferential prices on all their HIV-AIDS medicines. Love (n 63).
access to medicines. In Asia, threats by Indonesia, Vietnam, India and South Korea to grant a compulsory licence, and possibly revoke the patent for oseltamivir (Tamiflu) resulted in an increased supply of influenza drugs. Indonesia has issued three licences: two in 2004 for Lamivudine and Nevirapine as HIV/AIDS drugs and one in 2007 for HIV drug efavirenz. In another instance, India granted a licence for Bayer AG’s anti-cancer drug ‘Nexavar’ and authorised generic production at low cost.

The grant of compulsory licences in the interest of public health is also popular in developed countries. For instance, in 2001, the United States, facing a health crisis, threatened to use the flexibility on Bayer’s patented Ciprofloxacin (Cipro) for the treatment of anthrax. The Italian competition authority Autorità Garante della Concorrenza e del Mercato (AGCM), in 2005 and 2008, issued licences for Merck Sharp & Dohme (MSD)’s antibiotics that uses the active ingredients Imipenem/Cilastatina. French authorities also considered the use of a compulsory licence for the pill Ru 486 and subsequently amended its laws to allow broader use of the ex-officio licence for breast and ovarian cancer

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279 Love (n 63).
280 ibid. In 2004, intellectual property authorities issued compulsory licences for 5 patents in Taiwan and in 2005, another licence was issued for patents needed to manufacture and sell the generic copies of Tamiflu. ibid
284 Love (n 63)
genetic diagnostic testing patents due to excessive prices and licensing restrictions.  

The examples above suggest that the compulsory licensing flexibility has been important to the effort to sustain access to essential medicines. Whether issued to third parties or for use by government authorities, evidently, the measure has facilitated access to affordable generic medicines and impacted policy approaches to public health issues.  

If appropriately used in Nigeria, the flexibility can significantly enhance women’s right to health and facilitate their access to affordable medicines.  

6.8.1 Conditions for Granting Compulsory Licences in the TRIPS Agreement  

While Article 31 of the TRIPS Agreement defines the scope, procedural nature and conditions for the grant of compulsory licence, the Agreement allows considerable room for establishing the parameters and interpretation of the conditions for granting of the licence at the national level. However, members cannot make laws granting compulsory licence for frivolous reasons or automatically grant licences for no apparent justification. For this reason, Article 31(a) states that each authorisation for granting of a compulsory licence should be considered on its merits. This means that every licence shall be granted or authorised for government use taking into consideration the merits of

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286 For example, in the Indian case of *Bayer Corporation v Natco Pharma Ltd*. Order No. 45/2013 (Intellectual Property Appellate Board, Chennai), the Intellectual Property Appellate Board (IPAB) reiterates that the significant point to be taken into account in the consideration of compulsory licensing procedure (in this case, section 84 of the India Patents Act of 1970 as amended in 2005) is whether the ‘public interest’ has been satisfied, and in this case, whether the patented drug was reasonably affordable to the public. Paragraphs 42 and 43 respectively. (The court held that ‘[a]fter all, the compulsory licence procedure itself is only in public interest.’)  
288 With the exception of semi-conductor technology.  
the application for the licence, the specific facts of each case, including the value of royalty to be paid.

Although Pires de Carvalho argues that compulsory licences are to be granted only in exceptional circumstances, where serious reasons warrant it, this argument may not be supported by Article 31(b) of the TRIPS Agreement.\textsuperscript{290} The Article stipulates that a licence may be granted for use where the proposed user has made efforts to obtain a voluntary licence from the rights owner. There is little to indicate that the proposed licensee is required to furnish exceptional reasons or serious grounds to apply for the compulsory licence. All that the TRIPS Agreement in Article 31(b) stipulates is that the proposed licensee made efforts to negotiate a voluntary licence from the patent holder on ‘reasonable commercial terms and conditions’ and that such conditions and authorisation had not been successful within a reasonable period. Admittedly, it is ideal to limit the granting compulsory licences to cogent and important reasons in the interests of a patent holder, however, arguing that the licence be limited to ‘exceptional circumstances’ or ‘serious reasons’ may be taking the interpretation of the provision too far.

The obligation for prior negotiation in Article 31(b) can be waived by members in the event of a national health crisis, an emergency or other extreme exigent circumstance; public non-commercial use; and remedying of an anti-competitive practice.\textsuperscript{291} In the event of derogation for reasons of national emergency and other circumstances of extreme urgency, the rights holder shall be duly notified as reasonably practicable.\textsuperscript{292} The precise definition of what will constitute

\textsuperscript{290} ibid 317.

\textsuperscript{291} Article 31(b) of the TRIPS Agreement; Carlos M Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement (n 249) 320.

\textsuperscript{292} ibid
‘national emergency and other circumstances of extreme urgency’ for the purpose of a waiver of prior negotiation is vague and may be subject to ambiguous definitions. This has however, been clarified in Paragraph 5(c) of the Doha Declaration allowing members to define a national emergency or circumstances of extreme urgency, as earlier discussed.\(^\text{293}\) Thus compulsory licensing can be granted without prior negotiation in the case of a sudden and unexpected health crisis requiring immediate relief.\(^\text{294}\) This clarification extends the measure to the duration of the crises.\(^\text{295}\)

The rights and authorisation granted under a compulsory licence — as established under national law — are non-exclusive and non-assignable.\(^\text{296}\) This means that the licensee cannot transfer or grant a sub-licence, except with that part of the enterprise or goodwill that uses it.\(^\text{297}\) The patent holder retains the right to exploit and use the patented invention and voluntarily licence same to third parties.

The exception in Article 31(h) also requires that adequate remuneration be paid to the right holder, having regards to the economic value of the authorisation. The TRIPS Agreement does not define what constitutes ‘adequate remuneration’ but it has been suggested that the Agreement leaves considerable room for it to be interpreted in line with the national objectives and laws of each member.\(^\text{298}\)

\(^\text{293}\) See subsection 6.4 above.

\(^\text{294}\) Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health* (n 77) 15-17.

\(^\text{295}\) Ibid 17.

\(^\text{296}\) The TRIPS Agreement in Article 31(d) and (e).


\(^\text{298}\) Ibid 322.
6.8.2 Challenges to the Use of Compulsory Licencing as a Health Safeguard Measure

While the TRIPS Agreement allows members latitude to define their licence regimes\textsuperscript{299} and the Doha Declaration\textsuperscript{300} further paved the way for the practical use of the flexibilities by elaborating the terms of national emergencies, the larger question of what the phrase ‘other circumstances of extreme urgency’ encapsulates has been left to the qualified discretion of states to determine. Unvaryingly however, the liberal discretion of states to determine their licensing regime opens up the risk of being the subject of either additional standards or retaliatory measures by developed countries should developing countries attempt to define and utilise this measure. This is demonstrated by the US bilateral trade agreements and treaties with some developing countries to limit or exclude the circumstances for the granting of compulsory licensing.\textsuperscript{301} An example can be found in the 2001 US-Jordan FTA which provides very specific requirements for the use of compulsory licences.\textsuperscript{302} In the FTA, compulsory licencing is restricted only to remedy an anti-competitive practice, in the case of public non-commercial use, or in the case of ‘national emergency’ or situations of ‘extreme urgency,’ although Article 31 of the TRIPS Agreement or Doha Declaration gives a wider discretion.\textsuperscript{303} An Oxfam International report in 2007

\textsuperscript{299} Subject of course to the general standard and principles of the TRIPS Agreement.
\textsuperscript{300} See subsection 6.4.
\textsuperscript{302} The US also signed bilateral agreements with Sri Lanka and Albania which limit the circumstances for the grant and use of compulsory licenses. Correa, ‘Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries’ (n 283) 1.
maintains that these TRIPS-plus rules may have contributed to an increase in
the overall prices of medicines between 2001 and 2006, and would result in the
delay or limited use of the TRIPS-guaranteed flexibilities to reduce the prices of
measures through unilateral trade sanctions such as the US Trade Law ‘Special
301’ mechanism, should countries exercise a broad discretion to define their
licensing regimes or challenge the enforcement of compulsory licensing
working provisions of Article 68 of Brazil’s Industrial Property Law before the
WTO’s Dispute Settlement Body, as discussed earlier.\footnote{See subsection 6.4 above.} Consequently,
developing countries may choose not to issue the licences in the interests of
exigent public health crises, to avoid retaliatory measures or the fear of
jeopardising future investment and technology transfer opportunities.\footnote{Carlos M Correa, ‘Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries’ (n 283) 1.} The end
result may be higher prices of medicines such as the aforementioned case of
Jordan, and therefore, less availability and access to medicines.

In light of the above, Nigeria needs to desist from signing up to TRIPS-plus
treaties and agreements that could restrict the use of this important compulsory
licensing option to improve women’s better access to cheaper medicines. While
these TRIPS-plus agreements and treaties hold the promise of technological,
trade or market concessions, the human rights obligation of Nigeria, as pointed

\footnote{Countries such as India, Argentina, Brazil, Taiwan, and Thailand have been the target of US ‘Special 301’ punitive trade sanctions. Several developing countries were also been placed on the ‘Special 301’ list by the US Trade Representative (USTR) for retaliatory punitive trade sanctions for several reasons, including the provisions on compulsory licences in their national laws or draft laws.}

out earlier, exceed the purported economic growth, technological benefits and trading relations that might result from the treaties and agreements. As Oxfam International advised, the case of Jordan is an important lesson for countries to be careful when signing up to TRIPS-plus agreements that can undermine the broad use of the flexibilities to improve public health.

Also, the right to improve healthcare through Article 31 of the TRIPS Agreement, is subject to some qualifying conditions that could make the enforcement easier in principle than practice for developing countries. For instance, Article 31(f) requires that a licence shall be granted ‘predominantly for the supply of the domestic market of the member authorizing such use’ except to remedy anti-competitive practice, as determined by a judicial or ant-competitive authority. Only a few developing countries such as Brazil, India, China, Mexico, Argentina and South Africa could boast of adequate pharmaceutical manufacturing capacity to adequately produce generic medicines under a compulsory licence. Moreover, even these countries also need drugs that cannot be locally produced. The requirement for domestic supply may have significant effect on countries with little or insufficient pharmaceutical manufacturing capacity. For these countries the best option would be to import from other countries, in which case, the other country has to exercise an equivalent

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308 See 6.4.1.1 of this chapter and subsections 4.9.1 and 4.9.2 of Chapter IV.
312 Reichman (n 274) 249.
313 ibid; Matthews, ‘WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?’ (n 311) 78.
compulsory licence.\textsuperscript{314} The conditions for granting of compulsory licences in Article 31(f), however, constitutes a major problem for the countries with little or no manufacturing capacity to produce the drugs as they cannot rely on supply from other countries who wish to export the relevant pharmaceuticals under compulsory licence or government use.\textsuperscript{315} Thus effectively, Article 31(f) creates an encumbrance to this assistance since the use of the licence must be used ‘predominantly’ in the domestic market of the authorising and manufacturing country.\textsuperscript{316} Matthews also observes that this provision brings an additional problem for countries lacking in administrative proficiency, technical and legal expertise to issue and use this flexibility measure.\textsuperscript{317} Invariably, the ability to meet health demands and address public health crises, and ensure access to medicines through export under a compulsory licence is constrained by this restricted exception. Nonetheless, a close reading of the language of Article 31(f) suggests that a country can permit the ‘non-predominant’ part of the production for export under a compulsory licence.\textsuperscript{318} The Doha Declaration in Paragraph 6 has however, recognised and proffered a solution to the foregoing legal glitch regarding the requirement of domestic supply.

6.8.3 The WTO Solution on the Implementation Challenges in Accordance with Paragraph 6 of the Doha Declaration

Following the directive given to the TRIPS Council to expedite a solution for members with insufficient or lack of manufacturing infrastructures under

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{314} ibid 78.
\item \textsuperscript{315} ibid; Correa and Matthews (n 39) 19.
\item \textsuperscript{316} Matthews, ‘WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?’ (n 311) 78; Correa and Matthews (n 39) 19.
\item \textsuperscript{317} Matthews, Intellectual Property, Human Rights and Development: The Role of the NGO’S and Social Movements (n 42) 25.
\end{itemize}
\end{footnotesize}
Paragraph 6 of the Doha Declaration, a temporary waiver of the obligations under Article 31(f) and (h) was negotiated by the WTO members meeting with the TRIPS Council, to allow the export of medicines under compulsory licensing. This Decision was endorsed by the General Council of the WTO of 30 August, 2003, and is known as the ‘Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.’ The chairperson of the WTO General Council also reiterated the public health purpose of the Decision to facilitate access to medicines.

Although the Decision does not strictly create new TRIPS flexibilities, it contains essential waivers to allow countries to import generic medicines from another member country under a compulsory licence. The first waiver exempts the exporting country from the export restriction in Article 31(f), for the purposes of producing pharmaceutical products; the second waiver allows an exportation under compulsory licence to eligible members and developing or least-developed countries in line with UN classification; and thirdly, the requirement

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319 Musungu and Oh (n 32) xxi-xxii, 68-70; Matthews, ‘TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements’ (n 10) 221.


321 Musungu and Oh (n 32) xxi-xxii, 70; Matthews, ‘WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?’ (n 311) 83.


323 Musungu and Oh (n 32) 69-70; Matthews, ‘WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?’ (n 311) 83-84.


325 ibid Paragraphs 2(ii) and 6. Essentially, only least-developed countries with little or no manufacturing capacities can take advantage of this Decision. Other countries wishing to utilise this system are required to prove that they lack the requisite manufacturing capacity. This proof is by indicating that they have no manufacturing capacity in the pharmaceutical sector or insufficient capacity to meet local needs and health crises. Peter K Yu, ‘Access to Medicines, BRICS Alliances, and Collective Action’ (2008) 34 American Journal of Law & Medicine 345, 346.
to pay adequate remuneration to the rights holder by the user (importing country) under Article 31(h) of TRIPS is waived. Only the exporting country is required to pay the requisite adequate remuneration to the patent holder. Where the medicine is under a patent in the importing country, the importing country will authorise a compulsory licence to import the generic version of the patented medicines. However, where there is no patent protection for the medicine or for least-developed countries that may not have made provisions for the patent protection of pharmaceuticals under their domestic laws, the importing country need not issue a compulsory licence. Equally, the exporting country will issue a compulsory licence to export the patented medicines to the importing country. To utilise this Decision for export, the exporting country must make provisions for it under national laws, as patent law does not generally allow for production for export under compulsory licence.

After another protracted round of negotiation, the temporary waiver was amended to a permanent relief on the 6 December, 2005. The amendment contains a qualified condition on the grounds of approval by a two-thirds majority

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327 Ibid.
328 Ibid, Paragraph 2; Musungu and Oh (n 32) 69-70.
329 Musungu and Oh (n 32) 69-70. The Decision sets out certain conditions for its use. First the eligible importing country is required to notify the WTO TRIPS Council of the intention to exercise the provisions of the Decision, and both countries must notify the Council of the grant of the compulsory licence to export and import the patented medicines. Paragraph 2, Decision of the General Council of 30 August 2003. If the importing country is not a LDC, there is an additional requirement to demonstrate the lack of or insufficient manufacturing capacity in a manner specified in the annex of the Decision. Both import and export countries are required to provide certain safeguard measures, such as anti-diversion mechanisms, to prevent the diversion or re-importation of medicine under compulsory licence to unintended destinations and markets. This measure should be reasonable and proportionate to the ‘administrative capacities and to risk of trading diversion.’ Paragraph 4, Decision of the General Council of 30 August 2003; Ibid. Correa writes extensively on the practical determination, implementation and interpretation of the provisions of the Decision. See Carlos Correa, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WHO/EDM/PAR/2004.4, 2004), WHO Department of Essential Drugs and Medicines Policy (2004).See also Musungu and Oh (n 32) 69-70.
330 Ibid.
of WTO members. Once two-thirds have accepted the change, it will formally be incorporated into the TRIPS Agreement. The original deadline of 1 December, 2007 was subsequently extended to 31 December, 2017.

Within the realm of the WTO, the Decision is another important means to promote public health objectives as the provisions can be interpreted and implemented to facilitate access to medicines for all. The success of this mechanism is exemplified in the first back-to-back export under a compulsory licensing by Canada to Rwanda under the Paragraph 6 Doha Declaration and WTO waiver to supply AIDS drugs. In 2007, Rwanda made a request to the WTO Council for TRIPS to import the HIV drug TriAvir (patented by GlaxoSmithKline) from Apotex, a Canadian company and that it would not enforce any patent right granted to the said drug. Having amended its law to allow export under compulsory licence, Canada also issued a compulsory licence to allow Apotex to utilise nine patents, including the manufacture and

332 Once two-thirds of members have formally accepted it, the amendment will take effect in those Members and will replace the 2003 waiver for them. For each of the remaining members, the waiver will continue to apply until that Member accepts the amendment and it takes effect.
333 ibid
335 Musungu and Oh (n 32) 72; Correa, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (n 329) 2, 12.

Canada had been at the forefront of efforts to facilitate access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries through the use of the compulsory licensing mechanism to promote access to medicines. For example, Canada overrode Bayer’s patents on ciprofloxacin, and authorized generic manufacture for purposes of building a stockpile as protection against an attack of certain strains of anthrax.
export of TriAvir to Rwanda, and subsequently notified the TRIPS Council of the decision and licence.\footnote{World Trade Organization, \textit{Notification under Paragraph 2(c) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Canada (IP/N/10/CAN/1, 8 October 2007).}}

Nigeria has not incorporated the provisions of the Council Decision of 2003 to allow exports under a compulsory licence into its national law. In contrast, some developing countries such as India have done so. India incorporated the provisions of the Decision into its amended Patents Act in 2005.\footnote{Harshita Mathur, ‘Compulsory Licensing under Section 92A: Issues and Concerns’ (2008) 13 Journal of Intellectual Property Rights 464, 465.} Under Section 92A of the Patents Act,\footnote{Section 92A(3) states that Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.} companies can apply for a compulsory licence to export patented medicines to countries that request it. An attempt has also been made to utilise this provision for the supply of medicines. In 2007, Natco Pharma Ltd filed an application to obtain a compulsory licence for two anti-cancer drugs, Sutent and Tarceva, under patent ownerships by Pfizer and Roche respectively.\footnote{Mathur (n 340) 465; Yamane (n 282) 327.} The application sought to manufacture and export the drugs to Nepal for public health reasons.\footnote{In \textit{Natco Pharm Ltd v Pfizer/Roche}. Racha Bakhr, ‘India Grants First Compulsory Licence Under Patents Act’ 3 Intellectual Property Magazine 46, available at <www.rouse.com/media/126620/india_grants_first_compulsory_licence.pdf> accessed 17 September 2016; Yamane (n 282) 327.} Subsequently, the Indian patent office organised a hearing with the interested parties based on the application and objection to the hearing of the application by Natco.\footnote{Yamane (n 282) 327; Shamnad Basheer, ‘Natco Vs Roche/Pfizer: Hearing on the Right to Hearing’ (Spicy IP, 2008) <http://spicyip.com/2008/03/natco-vs-roche/pfizer-hearing-on-right.html> accessed 23 January 2016; Shamnad Basheer, ‘Natco Vs Pfizer: Joe Mathew Reports on Compulsory Licensing Decision’ (Spicy IP, 2008) <http://spicyip.com/2008/07/natco-vs-pfizer-joe-mathew-reports-on.html> accessed 23 January 2016.} Citing the Doha Declaration, Natco argued for the right of developing countries to have access to affordable drugs. Natco contended that the generic versions of the drugs can be
manufactured at one-fifth the cost of the original patented drug.\[^{345}\] Although the application for compulsory licence was later withdrawn by Natco Pharma Ltd, the case could have laid a significant precedent that could clarify the procedural modalities for the grant and issue of compulsory licences to export drugs. India is one of the main suppliers of essential medicines to developing countries, thus a decision in this regard could open up practical avenues for the supply of affordable drugs by generic producers. Nonetheless, the application generated a positive outcome. Pfizer established a donor programme to deliver free patient assistance to two leading cancer hospitals in Nepal.\[^{346}\]

The progressive action by India to adopt the Decision is a positive policy action for enhancing the availability of and access to affordable medicines around the world that Nigeria could perhaps imitate, to assist other African countries and indeed, other developing countries around the world. Nigeria could also make provisions allowing the use of compulsory licenses from foreign sources.

### 6.8.4 Compulsory Licensing Provisions in Nigeria

Section 11 of the Nigerian PDA 1970 makes provision for the granting of compulsory licences for patented inventions.\[^{347}\] First Schedule, Part I to the PDA 1970 enumerates the grounds for the procedures and grants of a compulsory licence by the court. According to Paragraph 1 of the First Schedule, any interested person can make an application for compulsory licensing on the following grounds, namely:

a) the patented article is not being worked in Nigeria

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\[^{345}\] Mathur (n 242) 465.
\[^{346}\] Yamane (n 282) 327.
\[^{347}\] Section 11 PDA states:

The provisions of the First Schedule to this Act shall have effect in relation to compulsory licences and the use of patents for the service of government agencies.
b) the degree of working the patented invention does not meet the reasonable demands for the product

c) the working of the patented article is hindered or prevented by the importation of the patented invention

d) and, refusal by the rights holder to licence the invention on reasonable terms has unduly and substantially affected industrial and commercial activities in Nigeria.\(^\text{348}\)

Under Paragraph 13, First Schedule, Part I to the PDA, a compulsory licence on the authority of the Minister is also made available for patented inventions that are essential for the defence or economy of Nigeria or public health and the licence can be satisfied through importation.\(^\text{349}\)

With regards to the current Nigerian PDA, an application for a compulsory licence can only be made after a period of four years from the date of filing an application for patent or three years after the patent grant.\(^\text{350}\) This period obviously limits the timeframe within which a licence can be sought. It may be argued that this period of undisturbed monopoly is to secure the interest of the patent holder to exploit the invention since obtaining marketing approval or

\(^{348}\) The text reads further that

If an invention protected by a patent in Nigeria cannot be worked without infringing rights derived from a patent granted on an earlier application or benefiting from an earlier foreign priority, a compulsory licence may be granted to the patentee of the later patent to the extent necessary for the working of his invention if the invention-
(a) Serves industrial purposes different from those served by the invention which is the subject of the earlier patent; or
(b) constitutes substantial technical progress in relation to that last mentioned invention.

\(^{349}\) First Schedule, Part I Paragraph 13 states:

The Minister by order in the Federal Gazette may provide that, for certain patented products and processes (or for certain categories thereof) declared by the order to be of vital importance for the defence or the economy of Nigeria or for public health, compulsory licences may be granted before the expiration of the period mentioned in paragraph 1 above and may permit importation.

\(^{350}\) First Schedule, Part I paragraph 1 states:

Subject to this Part, at any time after the expiration of a period of four years after the filing of a patent application or three years after the grant of a patent, whichever period last expires, a person may apply to the Court for the grant of a compulsory licence [...]

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patent could take a period of about four to nine years. However, the TRIPS Agreement does not place an obligation on members to provide such a cooling period and there is no justifiable reason why a licence cannot be granted to provide affordable access to medicines when it is expedient to do so, for example, in health crises, until a minimum period of time has elapsed. Some countries, such as India, make an exception to a similar period in cases of national emergency, extreme emergency and public non-commercial use. In the absence of such provisions under Nigeria’s PDA, applicants have to wait until four years after filing date, or three years after the grant of a patent has elapsed to apply for a licence.

Further, Paragraph 1, First Schedule to the PDA confers a duty on the court to grant, manage and maintain compulsory licences. Thus the PDA makes the court responsible for the grant of a compulsory licence. In Paragraph 5 (a), for example, the court assesses and must be satisfied that the patentee has failed to grant a voluntary licence before a compulsory licence is issued to an applicant. In Paragraph 8, the court decides whether to grant the licence and also determines the terms and royalties on which to grant the licence. It is also the duty of the court to cancel or vary the terms of the licence under Paragraph 11. In light of the already overburdened Nigerian judicial system, this enormous duty on the court raises the issue of delay especially in situations of health crises and emergencies. These obvious gaps and issues limit the effectiveness of the flexibility as a mechanism for ameliorating health situations in Nigeria.

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351 Gopakumar (n 133) 340.
352 Ibid
353 Paragraph 5(b) offers guarantees satisfactory to the court to work the relevant invention sufficiently to remedy the deficiencies (or to satisfy the requirements) which gave rise to his application.
Provisions of the NIPCOM Draft Bill 2007 have attempted to remedy this position. The First Schedule Part I of the Bill provides for similar grounds for the grant of a compulsory licence but further expands the scope and procedural requirements on which the licence may be granted. Apart from the reasonable non-working, insufficient working and refusal to provide a licence for commercial purpose, the Bill prescribes additional specific grounds for anti-competitive practices and abuse of intellectual property rights; the public interests; a public health national emergency; nutrition; and the development of vital sectors including ‘that of ensuring access to medicines for all.’ Fundamental, the bill ensures that compulsory licensing is made available for patented inventions that are either not available to the public at affordable prices, or are of insufficient quality or quantity. These extensive grounds for the granting of compulsory licences are indicative of the progressive steps taken by the Nigerian legislature to address the problems of access to medicines; however, the NIPCOM Bill falls short of other standard requirements, such as providing an option for export to other developing countries with insufficient manufacturing facilities as is the case in India.

6.9 Public Non-commercial Use of Patents (Government Use)

The public non-commercial or government use of a patented invention is another effective means, akin to compulsory licensing, that WTO members can employ to safeguard public health and curb monopoly abuses of patent rights. Article 31(b) of the TRIPS Agreement recognises the public and non-commercial use of patents ‘by or for the government’s without obtaining the voluntary licence

355 Part 1, First Schedule (1) (a)-(j).
356 ibid
of the patent holder. While the non-commercial use measure is similar to compulsory licensing, it is distinguishable by the nature and purpose of use. The TRIPS Agreement stipulates that government use is restricted to ‘public non-commercial’ use, while compulsory licence extends to both private and commercial use of an invention, although the conditions set out in Article 31 generally apply to both compulsory licence and government use.

The most significant advantage of this exception over compulsory licensing is that it permits skipping procedural requirements, such as the waiver of negotiations and prior voluntary consent; hence it makes enforcement simpler and faster. In some jurisdictions, some patent laws allow government authorities to make use of a patented invention without the need to issue a compulsory licence for this purpose. Thus, it is a useful flexibility for Nigeria and other WTO members to fast-track the availability and affordability of medicines, especially in emergency situations. Importantly, it is a measure for Nigeria to meet its human rights to health obligations, circumvent pharmaceutical patent holder’s rights and encourage the generic availability of essential and affordable medicines, particularly for women, in Nigeria. Its other advantages are very similar to compulsory licences mentioned above, i.e working a patent, promoting R&D, controlling anti-competition and the remedying of the adverse effect of patent monopolies, and facilitating access to cheaper medicines, amongst many others. While the government does not negotiate with the holder

357 Gopakumar (n 133) 341.
358 Musungu and Cecilia Oh (n 32) 20-21.
359 Ibid 21. As per Article 31(b) TRIPS of the Agreement.
360 Musungu and Oh (n 32) 35.
361 See subsection 6.8 above.
on a voluntary basis to issue a licence in this regard, the patent holder is still entitled to compensation and may sue the government for remuneration.\textsuperscript{362}

Current state practice in several countries indicates that the provision for government use is broadly defined to cover general public interest such as national security, nutrition, health and development of vital sectors.\textsuperscript{363} In the US for example, the provisions of 35 U.S.Code 28 comprehensively permits the government or its authorised person to use patents on the basis of virtually any public use.\textsuperscript{364} Using this non-commercial flexibility measure, the Malaysian government also approved the importation of generic ARV medicines on the authority of section 84 (1) of the Patents Act of 1983,\textsuperscript{365} which empowers the government or its authorised third party to exploit a patented invention in the event of a national emergency.\textsuperscript{366} It is worth noting that the use was resorted to after price negotiations between the government and the patent holders were unsuccessful.\textsuperscript{367} This government use authorisation in Malaysia is indicative of the alternative steps to be taken when licensing negotiations have resulted in a deadlock.

An important question often raised with regards to government use is the scope and interpretation of the term ‘public non-commercial use’ since it is not precisely defined in the TRIPS Agreement.\textsuperscript{368} It appears that governments are given considerable latitude to determine the grounds and circumstances for such government use. Undoubtedly, therefore, domestic public consumption in

\textsuperscript{362} As per Article 31(b) of the TRIPS Agreement.

\textsuperscript{363} For example, Section 65 of the Singapore Patent Act 1994 (No. 21 of 1994, as amended).

\textsuperscript{364} Musungu and Oh (n 32) 36-37.

\textsuperscript{365} As amended as of 15 May, 2002

\textsuperscript{366} Sections 49-51 and 84 of the Patents Act No. 291 of 1983, as last amended in 2006, provides for the grant of compulsory licence and government use. ibid

\textsuperscript{367} Zimbabwe’s declaration of a public health emergency to facilitate access to HIV/AIDS drugs is another example of government use.

\textsuperscript{368} It appears that the exact scope and definition of ‘public non-commercial use’ is at the discretion of Members.
the interests of improving access to medicines will come under this provision. But for developing countries that rely on imported drugs due to a lack of or insufficient manufacturing capacity, this provision may not offer sufficient incentives for pharmaceutical manufacturers since the purpose of production is restricted to non-commercial usage, particularly in poor countries. In that case, the generic manufacturers may not earn economic incentives through commercial means. Another issue is whether the government can resell drugs through private channels after it has acquired the use for non-commercial purposes. Arguably, although not expressly stated, it appears that nothing in the agreement prevents governments from distributing drugs through private means to recover the cost of drug production and distribution to its people.369

A significant achievement for public health has been recorded in the utilisation of the non-commercial TRIPS-compliant safeguard by government authorities. In Ghana, for instance, the Minister for Health declared an emergency situation on HIV/AIDS and issued a government use licence for the importation of generic HIV-AIDS medicines on October 26, 2005.370 Thailand also applied provisions of Article 31 of TRIPS Agreement to regulate prices of medicines.371 From 2006-2007 the government has issued three licences for AIDS and cardiovascular drug treatments under the public non-commercial use provisions of the patent law.372

369 Gopakumar (n 133) 341.
371 In 2006, the Department of Disease Control issued a compulsory licence for Efavirenz, an HIV/AIDS drug. On January 24, 2007, another licence was issued for Kaletra, another HIV/AIDS medication. The next day, a licence was issued for Plavix, a heart disease medication. Pier DeRoo, ‘Public Non-Commercial Use’ Compulsory Licensing for Pharmaceutical Drugs in Government Health Care Programs’ (2011) 32 Michigan Journal of International Law 347, 359; Love (n 63).
6.9.1 Government Use of Patent in Nigeria

For the government's authorisation and use of patents in Nigeria, the relevant provision is found in Part II of the First Schedule to the PDA 1970. Paragraph 15 of the Schedule allows the use of patented articles or inventions for the service of government agencies. Under Paragraph 15, ‘any’ minister is conferred the discretionary powers to take over, and authorise a third party or his agent to use, patented inventions in the interests of the public. This provision broadly allows the government to use, sell, purchase or make any patented invention or grant a licence to a third party, after which the patent holder is notified of this action. The determination of the public interest is at the discretion of the Minister or his/her authority who can exercise this flexibility option to expedite access to affordable medicines. Moreover, Paragraph 23, Part II of the First Schedule, to the PDA explicitly clarifies that ‘articles’ includes—(a) any drugs or pharmaceutical preparations, substances or materials.’ Paragraph 20, Part II of the First Schedule further provides a list of possible situations where the government might use the patented article in the event of an emergency. They include, among others: use for ‘the maintenance of supplies and services essential to the life of the community’; or ‘for securing a sufficiency of supplies and services essential to the well-being of the community.’ It appears that, on

373 First Schedule, Part II Paragraph 15 reads:
Notwithstanding anything in this Act, where a Minister is satisfied that it is in the public interest to do so, he may authorise any person to purchase, make, exercise or vend any patented article or invention for the service of a Government agency in the Federal Republic.

374 According to paragraph 16,
The authority of a Minister under paragraph 15 of this Schedule may be given—
(a) before or after the relevant patent has been granted;
(b) before or after the doing of the acts in respect of which the authority is given; and
(c) to any person whether or not he is authorised directly or indirectly by the patentee to make, use, exercise or vend the relevant article or invention.

375 First Schedule, Part II, Paragraph 18.

376 Others are: d) the promotion of productivity of industry, commerce and agriculture; e) fostering and directing exports and reducing imports; or f) ensuring that the whole resources of the community are available for use, and are used in a manner best calculated to serve the interests of the community. First Schedule, Part II, Paragraph 20,
the authority of Paragraph 15 of the First Schedule, the Minister can extend the scope of these circumstances.

Since medicinal supplies, as discussed in Chapter III, are essential to the rights to health and life the non-commercial use flexibility can be utilised as an effective means to secure access to essential and cheaper medicines for women in Nigeria. A proactive use of this flexibility by the state is exemplified in Mozambique. The Mozambique health authorities in 2004, relied on its domestic government use provision to declare a health emergency and issue a compulsory licensing to Pharco Mozambique Lda for the local production of HIV/AIDS drugs to increase the availability and access to the medicines. An issue with the government use provision in Nigeria, however, is that the authorising power to exercise this use is vested in any government Minister. This provision may give rise to a great degree of uncertainty and unnecessary bureaucratic challenges regarding the actual government agency to execute this provision.

Paragraph 15, Part II of the First Schedule to the NIPCOM Draft Bill 2008 provides the basis for government use of patents. Importantly, the term ‘public interest’ is explicitly defined in Paragraph 15 to include: ‘national security, nutrition, health, environmental protection or the development of other vital sectors of the national economy […].’ Notably, the power to authorise use by the government is vested in one Minister (the Minister responsible for intellectual

377 See the argument in subsections 4.4 and 4.4.1 of Chapter IV.
378 In April 5, 2004, Mozambique’s Deputy Minister of Industry and Commerce issued a compulsory licence for Pharco Mozambique Lda, a local producer to override the patent rights and to manufacture lamivudine, stavudine and nevirapine as a fixed-dose combination. Royalties were not to exceed two percent of sales. (Article 70 of the Industrial Policy Code (Decree No 18/99 of 4 May) was amended for this purpose.) The Consumer Project on Technology (CPTech) ‘Compulsory Licenses’ <http://www cptech.org/ip/health/cj/recent-examples.html#Mozambique> accessed 28 January 2016.
property). This could curb unnecessary bureaucratic challenges in the issuance and use of the flexibility.

6.9.3.4 Are Compulsory Licensing and Government Use the Most Significant Flexibility Options for Enhancing Access to Medicines in Nigeria?

Activism by civil societies NGO’s, as well as scholarly analysis and literature on the flexibilities seem to focus mostly on compulsory licensing or non-commercial use by governments, as a means to ease the tension between patent monopolies and health. Clearly, compulsory licensing and non-commercial use are particularly favoured as a means of addressing health objectives, probably because it is adequate as a short-term measure of making drugs more affordable to consumers, working a patent and controlling abuses of patent rights. The question that needs to be asked is whether compulsory licence and government use are the only ideal solutions for the long-term goal of securing the objectives of the right to health by ensuring access to medicines. In other words, while the high price of patented pharmaceutical drugs dominates the argument for access to medicines, assuming the high cost of drugs is no longer an issue associated with patent monopoly, would the problems associated with patents as possible barriers to accessing medicines still constitute a challenge? The answer is, yes, because the problems of access to medicines extend beyond pricing to include lack of research into neglected diseases; re-engineering of old patents for new patents and, in some cases,


impediments to follow-on research, all of which can impinge on the availability of, and access to, medicines.

Undoubtedly, the compulsory licensing safeguard is important and can be significant to expediting access to cheaper medicines in Nigeria. It is argued, however, that Nigeria should not concentrate only on issuing compulsory licensing as the dominant means of ensuring the availability and access to affordable medicines. In the event of national emergencies, health crises or instances where patent encroaches on access to medicines, a compulsory licence is a flexibility best suited to facilitate quicker access to inexpensive drugs and control anti-competitive practices. However, a broader solution for access to medicines should extend beyond just making medicines available at a cheaper price, working patents or controlling anti-competitive practices. Without a doubt, the broad use of a compulsory licence for all the aforementioned purposes will enhance better access to medicines. However, considering the fact that compulsory licensing/government use is an exception rather than the rule, and its grant is subject to conditions, Nigeria is better off concentrating on other means of enhancing overall health objectives through the use of the flexibilities. Rather than focusing on a small fraction of the intended recipients in the event of compulsory licences, Nigeria should ensure sustainable access to medicines by exploiting other flexibilities such as the exclusion of patentability; limits on data exclusivity; and early working and experimental use exceptions, which have greater implications for R&D to boost the availability of medicines in the longer term.

That said, it is imperative that the Nigerian government and appropriate authorities broadly use and interpret the compulsory licence and non-
commercial government use provisions in compliance with the country’s’ human rights obligations to fulfil and promote the right to health, and facilitate access to medicines.

In closing, Nigeria is better off utilising the TRIPS-compliant flexibilities in a manner that will ensure long-term success, such as making sure the local pharmaceutical industry is well developed to meet the health demands of the population. When other flexibilities are utilised in ways that can develop local pharmaceutical capacity, the benefits to be derived from compulsory licensing through generic sources are correspondingly enhanced.

In this light, the following flexibility option can be explored as a more sustainable and lasting measure to encourage R&D for the availability and accessibility of pharmaceuticals in Nigeria.

6.10 Exploring the Early Working Exceptions and Flexibility Limiting Patent Rights for Pharmaceuticals Research and Experimental Use, to Encourage Access to Medicines in Nigeria

Generally, the rights conferred on patent holders by Article 28(1) of the TRIPS Agreement are not absolute in the sense that the state can limit the rights in the public interest. Article 30 of the TRIPS Agreement also provides for the limitation of the patent owner’s rights, which can be utilised by members to promote access to affordable generic medicines, and permit the use of patented inventions for research and experimental purposes without the consent of the right holder. Article 30 states:

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal

381 UNCTAD and ICTSD (n 69) 106.
exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

A plain reading of this test suggests that Members are given considerable discretion within specified conditions to interfere with and limit the exclusive rights conferred by a patent. From an access to medicines and human right perspective, Nigeria can rely on this provision to limit the effect of a patent’s monopoly on access and facilitate the availability of and access to medicines within the stated conditions in TRIPS.

Although the TRIPS Agreement does not define the nature, scope and extent of the ‘limited exception,’ Article 30 makes it clear that the exception is subject to a three-way test: the limitation a) must not unreasonably restrain the normal enjoyment of the patent right; b) must not unreasonably prejudice the legal rights of patentees; and c) must take into consideration the legitimate interests of third parties.\textsuperscript{382} Again, the scope and wording of conditions for the exceptions in Article 30 appear to be vague and the TRIPS Agreement does not elaborate on how these conditions can be satisfied.\textsuperscript{383} Nonetheless, it has been argued that they are independent conditions, yet each must relate to the other.\textsuperscript{384} This interpretation of the conditions was adopted and expounded by the WTO Panel in the \textit{Canada-Patent Protection of Pharmaceutical Products (Canada-Patent Dispute)} dispute settlement case, although the Panel unduly narrowed down the scope of the Article.\textsuperscript{385}

\textsuperscript{382} Musungu and Oh (n 32) 34.
\textsuperscript{384} Ibid
In this case, the EU instituted a complaint against Canada to challenge the legality of some provisions of Canada’s Patent Act such as Section 55(2)(1), relating to the development and submission of information for marketing approval of pharmaceutical products without the consent of the patentee, as a breach of Article 28(1) TRIPS. The EU also alleged that Section 55(2)(2) and 55(2)(3) of the Canadian Patent Act (together with the Manufacturing and Storage of Patented Medicines Regulations), which allows the testing of medicines six months before expiration of the patent and makes provision for production and stockpiling of the generic version for immediate release after patent expiration without the owner’s consent, was also in violation of the patent holder’s right under Article 28(1) and Article 33 of the TRIPS Agreement.

Canada counter-argued that its patent laws duly conformed to its obligation under the TRIPS Agreement as each of the provisions is in accordance with the ‘limited exceptions’ to the patent holder’s rights within the meaning of Article 30 of the TRIPS. Among other things, the dispute panel was invited to determine the scope and extent of the ‘limited exceptions to the exclusive rights of a patent’ and whether a limitation or violation of the patent holder’s rights can be justified under Article 30.

In its decision, the panel elaborated on the objective, scope and meaning of the provision in Article 30 of the TRIPS Agreement. The Dispute Panel, in clarifying the three-fold criteria and scope of Article 30 stated that ‘[t]he three conditions

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386 Paragraph 3.1, Canada-Patent Dispute.
387 Ibid
388 Paragraph 3.2, Canada-Patent Dispute.
389 Argument by the EU in paragraph 4.6 Canada-Patent Dispute. In sum, the Panel found that the regulatory review exception of Section 55.2(1) is a ‘limited exception’ within the meaning of Article 30 of the TRIPS Agreement.
390 The panel clarified the criteria as follows:
(1) the exception must be ‘limited’;
(2) the exception must not ‘unreasonably conflict with normal exploitation of the patent’;
(3) the exception must not ‘unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.’
are cumulative, each being a separate and independent requirement that must be satisfied. Failure to comply with any one of the three conditions results in the Article 30 exception being disallowed.\(^{391}\) The panel defined the terms ‘limited’ and ‘exception’ separately and took the position that ‘limited exception’ within the context of Article 30 connotes ‘a narrow exception — one which makes only a small diminution of the rights in question’\(^{392}\) and it is measured by the extent to which the patentee’s rights have been curtailed.\(^{393}\) On this basis, the Panel found that the stockpiling provision for generic production was not justifiable within the permissible limitations envisaged by Article 30 of TRIPS.\(^{394}\) Accordingly, there was no limit to the quantity of production for the purposes of stockpiling, thus it constituted ‘a curtailment of the exclusionary rights granted to the patent holders.’\(^{395}\)

The panel, however, found that Canada’s regulatory review proviso was justified under the limited exception condition in Article 30 of TRIPS. The panel justified this limitation on the grounds that the scope of the curtailment of the patentee’s rights was confined to the conduct necessary to satisfy the requirements of the regulatory approval process, thus it will not hamper the rights holders as it will be ‘small and narrowly bonded.’\(^{396}\) Accordingly, since the testing requirement is for the purposes of obtaining government’s regulatory approval, as long as it was for that reason and not commercial purposes, it was permissible under Article 30.\(^{397}\) In so doing, the panel gave authority for the Canadian government to allow the generic producers to conduct clinical trials and tests on a patented

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\(^{391}\) Paragraph 7.20, Canada-Patent Dispute.
\(^{392}\) Paragraph 7.20, Canada-Patent Dispute.
\(^{393}\) Paragraph 7.30, Canada-Patent Dispute.
\(^{394}\) Paragraph 7.32, Canada-Patent Dispute.
\(^{395}\) Paragraph 7.36, Canada-Patent Dispute.
\(^{396}\) Paragraph 7.34-7.36, Canada-Patent Dispute.
\(^{397}\) Paragraph 7.45, Canada-Patent Dispute.
product as a reasonable precondition for securing regulatory approval of a generic substitute for use upon determination of the patent production of drugs, before the expiration of the patent.

Nevertheless, the panel left many of questions open. For instance, although the problems of accessing affordable essential medicines vis-à-vis patent rights were raised several times in the submission of parties in the dispute, the panel did not comprehensively elaborate on the use of the ‘limited exception’ in Article 30 of TRIPS within the specific context of access to affordable medicines. Thus the opportunity to create a precedent for the use of Article 30 as a measure to facilitate access to affordable drug therapies by limiting the rights of the patent holder was lost.

Additionally, it also appears that the ‘limited’ condition, as elaborated by the panel, further narrowed down the scope of the exclusion of rights in Article 30 of TRIPS. The panel adopted a narrow view by stating that the word ‘exception’ in Article 30 implies a limit on the extent of the derogation, which is further narrowed down by the term ‘limited’. Therefore, the limitation in Article 30 ‘is

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398 For example, Canada argued that the legitimate interests of third parties under Article 30 of TRIPS took into account the need to ‘[…] protect public health – a value recognized in Article 8.1 of the TRIPS Agreement - through promoting access to cost-effective generic medicines following patent expiry and, in this connection, they took into account the legitimate interests of individuals, private insurers and public sector entities that financed health care in maintaining access to affordable medicines.’ Paragraph 4.0 Canada-Patent Dispute.

399 The panel, however, mentioned the importance of granting exclusive patent rights to holders when considering what ‘normal exploitation’ signifies thus:

The normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity. The specific forms of patent exploitation are not static, of course, for to be effective exploitation must adapt to changing forms of competition due to technological development and the evolution of marketing practices. Protection of all normal exploitation practices is a key element of the policy reflected in all patent laws. Patent laws establish a carefully defined period of market exclusivity as an inducement to innovation, and the policy of those laws cannot be achieved unless patent owners are permitted to take effective advantage of that inducement once it has been defined. Paragraph 7.55 Canada-Patent Dispute.

400 The panel provided an interpretation of what “limited” means in Article 30 thus:

The word “exception” by itself connotes a limited derogation, one that does not undercut the body of rules from which it is made. When a treaty uses the term “limited exception”, the word “limited” must be given a meaning separate from the limitation implicit in the word “exception” itself. The term “limited exception” must therefore be read to connote a narrow exception - one which makes only a small diminution of the rights in question.
to be determined by reference to the limitation of the exclusive rights granted under Article 28 of the TRIPS Agreement rather than by the economic impact of the exception, which is examined under the other conditions of Article 30 of the TRIPS Agreement.’ Scholarly analysis of this decision indicates disappointment that the panel unnecessarily whittled down the permissible scope of the exception for health and access to medicines and limited the discretion given to members to define their national objectives.401 For example, an interpretation of the narrow scope of the panel’s decision will not permit the use of the exception to produce and stockpile a large quantity of medicines for distribution to a large part of the population in the interest of public health. Hestermeyer rightly argues that the panel’s narrow interpretation ‘would not permit an exception under Article 30 that could meaningfully enhance access to medicine in the developing world, such as a governmental non-commercial use permitting the Government to produce the medicine and to provide it to large parts of the population.’402

The panel should have considered this limited exception in light of the general principles and objectives of the TRIPS Agreement as prescribed in Articles 7 and 8, instead of relying on the literal definitions of ‘limited’ and ‘exception’ to determine the extent to which the state could derogate the patentee’s rights.403 The TRIPS Agreement is more than an instrument that confers rights to the patent holder; it is a regulator of rights and obligations of patent holders and users. It can be said that the flexibility provisions of Article 30 TRIPS Agreement


403 According to Hestermeyer, ‘the panel’s reliance on the narrow scope of exceptions is in direct contradiction both to a statement by the Appellate Body that the mere characterization as an exception does not in and of itself justify a narrower interpretation of a provision and to the principle of in dubio mitius.’ ibid 234.
corresponds with the objectives and principles in Articles 7 and 8 of the Agreement by ensuring that the protection of private patent rights is balanced against the public interest.\textsuperscript{404} It is argued that one of the purposes of Article 30 is to give the state a greater flexibility to limit the patent owner’s rights, when it is expedient to do so to achieve the balance of rights and obligation between ‘producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.’\textsuperscript{405} It is worth noting that the panel in the Canada-Patent Dispute case stated that the aim of Article 30 is not to ‘renegotiate the basic balance of the Agreement.’\textsuperscript{406} However, it is argued that states can determine this ‘balance’ by granting patent rights and also making exemptions to allow the broader use of a patented invention for public policy and health purposes under Article 30 of TRIPS.\textsuperscript{407} Moreover, the Doha Declaration in Paragraph 5(a) gives countries latitude in the interpretation and implementation of the TRIPS Agreement in light of its objectives and principles; thus countries can reasonably determine the ambit of the exceptions in Article 30.\textsuperscript{408} Suffice to say that the panel’s decision in allowing the testing process for regulatory approval, and thus justifying the early working (Bolar) exception in

\textsuperscript{404} See the argument in subsection 2.5.4 of Chapter II and subsection 5.4 of Chapter V.
\textsuperscript{405} See paragraph 7.23, Canada-Patent Dispute.
\textsuperscript{406} Paragraph 7.26 Canada-Patent Dispute. The Panel attempted to draw a compromise between Canada and the EU’s arguments by allowing certain adjustments under Article 30 but restrained any purported ‘renegotiation of the basic balance of the Agreement’ enshrined in the principles and objectives of TRIPS Agreement. Yu, ‘The Objectives and Principles of the TRIPS Agreement’ (n 401) 5.
\textsuperscript{407} Correa, Implications of the DOHA Declaration on the TRIPS Agreement and Public Health (n 77) 29. It is important to point out that the legal interpretation of WTO law by the WTO Panel or its Appellant Body does not bind all Members of WTO and it is not a binding stare decisis for disputes between different parties, even if it is on the same issue and question of law. WTO, ‘Disputes - Dispute Settlement CBT - Legal Effect of Panel and Appellate Body Reports and DSUB Recommendations and Rulings - Legal Status of Adopted/Unadopted Reports in Other Disputes - Page 1’ (Wto.org) Available at <https://www.wto.org/english/tratop_e/dispu_e/disp_settlement_cbt_e/c7s2p1_e.htm> accessed 10 June 2016.
\textsuperscript{408} The historical negotiation of Article 30 of the TRIPS Agreement and possible interpretations of the text are extensively analysed in the UNCTAD and ICTSD (n 69).
Canada’s law as compatible with the provisions of Article 30 of TRIPS, confirms the utility of the provisions as a flexibility measure to ensure access to affordable medicines, particularly generic pharmaceuticals.\(^{409}\)

On the authority of Article 30 of TRIPS, Nigeria can promote its public health objectives including the facilitation of scientific research, and dissemination of knowledge and education, by limiting the rights of patent holders, to ensure that incremental R&D is not impeded by patent protection.\(^{410}\) The state can also make exceptions to patent holder’s rights for public health purposes, including the promotion of technology transfer and the prevention of anti-competition practices. This Nigeria can do by allowing generic producers or third party researchers to access and use the patented invention within the specific exemptions that the state deems fit to specify (within the confines of the conditions in the Article). Since a cardinal aim of a patent as per Article 7 TRIPS is to contribute to promoting technological innovation for social welfare which will include access to innovative medicines, and foster pharmaceutical R&D and dissemination of knowledge, the Article 30 exception can be invoked to complement this objective.

There is currently no internationally agreed list of exceptions to patent rights based on Article 30 of TRIPS. However, it is generally accepted that states can rely on Article 30 of TRIPS to adopt some exceptions to patents rights, such as providing for early working (Bolar-type) exemptions,\(^{411}\) experimental and

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\(^{409}\) Chapter III in subsection 3.7.1.1 demonstrated that generic drugs are generally much less expensive than the patented versions and competition from several generic producers can deliver greater access benefits to consumers. As soon as a medicine’s patented term expires, generic producers can compete and also reproduce the drug, which can lead to a significant price drop. US Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (DIANE publishing) 9.

\(^{410}\) Musungu and Oh (n 32) 55.

\(^{411}\) Also called the Bolar exception after the *case of Roche Products, Inc. v Bolar Pharmaceutical Col.*, Inc. 733 F.2d 858 (Fed. Cir. 1984). In that case, Roche an MNC had a patent for the drug flurazepam. A year before expiration of the patent term, Bolar Pharmaceuticals, a generic company, began experimentation of the drug. Thereafter, Bolar commenced a process to produce the drug by submitting an FDA application for approval. Roche instituted a suit for infringement. Bolar argued that experimental use
research use purposes, and research testing of a drug before the expiration of the patent term under national law.\textsuperscript{412}

6.10.1 Early Working (Bolar-Type) Exemptions

The so-called Bolar-type exemption,\textsuperscript{413} or early working exclusion, allows generic medicines producers to make a request to the appropriate health registration or regulatory authorities to undertake testing or marketing approval of the generic versions of a product before the patent expiration.\textsuperscript{414} This flexibility option is relevant to Nigeria’s obligation towards its women’s right to health by improving access to medicines. For health purposes, this flexibility has the advantage of securing access to affordable medicines, and facilitating competition amongst many drug producers almost as soon as the patent term expires.\textsuperscript{415} This exemption is also important to expediting the effectiveness of compulsory licences since generic producers can test and register their products for the purposes of satisfying a compulsory licence.\textsuperscript{416} Therefore, when a domestic law makes provision for the early working of a patent for this purpose, a generic producer can commence pharmaceutical testing or clinical experimentation to obtain regulatory approval without seeking the consent of the

\textsuperscript{412} Musungu, Villanueva and Blasetti (n 23) 17.

\textsuperscript{413} Also called the safe harbour exemption in some countries.


The WTO panel decision in the Canada-EU Patent case is relevant as a useful test case for Nigeria to adopt in interpreting the Bolar-type exception in accordance with Article 30 flexibility to promote the generic availability of medicines during the subsistence of patent, for use immediately after the patent expiration.

The Bolar-type exemption appears to be much more popular in the national laws of developed countries than it is in developing countries. For instance, the US in U.S.Code 271(e)(i) (or Hatch-Waxman exemption) exempts from infringement certain acts relating to the research, development and testing of drugs and medicinal products for purposes of Food and Drugs Administration (FDA) regulatory approval. One purpose of this provision, among others, is to establish a framework to enable generic competitors to enter the market after patent expiration and to encourage research activities. The scope of this exemption was considered by the US Courts in Merck KGaA v Integra Lifesciences I, Ltd. The US Supreme Court held that the exemption 'provides a wide berth for the use of patented drugs in activities related to the federal regulatory process.' The court further clarified that 'reasonably related' in the text of U.S.Code § 271(e)(i) and the scope of the provision extends to all reasonable uses of patented compounds in preclinical studies for the purpose of

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417 Carlos Correa, Integrating Public Health Concerns into Patent Legislation in Developing Countries (n 414) 68-69.
418 Musungu and Oh (n 32) 56-57.
422 ibid paragraph 202.
423 In 35 U.S.C. § 271(e)(1), "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product [...] which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."
development or submission of information for regulatory approval under the FDA, even when it is subsequently not submitted to the FDA.\textsuperscript{424} Fundamentally, the court broadly interpreted the provision to lay precedence for the use of a patented invention by a third party to conduct testing and trials when the patent still subsists. This indicates a positive effect for the manufacture, use and access to affordable drugs.

6.10.2 Experimental and Research Use Exemption

It is generally argued that patent protection plays an important part in encouraging pharmaceutical innovation.\textsuperscript{425} Chapter III illustrates,\textsuperscript{426} however, that a patent monopoly of technological innovations could be damaging to technological progress, because generally, no one can use a patented idea without the permission of the patentee as part of the exclusive rights under 28 of the TRIPS Agreement.\textsuperscript{427}

Another way to ensure that the monopoly rights conferred by patents do not endanger further creativity and innovation in Nigeria is to make exemptions for the use of patented invention for research purposes.\textsuperscript{428} Hence, despite the rights conferred by patents, the experimental and research use exception allows third parties and the government to leverage on the invention for scientific and pharmaceutical research and academic purposes without infringing the patentee’s rights. This exemption is particularly relevant for research-based institutions, universities, and scientific/pharmaceutical companies and even

\textsuperscript{424} The court added that there must be a ‘reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect.’ 545 U.S. 202-206.
\textsuperscript{426} See subsection 3.6.2.1 of Chapter III.
traditional medicines practitioners/native healers wishing to utilise the patented idea to develop new inventions, test or build new knowledge and improve the existing innovation (or drug) which can be beneficial to the availability of essential medicines. Exceptions for research purposes could commonly apply to test, trials, procedures and all aspects of experimentation and research use of the patented invention. Generally, these exemptions do not cover instances where the main purpose of research is for commercialisation; however, if the research activity aims to improve or build on a patented invention for commercialisation, some laws may exempt such activities from patent infringements.

Studies indicate that most countries have enacted specific domestic legislation for research and experimental use of patents. India, for example, specifically provides such exceptions for scientific and experimental use. Within Africa, some states, including the Organisation Africaine de la Propriété Intellectuelle (OAPI) Members, in accordance with their obligations under the Bangui Agreement, have enacted this exception into their domestic laws.

Nonetheless, it is observed that not many developing countries have made the necessary legislative adjustment to accommodate the full use of the early

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\[^{430}\] UNCTAD and ICTSD (n 69) 437. For example, under Article 27(b) of the Community Patent Convention 1975, if an activity is done for experimental use with the purpose of improving or leveraging on an invention, even if it is done for commercial purposes, such acts are exempted from infringement cases. The Research or Experimental Use Exception: A Comparative Analysis: Prepared for Health Canada (Centre for Intellectual Property Policy 2004) 5.

\[^{431}\] Sisule Musungu and Cecilia Oh’s study demonstrated that derogation of patent rights for research and experimental purposes has gained popularity in the laws of the Latin American, Asian and Caribbean countries. The report however recorded lower provisions in African countries at 59%. Musungu and Oh (n 32) 56.

\[^{432}\] The India Patents Act of 1970 Section 107A reads: Certain acts not to be considered as infringement—For the purposes of this Act, (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product. Musungu and Oh (n 32) 56; UNCTAD and ICTSD (n 69) 106.

\[^{433}\] Musungu and Oh (n 32) 56.
working and experimental or scientific use exception under domestic legislation.\textsuperscript{434} What does this say about the zeal to promote cheaper access to medicine through generic means in the countries that have not made these specific provisions?\textsuperscript{435} However, some African countries, such as South Africa\textsuperscript{436} and Zimbabwe,\textsuperscript{437} make the provision for early working under their national laws. These legislative actions are worth following by other African countries.

6.10.3 Early Working, Research and the Experimental Use Exemption in Nigeria

The Nigerian PDA of 1970 in Section 6(3) states that:

The rights under a patent-

(a) shall extend only to acts done for industrial or commercial purposes;

Although not expressly stated, it can be said that this provision makes an exemption for private non-commercial use of a patented invention, although this provision has not been elaborated by the PDA or Nigerian courts. While the law does not specifically mention the early working and scientific use exclusion, it may also be argued that a broad interpretation of Section 6(3) gives credence to

\textsuperscript{434} The study by Musungu and Oh in 2006 reports that many African developing countries did not make provisions for early working and few national laws in Latin American and African countries provide for the early working exception. The national legislation in developing countries that allow the Bolar-type exception in Asia are India, Thailand and Malaysia and in Africa, notable exceptions were Egypt, Kenya and Nigeria. Musungu and Oh (n 32) 56-57.

\textsuperscript{435} It is argued that although a few countries in African can boast of sufficient pharmaceutical production capacity (Osewe, Nkrumah and Sackey (n 67) 22), it is essential that they incorporate this exception under their domestic law to accelerate the production and availability of generic medicines for potential or future generic producers. While making efforts to build up their pharmaceutical base, they can still make provision for foreign companies to gain regulatory approval and produce the medicines for use after the patent term expiration in their countries. Musungu and Oh (n 32) 33; CIPR (n 136) 50.

\textsuperscript{436} A Bolar-type provision exists in the South African Patents Act, 1978 as a new section 69A.

This reads:

(1) It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.

\textsuperscript{437} Section 24(5) of the Zimbabwe Patents Act (Chapter 26:03, as amended up to Act No. 20/1994) provides:

The rights granted in subsection (4) shall not be construed as prohibiting any person from making, constructing, using or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law that regulates the manufacturing, construction, use or sale of any product.
the exclusion of patent rights for research, experimental use, and furtherance of innovation purposes in Nigeria, in so far as it is not for industrial or commercial purposes. Nevertheless, the provisions on exemptions would benefit from further clarification and definitions of the exact scope and terms of use of a patent without infringing the patentee’s rights. For example, Trinidad and Tobago’s Patent Act 1996 (as amended) makes a similar provision for non-industrial and commercial use of patents as Nigeria, yet the Act was expanded and provides that ‘acts done for experimental purposes relating to the subject matter of the relevant patented invention’, shall not be the subject of patent infringement. This additional requirement is worthy of emulation as a crucial step to scaling up the research, production and availability of medicines in Nigeria to enhance accessibility to pharmaceuticals. In the interest of women’s right to health, such amendment could enhance the access to affordable generic medicines from alternative sources and also facilitate incremental R&D leading to opportunities for the enhancement of human development.

It is imperative for Nigerian patent law to make explicit provisions for early working or experimental use of patented inventions. This is because uncertainty about the extent to which researchers can impinge on the patent holder’s rights for research purposes, or the extent to which generic producers can seek for preparatory approval, could discourage generic producers or researchers from

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438 The PDA does not explicitly define what industrial and commercial purposes mean, however, a literal interpretation of commercial would mean that the exclusive monopoly rights granted to a patent holder would relate only to acts that are directly or indirectly for financial gain. Sisule F Musungu, ‘Access to Art and other Essential Medicines in sub-Saharan Africa: Intellectual Property and Relevant Legislations’ (United Nations Development Programme (UNDP) Regional Service Centre for Eastern and Southern Africa 2007) 27.

439 Patents Act of 1996 (Amended by 54 of 2000) in Section 42 states: The rights conferred by a patent shall not extend to— (a) acts done privately and for non-commercial purposes. Sisule Musungu and Cecilia Oh (n 32) 32.

440 See also Kenya’s patent law in Article 58(1) Kenya Industrial Property Act (2001) (as amended).
working in the area where the invention is patented for risk of being sued for infringement. Besides discouraging researchers from conducting important medicinal research and scientific inquiries, it could also hinder follow-on pharmaceutical innovation and R&D and open the door to needless patent litigation.

The NIPCOM Draft Bill of 2007 in Article 112(3) on the other hand, provides an extensive list of exceptions to the rights of the patent holder. The provision excludes from patent rights infringement, private and non-commercial uses of patents, including for purposes of experimental and scientific research and testing, regulatory approval and the use of an invention for the preparation of medicines and teaching purposes. As revealed in Chapter II,\textsuperscript{441} since patents are also granted on the justification that the disclosure will encourage the diffusion of knowledge and further improvement by inventors, the R&D exception is an important avenue for putting this justification to use in Nigeria. Fundamentally, an enactment of the NIPCOM Bill provision will serve as an incentive to local and foreign generic producers to engage in clinical trials and testing without the challenge of litigation for patent infringements. The view is further expressed that while the bill provides sufficient grounds for the excluding the patentee’s rights for the purposes of clarity, the legislation should provide illustrative grounds for the use of the exceptions specifically for purposes of expediting access to cost-effective essential medicines.\textsuperscript{442}

\textsuperscript{441} See the arguments in subsection 2.3.2 of Chapter II and Subsection 3.6.2.1 of Chapter III.

\textsuperscript{442} By way of example, the Australian Patents Act of 1990 in Section 119C provides several descriptive grounds for the exception of patent rights for experimental purposes. The Act (as amended by Act No. 59, 2015) provides as follows:

\begin{itemize}
  \item determining the properties of the invention;
  \item determining the scope of a claim relating to the invention;
  \item improving or modifying the invention;
  \item determining the validity of the patent or of a claim relating to the invention;
\end{itemize}
6.11 Conclusion: Utilising the TRIPS Flexibilities to promote the right to health and Facilitate Women’s Access to Medicines in Nigeria

From the foregoing, the flexibilities in the TRIPS Agreement, as reaffirmed in the Doha Declaration, signify an important milestone for WTO members, especially the developing countries, to offset the adverse effect of patent rights on access to patented medicines and also facilitate the availability and access to essential drugs. It is, therefore, imperative that Nigeria’s human rights response to the issue of women’s access to medicine include the full implementation and exercise of many opportunities that the flexibilities offer in ameliorating the price and other counter effects of patent rights.

The implementation, use and enforcement of the flexibilities should also be approached from a human development paradigm. As argued in Chapter V, having access to medicines can play a significant role in enhancing the opportunities, choices and quest for women and all Nigerians to live long and healthy lives, and also pursue other development objectives. Thinking in terms of enhancing the human capabilities as analysed in the previous chapter, the Nigerian government can seek to build up the health capabilities of its population and enhance their human development through the instrumentality of the flexibilities. Importantly, therefore, the regulatory and institutional reform of the patent system to promote access to medicines should be approached in light of the human development needs of Nigerians and the right to development obligation of the state. Furthermore, since the guarantee, realisation, promotion and protection of the right to development, as discussed in Chapter V, is also dependent on creating opportunities for the citizens to build their human capabilities, the Nigerian government will thus have to ensure that the flexibilities are implemented in a manner that promotes the development of its citizens and collectively, the society.

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determining whether the patent for the invention would be, or has been, infringed by the doing of an act. Under section 113A of the Patents Act 1990, several acts for obtaining regulatory approval of pharmaceuticals are exempted.
development potentials and enhance their standards of living, the state should consider the implementation, utilisation and design of the flexibilities as a necessary action to protect health and fulfil its right to development obligations.

The flexibilities in national laws though significant, however, offer only a partial solution to the issue of providing access to affordable medicines in Nigeria. It also requires the government’s commitment, strong policy determination to actually utilise the health reliefs, administrative competence and technical proficiency to effectively exercise the flexibilities. It is also linked to several other factors, such as a well-established pharmaceutical industrial capacity and other support systems and policies. Thus efforts to make essential medicines more accessible should extend beyond the implementation of the flexibilities under national law, though significant should not be underestimated.
CHAPTER VII: CONCLUSION AND FINAL RECOMMENDATIONS

Having made a case for women's access to essential medicines from a human rights perspective in the previous chapters, this chapter concludes and draws the thesis together by making recommendations for reforms of the structures and systems necessary to promote women’s access to high quality medicines for the enhancement of their human development and health capabilities.

7.1 General Summary of the Thesis

This thesis considered the issue of women’s accessibility to medicines in Nigeria within the context of patent law and the argument that the international IP provisions in the TRIPS Agreement can contribute to the conundrum of accessibility in developing countries. The thesis argued from a public perspective in Chapter II that the patent system and the rights conferred to inventors underlay a social welfare objective and the benefit of the system to society would be maximised if it could access and utilise patented inventions such as pharmaceuticals. Likewise, it argued that the TRIPS Agreement was negotiated with the objective that it would stimulate local innovation, promote socio-economic welfare and facilitate technological development. These objectives are codified in the Preambles and Article 7 of the Agreement. The issue, however, remains that the patent rules contained therein can be used to cause barriers to accessing affordable essential life-saving drugs and vaccines for the poor in Nigeria and other developing countries, with significant implications for their human rights and human development potential. It is acknowledged that while several factors influence the problems of access to medicines, pharmaceutical patents rights can contribute to the problems of
unavailability and also, interfere with access to essential medicines at an affordable cost.

Against this backdrop, Chapter III analysed the debate that while patent law is essential to incentivising R&D, the rights could create problems for, and impact on public health. This considered debate presents the patent dilemma: on the one side, a patent is seen to facilitate research activities and increase the transfer of valuable technologies; on the other side, however, a pharmaceutical patent’s monopoly right could prevent competition and reduce affordable access to the patented invention, which has human rights and human development implications.¹ These views have provoked discussions on whether the purported benefits of patents in encouraging innovation, research and novel drug discovery and its consequential development benefits, outweigh the adverse cost to public health and access to life-saving medicines. The central question this dilemma poses is how to balance the cost and benefit of patents to society. It was argued that the challenge for the Nigerian government, particularly, within the context of women’s access to medicines, will be to ensure that patent rights, which should promote new inventions for public benefit, do not hamper affordable access to the fruits of these inventions, especially medicines that are essential to human lives and their wellbeing.

It is acknowledged that accessibility to medicines is important to the wellbeing of everyone in Nigeria; however, this study particularly focused on Nigerian women, regardless of age. Although the result of this study is structured to have wider benefit implications for everyone in Nigeria, the issue of access was approached within the context of women’s socio-economic realities and

¹ It was argued that although these issues are not inherent in patent law, they are a result of the manner in which patent holders utilise and enforce their rights.
inequalities. Since the problem of access to affordable essential medicines *viz* patent rights is associated and more challenging for the poorest in developing countries, and women and children make up the majority of the poor, it is most likely that they have even less access to medicines. Consequently, their socio-economic status, experience and perspective offer an additional support to argue for policy interventions to improve access to medicines in Nigeria.

In making the argument for increased accessibility to health treatments in Nigeria, the thesis made the case for women’s access through the lens of human rights to health, life and development. Essentially, human rights provides the jurisprudential justification and legal force in which this study argues for the consideration, interpretation and circumvention of patent rights in favour of increased access to medicines in Nigeria. The thesis argues in Chapter IV that it is the primary responsibility of Nigeria to meet the basic healthcare needs of the citizens. For women, this also includes providing an appropriate healthcare delivery system, timely and adequate health interventions such as medicines, and making proactive efforts to address other health determinants and gender inequalities. Fulfilling this human rights obligation also requires the state to ensure that the exercise of patent rights does not hamper access to affordable medicines as a constituent of the right to health and life. Equally, it is argued that human rights principles can serve as a basis for the resolution of the conflict between private patent rights and public healthcare in favour of health and human welfare where the proprietary rights undermine access to important health treatment. Moreover, human rights norms provide the legal basis for a broader interpretation and implementation of the flexibilities in favour of accessing affordable pharmaceuticals.
To further enrich the argument for increased accessibility to affordable and high-quality medicines in Nigeria, this study argues that access to medicines is not only an essential component of health and wellbeing, it is also helpful for the purpose of enhancing people’s choices, opportunities, and basic freedoms to achieve their basic health goals and development. Thus facilitating women’s access to medicines should form part of the development goals of the Nigerian government. It is also important that this development objective is approached from a people-centred human development paradigm, not one based solely on economic growth. Furthermore, it is argued in Chapter V that while a patent is important to securing the goals of human development, it could also impact adversely on access to medicines and therefore, the opportunities and choices for human development. It is the duty of the Nigerian government to ensure that patent protection which promotes technological developments and pharmaceutical R&D does not hamper women’s human development.

In Chapter VI, this study centrally points to the flexibilities that can be used by Nigeria to address and counter-balance the impact of patents on essential pharmaceuticals and enhance women’s access to medicines. They include among others: government use and compulsory licenses to allow government authorities or third parties to use an invention without the consent of the owner; patentability standards and limitations on the grant of ‘new or second uses’ of old patents; public policy, order and morality exclusions; research/experimental use and early-working exemptions to facilitate the research and production of medicines and other limited exceptions.\(^2\) These flexibilities have been confirmed by the Doha Declaration in 2001.

\(^2\) Another important flexibility which was not considered in detail in this thesis is the exhaustion of rights flexibility and parallel imports to allow the importation and resale of a patented product.
Significantly, the Declaration affirmed that members can interpret and implement the TRIPS Agreement in a way that supports the right to public health and facilitates access to medicines for all. Despite the reaffirmations of the flexibilities at Doha in the interests of public health, other challenges relating to legal and regulatory conditions, lack of technical knowledge, limited resources, insufficient manufacturing capacity and absence of basic infrastructure, raise questions about the extent to which the flexibilities can address the problems of access to medicines within the context of patent law. These doubts also arise in light of TRIPS-plus sanctions that threaten and limit the ability of developing countries to invoke health safeguards in the interests of public health. Notwithstanding, it is argued that the available flexibilities provide important mechanisms to promote and increase the availability of affordable medicines for women in Nigeria. Consequently, this thesis argues for a broad-based incorporation and adaptation of the flexibilities into the patent law and other relevant policies of Nigeria and also, the implementation and interpretation thereof in the interests of public health.

7.2 Nigeria and Access to Medicines: The Way Forward

In Nigeria, addressing the conundrum of access to medicines requires manifold intensive intervention from within the country. In proposing ways to address the challenges of access to medicines in Nigeria, two central recommendations run throughout this study. First is a proposal for the reform of the substantive and procedural provisions of the patents law and system; second is the improvement of human welfare, social, economic conditions and other national support systems. While the second aspect is highlighted as important for promoting and enhancing access to medicines, this thesis essentially focuses on the first.
7.2.1 Reforming the Patent System in Nigeria

First, this thesis recommends a reform of the legislative and regulatory framework of the patent system in Nigeria to better facilitate the availability of, and access to affordable medicines in the interests of the citizens’ human rights and human development. While there are many ways of doing this, this thesis specifically recommends that the obviously obsolete patent law is amended to bring it into compliance with its obligations under the TRIPS Agreement. In line with the human rights duties of the Nigerian State, this amendment should be approached with the pro-development objective of encouraging important and innovative pharmaceutical R&D, at the same time as promoting the production of generic medicines for domestic consumption to enhance the availability of, and access to, cheaper essential medicines. In conforming to Nigeria’s TRIPS obligations, the patent law should be designed in a way that promotes important R&D, while minimising any interference with access to high quality and affordable new pharmaceuticals, incremental R&D and generic manufacturing or re-entry after the expiration of a patent term.

It is particularly identified that the flexibilities can play an important role in this respect. The fundamental element is the language of the law in prescribing the protection and the exceptions to the right, including the derogation for public use. As Article 8 of the TRIPS Agreement, supported by Paragraph 4 of the Doha Declaration allows members the discretion to ‘adopt necessary measures’ consistent with the general provisions of the Agreement in cases where it is expedient to protect public health and promote the interests of the public, this thesis highly recommends the full incorporation of all TRIPS flexibilities provisions, as well as tailoring the rules to ensure women and indeed, all
Nigerians access to essential medicines. This would enable the government and citizens to take advantage of the health safeguards and exceptions to actively promote the availability of, and accessibility of affordable life-saving medicinal treatments. Where the flexibilities already exist under the national law, they should be suitably adjusted to safeguard public health and improve access to affordable medicines without unnecessary delays. The incorporation and amendment of the patent law in the public interest should take into cognisance the importance of the flexibilities to the objectives and aims of the rights to health, life, human development and access to medicines as articulated in Chapters IV and V of this thesis.

7.3.1 Promoting the Use of the TRIPS-compliant Flexibilities to Enhance Women’s Rights to Health and Human Development in Nigeria

The following specific recommendations are made for the calibration of some of the flexibilities to circumstances of public interest for the enhancement of women’s access to cost-effective life-saving medicines and human development. Specific recommendations are made in the section on how to amend the Nigerian Patents and Designs Act (PDA) of 1970 to provide and make effective use of the health safeguards.

7.3.1.1 Recommendation I: Amending the Patentability Criteria in Nigeria, in the Interests of Access to Medicines

Chapter VI identified that the Nigeria PDA of 1970 allows the ‘improvement’ of an already patented article which would permit the patenting of the new use of an existing medicine and new therapeutic indication of a known drug, in so far it meets the threshold of newness, industrial applicability and inventiveness. It is

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3 See subsection 6.6.1 of Chapter VI.
also argued that the problem with this provision is that it could be used as a legal strategy by patent holders to slightly modify and extend the patent term of drugs on the brink of expiration, thereby obstructing the availability of cheaper generic drugs. In light of these issues it is recommended that Nigeria, as per its human rights responsibilities, enact patent requirements that will protect pharmaceutical R&D that are significantly ‘innovative,’ improve the quality of patents granted and reduce the anti-competitive costs and effect to public health.

There are two identified ways of tightening the legal scope and standards of patent protection in Nigerian law. Firstly, increase the threshold of the innovation patentability standard to explicitly exclude or limit the patenting of new medical, or subsequently indicated use of a patented product and/or process.4 Secondly, clarify the term and standard of ‘improvement’ to exclude certain types of innovations that do not substantially indicate enhanced ‘efficacy.’

In the first instance, Nigeria could exclude new or known uses from patentability to limit the scope of a newly discovered use or second use of a known medical substance that does not substantially indicate ‘efficacy.’ For instance, Members of the Andean Community of Nations5 provide a particularly broad exemption for new uses of patents thus:

Products or processes already patented and included in the state of the art […] may not be the subject of new patents on the sole ground of having been put to a new use different from that originally contemplated by the initial patent.6

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5 Article 21 Decision 486 of the Andean Community Commission, 2000 (Decision 486). The Andean Community (Comunidad Andina) is a customs union comprising of Bolivia, Colombia, Ecuador, and Peru.

6 Decision 486 of the Andean Community Commission, 2000 (Decision 486).
Perhaps, Nigeria could take a cue from this strict non-patentability of new uses of known patents.

Although the current PDA succinctly provides a patentability standard that is broadly consistent with TRIPS, similar to other countries such as India’s, the European Union, the PDA could also specifically limit the grant of patents to new or further use of some pharmaceutical products, processes or substances. Nigeria can take a hint from Section 3(d) of India’s Patent Act and restrict certain clearly listed categories of known substances from patent protection and specifically prohibit frivolous claims of anything contrary to well established natural law.

Also, the policy makers can clarify the provision on ‘improvement upon patented inventions’ in the PDA to clearly differentiate between novel inventions and substantial new indication, and ne inventions that are only minor incremental modifications of existing medicines to avoid an ambiguous interpretation of the section. The clarification of the term ‘improvement’ should ensure that the new uses are genuine therapeutic enhancements of older versions by clearly defining the degree of such ‘improvement.’ The provision should state that only significant improvement which substantially meets the patentability criteria of novelty, inventiveness and industrial applicability is allowed. For this purpose, patent law should only allow substantial new development which will ensure that only efficacious innovative drugs that contain new active ingredients and provide significant medicinal benefits are protected. The PDA should exclude minor

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7 Criteria for patentability are defined in Section 2(j) Indian Patent Act in three-fold standards of novelty, inventive step and industrial application.
8 The European Patent Convention (EPC) puts forth four criteria of patentability; and an invention is patentable if, (i) it is novel (Article 54 EPC), (ii) involves an inventive step (Article 56 EPC), (iii) is capable of industrial application (Article 57 EPC), and (iv) is not excluded by Article 52(2) and (3) EPC.
9 See section 3(d) of the Patents (Amendment) Act cited in subsection 6.6 of Chapter VI
incremental enhancements, no matter how novel and innovative unless the modification substantially changes the general therapeutic nature of the invention. Narrowing the definition of novelty or limiting the scope of ‘improvements,’ could reduce the patenting of minor increments and frivolous extension of patent terms which could in turn impact on the accessibility to affordable generic medicines. Restricting patentability will also make allowance for the early entry of generic drugs that could facilitate competition, reduce prices of drugs and promote better access to affordable medicines.

In addition, to lessen the possibility of ‘evergreening’ where patent terms are prolonged based on minor amendments as discussed in Chapter VI, it is important to extend the administrative duties of the Nigerian patents registration officials beyond mere registration of patent applications. For this purpose, there is a need for a patent examination system that will guard against the problems inherent in a registration system where patents are relatively easy to file and much harder to challenge. The European Patent Office for example, carries out a substantive examination of all patent applications. In this vein, the proper examination and assessment of patents in Nigeria might be another means to guard against the practice of extending the protection period of a patent and blocking generics entry and avoiding the registration of low quality patents, which could have anti-competitive effects and unjustifiably increase the price of the end products. Realistically, this is not to suggest a thorough investigative examination system. Even in developed countries like the US for example,

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10 See subsection 6.6 and 6.6.1 of Chapter VI
12 See the discussion in subsection 6.6.1 of Chapter VI
patents are examined based on the ‘preponderance of evidence’, that is with due consideration of the evidence and persuasive argument of the applicant rather than by clear and convincing evidence.13

It is also important to provide adequate funding for the patent officials to efficiently examine the quality of patent applications, particularly with regards to preventing the grant of frivolous pharmaceutical patents. Without sufficient resources, it would be nearly impossible to effectively and accurately examine and screen trivial and questionable patent claims. The Patent and Designs Registry is a unit in the Commercial Law Department of the Ministry of Industry, Trade and Investment. This means that the Patent Registry is dependent on the policy decisions, administrative powers and budget allocation of the Ministry. The registry has no control over the funds it generates from patent applications which could enable it to administer the affairs of patents effectively.14 Lack of control over the resources it generates or insufficient resource allocation may also mean that registry staff are not regularly trained in up-to-date patent practices and regulation. In terms of administrative control of matters relating to patents, its powers are limited to the formal examination, grant of patent and administration of patent rights.15 Patent support services such as registration of patent-related technology transfer and foreign direct investment, monitoring of patent licensing and promotion of innovation, are entrusted to the National Office of Industrial Property (NOPTAP).16 NOPTAP is also actively engaged in

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15 This is in addition to other functions such as regulating the filings of trademarks and industrial designs.
raising public awareness and training the public in knowledge about patents as well as assisting inventors in patenting their inventions.\textsuperscript{17} This ought to be one of the main functions of the Patents and Designs Office. With limited funding, however, it may be impracticable to undertake this important responsibility. Thus it is highly recommended that the patent office is adequately funded, particularly if it is to undertake the substantive examination of patents.

It is also imperative that the patent officials receive regular, up-to-date scientific, legal and technical training to build their capacities to assess patent claims and reject applications with insignificant improvements. An additional or alternative arrangement would be to put in place a system where independent individuals who possess the necessary legal, scientific and technical expertise are registered to carry out assessments and examination of patent applications at the patent office. Currently, the sole system in place allows the registration of agents who only guide or advise inventors through the patent application process.\textsuperscript{18} Many developed countries, as well as international organisations, are increasingly offering capacity training to developing countries’ patent offices,\textsuperscript{19} although scholars are sceptical that the intention is only to serve the overarching purpose of ensuring swift TRIPS implementation and entrenching stronger IP

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\textsuperscript{17} Ibid


standards.\textsuperscript{20} The World Intellectual Property Organization (WIPO), the World Trade Organization (WTO) and some non-governmental organizations (NGO’s) also render advice and legal or technical assistance to developing countries and Nigeria can take advantage of the technical skills and legal support opportunities they offer.\textsuperscript{21} It is however, vital that the goal of guaranteeing and protecting public health and promoting the Nigerian people’s human development is clearly identified as the main objective of any technical and capacity building assistance.

To detect pre-grant defective claims, it is also imperative to put in place a procedure for public scrutiny of patent applications before and after they are granted. The public should also be given the opportunity to check frivolous claims and challenge same; however, this should be without prejudice to the patent applicant. Furthermore, it is suggested that the administrative procedure for the pre or post grant review or challenge of patents be made simple and transparent. To realise this mission, the patent legislation should formulate a process for opposing patent applications and grants that do not meet the patentability criteria or claims with modifications of existing products within a specific time frame, without the need for recourse to the judicial system. The law should specify the means of addressing such oppositions without delay.

It is important to reiterate that any amendment of the patent law with regards to patentability is guided by the state’s human rights obligations to guarantee the

\textsuperscript{20} These scholars highlight the underhanded nature of technical assistance and capacity building from international organizations and developed countries. Carolyn Deere, \textit{The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries} (Oxford University Press 2008) 19; Sudip Chaudhuri, \textit{The WTO and India’s Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries} (Oxford University Press 2005) 106-107.

enjoyment of the right to health via the accessibility of affordable medical treatments that are safe and of good quality, in an acceptable manner.

7.3.1.2 Recommendation II: Amending the Public Morality and Public Order Provisions to Safeguard Access to Medicines in Nigeria

In view of public health objectives and the goal of securing women’s right to health, enacting an appropriate scope of patentability in Nigeria is crucial to accessing medicines. Where the terms are too rigid and narrow, they risk restricting the innovation climate of the country, whereas, when the provisions are too lax, they admit ambiguity in terms of interpretation and enforcement. Chapter VI reveals that the patentability exceptions with regards to public order and morality in Nigeria’s patent law are too ambiguous, which could defeat the main purpose of having the provision.\textsuperscript{22} Chapter VI also indicates that the TRIPS Agreement in Article 27(2) clearly relates the concept of \textit{ordre public} and morality to the protection of humans, animals and health; however, the Nigerian patent law is yet to explicitly link the probation of patentability on grounds of public order and morality with its citizens’ health.\textsuperscript{23} Therefore, it is important that the current patent regime in Nigeria is reformed to specify the grounds for the interpretation of the concept \textit{ordre public} in the interests of public health and access to medicines. This clarification is imperative in the face of increasing monopoly over biotechnology, traditional medicinal plants properties and genetic material which could affect medical research and consequently, the availability of and access to medicines. This reform should be done in Nigeria to avoid the monopolisation of inventions in crucial areas that could affect humans, especially their health, animals and the environment.

\textsuperscript{22} See also the discussion in 6.7.1 of Chapter VI.
\textsuperscript{23} See discussion in subsection 6.7 of Chapter VI.
This reform should also reflect a comprehensive patentability standard which includes provisions to specifically exclude diagnostic, therapeutic and surgical methods in order to promote access to health treatments. This approach is substantiated by the recommendations of the IPR Commission for developing countries, particularly those without research capabilities, to ‘strictly exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products.’

Similar to the consideration above, while it is important for Nigeria’s national legislation to contain all the TRIPS flexibility provisions, a proficient patent examination system and administration is necessary to judge and decide whether to grant or deny a patent on the basis of moral, and public interest grounds to prevent any consequential adverse effect on health, plants and animals and the environment.

7.3.1.3 Recommendation III: Adapting and Utilising the Compulsory Licensing Medium and Government Use Flexibilities to Promote Access to Affordable and Essential Medicines in Nigeria

While the Nigerian government has put in place national legislation for the granting of compulsory licensing and government use that could ensure the availability of cheaper generic drugs options as revealed in Chapter VI, more needs to be done to put this flexibility option to significant use. From a public health perspective, it is worth stating that the grounds for issuing compulsory licensing in Nigeria are quite limited. In any case, compulsory licensing revolves around working the patented invention and the public interests of security,

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25 See discussion in subsection 6.8.4 of Chapter VI.
economy and health, without elaborating on additional public health circumstances when it can be used. While the public interest grounds in Nigeria’s patent law is similar to that of other nations such as India, the circumstances and basis for issuance are restricted to limited circumstances. The patent law does illustratively list other possible grounds for granting compulsory licences, such as the adequate supply of cheaper medicines and use in the event of health emergencies. Furthermore, it was observed in Chapter VI that although the provisions for anti-competition practices can be inferred, the PDA ought to expressly provide for the grant of a compulsory licence to remedy these practices. For instance, the Indian Patent Act of 1970 spells out analogous but more extensive grounds for granting compulsory licenses for a dependent patent, instances where reasonable public requirements have been satisfied, unaffordable price of the invention for the public; the non-working of the patent in India, circumstances of national and extreme emergency, and public non-commercial use. Importantly, India’s Patent Act provides for the grant of compulsory licensing for health relief specifically and also makes provision for granting of compulsory licences for purposes of export to countries with limited or no manufacturing capacity. In comparison to India, the current Nigerian PDA does not contain provisions pertaining to national or extreme emergency to expeditiously invoke a

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26 Section 84 of the Indian Patents Act, 1970, as amended by Act No. 15 of 2005, states the grounds for grant of compulsory licence as follows:
(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
(b) that the patented invention is not available to the public at a reasonably affordable price, or
(c) that the patented invention is not worked in the territory of India.

27 However, the Minister is conferred a broad discretion on the applicability of the licensing provisions in Paragraph 13 First Schedule, Part I to the PDA. According to the provision, the Minister by order in the Federal Gazette may provide that, for certain patented products and processes (or for certain categories thereof) declared by the order to be of vital importance for the defence or the economy of Nigeria or for public health, compulsory licences may be granted before the expiration of the period [...].

28 See subsection 6.8.4 of Chapter VI.


30 Section 92A of the India Patents Act, 1970.
compulsory licence in events of health crises, nor is there a provision for exports under a licence.

In another example, Belgium went further than the provision allowed in Article 31 of TRIPS in making provisions for compulsory licensing by relying on the basis of Articles 8 and 30 of TRIPS to make specific provisions for a compulsory licence in the interests of public health and availability of medicines, including specific fast-tracked measures for health crises. Article 31 bis § 1 of the Belgium Patent Act 1984 expressly states that ‘in the interest of health', the King, by decree established after consultation with the Council of Ministers, can grant a licence, for the exploitation and application of an invention protected by patent. For this purpose, the products for compulsory licences include:

a) A medicine, a medical device, a product or medical device used for performing a diagnosis, a derived or combinable therapeutic product;

b) The process or product necessary for the manufacture of one or more products indicated under a);

c) A diagnostic method applied outside of the human or animal body.

This provision explicitly includes medicines as one of the grounds to exploit the compulsory licensing flexibility, which will include affordable access to medicines. For effective utility, the compulsory licensing provisions in the current PDA should be reviewed to include additional public health-friendly grounds as bases for the grant. It is suggested that Nigerian patent law could

(The translated version is available at <https://www.iip.or.jp/e/e_publication/pdf/vol64_overwalle_and_zimmeren.pdf> accessed 1 June 2015) 5.

32 In the case of health emergencies, the Minister responsible for public health is obliged to take additional measures to accelerate or bypass the procedure for grant of compulsory licensing in Article 31 BIS § 6 paragraph 5 of the Belgium Patent Act. Van Overwalle and van Zimmeren ibid 7: K Outterson and AS Kesselheim, ‘Market-Based Licensing for HPV Vaccines in Developing Countries’ (2008) 27 Health Affairs 130, 136-137.

33 Emphasis added.

34 For detailed analysis of the provision, see Van Overwalle and van Zimmeren (n 31)
emulate the foregoing countries (India and Belgium) and expressly list illustrative public health grounds for the issuance of compulsory licences. The grounds for utilisation of the flexibilities should be broadly specified, for example, allowing the importation and export of medicines under compulsory licences.

It may also be that the provision of compulsory licensing in Nigeria is deliberately left open so that it can be broadly interpreted. If this is the case, the judiciary and relevant authorities should widely interpret and enforce the provisions on compulsory licences in the interest of improving access to medicines in Nigeria, to promote women’s and all Nigeria’s human rights through accessibility to life-saving health treatments.

The procedural grounds for the grant and use of compulsory licences or government use would benefit from additional reforms to make the provision straightforward, simpler, transparent, fast and easier to administer. Equally, the Nigerian legislature should fully exploit the flexibilities by establishing a clear decision-making process for determining the basis for the grant of compulsory licences and government use, including the option for export to other countries. The responsible government agencies should also ensure that the legal conditions for the grant are satisfied to avoid triggering expensive and unnecessary litigation from patent owners in a bid to thwart the derivable benefits. Where discretion can be exercised, in the case of health emergencies for example, the interest of the public’s right to health should supersede private patent rights considerations.

The decision-making process for the adequate utility of these flexibilities lies with at least four government agencies in Nigeria and their duties would often overlap. The Ministry of Health is responsible for determining health challenges
and procuring medicines; the regulatory agency, the National Agency for Food and Drugs Administration and Control (NAFDAC) controls the importation, export, distribution and use of drugs; the Ministry of Justice is tasked with the domestic implementation and reform of the law; and the Ministry of Industry, Trade and Investment is concerned with the administration of patent rights and the implementation of the TRIPS Agreement in general. The courts also play a role in the granting and regulation of compulsory licences. Therefore, the effective enforcement of the flexibilities depends on the coordinated, collaborative and individual responsibility of these agencies and the courts. It is important to clarify and assign specific roles and responsibilities to each organisation involved in the process of ensuring access to medicines through compulsory licensing and government use. The determination and designation of responsibility of each authority should be clearly stated to avoid multiplicity, unnecessary overlap, administrative delays and negation of duties.

The legal text, in articulating the terms for use of the flexibilities in Nigeria, should also state the compensation procedure, and provide an opportunity for the patent holder to request a hearing on the use of the flexibilities on his patents, except where it is expedient not to do so e.g, in emergency or urgent circumstances. The grievance procedure should be in the form of a quasi-judicial review of the complaint and thereafter, recourse to judicial redress. The creation of an independent public administrative body with quasi-judicial powers to determine and manage the utilisation of compulsory licences and non-commercial use by the Nigerian government towards addressing exigent public health concerns would be another way of ensuring efficient utilisation of these flexibilities.

35 For example, in India, the Comptroller of Patent Office hears both parties in an application for the use of compulsory licence. Blu Tirohi, Law for Artists: Copyright, The Obscene and all the Things in Between (Routledge 2014) 167.
This administrative body would reduce the burden on the court and expedite the licensing process for use. Such an arrangement could promote transparency by determining the guidelines or the payment of compensation to avoid ambiguity and deadlock in the negotiation of royalties. Adopting this recommendation has important implications for future practice in terms of setting up the guidelines for remuneration, procedures, the terms of licence granting and rights of appeal. Another advantage of this approach is that such a body would have quasi-judicial decision-making powers to ensure speedy adjudication, thereby saving the cost of expensive legislation.

Importantly, the Nigerian government and policy makers must ensure that the compulsory licences issued and government use are in the interests of the public for example, ameliorating health and not a profit making venture for opportunistic generic manufacturers. The prescription of the law on the grounds of exercising the safeguard should also guide the review process and check any implementation of the flexibilities done in bad faith. It is important that the review and legal redress does not defeat the purpose of the flexibilities; therefore, the panel or court should exercise discretion in favour of health to refuse or grant a stay on the execution of the flexibilities pending the outcome of the complaint. It is also imperative that there is prior notification to the patent holders before issuing compulsory licences to maintain a patent-friendly environment, except where it is not expedient to do so in emergency situations. In the case of a deadlock in negotiations, the overall public health consideration should override

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36 For example, the Belgium Patent Act in Article 35(1) prescribes the setting up of a compulsory licensing commission with the specific allocated task of handling issues related to compulsory licensing.


38 Commission on Intellectual Property Rights ibid.
the private interest of the patentee; however, compensation should be paid for
the inconvenience caused.

Nigeria’s authorities should resist TRIPS-plus pressures and desist from rules in
FTAs that would limit, undermine, exclude or affect the implementation of the
flexibilities with regards to the right to health. The Nigerian legislators can do this
by specifically enacting laws that prevent the introduction of TRIPS-plus rules
which would thwart public health objectives. The previously discussed principles
of the right to health and life in Chapter IV and human development goals in
Chapter V\(^\text{39}\) should guide the assessment of TRIPS-Plus rules which directly or
indirectly impose additional IP requirements.

The responsibility of the Nigerian government to improve access to
pharmaceuticals through the instrumentality of compulsory licences and the
non-commercial use option do not end with laws. Successful implementation of
the compulsory licensing and government use legal remedies for example,
would depend upon important factors such as the availability of a functioning
pharmaceutical industry and an effective administrative control system to
monitor the impact of patents on access to medicines and swiftly engage the
use of the flexibilities.

\textbf{7.3.1.4 Recommendation IV: Maximising the Benefits of the Exemptions to
Patent Rights Flexibility in Nigeria}

The experimental and research use exemption is strongly recommended as a
means of encouraging research by the budding generic production and
research-intensive pharmaceutical industry in Nigeria to expedite the access to
medicines by women and indeed, everyone else in Nigeria. With respect to

\(^39\) See the discussion in Part I of Chapter IV and subsection 5.7 of Chapter V.
pharmaceutical patents, the early working provision is important for facilitating regulatory approval before the commercialisation, availability and production of generic medicines at the end of a patent term by generic manufacturers and researchers.

Nigerian patent law does not expressly make an exemption for research purposes as revealed in Chapter VI, though this can be inferred. To avoid ambiguity, it is recommended that the provision with regards to the exemption of patent rights specifically allows experimentation and early working, as well as academic uses of the patent for commercial use after the patent expiration. This should be expressly stated in the national patent law and other research and development policies. Making research exemptions to patent rights could facilitate the availability of additional new drugs and the Bolar-type exceptions could expedite the availability of cheaper medicinal alternatives immediately after a patent's expiration. The existence of an alternative source may promote competition and drive down prices of drugs which will benefit women and all Nigerian consumers.

The law in Nigeria should expressly state that the exemption covers both generic and novel drugs researches and discoveries. Furthermore, it is recommended that the experimental use and Bolar-type provision is without limit of its territorial scope. That is, the exception can also be broadly defined to facilitate approvals for generics production for export to other countries with insufficient or no manufacturing sector as per Paragraph 6 of the Doha Declaration.

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40 See subsection 6.10.3 of Chapter VI.
7.4 Towards Guaranteeing the Right to Health through Access to Essential Medicines in Nigeria: Adopting an All-encompassing Approach

Although this thesis fundamentally endorses the implementation and use of the flexibilities to enhance women’s access to medicines in Nigeria, it is acknowledged that finding a solution to access problems requires a multifaceted response. First, it is important that women’s right to health and access to medicines as a constituent of the right is respected, fulfilled, guaranteed and protected in Nigeria.

7.4.1 Incorporating a Human Rights Perspective to Secure Women’s Access to Medicines and Health in the Light of Patent Rights in Nigeria

Access to medicines as a matter of right has the potential to contribute to an improvement in Nigerian women’s wellbeing and by extension, children that rely on women for child-care. For a concerted effect however, the Nigerian government must domesticate the relevant international human rights provisions such as the International Covenant on Economic, Social and Cultural Rights (ICESCR), the International Covenant on Civil and Political Rights (ICCPR), and the Universal Declaration of Human Rights (UDHR), and promote their use by the courts and other relevant authorities to assuage the adverse effect of patents, especially in cases where it undermines the right to health and leads to unreasonably high costs of medicines.41

There is a corresponding duty on the Nigerian government to ensure that access to affordable medicines as a human right to health entitlement is not

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41 For example, the General Comment No.17 in Paragraph 35 enjoins State parties ‘to prevent unreasonably high costs for access to essential medicines.’ See UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1 (c) of the Covenant) (12 January 2006, E/C.12/GC/17, 2006).
impeded by other laws and regulations or actions of third parties such as patent holders’ rights. Since the quintessence of the right to health is access to the relevant medicines, health facilities, and conditions, it is a duty of the Nigerian state to fulfil and promote the right to health at all levels of state activities, including national health policies, and to ensure that provisions of trade agreements are not enforced in ways that restrict access to medicines. As noted by the CESCR, if the country ‘[…] adopts legislation or policies that are manifestly incompatible with pre-existing domestic or international legal obligation relating to the right to health,’ it is in violation of the duty to guarantee and protect the right to health. Many members of the WTO (including Nigeria) are State parties and have ratified the ICECSR. As Desierto argues, State Parties to both the TRIPS Agreement and human rights covenants and instruments have an obligation under the ICECSR to ensure their commitment under the WTO does not contradict the enjoyment of rights under the covenant.

While access to medical care and healthy working conditions is a non-justiciable constitutional duty on the state, it is imperative that the right to healthcare is recognised as an enforceable human rights claim in the Constitution of Nigeria. Perhaps it is not out of place to suggest that the Nigerian legislature should take a cue from South Africa and purposely provide for the right to healthcare and specifically mention affordable medicine as a justiciable right in the

45 Diane Desierto, Public Policy in International Economic Law: The ICESCR in Trade, Finance, and Investment (OUP Oxford 2015) 284. Note however that the provisions of ICESCR are not applicable to all relations between the WTO members that are not signatories to the human rights instruments. Diane Desierto ibid 205.
Constitution.\textsuperscript{46} Human rights scholars argue that a claim can only be justly called a right if it is recognised as such, or it is capable of attracting some form of legal sanction and remedy.\textsuperscript{47} Devoid of legal enforcement, the provisions on access to healthcare facilities including medicines in the 1999 Constitution would be mere moral aspirations, bereft of legal rights that can attract binding sanctions for violations.\textsuperscript{48} While the right to health in the African Charter can be relied upon to exert a duty on the state, it is still important that the right to access adequate healthcare including medicines in the Nigerian Constitution is secured as an enforceable human right. If this right is contained in the Constitution, it will supersede any other right contained in other laws, such as a patentee’s right under patent law, when it contradicts the constitutional provisions.\textsuperscript{49} Until then, it can only be hoped that the judiciary and government respect the rights to health under the African Charter and fulfil their duty to provide adequate medical and healthcare facilities as contained in Section 17(1)(c)(d) of the Constitution.\textsuperscript{50}

7.4.2 The Role of the Nigerian Judiciary in Promoting Access

The judiciary in Nigeria can play an important strategic role in ensuring that the enforcement and judicial interpretation of patents provisions and claims do not conflict with rights to health and access to medicines. It is recommended that human rights and human development principles also influence the courts’ decision-making processes. Furthermore, the judiciary should play a central part

\textsuperscript{46} The Rights to healthcare are contained in three sections of the South African Constitutions, Act 108 of 1996, in Section 27 including the rights to reproductive health of women, and basic healthcare for children. Unlike the Nigerian constitution, these rights can be enforced in Court and the Constitution requires the state to ‘respect, protect, promote and fulfil these rights alongside those from international treaties.’ See Hans V. Hogerzeil, Melanie Samson and Jaume Vidal Casanova, ‘Ruling for Access Leading Court Cases in Developing Countries on Access to Essential Medicines as part of the Fulfilment of the Right to Health’ (World Health Organization Department of Essential Drugs and Medicines Policy 2004) 30.


\textsuperscript{48} Ibid

\textsuperscript{49} The Constitution is the grundnorm in the Country. This means no other law, judicial decision or policy can override its specific provisions.

\textsuperscript{50} This suggestion is made bearing in mind the rigid and rigorous process of Nigeria in amending the constitution.
in interpreting the flexibilities in the interests of public health and laying down precedents that promote human rights to health and access to medicines, as exemplified in the Indian case of *F. Hoffmann-La Roche Ltd and Anr. v Cipla Ltd.* It is also suggested that there is a need for regular training and capacity building to inform and educate judicial officers, as well as patent officials, and regulatory authorities on the relationship between patent rights and access to medicines, especially ways in which IP impacts on access to medicines and the necessary interventions available to mitigate this effect.

Furthermore, other external factors and infrastructural development must be put in place to address and improve the availability and access to affordable and safe quality essential medicines. Some recommendations, although not the core focus of this thesis, are made in the following.

### 7.4.3 Social Welfare Improvement, Other Policy and Infrastructural Reforms to Enhance Access to Medicines in Nigeria

A thorough analysis of the legal and infrastructural environment of Nigeria reveals that the solution for access to medicines extends beyond the patent system. A workable welfare system that puts into place an effective framework for the distribution of medicines at affordable rates; a national insurance scheme; and a robust healthcare system to guarantee regular access to medicines are interventions that could contribute in bolstering access to medicine in Nigeria.

Addressing social factors, traditional practices, and cultural barriers is equally relevant in effectively enhancing women’s health and rectifying the issue of

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51 148 (2008) DLT 598, MIPR 2008 (2) 35. In delivering the judgment in the case, the Judge ruled with regards to the ‘right of the general public to access life-saving drugs which are available and for which such access would be denied if the injunction were granted.’ Judgment delivered by Ravindra Bhat, J. This case was discussed in Chapter IV, subsection 4.9.2.
women’s access to medicines in Nigeria. In Chapter III, it was identified that women face social, cultural and traditional discrimination.\textsuperscript{52} It is the responsibility of the government to ensure that women are protected from adverse socio-cultural and traditional practices, violence and bias that endanger their health and general well-being. Nigeria should, therefore, seek to constitutionally guarantee, initiate policies on and reaffirm women’s basic human rights for freedom from all discriminatory practices that can impinge on their health. Furthermore, national laws and policies must be backed up by practical efforts to safeguard and promote women’s fundamental human rights, including the right to health.\textsuperscript{53} Progressively, the disadvantaged and vulnerable in society, such as women and children, should receive special attention with regards to their healthcare needs as part of improving and securing their welfare and wellbeing.

Other infrastructural factors should be reviewed to facilitate the availability and accessibility to medicines such as: good transportation and distribution systems to ensure adequate distribution of medicines. Also, technical rules, export/import duties, tariffs and taxes that could increase the price of medicines or undermine the practical exploitation of the flexibilities should be reviewed and amended accordingly.

As briefly mentioned in chapter III, there is currently no price control mechanism or policy on pharmaceutical products in Nigeria.\textsuperscript{54} To make the prices of medicines and health products more affordable to women and Nigerians in

\textsuperscript{52} In subsections 3.4, and sub-subsections 3.4.1, 3.4.2 and 3.4.3 of Chapter III.

\textsuperscript{53} As Mann argues, ‘preventing human rights abuses [...] to the extent that it involves protecting the vulnerable, must be understood as a challenge to the political and societal status quo.’ Jonathan Mann, ‘Health and Human Rights: If Not Now, Then When?’ (1997) 2 Health & Human Rights 113, 117

general, the Nigerian policy-makers in addition to incorporating and implementing the flexibilities, need to set up a price control mechanism and regulatory authority to curb the high market prices of medicines and pharmaceuticals. There are many price control options that can be employed to regulate drug prices. Price control intervention can be in the form of regulating the price of individual drugs, placing a limit on total spending, promoting competition from generic manufacturers and cheap sources, among many other mechanisms. The price control policy or the designated regulatory authority can also fix ceiling prices of essential drugs or formulation packs of drugs to regulate the cost. The previously analysed compulsory licence as a flexibility can also play an important role in controlling the price of medicines. However, it must be stated here that the degree of price control should not be so strong as to distort incentives in the drug market or result in a lower supply of medicines.

It is noteworthy that the quest for access to medicines in Nigeria cannot be adequately addressed by over-dependence on foreign products. As mentioned in Chapter VI, other external factors such as a fully functional and capable domestic pharmaceutical base must be in place to facilitate the use of the flexibilities. It is advised that Nigeria continually strive to promote and develop a viable local pharmaceutical industry to cater for the national medicinal needs of

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55 Jakkrit Kuanpoth, *Patent Rights in Pharmaceuticals in Developing Countries: Major Challenges for the Future* (Edward Elgar Publishing 2010) 136. Under a functional social insurance scheme, the government can also regulate prices directly by negotiating with and purchasing the drugs from the manufacturers.

56 In India for example, the government regulatory agency National Pharmaceutical Pricing Authority (NPPA) under the authority of India’s medicines price control legislation, the 2013 Drugs (Prices Control) Order, fixes price ceilings on essential medicines based on mark-up cost or input cost or market-based mechanisms. ibid 136. See more at http://www.nppaindia.nic.in/.


57 See subsection 6.8 of Chapter VI.

58 Kuanpoth (n 54) 137.

59 See subsections 6.4.1.1 and 6.5 of Chapter VI.
its populace. With a rich biodiversity, medicinal and herbal plants, Nigeria’s pharmaceutical sector has the potential to grow to a size that could cater for the healthcare needs of the people.

In light of the problems of research for neglected diseases as identified in Chapter III, alternative, collaborative and supplementary research mechanisms of incentivising the R&D of neglected diseases such as public-private partnerships (PPPs), Prize Funds, Advanced Market Commitments (AMC), medicines patent pools, patent buyout schemes and open source medicine initiatives, should be encouraged and explored in Nigeria.

These avenues provide the means for pooling resources, data, and expertise to promote pharmaceutical R&D, licensing and drug production, towards the public health objectives of providing the necessary treatments, especially for populations afflicted by poverty.

One of the issues that became clear during the study for this thesis and cannot be ignored, is that the general healthcare system in Nigeria needs to be reformed and improved to enhance access to essential medicines.

Lastly, it is also important that the Nigerian Intellectual Property Commission (NIPCOM) Bill of 2007 with the suggested recommendations in this thesis be passed into law with immediate effect.

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60 Nigeria is a country that is rich in biodiversity and endowed with a variety of medicinal plants such as neem (Azadirachta indica), Africa nutmeg (Monodora myristica) bitter leaf (Vernonia amygdaline) for treating diseases and infections, catharanthus roseus (rosy periwinkle) for leukaemia treatment and many other traditional medicinal and herbal plants. Emma-Okafor, and others, ‘Biodiversity Conservation for Sustainable Agriculture in Tropical Rainforest of Nigeria’ (2009) 2(7) New York Science Journal 82. Studies indicate that a significant number of drugs are produced from plant extracts and natural products. See SMK Rates, ‘Plants as Source of Drugs’ (2001) 39 Toxicon 603. With the abundance of plants and herbs, and bio-genetic resources of Nigeria, the prospects for drug discovery research are great and should be further explored by drug manufacturers and promoted by the government. Bala Yauri Muhammad and Ahmed Awaisu, ‘The Need for Enhancement of Research, Development, and Commercialization of Natural Medicinal Products in Nigeria: Lessons from The Malaysian Experience’ (2008) 5(2) African Journal of Traditional, Complementary and Alternative medicines (AJTCAM) 120 - 130.

61 See subsections 3.6.3 and 3.6.3.1 of Chapter III.

62 This was mentioned in 3.6.3.1 of Chapter III.
It is worth stressing that the quest for access to medicines requires a broad-based national effort by government, the pharmaceuticals sector, research institutes and universities, private and public individuals and organisations, judicial authorities, regulatory control authorities and, significantly, a robust health care system. Most importantly, a good and stable democratic governance system, regulatory structure and political will-power to effectively and convincingly monitor the effect of patents on public health and utilise the flexibilities in this regard are paramount in the context of access to medicines.

It goes without saying that the proposals in this thesis are illustrative of the many ways in which Nigeria can effectively address the problems of access to medicines for women and indeed, everyone in Nigeria.
BIBLIOGRAPHY

Books and Edited Collections


Abbott FM, Trends in Local Production of Medicines and Related Technology Transfer (World Health Organization 2011)


Ariana P and Naveed A, ‘Health’ in Severine Deneulin and Lila Shahani (eds), An Introduction to the Human Development and Capability Approach (Earthscan and IDRC 2010)

Bale HE, ‘Patents, Patients and Developing Countries: Access, Innovation and the Political Dimensions of Trade Policy’ in B Granville (ed), The Economics of Essential Medicines (Royal Institute of International Affairs 2002)


Bennett JE, Dolin R and Blaser MJ, Principles and Practice of Infectious Diseases (Elsevier Health Sciences 2014)
Bentham J, *The Rationale of Reward* (R Heward 1830)


Bole T and Bonderson W (eds), *Rights to Health Care* (Kluwer 1991)


Cheng D, ‘Advancing the Ebola Pipeline Requires Continued Collaboration between Public and Private Stakeholders’ (Global Data 2014)


Clark JB, Essentials of Economic Theory (The Macmillan Company 1907)


Cloatre E, Pills for the Poorest: An Exploration of TRIPS and Access to Medication in Sub-Saharan Africa (Palgrave Macmillan 2013)

Cohen JE, Configuring the Networked Self: Law, Code, and the Play of Everyday Practice (Yale University Press 2012)

Comerford K, R&D and Licensing: Building Value through Intellectual Assets (Elsevier 2007)


Cook RJ, Women’s Health and Human Rights (World Health Organization 1994)

Cornish WR, Intellectual Property: Patents, Copyrights Trademarks and Allied rights (Sweet and Maxwell 1993)

Correa CM, Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options (Zed Books Ltd 1999)

—— Integrating Public Health Concerns into Patent Legislation in Developing Countries (South Centre 2000)

—— Intellectual Property Rights, the WTO and Developing Countries: The TRIPS and Policy Options (Zed Books 2000)

—— Implications of the Doha Declaration on the TRIPS Agreement and Public Health (EDM series 12, World Health Organization 2002)

—— 'Pro-Competitive Measures under the TRIPS Agreement to Promote Technology Diffusion in Developing Countries' in Peter Drahos and Ruth Mayne (eds), Global Intellectual Property Rights: Knowledge, Access and Development (Palgrave Macmillan 2002) 42.

—— 'The TRIPS Agreement and Developing Countries' in International Trade Law Center, Arthur E Appleton and Michael G Plummer (eds), The World Trade Organization: Legal, Economic and Political Analysis (Springer Science & Business Media 2007)


Deere C, The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries (Oxford University Press 2009)

Desai M and Chand D, 'Fundamental Right to Health and Public Health Care' in Mihir Desai and Kamayani Bali Mahabal (eds), Health Care Case Law in India (Centre for Enquiry into Health and Allied Themes (CEHAT) and India Centre for Human Rights & Law (ICHRL 2007)


Drahos P, A Philosophy of Intellectual Property (Dartmouth 1996)


Dutfield G and Suthersanen U, 'Innovation and Development' in Uma Suthersanen, Graham Dutfield and Kit Boey Chow (eds), Innovation Without Patents: Harnessing the Creative Spirit in a Diverse World (Edward Elgar Publishing 2007)


Eko L, American Exceptionalism, the French Exception, and Digital Media Law (Lexington Books 2013)

Eleutheriadès PZ, Legal Rights (Oxford University Press 2008)

and Maskus KE, ‘Why We Study Intellectual Property Rights and What We Have Learned’ in Carsten Fink and Keith E Maskus (eds), Intellectual Property and Development: Lessons from Recent Economic Research (World Bank and Oxford University Press 2005)

Finnis J, Natural Law and Natural Rights (Clarendon Press 1980)


Freeman MDA, Lloyd’s Introduction to Jurisprudence (9th edn, Sweet & Maxwell 2014)

Fremont-Barnes G, Encyclopedia of the Age of Political Revolutions and New Ideologies, 1760-1815 (Greenwood Press 2007)


——— The TRIPS Agreement: Drafting History and Analysis (3rd edn, Sweet & Maxwell 2003)


——— ‘Patentability Criteria as TRIPS Flexibilities, Examples of India and China’ in Ruth L Okediji and Margo A Bagley (eds), Patent Law in Global Perspective (Oxford University Press 2014)


and Rights: Trade Liberalization and Reproductive Health in Developing Economies (Zed Books 2006)


Haq MU, Reflections on Human Development (Oxford University Press 1995)


Hippel EV, Democratizing Innovation (MIT Press 2005) 89


Jester MH, Patents and Trademarks Plain & Simple (Career Press 200)

Johnson JA and Stoskopf CH, Comparative Health Systems: Global Perspectives (Jones and Bartlett Publishers 2010)

Kalu KN, Ogbuanu C, and Ogbuanu I, ‘Nigeria’ in James Johnson and Carleen Stoskopf (eds), Comparative Health Systems: Global Perspectives (Jones & Bartlett Learning 2010 Sudbury)


Laxminarayan R and others, 'Drug Resistance' in Dean T Jamison and others (eds), *Disease Control Priorities in Developing Countries* (2nd edn, World Bank 2006)


Locke J, *Two treatises of Government* (Whitmore and Fenn and C Brown 1821)

Lucchini S and others, ‘Decrease in Prices of Antiretroviral Drugs for Developing Countries: From Political "Philanthropy" to Regulated Markets?’ in JP Moatti, and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries: Issues and Challenges* (ANRS 2003)

Macintyre S, Hunt K and Sweeting H, ‘Gender Differences in Health: Are Things Really as Simple as They Seem?’ in Michael Bury and Jonathan Gabe (eds), *The Sociology of Health and Illness: A Reader* (Routledge 2013)


Mandara MU, 'Female Genital Cutting in Nigeria: Views of Nigerian Doctors on Medicalization Debate' in Bettina Shell-Duncan, Ylva Hernlund (eds), *Female "Circumcision" in Africa: Culture, Controversy, and Change* (Lynne Rienner Publishers 2000)

Marks SP, 'Access to Essential Medicines as a Component of the Right to Health' in Andrew Clapham and Mary Robinson (eds), *Realizing the right to health* (Rüfer & Rub 2009)
—— ‘The Emergence and Scope of the Human Right to Health’ in Jose M Zuniga, Stephen P Marks and Lawrence O Gostin (eds), Advancing The Human Right To Health (Oxford University Press 2013)


Merges RP, Justifying Intellectual Property (Harvard University Press 2011)


—— Global Biopiracy: Patents, Plants, and Indigenous Knowledge (UBC Press 2011)


—— and Oh C, The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines? (South Centre 2006)

—— and Villanueva S and Blasetti R, Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks (South Centre 2004)


Nguyễn TT, *Competition Law, Technology Transfer and the TRIPS Agreement* (Edward Elgar 2010)


——, *Women and Human Development* (Cambridge University Press 2000)

——, *Creating Capabilities: The Human Development Approach* (Harvard University Press 2011)


Park JH, Patents and Industry Standards (Edward Elgar Publishing 2010)


Pigou AC, The Economics of Welfare (Palgrave Macmillan 2013)


PN Bhagwati ‘Creating a Judiciary Culture to Promote the Enforcement of Women’s Human Rights’ in Andrew Byrnes, Jane Frances Connors and Lum Bik (eds), Advancing the Human Rights of Women: Using International Human Rights Standards in Domestic Litigation (Commonwealth Secretariat 1997)


Potter PB and Biukovic L, Globalization and Local Adaptation in International Trade Law (UBC Press 2011)


Salam M, Principles and Practice of Urology (Jaypee Brothers Medical P 2013)


Schermers HG, ‘The International Protection of the Right of Property’ in F Matscher and H Petzold (eds), Protecting Human Rights: The European Dimension (Carl Heymanns Verlag KG 1990)

Sebastian Haunss, Conflicts In the Knowledge Society: The Contentious Politics of Intellectual Property (Cambridge University Press 2013)


Sen A, Development as Freedom (Oxford University Press 2001)


Sigerist HE, Medicine and Human Welfare (Yale University press 1941)


Sprankling JG, The International Law of Property (OUP Oxford 2014)


—— From Goods to a Good Life: Intellectual Property and Global Justice (Yale University Press 2012)

Sutton J (ed), Words of Wellness: A Treasury of Quotations for Well-Being (Hay House Inc 1991)


’t Hoen EFM, ‘TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond’ in Jean-Paul Moatti and others (eds), Economics of AIDS and Access to Care in Developing Countries: Issues and Challenges (ANRS 2003)


Vadi V, *Public Health in International Investment Law and Arbitration* (Routledge 2012)


Yankey GS, *International Patents and Technology Transfer to Less Developed Countries: The Case of Ghana and Nigeria* (Avebury 1987)


Zemer L, The Idea of Authorship in Copyright (Ashgate 2007)


Zuniga JM, Marks SP and Gostin LO, Advancing the Human Right to Health (Oxford University Press 2013)

Journal Articles


Adedini SA and others, ‘Barriers to Accessing Health Care in Nigeria: Implications for Child Survival’ (2014) 7 Global Health Action 2


Allirajan M, ‘SC Decision on Glivec is Negative Credit for Branded Drug Firms: Moody’s’ The Times of India (India, 4 April 2013)


—— ‘Non-Obviousness’ (2003) 43(3) IDEA 475


Caldera A and Zarnic Z, 'Affordability of Pharmaceutical Drugs in Developing Countries' Kiel Institute for World Economics Working paper No. 419


Cernic JL, 'Corporate Obligations under the Right to a Healthy Living Environment' (2012) 3 Danube Law and Economics Review 21


Chirac P and Torreele E, 'Proportion of New Drugs Developed over the Period from 1975 to 2004 that were for Neglected Tropical Diseases and Tuberculosis’ (2006) 12 Lancet


‘Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing’ (2011) South Centre Research Paper 41


Fagan A, ‘Human Rights’ The Internet Encyclopaedia of Philosophy (IEP)


—— and others, ‘Are Patents Impeding Medical Care and Innovation?’ (2010) 7 PLoS Med 1


Hart HLA, ‘Are There Any Natural Rights?’ (1955) 64 The Philosophical Review 175


—— ‘Regime Shifting in the International Intellectual Property System’ (2009) 7(1) Perspectives in Politics


Hotez PJ, ‘Empowering Women and Improving Female Reproductive Health through Control of Neglected Tropical Diseases’ (2009) 3 (11) PLoS Neglected Tropical Diseases 1


Levin RC and others, ‘Appropriating the Returns from Industrial Research and Development’ (1987) 3 Brooking Papers on Economic Activity


Lobo DA and others, ‘The Neglected Tropical Diseases of India and South Asia: Review of their Prevalence, Distribution, and Control or Elimination’ (2011) 5 PLoS Neglected Tropical Diseases


—— and Penrose E, 'The Patent Controversy in the Nineteenth Century' (1950) 10 Journal of Economic History 1


—— TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements’ (2005) 27 European Intellectual Property Review 420


Merz JF and others, ‘Diagnostic Testing Fails the Test: The Pitfalls of Patents are Illustrated by the Case of Hemochromatosis’ [2014] 415 Nature 577


Nour NM, ‘Schistosomiasis: Health Effects on Women’ (2010) 3(1) Reviews in Obstetrics and Gynecology


Ojanuga DN and Gilbert C, 'Women's Access to Health Care in Developing Countries' (1992) 35 Social Science & Medicine 613


Okeke TC, Anyaehie USB and Ezenyeaku CCK, ‘An Overview of Female Genital Mutilation in Nigeria’ (2012) 2 Annals of Medical and Health Sciences Research 70


Olanrewaju S, ‘MDGs: So Much Done, So Much More Undone’ (Advocacy for Maternal and Infant Health in Nigeria (AMIHN) 4 August 2011)


—— ‘Patents for Drugs and the Right to Development in International Law’ (2015) 8(1) Law and Development Review 82


Riddle CA, ‘Well-Being and the Capability of Health’ (2013) 32 Topoi


Roffe P, ‘Bilateral Agreements and a TRIPS-Plus World: The Chile-USA Free Trade Agreement’ [2004] Quaker International Affairs Programme


481


—— ‘TRIPS was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP” (2011) 18 Journal of Intellectual Property Law


Sood M, ‘Natco Pharma Ltd. V. Bayer Corporation and the Compulsory Licensing Regime in India’ [2013] NUJS Law Review


Stedman JC, ‘Invention and Public Policy’ (1947) 12 Law and Contemporary Problems 649


Statutes, Treaties and Declarations


African Charter on Human and Peoples’ Rights (Ratification and Enforcement) Act Chapter A9


Amendment of the TRIPS Agreement, Decision of 6 December 2005’ (WTO doc. WT/L/64/ , 8 December 2005)


Constitution of India 1949, as amended in 1951

Constitution of the Federal Republic of Nigeria 1979


Corrupt Practices and Other Related Offences Act of 2000

Declaration on the Right to Development Adopted by General Assembly Resolution 41/128 of 4 December 1986

Doha WTO Ministerial 2001: Ministerial Declaration (WT/MIN(01)/DEC/1, 2001)


European Commission, WTO Ministerial Declaration on the TRIPS Agreement and Public Health (European Commission, 19 November 2001)


Fundamental Rights (Enforcement Procedure) Rules, 2009


Ghana Patent Law 2003 (Act 657)


Japan Patent Act (Act No. 121 of 13 April 1959, as amended up to 2006)

Law No. 9,279 of May 14, 1996, effective May 1997 (Industrial Property Law Act)


Medicines and Related Substances Control Act 101 of 1965 after amendment by the Medicines and Related Substances Control Amendment Act (Act 90 of 1997)

Medicines and Related Substances Control Amendment Act, No. 90 of 1997 (Medicines Act)


Patent Act of the republic of South Korea (Act No. 950 of December 31, 1961, as amended up to Act No. 6411 of February 3, 2001)


Patents (Manufacture of Patented Antiretroviral Drugs) (Authorization), Regulations, 2004 Regulation 3

Political Constitution of the Republic of Costa Rica 1949 (as amended)

Singapore Patents Act (Revised Edition 2005, as amended up to the Statutes (Miscellaneous Amendments) Act 2014)

South Africa Patents Act 1978 (Act No. 57 of 1978, as amended)


The Patents and Designs Decree of 1970

The Registration of United Kingdom Patents Ordinance (Act) 1948, the Patent Rights (Limitation) Decree 1968

Trade Agreement between the European Union and its Member States, of the One Part, and Colombia and Peru, of the Other Part (Official EN Journal of the European Union Volume 55 21 December 2012)

Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part (Official EN Journal of the European Union 30 October 2008)


UN General Assembly, Universal Declaration of Human Rights (Adopted and proclaimed by General Assembly resolution 217 A (III) of 10 December 1948)

United States Code Title 35 – ‘Patents.’ Appendix L - Patent Laws


WTO Ministerial Conference: The Declaration on the TRIPS Agreement and Public Health (Adopted on 14 November 2001 WT/MIN(01)/DEC/W/2)

Cases

Adewole v Jakande (1981) 1 NCLR


Anheuser-Busch Inc. v Portugal Application No 73049/01 (2007) 44 EHRR 42

Anthony Olubunmi Okogie (Trustee of Roman Catholic Schools) & Others vs Attorney General of Lagos State (1981) 2 NCLR 350


Association for Molecular Pathology v Myriad Genetics, Inc. 569 U.S. (2013)


Bamidele Aturu v Minister of Petroleum Resources and Others (2013) Suit No FHC/ABJ/CS/591/09

Bayer Corporation v Natco Pharma Ltd. Order No. 45/2013 (Intellectual Property Appellate Board, Chennai

Brazil — Measures Affecting Patent Protection (WT/DS199/1 G/L/385 IP/D/23 8 June 2000 (00-2254)


Ediciones de la Flor SA v. Fontanarrosa Franco s. Acción Mere Declarativa, file no. 1420/08, the court of First Instance on Civil and Commercial Matters No. 12 of Rosario


European Communities - Measures Affecting Asbestos and Asbestos-Containing Products: Appellate Body Report (WT/DS135/AB/R April 5 2001)

Gbemre v Shell Petroleum Development Company Nigeria Limited and Others (2005) AHRLR 151 (NgHC 2005)

General Sani Abacha & 3 others v Gani Fawehinmi (2000) 4 FWLR 533

Howard Florey/Relaxin (Oppositions by Fraktion der Grünen im Europäischen Parlament) (Lannoye), Opposition Division, 8th December, 1994 [1995] E.P.O.R. 541, T 0272/95

International Ms Vera Salazar Navarro vs Caja Costarricense de Seguro Social Constitutional Court (2001) File n°01-009007-CO

Kendall v Winsor (1858) 21 How. 322


Minister of Health v Treatment Action Campaign (2002) Constitutional Court of South Africa (CCT) 8/02

Morton Salt Co. v G. S. Suppiger Co. (1942) 314 U.S. 488

Motion Picture Patents Co. v Universal Film Mfg. Co. [1917] 243 U.S. 502]

Mr William García Álvarez vs Caja Costarricense de Seguro Social Constitutional Court (1997) File 5778-V-97

Mrs Sidonia Vargas v Hospital San Juan de Dios Constitutional Court [1994] File 2390- C- 94

Natco Pharma Ltd v Bayer Corporation – Application for Compulsory License under Section 84(1) of the Patents Act 1970 in respect of Patent No 215758 Controller General of Patents, Mumbai, CLA No 1 of 2011 (unreported)


Novartis AG v Union of India (UOI) and Ors Civil Appeal No. 2706-2716 of 2013

Novartis AG v Union of India (UOI) and Ors, (2007) A.I.R 24751 (Mandras H.C)

Novartis AG v Union of India. IPAB Order No 100/2009.

Novartis Pharma AG c/ Monte Verde S.A. s/ varios propiedad industrial e intelectual Causa No. 5.619/05 (Arg.), Câmara Federal de Apelaciones [CFed.] [Federal Appeals Court] 1/2/2011

Ogudu v State (1994) 9 NWLR (Pt.366) 1


Paschim Banga Khet Samity v State of West Bengal, Case No. 169, Judgment of 6 May 1996, Indian Supreme Court,

Patricia Asero Ochieng, Maurine Atieno, Joseph Munyi, and AIDS Law Project v Attorney (2009) General Petition No. 409 (High Court of Kenya)

Pennock v Dialogue (1829) 27 U.S. 2 Pet. 1 19

Peter Nemi v A.G of Lagos [1994]1LRC 376
Pharmaceutical Manufacturers’ Association of South Africa et al v President of the Republic of South Africa, (1998) Case No 4183/98, Notice of Motion in the High Court of South Africa (Transvaal Provincial Division)

Roche Products, Inc. v Bolar Pharmaceutical Col., Inc. 733 F.2d 858 (Fed. Cir. 1984)

Smith Kline and French Laboratories Ltd v Netherlands (1990) Application No 12633/87 ECHR Decision and Reports

Social and Economic Rights Action Centre (SERAC) and another v Nigeria (2001) AHRLR 60 (ACHPR 2001)


Street Children (Villagrán Morales et al.) v Guatemala [1999] Inter-American Court of Human Rights (IACrHR)


Transgenic animals/Harvard (Harvard/ Oncomouse) (2005) OJEPO, 229, T 0315/03


United States Diplomatic and Consular Staff in Tehran (United States of America v Iran) Judgments I.C.J. Reports 1980

United States v Masonite Corp. [1461] 316 U.S. 265 278, 62 S.Ct. 1070


Reports and Others


Basheer S, ‘First Mailbox Opposition (Gleevec) Decided in India (March 11)’ (Spicy IP 2006)

Basheer S, ‘Natco Vs Pfizer: Joe Mathew Reports on Compulsory Licensing Decision’ (Spicy IP 2008)
BBC News, ’Glaxosmithkline to ’Drop Patents in Poor Countries for Better Drug Access’” (BBC News, 2016)


Commission on IP, Business Action to Stop Counterfeiting and Piracy (BASCAP) and Commission on Intellectual Property (ICC), Intellectual Property: Powerhouse for Innovation and Economic Growth (Business Action to Stop Counterfeiting and Piracy (BASCAP) and Commission on Intellectual Property (ICC))

Commission on Macroeconomics and Health, Macroeconomics and Health: Investing in Health for Economic Development (World Health Organization 2001)

Committee for Development Policy, The United Nations Development Strategy Beyond 2015 (United Nations publication)


Committee on Economic, Social and Cultural Rights (CESCR), General Comment No 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Paragraph. 1 (c) of the Covenant)


Communication from India, Applicability of the Basic Principles of the GATT and of Relevant International Intellectual Property Agreements or Conventions’ (MTN.GNG/NG11/W/39 1989)
Consumer Project on Technology, ‘TAC Statement on Competition Commission Announcement’ (Consumer Project on Technology 2016)

Cooke JG and Tahir F, ‘Maternal Health in Nigeria: With Leadership, Progress is Possible’ (Center for Strategic and International Studies 2013)


Council for Trade-Related Aspects of Intellectual Property Rights (2001), ‘Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela’ IP/C/W/296


Ebola Treatment Trials to be Fast-Track in West Africa’ (Wellcome 2014)

Essential inventions, ‘Cameroon Request for Compulsory License’ (2016)


Federal Ministry of Health (FMoH) and World Health Organisation (WHO), Access to and Rational Use of Medicines at the Household Level (Federal Ministry of Health Nigeria 2010)

Federal Ministry of Health and World Health Organisation, Baseline Assessment of the Nigerian Pharmaceutical Sector (Federal Ministry of Health 2002)


Holmes R and others, *Social Protection in Nigeria: Mapping Programmes and their Effectiveness* (Overseas Development Institute 2012)


International Centre for Trade and Sustainable Development, ‘India Grants First Compulsory License to Generic Drug Producer’ (2012) 16(10) Bridges


Johnson & Johnson Announces Formation of Ebola Vaccine Development Consortia, Gains Funding From Innovative Medicines Initiative’

Johnson & Johnson Announces Major Commitment to Speed Ebola Vaccine Development and Significantly Expand Production | Johnson & Johnson'


Lawyers collective, ‘Supreme Court Says No to Bayer, Upholds Compulsory License on Nexavar’ ([Lawyerscollective.org](http://Lawyerscollective.org))


Love JP, ‘Recent Examples of the Use of Compulsory Licenses on Patents: Brazil’ (2016)

*Maastricht Guidelines on Violations of Economic, Social and Cultural Rights* (January 22-26 1997)


*Médecins Sans Frontières* (MSF) ‘HIV/AIDS Treatment in Developing Countries: The Battle for Long-Term Survival has Just Begun’ (Campaign for Access to Medicines Médecins Sans Frontières 2009)


*Médecins Sans Frontières* (MSF), *R&D System is Failing to Meet Health Needs in Developing Countries* (Médecins Sans Frontières 2005)

*Médecins Sans Frontières* (MSF), *Untangling the Web of Antiretroviral Price Reductions* (14th edn, Médecins Sans Frontières’ 2011)

*Médecins Sans Frontières*, *How a Global R&D Convention Could Fill the Gaps Left by Today’s Medical Innovation System* (Médecins Sans Frontières 2012)


MSF, ‘The Impact of Patents on Access to Medicines’ ([MSF.org](http://MSF.org))

National Cancer Institute, ‘BRCA1 & BRCA2: Cancer Risk & Genetic Testing’ (National Cancer Institute, 2016)


National Population Commission (NPC) [Nigeria] and ICF Macro, Nigeria Demographic and Health Survey 2008 (Nigeria National Population Commission and ICF Macro 2009)

National Population Commission (NPC) [Nigeria] and ORC Macro, Nigeria Demographic and Health Survey 2003 (National Population Commission (NPC) [Nigeria] and ORC Macro 2004)

NHS, ‘About the National Health Service (NHS) in England’ (Nhs.uk)

Nigeria: International Trachoma Initiative (Trachoma.org)


Pharmaceutical Research and Manufacturers of America, ‘2016 Biopharmaceutical Research industry Profile’ (PhRMA 2016)

Pharmaceutical Research and Manufacturers of America, 2016 Biopharmaceutical Research industry Profile (PhRMA 2016)

Pharmaceutical Research and Manufacturers of America, Biopharmaceutical Research & Development: The Process behind New Medicines (PHARMA 2015)

*Report of the Constitution Drafting Committee* Vol 1 (Government Printer 1976)


Ronald Grisanti, *‘Nexium Prilosec Epiphany’* (Functional Medicine University)


Sachs J, *‘Macroeconomics and Health: Investing in Health for Economic Development’* (World Health Organization 2001)

Sáenz MDR, Bermúdez JL and Acosta M, *‘Universal Coverage in a Middle Income Country: Costa Rica’* (World Health Organization 2010)


Spicy IP, *‘Breaking News!! SC Dismisses Bayer’s SLP Against India’s First CL’* (Spicy IP)

The Consumer Project on Technology (CPTech) *‘Brazilian Statement on Compulsory License for Nelfinavir’* (Cptech.org)

The Consumer Project on Technology (CPTech) *‘Compulsory License for Antiretrovirals, Zambia’* (Cptech.org)

The Consumer Project on Technology (CPTech) *‘Compulsory Licenses’* (Cptech.org)
The Consumer Project on Technology (Cptech), ‘Cipro Compulsory Licensing Dispute’ (Cptech.org)


Thomas G and Thomas K, ‘Top Court in India Rejects Novartis Drug Patent’ The New York Times ( New Delhi, 1 April 2013)


U.S. Department of Health & Human Services (HHS), 'HHS Contracts with Mapp Biopharmaceutical to Develop Ebola Drug' (HHS.gov 2015)


UN Commission on Human Rights, Commission on Human Rights Access to Medication in the Context of Pandemics such as HIV/AIDS (Res 2001/33 23 April 2001)


UN Commission on Human Rights, Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria (UN Doc A/RES/58/179 22 December 2003)

UN Commission on Human Rights, Commission on Human Rights Resolution 2004/26: Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria, (Res 2004/26 16 April 2004)


UN Committee on Economic, Social and Cultural Rights, Concluding Observations of the Committee on Economic, Social and Cultural Rights: Ecuador (E/C.12/1/Add.100 7 June 2004)


UN General Assembly, The Right to Development: Report of the Secretary General (UN Doc A/66/216, 1 August 2011)

UN Human Rights Committee (HRC), CCPR General Comment No.6: Article 6 (Right to Life), 1982


United Nations Development Programme (UNDP), 'What is Human Development?'


United Nations, *The Role of Patents in the Transfer of Technology to Developing Countries: Report of the Secretary-General* (Martinus Nijhoff 1964)
United Nations Women, *Beijing Declaration and Platform for Action: Beijing+5 Political Declaration and Outcome* (UN Women 2014)


USAID, Broad Institute and Illumina Form a Public Private Partnership Combating the Ebola Epidemic in West Africa (Broadinstitute.org)


WHO and FIND, ‘Foundation for Innovative New Diagnostics and WHO collaborate to Improve Diagnosis of Sleeping Sickness with a Gates Foundation Grant’ (WHO and FIND Press Release 2006)


World Health Organisation, ‘Global Price Reporting Mechanism’ (WTO.org)

World Health Organisation, ‘Right to Health Fact Sheet’ (World Health Organisation)


World Health Organization (WHO) and World Trade Organization (WTO), *WTO Agreements and Public Health: A Joint Study by the WHO and WTO Secretariat* (World Health Organization and World Trade Organization 2002)

World Health Organization 'The Nigerian Health System' (WHO)


World Health Organization, 'Globalization, TRIPS and Access to Pharmaceuticals' (WHO Policy Perspectives on Medicines, No 3, 2001)


World Health Organization, ‘Technical Cooperation Activities: Information from Other Intergovernmental Organizations’ (WHO Doc. IP/C/W/305/Add.3 2001)


World Health Organization, 'Female Genital Mutilation' (World Health Organization)


World Health Organization, 'Increasing Access to HIV Treatment in Middle-Income Countries: Key Data on Prices, Regulatory Status, Tariffs and the Intellectual Property Situation' (World Health Organization 2014)

World Health Organization, 'Leprosy Update' (2011) 86(36) Weekly Epidemiological Record (WER)


World Health Organization, *Zika Virus* (World Health Organization 2016)


World Trade Organization, ‘WTO | Dispute Settlement - The Disputes - DS199’ (*Wto.org* 2016)

World Trade Organization ‘Female Genital Mutilation’ (World Trade Organization 2016)


World Trade Organization, ‘WTO: Intellectual Property (TRIPS) - TRIPS and Public Health: Compulsory Licensing of Pharmaceuticals and TRIPS’ (*wto.org*)

World Trade Organization, ‘Disputes - Dispute Settlement CBT - Legal Effect of Panel and Appellate Body Reports and DSB Recommendations and Rulings - Legal Status of Adopted/Un-adopted Reports in Other Disputes - Page 1’ (*Wto.org*)