Expanding the Role of Morality and Public Policy in European Patent Law

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Contents

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1 Introduction

Recent and projected advances in technology give rise to difficult questions about the interaction between patents and the public interest. Not only are there patents for inventions where the invention or its commercial exploitation is potentially immoral or against public policy, there are patents for inventions which, in their operation, have ethically problematic effects, creating public interest concerns. Patent law often takes an excessively economic approach and fails to appropriately accommodate the public interest, with important ethical consequences. The concepts of morality and public policy are ways in which the law can address the public interest balance. However, they are generally treated as conceptually distinct, and legally separate. In this chapter, we argue that the analysis of morality and public policy in European patent law ought to be given more attention and should not be separated off from broader public interest concerns relating to the operation of the patent system. Instead, we argue that morality and public policy should be seen as part of the public interest as a whole, and that issues of morality and public policy concerns (such as access to medicine) are part of the same continuum. Employing a stronger role for human rights (specifically human dignity) in patent law has the potential to draw these areas together to make the law more coherent across these two types of potentially problematic inventions. In turn, this practice would expand the role of the public interest in patent law.

In European patent law, provisions exist to ensure that patents are not granted for inventions, the commercial exploitation of which is deemed to be generally against public policy or morality. There are additional specific provisions against the patentability of processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit.

These provisions have the effect of linking patents, a predominately economic tool, and human rights. Morality and public policy have been long-standing features in national and European patent laws. The Statue of Monopolies would not allow protection for inventions that were deemed 'generally inconvenient', 17th century patent laws in the United Kingdom prevented patentability on inventions prejudicial to subjects, and they were explicit exceptions in subsequent laws and from then on.[2] Their inclusion in European patent laws was never questioned.

However, explicit human rights discussions in patent law are a relatively recent development. Since human rights has become a part of patent law, the morality/public policy provisions have taken on a different role. On the implementation of the Biotech Directive,[3] human dignity became a significant consideration for biotech inventions in the European Union (EU). The provisions of the Directive were then incorporated into the Implementing Regulations of the European Patent Convention (EPC). The European Convention on Human Rights and the EU Charter of Fundamental Rights have also had an impact, with their provisions on fundamental rights and human dignity being referred to in cases raised to the Court of Justice of the European Union (CJEU) and in cases before the Boards of Appeal of the European Patent Office (EPO) respectively.[4]

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[2] Statute of Monopolies 1623, VI; UK Patent Law Amendment Act 1852, p427.

[3] Directive 98/44EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (Biotech Directive).

[4] Case C-34/10 *Oliver Brüstle v Greenpeace* ECLI:EU:C:2011:669; T149/11 *Method and device for processing a slaughtered animal or part thereof in a slaughterhouse* of 24.01.2013.

In this chapter, we first explore the role that the morality and public policy provisions have played in European patent law and argue that these concepts be considered in more depth. Following a brief historical overview of these provisions, this chapter examines the related case law in detail.[5] The focus will be on the interpretation of the general provision and also the specific exception relating to the use of human embryos for industrial or commercial purposes. Morality is a contested concept, and there is no single European morality. Moreover, conceptions of morality and public policy can vary over time. It is therefore difficult for courts to rule on such questions, but it is nonetheless not impossible for them to do so.[6] However, as will be expanded on below, to date, morality has only been interpreted by the CJEU and Boards of Appeal in very narrow manner in relation to patents. Although these cases have taken huge strides forward for the consideration of human rights in patent law, we argue that the conception of morality and its interpretation ought to be broader.

We then explore some of the wider public interest concerns arising from patents, including a case study on gene patents. The examination of these provisions have implications for the use of patents in accordance with the public interest, for which, we argue, the concept of human dignity is important.

In the final sections of this chapter, we explore how, through the better employment of human dignity in patent law in Europe, moral and ethical concerns can be better addressed. Given the significance and relevance of morality and ethics in modern technology that currently exists and the inevitable advances that will be made in the future, we suggest that these concepts should be considered in more detail in relation to the public interest. We argue that the principle of human dignity, which is expressly referred to in the relevant legislation, and has been drawn on by the Boards of Appeal and the CJEU, is an appropriate and sensible principle to apply in this respect.[7]

In our view, importing a deeper and more nuanced consideration of human dignity in patent law would help to address moral and ethical concerns and support a better equilibrium between the private economic interests of patent holders and the public interest.

2 Morality and public policy in European patent law

The provisions with which this paper is concerned are found primarily in the EPC, the Biotechnology Directive, and their corresponding national Patents Act provisions. There are two different types of provision in European patent law.

The first, Article 53(a) EPC, is the more general, and provides that patents are not granted for inventions the commercial exploitation of which would be contrary to *ordre public*

[5] We focus in this chapter on the European perspective and rely therefore on the case law and practice of the European Patent Office and the European Union.

[6] Courts in this context include the quasi-judicial Boards of Appeal of the EPO.

[7] Although the principle of human dignity encompasses only human morality and does not extend to non-human aspects of morality, the majority of ethical issues arising from current patent law cases have an explicit link with humans, thus the principle of human dignity assists with the resolution of moral and ethical concerns in this arena. It is possible that the principle of human dignity will not adequately address some environment concerns, or issues of animal ethics, although the involvement of humans in the patented invention in such cases may be sufficient to enliven the principle in any case (see for example T149/11 *Method and device for processing a slaughtered animal or part thereof in a slaughterhouse* of 24.01.2013).

or morality.[8] The corresponding provision of the United Kingdom (UK) Patents Act, s 1(3), uses the term 'public policy' rather than '*ordre public*', but the terms equate.[9]

The second set of provisions are more specific and are found in Rule 28(a)-(d) of the Implementing Regulations of the EPC 2000. These provisions were voluntarily incorporated into the EPC following the introduction of the EU Biotech Directive.[10] Rule 28 provides:

> Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:
> (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.

These provisions have also been incorporated into the national laws of European Union Member States as a result of the Biotech Directive and are applicable in all Contracting Member States of the EPC as a result of Rule 28. Therefore, national patent offices, the European Patent Office, national courts, the Boards of Appeal of the EPO and the CJEU may all be called upon to interpret these provisions.[11]

If a patent application falls within one of these four types of invention, it is denied patentability under this provision. If an application falls outside these provisions, the application then needs to be assessed to determine whether it nonetheless falls within the Art 53(a) prohibition.[12] Furthermore, the grant of the patent can be opposed, and the validity of a patent can be challenged, on the basis of these provisions.[13]

2.1 The history of the provisions in European patent law

Modern patent law has always had an ethical dimension, which can be gleaned from the social contract on which it exists.[14] The social contract is at the core of patent law and ensures that the interests of the patentee are balanced with those of society. Patent law gives inventors an exclusive right, however, in order to balance that exclusivity against the public interest the right is limited in time and the invention must be sufficiently disclosed. These requirements ensure that the public can work the invention once the exclusive right lapses.

Internationally, the exclusion of inventions from patenting is permitted by Art 27(2) of the Agreement on Trade Related aspects of Intellectual Property (TRIPS), which provides that

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[8] Art 53(a) EPC. No such exception to patentability on the basis of morality exists in US or Australian law.
[9] Chartered Institute of Patent Agents, *CIPA Guide to the Patents Acts* (8th ed Sweet & Maxwell, London 2016) [1.21]. s1(3) PA 1977 is also mentioned in s130(7) PA 1977 which requires that the provisions mentioned therein "are so framed as to have, as nearly as practicable, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention".
[10] When the Biotech Directive was implemented the European Patent Organisation decided to incorporate its provisions into the Implementing Regulations of the EPC in order to have a consistent approach towards biotech patents.
[11] The Unified Patent Court will also play a role if it becomes operational.
[12] T315/03 *Transgenic animals/HARVARD* of 6.7.2004, Reasons 6.1.
[13] Article 100 EPC; s72(1) Patents Act 1977 (UK).
[14] European Group on Ethics in Science and New Technologies (European Commission), 'Opinion on ethical aspects of patenting inventions involving human stem cells' (2002), available at <https://publications.europa.eu/en/publication-detail/-/publication/687b0402-32b8-4b1a-905e-b7885d2a3eac> last accessed 9 August 2019, 1.18.

member states "may exclude from 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."[15] However, the inclusion of these provisions in patent laws pre-exist TRIPS.

For the UK, it could even be said that something akin to a morality/public policy provision can be seen in the 1623 Statute of Monopolies where it says that patents would not be granted if they are "altogether contrary to the Lawes of this Realme" and further on "soe as alsoe they be not contrary to the Lawe nor mischievous to the State, by raising prices of Commodities at home, or hurt of Trade, or generally inconvenient".[16] Here, the current day language can be seen emerging and although it might not specifically mention morality or public policy, something that is contrary to the laws of the realm, something that is mischievous to the State, or generally inconvenient, demonstrates a consideration of something other than the economic interests involved in patent law and a link to something akin to morality/public policy. This interpretation has also been inferred from the Statute of Monopolies in other jurisdictions, such as Australia, where it has been argued that 'generally inconvenient' could have been intended as a broad public interest test.[17]

This language can also be seen in the UK Patent Law Amendment Act 1852, which was introduced following criticisms on the functioning of the patent system at the time.[18] It is stated in the example given of a granted patent that "if at any Time during the said Term hereby granted it shall be made appear to Us, Our Heirs or Successors, or any six or more of Our or their Privy Council, that this Our Grant is contrary to Law, or prejudicial or inconvenient to Our Subjects in general…these Our Letters Patent shall forthwith cease, determine, and be utterly void to all Intents and Purposes."[19] Reflections of the Statute of Monopolies can be seen in the language being used here, but this Act also goes further by explicitly allowing the revocation of a patent if it is prejudicial to society.

Explicit provisions appear in the 1883 UK Patents, Designs and Trade marks Act and then continue to be included in subsequent pieces of legislation such as the 1907, 1949 and 1977 (as amended) Patent Acts. It is clear that from very early on in patent law, in the UK at least, morality and public policy provisions are included.[20]

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[15] Art 27(2) TRIPS.

[16] Statute of Monopolies 1623, I and VI.

[17] Statute of Monopolies 1623, I and VI. Other jurisdictions, such as Australia, do not make explicit mention of morality even today. However, the Australian Patent Act is based on the Statute of Monopolies and has this similar phrasing. It is arguable that the words 'generally inconvenient' were intended to be a broad public benefit test, incorporating considerations of the public interest, and that such considerations could be employed in excluding patents on this basis. However, there is little evidence that courts or patent offices would be inclined to rely on such public interest considerations unless explicitly directed to do so – see Chris Dent, '"Generally Inconvenient": The 1624 Statute of Monopolies as Political Compromise' 33 Melbourne University Law Review 415, 446; Peter Drahos, 'Biotechnology Patents, Markets and Morality' (1999) 21 EIPR 441, 441; Dianne Nicol 'On the Legality of Gene Patents' [2005] MelbULawRw 25; Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health Report* (Australian Law Reform Commission 2004) available at <https://www.alrc.gov.au/publications/report-99> last accessed 9 August 2019.

[18] For more on the history of patent law and issues with letters patent being granted by the crown, see: Lionel Bently, Brad Sherman, Dev Gangjee and Philip Johnson, *Intellectual Property Law* (5th edn, OUP 2018) 394-397.

[19] UK Patent Law Amendment Act 1852, p427.

[20] The same can be said for other countries in Europe but that is beyond the scope of this paper. See: Viola Prifti, 'The Limits of "*Ordre Public*" and "Morality" for the Patentability of Human Embryonic Stem Cell Inventions' (2019) 22 Journal of World Intellectual Property 2, 4.

For the EPC, discussions on this provision are seen in the Travaux Préparatoires.[21] However, what is relevant here about these discussions is that they revolve around the wording of the provision and whether terms should be defined more so than whether or not they should be included at all. The main questions discussed were whether "if the use of the invention is contrary to 'ordre public' or morality in only one of the Contracting States, will grant of a European patent be excluded?"[22] and whether there was "a 'European' definition of morality? [or] Should national definitions be applied or is it necessary to consider what is common to them all?"[23] It was recognised that no European definition of morality existed and that it was enough to mention morality and leave its interpretation up to European institutions.[24]

2.2 Morality, Public Policy and Human Dignity

From this brief historical overview, it appears that there has always been a public interest dimension to patent law, with morality and public policy being an explicit concern in modern patent legislation but implicit possibly as far back as the Statute of Monopolies.

This public interest dimension has consistently been for the benefit of society. The social contract that underpins the patent system attempts to find the balance between the rights of the patentee and society. Provisions preventing the exploitation of inventions for reasons of morality and public policy have at their core the protection of society, of human rights and human dignity especially.[25] The protection of society and human dignity in patent law has expanded greatly, especially with the introduction of the Biotech Directive and its incorporation into the Implementing Regulations of the EPC.

The CJEU has explicitly confirmed the need for patent law to take into account the link between human dignity and patent law in relation to morality in the *Brüstle* case (explored below at **Error! Reference source not found.**). Patent institutions are also beginning to recognise the role of human dignity in the interpretation of patent law, with the Technical Board of Appeal of the European Patent Office stating that "'ordre public' must be seen in particular as defined by norms that safeguard fundamental values and rights such as the inviolability of human dignity and the right of life and physical integrity."[26] It is clear that morality, public policy and human dignity are becoming significant concepts in European patent law.

The tension between the private interest of the inventor and the public interest is often in delicate balance in the grant of patents. The balance must be struck between providing sufficient incentive to encourage the creation of new and useful technologies on the one hand, as against the public interest in accessing those new and useful technologies.[27] Patent law has traditionally been conceived of as a tool for promoting both private and public interests, with

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[21] Travaux Préparatoires EPC 1973, available at < https://www.epo.org/law-practice/legal-texts/epc/archive/epc-1973/traveaux.html> last accessed 9 August 2019.

[22] Travaux Préparatoires EPC 1973, Article 53, Comments on the first Preliminary Draft Convention relating to a European patent law of 14 March 1961, LT 234/82 Section 14 IV/2071/61 – E, 5.

[23] Patents Working Party, Proceedings of the 1st Meeting of the Patents Working Party held at Brussels from 17 to 28 April 1961, Section 5, IV/2767/61-E, 6.

[24] Patents Working Party, Proceedings of the 1st Meeting of the Patents Working Party held at Brussels from 17 to 28 April 1961, Section 5, IV/2767/61-E, 7.

[25] Charter of Fundamental Rights of the European Union 2012/C 326/02, Article 3.

[26] T149/11 *Method and device for processing a slaughtered animal or part thereof in a slaughterhouse* of 24.01.2013.

[27] The justifications for intellectual property are rehearsed in detail elsewhere, and this paper does not seek to address objections to the existence of patents per se. Moreover, we focus primarily on the traditional utilitarian justification for patents, rather than any human rights justification for the existence of patent rights: Rochelle Cooper Dreyfuss, 'Patents and Human Rights: Where Is the Paradox?' in FW Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar 2010).

the public interest understood in terms of the progress of technology and economic advancement.[28] However, there is increasing recognition that a purely economic approach fails to capture important aspects of the public interest. Dreyfuss notes that "No one is fully served by a system that depends on the market alone to encourage innovation."[29] When the technologies in question are not merely desirable or nice to have, but are necessary for the flourishing of humanity, then the question of access goes beyond the balancing of economic incentives and has human rights implications.

Morality and ethics can be slippery concepts, which can be difficult to apply in practice. Understandings of morality, the concept of something being right or wrong, and ethics, which goes further but also includes issues of morality, can be different for different people. It can therefore be difficult for patent offices and courts to apply such broad concepts.[30] Human rights frameworks arguably provide a more concrete legal framework on which to base arguments about the implications of ethics and morality for the public interest. As van Overwalle notes, "For patent law to be widely accepted and generally recognized as a tool fostering both private and public interest, it is vital that current patent law regimes are inextricably linked with human rights discourse, and that human rights assist in defining the utter limits of patent rights."[31]

The place of human dignity in international human rights law has been debated for quite some time, but it has a more recent connection with patent law.[32] The European Group on Ethics has noted the importance of the principle of human dignity in relation to patents on human embryonic stem cells.[33] More broadly, the Committee on Economic Social and Cultural Rights, has affirmed the importance of excluding from patentability inventions where their commercialisation would jeopardise human dignity. [34]

The purpose behind the public interest provisions is to protect society and ensure that there are considerations of a moral and ethical nature in patent law. Those considerations come in the form of a question as to whether the commercial exploitation of the invention is moral or against public policy. Given the importance of the balance between private and public interests in patent law, how these provisions are being interpreted is extremely important. It is only when these provisions are interpreted that we can see whether a more detailed or more expansive consideration of morality/public policy, is necessary in order to protect the public interest.

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[28] Geertrui van Overwalle, 'Human Rights' Limitations in Patent Law' in FW Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar 2010) 241-242.

[29] Dreyfuss, 90.

[30] As is evident in the case law, discussed below at 3.

[31] Van Overwalle.

[32] Van Overwalle, 244; Aurora Plomer, 'Human Dignity, Human Rights, and Article 6(1) of the EU Directive on Biotechnological Inventions' in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (OUP 2009); Agnieszka Kupzok, 'Human rights in the case law of the EPO Boards of Appeal' in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015); Aurora Plomer, 'Human dignity and patents' in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015); David Resnik, 'Embryonic Stem Cell Patents and Human Dignity' (2007) 15(3) Health Care Analysis 211.

[33] Opinion No. 15 of the European Group on Ethics in Science and New Technologies to the European Commission, 'Ethical Aspects of Human Stem Cell Research and Use' 14 November 2000.

[34] COMMITTEE ON ECONOMIC, SOCIALAND CULTURAL RIGHTS, Thirty-fifth session, Geneva, 7-25 November 2005, General Comment No. 17 (2005) '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', GE.06 -40060 (E) 020206, [35].

3 Interpretations of the morality/public policy provisions

As has been shown above, morality and public policy have been an implicit part of patent law since the introduction of a law relating to patents, appearing explicitly in modern legislative texts. It can therefore be argued that these provisions (both general and specific) are of significant importance to patent law from a legislative perspective, and relatedly, even more so, from a societal perspective, with strong links to human dignity.[35] The provisions exist to ensure that patents are not granted for inventions whose commercial exploitation is deemed immoral or contrary to public policy.

However, whether the provisions are fulfilling that purpose depends on the extent to which they are considered at examination stage and in case law. A question thus arises as to what extent these provisions are being considered when raised before a tribunal, and whether the public interest dimension of patent law is being taken into account adequately.

The following section will examine the case law on the provisions from the Boards of Appeal of the EPO and the CJEU.[36] It will first discuss the interpretation of the general provision, and then move on to examine the specific example of the exception relating to the use of human embryos for industrial or commercial purposes.

3.1 The interpretation of the general provision

The general provision, found in Article 53(a) EPC, states that:

> 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

The relationship between this general provision and the specific provisions (which will be elaborated on further below) is that if an invention does not fall within one of the specific provisions but might still be potentially immoral/against public policy, the general provision will then be considered.[37] Although the specific provisions are dealt with first when appropriate, it is relevant at this point to discuss the general principles and how they have been interpreted.

When the Boards of Appeal have considered Article 53 EPC, whether part (a), (b), or (c), they have consistently suggested a narrow approach to the exceptions.

In *Oncomouse*,[38] when interpreting Article 53(a) EPC, the Boards proposed a balancing approach to determine if the invention in question was immoral. A number of factors were taken into account including the potential benefit to mankind, the suffering of the animal, harm to the environment and potential threats to evolution. The Board weighed these factors against

[35] As previously noted in footnote 6, although the principle of human dignity encompasses only human morality and does not extend to non-human aspects of morality, the majority of ethical issues arising from current patent law cases have an explicit link with humans, thus the principle of human dignity assists with the resolution of moral and ethical concerns in this arena.
[36] Decisions of individual national courts will not be expanded upon because the decisions of the Boards of Appeal of the EPO and the CJEU are more relevant to the focus of this chapter and should filter down into national courts as persuasive authorities.
[37] T315/03 *Transgenic animals/HARVARD* of 6.7.2004 and G2/06 *Use of embryos/WARF* of 25.11.2008.
[38] T19/90 *Onco-Mouse* of 3.10.1990.

one another and ruled in favour of the patentee given the potential benefits to mankind – the benefit was related to developments in cancer treatment. The balancing approach is considered to lead to quite a narrow interpretation of the exception as many potential benefits to mankind could outweigh harm caused to animals, as long as the benefit is *potentially* significant.[39] However, it does take into account both sides of the argument.

In the *Howard Florey/Relaxin* case, an even stricter and narrower test was promoted by the Opposition Division.[40] Relying on previous case law, including *Oncomouse*,[41] the Opposition Division stated that "patents would not be granted for inventions which would universally be regarded as outrageous"[42] and also considered the Guidelines where it was stated that "Article 53(a) EPC is likely to be invoked only in rare and extreme cases, for example that of a letter bomb."[43] They quoted the general guidance given encouraging that a "fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable. If it is clear that this is the case, objection should be raised under Article 53(a); otherwise not". When the case was appealed, the Board of Appeal agreed with the Opposition Division.[44]

The so-called threshold approach can generally be regarded as stricter than the utilitarian balancing approach and promotes a very narrow interpretation of the exceptions to patentability. Being "universally regarded as outrageous" is a very high bar.

Another relevant development by the Boards of Appeal has been the attempt to define morality and *ordre public*. In *Plant Genetic Systems*, the Board stated that:

> The concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the EPC, the culture in question is the culture inherent in European society and civilisation. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is not in conformity with the conventionally-accepted standards of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality.[45]

> It is generally accepted that the concept of 'ordre public' covers the protection of public security and physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. Accordingly, under Article 53(a) EPC, inventions the exploitation of which is likely to breach public peace or social order (for example through acts of terrorism) or to be seriously prejudice the environment are to be excluded from patentability as being contrary to *ordre public*.[46]

[39] The benefit was not significant enough in the Upjohn decision, where the invention related to treating baldness.
[40] *Howard Florey/Relaxin* [1995] EPOR 541 (EPO (Opposition Division)) 6.1.
[41] T19/90 *Onco-Mouse* of 3.10.1990 (related to 53(a)) and T320/87 *Hybrid plants* of 10.11.1988 (related to 53(b)).
[42] *Howard Florey/Relaxin* [1995] EPOR 541 (EPO (Opposition Division)) 6.2.1
[43] *Howard Florey/Relaxin* [1995] EPOR 541 (EPO (Opposition Division)) 6.2.1, referring to Guidelines for Examination then at C-IV.3.1.
[44] T 272/95 *Relaxin/HOWARD FLOREY INSTITUTE* of 23.10.2002.
[45] T356/93 *Plant cells* of 21.2.1995, Reasons 6.
[46] T356/93 *Plant cells* of 21.2.1995, Reasons 5.

National regulation does not enter the discussion in the assessment[47] and opinion polls are not considered to necessarily reflect norms of conventionally accepted standards of conduct.[48] It must be the commercial exploitation of the invention, rather than the subject-matter of the patent that is contrary to morality or *ordre public*.[49] Furthermore, if the invention can also be exploited in a way which does not and would not infringe *ordre public* or morality it is not sufficient to deny patent protection pursuant to Art 53(a) EPC.[50]

These elaborations have not added much to the understanding of when something is to be considered as contrary to morality or public policy by the Boards of Appeal. Relating the definition of morality to a European consensus when one cannot be said to exist is especially problematic.

It is clear that in certain instances, not all thirty-eight EPC Contracting Member States would agree on what is moral and what is not. Indeed, perceptions of morality change over time. Why then did the Boards of Appeal define morality as they did? The Boards could be considering what they believe morality to mean, or could be ensuring that they appear to be considering morality on the surface when in reality it is not something they are entirely concerned with – a case of window-dressing.

Alternatively, the Boards may not consider themselves to be best placed to determine what is contrary to morality for the purposes of patent law. This is where the narrow interpretation of the exceptions is useful. When considering the attempts by the Boards of Appeal to interpret the general provision a consistently narrow approach can be seen, one that often comes down in favour of the patentee. Given the *raison d'être* of the EPO is to grant patents, this is not surprising.

By implementing a narrow approach towards the exceptions to patentability, it becomes easier to decide what is immoral or against public policy. For example, by having a broad definition of morality relating to "conventionally accepted standards" tied to a narrow test relating to matters that are "universally regarded as outrageous", only the most immoral will be rejected. If the exploitation of an invention is not so immoral that it forms a conventionally-accepted standard then morality may be skipped over and Boards instead place the majority of their reasoning on another of the patentability criteria such as sufficiency, for example.

However, there are signs that this very narrow approach may be shifting. Most recently, the Board of Appeal has interpreted Article 53(a) with an explicit focus on human dignity. They found that *ordre public* had to be seen "as defined by norms that safeguard fundamental values and rights such as the inviolability of human dignity and the right of life and physical integrity."[51] Although the reasoning and discussion in this decision focussed on a particular aspect of the invention, which was quite odd, and it was not a very detailed consideration of *ordre public*, it does display the willingness of the Board to discuss human dignity.

3.2 The interpretation of specific provisions

The specific provisions, contained in Rule 28 EPC, state that under Article 53(a), patents will not be granted in relation to inventions relating to specific subject-matter including processes for cloning human beings, processes for modifying the germ line genetic identity of human

[47] Art 53(a) EPC; UK Patents Act 1977 s1(4); T356/93 *Plant cells* of 21.2.1995, Reasons 7.
[48] T356/93 *Plant cells* of 21.2.1995, Reasons 15. See also: Amanda Warren-Jones, 'Identifying moral consensus: why are the patent courts reticent to accept empirical evidence in resolving biotechnological cases?' (2006) 28(1) EIPR 26.
[49] T866/01 *Euthanasia Compositions/Michigan State*, Reasons 5.6.
[50] T866/01 *Euthanasia Compositions/Michigan State*, Reasons 5.8.
[51] T149/11 *Method and device for processing a slaughtered animal or part thereof in a slaughterhouse* of 24.01.2013, Reasons 2.5.

beings, uses of human embryos for industrial or commercial purposes, and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit.

The specific provision which has received the most interpretative attention is Rule 28(c) – uses of human embryos for industrial or commercial purposes, or in other words, the commercial exploitation of human embryos.[52] Therefore, this part will focus on the interpretation of this provision by the Boards of Appeal of the EPO and the CJEU.[53] From the cases that have been decided, we can draw some conclusions as to the respective institution's approach towards the morality/public policy provisions.

3.2.1 EPO Case law

The first case to look directly at the human embryo exception was the *Edinburgh patent* Opposition Division decision.[54] It was decided that a broad interpretation of Rule 23(d) (as it then was) was the only appropriate way forward.[55] This was partly due to the existence of Rule 23(e)(1) which stated that the human body, at the various stages of its formation and development cannot constitute patentable inventions (including the discovery of a gene sequence). It was decided that if Rule 23(d) was narrowly interpreted it would exist for no reason because Rule 23(e)(1) would already exclude it.[56]

The next to discuss the exception was the *WARF* referral to the Enlarged Board of Appeal.[57] The Technical Board of Appeal said that the Opposition Division in the *Edinburgh patent* case had been wrong as both Rule 23(d) and Rule 23(e)(1) dealt with similar subject matter and intentionally over-lapped.[58] However, more relevant here is the passage from this decision where the Board stated that the "EPO was not and should not act as a moral censor of controversial technologies. The EPO's expertise was in the field of patents, not in resolving controversial moral and ethical issues. The regulation of controversial technologies was a matter for legislators rather than the EPO."[59]

The Board went on to promote a narrow reading of the exception and one that was very pro-patent. It was stated that "in cases where a provision of the EPC was capable of bearing two alternative meanings, one of which resulted in refusal of the application on ethical grounds (ie the broad interpretation) and one of which permitted grant (ie the narrow interpretation), the correct approach was to construe the provision narrowly."[60] They went on to promote the balancing test from *Oncomouse*, weighing the moral objections against the usefulness of the invention for humanity, but also referred questions to the Enlarged Board of Appeal.[61]

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[52] For examination guidance related to this provision from the EPO, see: Guidelines for Examination, G.II.5.3, available at: <https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_3.htm> last accessed 29 October 2019.

[53] Rule 28(d) is a reflection of Article 6(2)(c) of the Biotech Directive, as incorporated into the Implementing Regulations of the EPC. For further discussions on this topic, see: Viola Prifti, 'The Limits of "*Ordre Public*" and "Morality" for the Patentability of Human Embryonic Stem Cell Inventions' (2019) 22 The Journal of World Intellectual Property 2.

[54] Interlocutory decision of the Opposition Division dated 21 July 2003 concerning European patent 0 695 351 (*Edinburgh patent*).

[55] *Edinburgh patent*, Reasons 2.5.3, Sheet 22.

[56] *Edinburgh patent*, Reasons 2.5.3, Sheet 22.

[57] T1374/04 *Stem cells/WARF* of 18.11.2005 (Interlocutory Decision).

[58] T1374/04, 9.

[59] T1374/04, 10.

[60] T1374/04, 10-11.

[61] T1374/04, 12.

When the Enlarged Board of Appeal decided on the *WARF* case,[62] they began by referring to the legislators intention and concluded that an invention such as the one concerned should not be protected. The Board appeared to reject the argument put forward by the appellant that an embryo meant "14 days or older, in accordance with usage in the medical field".[63] They were of the opinion that as human embryo had not been defined by the legislator and that because the purpose of the legislation was to protect human dignity, a restrictive meaning of human embryo would "undermine the intention of the legislator".[64]

Furthermore, they stated that "what is an embryo is a question of fact in the context of any particular patent application".[65] Instead of the usual narrow interpretation that has been seen in relation to the exceptions, the Enlarged Board gave quite a broad meaning to human embryo in this context in the name of human dignity.[66] When considering the invention it was decided that it was immoral to destroy a human embryo. This was decided without discussing whether that would ever be permitted. They did not reason this point in relation to the invention in question and, we argue, missed an opportunity to do so.[67]

The Board implied that this decision was so clear cut that it was not necessary (or appropriate) for them "to discuss further arguments and points of view put forward in these proceedings such as whether the standard of ordre public or morality should be a European one or not, whether it matters if research in certain European countries involving the destruction of human embryos to obtain stem cells is permitted, whether the benefits of the invention for humanity should be balanced against the prejudice to the embryo, or what the point in time is to assess ordre public or morality under Article 53a EPC."[68] However, we argue that it was necessary and appropriate for them to do so.

Instead, the reasoning focusses on whether there had been a commercial exploitation of the invention and the immorality of the invention is assumed without further discussion. It was noted that it is not the patenting that should be questioned regarding *ordre public* and morality, but the performing of the invention.[69] The Enlarged Board then equated the making of the invention with its commercial exploitation[70] linking this to the rights granted to the patentee to stop third parties from making or using a protected invention.[71] From this reading, the Board

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[62] G2/06 *Use of embryos/WARF* of 25.11.2008 (*WARF*). For further discussions on the *WARF* case, see: Sigrid Sterckx and Julian Cockbain, 'Assessing the Morality of the Commercial Exploitation of Inventions Concerning Uses of Human Embryos and the Relevance of Moral Complicity: Comments on the EPO's WARF Decision' (2010) 7(1) SCRIPTed 84; Sigrid Sterckx, 'The European Patent Convention and the (non-) patentability of human embryonic stem cells – the WARF case' [2008] 4 IPQ 478.

[63] *WARF*, Reasons 19 and 20.

[64] *WARF*, Reasons 20.

[65] *WARF*, Reasons 20.

[66] For more on the interpretation of Article 53(a), see: Ella O'Sullivan, 'Is Article 53(a) EPC still of narrow interpretation?' (2012) 7(9) JIPLP 680.

[67] This decision has been criticised for going too far and giving too broad a reading. See: Aurora Plomer, 'Human Dignity, Human Rights, and Article 6(1) of the EU Directive on Biotechnological Inventions' in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (OUP 2009).

[68] *WARF*, Reasons 31.

[69] *WARF*, Reasons 29

[70] For a discussion on the meaning of commercial exploitation, see: Amanda Warren-Jones, 'Morally regulating innovation: what is "commercial exploitation"?' [2008] 2 IPQ 193. Examining Beyleveld and Brownsword's contention that this provision goes beyond its literal meaning, she discusses how 'exploitation' has been widely interpreted to include the development of the invention. This practice is seen to continue despite the Boards of Appeal in the *Oncomouse* decision stating that Article 53 "raises no question of the morality of patenting a particular invention or of the morality of that invention *per se*… Neither the making of the invention nor the process of patenting an invention can be seen as contrary to *ordre public* or *morality*". However, Warren-Jones contends that there may be certain circumstances where this is useful, such as "where the immorality inherent in the development of an invention must be continually repeated in order to use the invention" (p202).

[71] *WARF*, Reasons 25.

appears to be saying that making an invention that is immoral amounts to an immoral commercial exploitation of the invention regardless of its intended use. Despite the note, the focus seems to be more on the morality of the invention rather than its commercial exploitation, if viewing commercial exploitation from the perspective of intended use. This is problematic and a departure from previous jurisprudence.

As a result of the invention being deemed immoral – coupled with the link made between the commercial exploitation of an invention and the making of the invention – its commercial exploitation was automatically deemed immoral. The potential use of the invention was never considered.[72] There was no balancing test or threshold test used to determine the morality of the commercial exploitation of the invention. The result of the failure of the Board to make explicit their reasoning is a level of legal uncertainty, with parties left wondering whether this means that the use of a human embryo at any stage of development would be deemed immoral by the EPO, or just a use that results in its destruction.

In this case, the Enlarged Board are saying all the right things – that the legislators intention needs to be taken into account, that a narrow restriction would be bad for human dignity – and considerations of morality and public policy are being highlighted, but they are not discussed or explored in any meaningful way. No guidance has been given for future cases and the implications of this can be seen below.[73]

Additionally, the Board also decided that if an invention requires the destruction of the human embryo and that is not mentioned in the application, it should still be taken into account.[74] This is another broad interpretation where the Enlarged Board decided that if the invention required the destruction of a human embryo and that was not included in the application, it would still be relevant.[75] We can see here that the Enlarged Board is looking beyond the patent application to ensure that patents are not granted due to crafty drafting. This was a significant step forward for considerations of human dignity and morality in patent law.

The Enlarged Board ultimately decided that patents would not be granted on claims to products that involved the destruction of human embryos even if that method was not part of the claims. As a result, subsequent cases involving human embryos have followed suit.

In *CALIFORNIA*, the Board referred to *WARF* and made similar reference to morality.[76] The Board determined whether the invention in question necessarily involved the destruction of human embryos. It did and so the invention fell under Article 53(a) and Rule 28(c). In *TECHNION*, the Board again focussed on the manner in which the human embryonic stem cells were obtained and whether this involved the destruction of the human embryo.[77] They did

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[72] There is a question as to whether it must be considered given the definitional nature of Article 6(2) Biotech Directive, however, we argue that it should be considered to ensure a well-rounded analysis. For more on the definitional nature of these provisions see: Aurora Plomer, 'After *Brüstle*: EU accession to the ECHR and the future of European patent law' (2012) 2(2) QMJIP 110.

[73] For a similar view, see: Paul Torremans, 'The Construction of the Directive's Moral Exclusions under the EPC' in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (OUP 2009).

[74] *WARF*, Reasons 22.

[75] This is especially broad when contrasted to the interpretation of the plant and animal variety exception. In *Novartis*, the Enlarged Board decided that an application that did not specifically claim plant varieties but could 'embrace' plant varieties would be allowed (G1/98 *Transgenic plant/NOVARTIS II* of 20.12.1999, Reasons 3.10). This reasoning was then also applied to animal varieties in *Transgenic Animals/HARVARD* (T315/03 *Transgenic animals/HARVARD* of 6.7.2004, Reasons 11.8). In those cases, as long as a single plant or animal variety was not claimed in the application, the exception would not apply, even if the plant or animal variety fell within the scope of its claims.

[76] T522/04 *Stem cells/CALIFORNIA* of 28.5.2009.

[77] T2221/10 *Culturing stem cells/TECHNION* of 4.2.2014. For more detail on the *TECHNION* case, see: Aurelie Mahalatchimy et al, 'Exclusion of patentability of embryonic stem cells in Europe: another restriction by the European Patent Office' (2015) 37(1) EIPR 25.

mention *WARF* and the *Brüstle* decision (which had been decided two years previously by the CJEU, mentioned in detail below), however, the focus was on the technicalities of whether that which was not claimed in the patent application – how they came to be in possession of human embryonic stem cells and whether that involved the destruction of a human embryo – was relevant to their consideration.[78] Only a few months later in *ASTERIAS*, the Board again focussed on how the human embryonic stem cells were obtained relying on *WARF* and *Brüstle* and the idea that "if for implementation of an invention a human embryo was destroyed, the point in time at which such destruction took place was irrelevant."[79]

From these cases, we can see a general avoidance of examining the detail of morality and the Boards of Appeal (following the Enlarged Board in *WARF*) focussing very narrowly on the specific aspect of how the invention was made rather than discussing the broader morality and public policy concerns of whether the use of the embryo should ever be permitted. Whilst the immorality of the destruction of embryos is being assumed, it is not being discussed in detail. Instead, the reasoning in each of these decisions focuses on whether there was a commercial exploitation deemed to be immoral – commercial exploitation being linked to the making of the invention.

3.2.2 CJEU Case Law

This provision has also been interpreted by the CJEU in two well-known decisions – *Brüstle* and *ISCC*.[80] The CJEU, on the one hand, has been criticised for defining human embryo in *Brüstle* and then having to backtrack on that in *ISCC* given the incorrect scientific evidence that had been presented in the *Brüstle* case.[81] On the other hand, these cases, the *Brüstle* case especially, have considered what morality means to a greater extent in this context and have highlighted how important the discussion around human dignity is.

In *Brüstle*, the Court began its consideration on the meaning of human embryo by stating that it was "not called upon, by the present order for reference, to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions of the Directive" but went on to explicitly consider the moral underpinnings of the Biotech Directive and its essential objective of protecting human dignity.[82] The Court went on to say that, given these objectives, human embryo should be regarded in a wide sense and defined it as a fertilised human ovum capable of commencing the process of development of a human being, and a non-fertilised human ovum that had been stimulated by parthenogenesis.[83]

The issue with this definition was that inventions that used non-fertilised human ova that had been stimulated by parthenogenesis were capable of commencing development of a

[78] *TECHNION*, Reasons 26.
[79] T1441/13 *Embryonic stem cells, disclaimer/ASTERIAS* of 9.9.2014, Main Request.
[80] Case C-34/10 *Oliver Brüstle v Greenpeace* ECLI:EU:C:2011:669 (*Brüstle*); Case C-364/13 *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks* ECLI:EU:C:2014:2451 (*ISCC*).
[81] For discussions on the *Brüstle* and *ISCC* cases, see: Aurora Plomer, 'After *Brüstle*: EU accession to the ECHR and the future of European patent law' (2012) 2(2) QMJIP 110; Andrea Faeh, 'Judicial activism, the Biotech Directive and its institutional implications: is the court acting as a legislator or a court when defining "human embryo"?' (2015) 40(4) EL Rev 613; Scott Parker and Paul England, 'Where now for stem cell patents?' (2012) 7(10) JIPLP 738; Shawn Harmon, Graeme Laurie & Aidan Courtney, 'Dignity, Plurality and Patentability: The Unfinished Story of Brüstle v Greenpeace' (2012) 38 European Law Rev 92; Ana Nordberg and Timo Minssen, 'A "Ray of Hope" for European Stem Cell Patents or "Out of the Smog into the Fog"? An Analysis of Recent European Case Law and How it Compares to the US' [2016] 47 IIC 138; Ella O'Sullivan, 'International Stem Cell Corp v Comptroller General of Patents: the debate regarding the definition of the human embryo continues' (2014) 36(3) EIPR 155.
[82] *Brüstle*, para 30.
[83] *Brüstle*, para 35.

human being but did not have the capacity of developing into a human being.[84] As a result, the CJEU clarified this definition in *ISCC*. Now, in order to fall under the definition of a human embryo for the purposes of the Biotech Directive, any non-fertilised ovum stimulated by parthenogenesis must have the "inherent capacity of developing into a human being".[85]

Although the definition may be problematic in some other respects, in our view, by considering the moral nature of this question and its links to human dignity, the CJEU have taken strides forward for the consideration of human rights issues in patent law.[86] The Court examined the Biotech Directive in great detail and came to the conclusion that its context and aim were to "exclude any possibility of patentability where respect for human dignity could thereby be affected."[87] *Any* possibility denotes a very wide margin of interpretation and consideration of human dignity, which allows patent law to take this into account more regularly. In doing so, the discussion surrounding human dignity and patent law can move forward and human dignity cannot be ignored.

The CJEU has also considered the commercial exploitation of the invention. In *Brüstle*, the issue was discussed in relation to whether the use of human embryos for scientific research was a use for an industrial or commercial purpose. The Court decided on this but it did not appear to be the main focus of the decision. It was stated that the grant of a patent implied industrial or commercial application and that only therapeutic or diagnostic methods applied to the human embryo would be patentable.[88] This aspect of the decision deserves a little more attention. Again we see the focus on the invention rather than its commercial exploitation. The potential use of the invention was not considered and it arguably should have been.

Finally, the CJEU also followed the same route as the Boards of Appeal when it came to whether the destruction of a human embryo was involved in the making of the invention but was not mentioned in the application.[89] This is an important addition for considerations of human dignity in patent law, as discussed above in relation to the *WARF* case.

4 Public interest concerns beyond the morality/public policy provisions

Consideration of questions of morality and public policy in European patent law tends to be primarily focused on the provisions explored in the previous sections of this chapter. As we have noted, these provisions are narrow in their scope, being considered mostly at the point of patent grant, and they have been further narrowed in their interpretation. However, the public interest implications of patent law are broader, in ways that are closely linked to the concerns evident in the cases arising from these provisions. Many of the recent controversies in patent law, especially in the life sciences, are both related to the intrinsic nature of the invention, but

[84] It has also been argued that the CJEU should have questioned when the human embryo would be entitled to the full guarantee of human dignity. See: Ansgar Ohly, 'European Fundamental Rights and Intellectual Property' in Ansgar Ohly and Justine Pila (eds), *The Europeanization of Intellectual Property Law: Towards a European Legal Methodology* (OUP 2013).
[85] *ISCC*, para 28. However, the definition remains controversial as there is no consensus in Europe on the morality or patentability of human embryonic stem cell research.
[86] For more on this issue, see: Justine Pila, 'A Constitutionalized Doctrine of Precedent and the *Marleasing* Principle as Bases for a European Methodology' in Ansgar Ohly and Justine Pila (eds), *The Europeanization of Intellectual Property Law: Towards a European Legal Methodology* (OUP 2013) 233-240. For a counter argument, see: Aurora Plomer, 'After *Brüstle*: EU accession to the ECHR and the future of European patent law' (2012) 2(2) QMJIP 110.
[87] *Brüstle*, para 34.
[88] *Brüstle*, para 46.
[89] *Brüstle*, para 50 and 51.

also to the way in which it is commercialised or exploited in practice, more remote from the grant of the patent.

Many controversies relate to questions such as access to medicine, but other areas, such as the relationship between patents and access to technologies to combat climate change, are also becoming of increasing concern.[90] We argue that a more holistic consideration of the public interest in patent law, by both patent offices and courts, would better reflect the requirements of human rights and human dignity especially.[91]

4.1 Gene patents – an illustrative case

The recent controversy over patents on human genes provides a useful illustration of our argument in this respect. Patents on human genes have long been controversial, with the breast cancer gene patents controlled by Myriad Genetics acting as a lightning rod for public and academic concern, with the *Myriad* case "emblematic of the fear that patents on human genetic material would have an adverse impact on access to useful technologies, both for research and for clinical use".[92] The moral and ethical implications of these patents are at the core of the objections to these patents but the concerns extend beyond the scope of, and are not addressed by, the core provisions of European patent law which we discuss in section 3 above.

The debate about the patentability of human genes will be familiar to patent law scholars and experts.[93] Objections to gene patents on morality and public policy grounds were regularly raised in the popular and academic press by various groups[94] and there was widespread public opposition to the concept of ownership of genes.[95] There was a concern that patents on human genes would result in a lack of respect for human life and a devaluation of human dignity via commercialisation and instrumentalization of human beings.[96] However, it is generally accepted that human dignity is not directly violated by gene patents and that any effect is indirect in nature.[97]

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[90] For an outline of issues relating to Intellectual Property and climate change see for example: Kristina Lybecker and Sebastian Lohse 'Innovation and Diffusion of Green Technologies: The Role of Intellectual Property and Other Enabling Factors. Global Challenges Report' (2015) WIPO, Global Challenges Report.

[91] As set out in the Charter of Fundamental Rights of the European Union. Although this is clearly an EU instrument, the EPO has recently referred to it in decision T149/11 – see: Agnieszka Kupzok, 'Human rights in the case law of the EPO Boards of Appeal' in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015).

[92] Timothy Caulfield et al, 'Evidence and Anecdotes: An Analysis of Human Gene Patenting Controversies' (2006) 24 Nature Biotechnology 1091.

[93] For a discussion of the law around the patenting of human genes in Europe, see: Aisling McMahon, 'Gene Patents and the Marginalisation of Ethical Issues' (2019) 41(2) EIPR 608; Naomi Hawkins, 'Human Gene Patents and Genetic Testing in Europe: A Reappraisal' (2010) 7 SCRIPTed 454; Naomi Hawkins, 'A Red Herring – Invalidity of Human Gene Sequence Patents' (2016) 38 EIPR 83.

[94] Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (Nuffield Council on Bioethics, London 2002); FB Charatan, 'US Religious Groups Oppose Gene Patents' (1995) 310 British Medical J 1351. For a summary of moral objections to gene patents see David Resnik, *Owning the Genome: A Moral Analysis of DNA Patenting* (State University of New York Press, Albany 2004) 3.

[95] See for example Tim Radford, 'Patenting DNA "Not in Public Interest"' *The Guardian* (London 23 July 2002) <https://www.theguardian.com/uk/2002/jul/23/science.genetics> accessed 29 October 2019.

[96] Timothy Caulfield and Roger Brownsword, 'Human Dignity: A Guide to Policy Making in the Biotechnology Era?' (2006) 7 Nature Review Genetics 72, 73; Australian Law Reform Commission, *Genes and Ingenuity: Gene Patenting and Human Health Report* (Australian Law Reform Commission, Canberra 2004) 68.

[97] David Resnik, *Owning the Genome: A Moral Analysis of DNA Patenting* (State University of New York Press, Albany 2004) 95.

In Europe in the 1990s and early 2000s there were a number of opposition proceedings in relation to gene patents and early cases mooted the morality and public policy exception as a basis for overturning gene patents. However, these objections were given short shrift by the Boards of Appeal of the EPO.

In *Howard Florey/Relaxin*,[98] the Green Party opposed the Howard Florey Institute's patent for the gene coding for relaxin on three *ordre public* and morality grounds. The first of these was that the use of pregnancy for profit was offensive to human dignity, the second was that the patent in question was a patent over life and therefore immoral, and the third was that patenting DNA was equivalent to slavery.[99] Each of these arguments was rejected by the Opposition Division which held that the patent did not in fact involve the patenting of human life, abuse of pregnant women or slavery,[100] but that DNA should be treated as a chemical substance and treated in the same manner as other chemical substances, such as pharmaceuticals.

In *Breast and Ovarian Cancer/University of Utah*,[101] an opponent argued that there was a contravention of the morality provisions constituted by a failure to obtain specific consent from the donor of cells used to derive the invention to commercial exploitation of the research results, and the lack of a benefit sharing agreement. The Board was not persuaded by this argument observing that the EPC does not require either evidence of informed consent or a benefit sharing agreement and that although the Biotech Directive provides that there must have been an opportunity to express free and informed consent in accordance with national law, there was no procedure to verify this informed consent in the patent framework. The Board held that there was therefore no prohibition on the BRCA1 patent as a result of Art 53(a) EPC.[102] The socio-economic consequences of the patent were raised by another opponent, which argued that the patent would result in increased costs for patients and would also influence the way in which diagnosis and research would be organised in Europe in a way that would be clearly to the detriment of patients and doctors.[103] The group of patients suspected to carry a predisposition to breast cancer would be faced with severe disadvantages and would become dependent on the patent proprietor and, it was argued, this was contrary to human dignity. The Board also rejected this argument, holding that Art 53(a) applied only where the exploitation of the invention (as opposed to the exploitation of the patent) would be contrary to *ordre public*. It is therefore clear that these general objections on the basis of morality/public policy are insufficient under current interpretations to satisfy the requirements of Art 53(a) in relation to patents on human genes.

Although Art 53(a) is too narrow to address these objections to gene patents, ethical and moral concerns persist. The core of the objection is focused on questions of access to medicine.[104] Gene patents arguably limit access to medicine through increasing prices, reducing the breadth of provision, reducing quality of testing, and reducing research.[105] These

[98] *Howard Florey/Relaxin* [1995] EPOR 541 (EPO (Opposition Division)).
[99] Ibid 6.1.
[100] Ibid 6.3.
[101] T1213/05 *Breast and Ovarian Cancer/University of Utah* of 27.9.2007, Reasons 45-47.
[102] Naomi Hawkins, 'Human Gene Patents and Genetic Testing in Europe: A Reappraisal' (2010) 7 ScriptEd 453.
[103] T1213/05 *Breast and Ovarian Cancer/University of Utah* of 27.9.2007, Reasons 52.
[104] For an exploration of the nature of objections to gene patents see: Hawkins, 'A Red Herring – Invalidity of Human Gene Sequence Patents'.
[105] Hawkins, 'A Red Herring – Invalidity of Human Gene Sequence Patents', 88.

issues have clear moral and ethical implications.[106] Such concerns are evident in the US and Australian cases overturning the breast cancer gene patents in those jurisdictions and the cases at all levels make reference to questions of access to medicine. Although these concerns were evidently the key motivation for bringing the cases, the legal basis for the decisions does not relate to the ethical questions and the US and Australia decisions in Myriad "display no real engagement with the potential healthcare implications of patents on isolated genes".[107]

Moreover, case law to date has largely focused on invalidating or narrowing gene patents. However, overturning the existence of a patent is only one means of addressing concerns about its unethical or immoral impact. Invalidity is a blunt tool and there may be other more nuanced, targeted, and effective means of addressing the ethical implications of patents, explored further in section 6 below.

5 What role do morality and public policy play in patent law?

Patents and the public interest are connected, and the creation, operation and interpretation of the patent system is linked to moral and ethical standards.[108] However, not all inventions raise morality or public policy concerns, and not all inventions which give rise to these issues do so in the same way. In our view, there is an important distinction between two different categories of concerns which can arise from inventions:

1. Inventions where all commercial exploitation of the invention is immoral or against public policy. Examples include the invention of a new type of letter bomb or land mine. Such inventions include, for example, those traditionally deemed to be immoral as contained in the Guidelines for Examination in the EPO.
2. Inventions where some, but not all, commercial exploitation of the invention is immoral or against public policy, or which raise moral or ethical concerns. Such inventions might involve technology with a dual use for moral and immoral purposes, such as CRISPR technology, which could be used for both problematic germ line gene editing and uncontroversial gene editing for research purposes. Alternatively, some commercial exploitation of the invention may raise public interest concerns through, for example, questions of equality of access. In this case, the invention is not morally questionable, but the operation of the patent system in relation to that invention gives rise to broader questions about the public interest and patent law.

The second of these categories is not traditionally treated as part of any analysis of morality or public policy in European patent law. These questions are viewed as beyond the scope of the legal provisions and therefore tend to be discussed in different academic literatures, removed

[106] Aisling McMahon, 'Gene Patents and the Marginalisation of Ethical Issues' (2019) 41(2) EIPR 608 and discussion in Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (Nuffield Council on Bioethics 2002 available at <http://nuffieldbioethics.org/wp-content/uploads/2014/07/The-ethics-of-patenting-DNA-a-discussion-paper.pdf> last accessed 29 October 2019.
[107] Aisling McMahon, 'Gene Patents and the Marginalisation of Ethical Issues' (2019) 41(2) EIPR 608.
[108] Peter Drahos, 'Biotechnology Patents, Markets and Morality' (1999) 21 EIPR 441, 441.

from the doctrinal and textual analysis of the provisions in European patent law. However, the concerns raised in category two have important implications for the public interest.

In this paper, we argue that morality and public policy should be viewed more broadly, and therefore that the two categories above should be viewed as linked and part of a continuum of the public interest. The analysis of the legal provisions should not be separated off from these broader questions relating to the public interest of the operation of the patent system. Employing a stronger role for human rights/dignity has the potential to draw these areas together and to make the law more coherent across these two categories. Below, we explore the nature of the concerns for each of these categories in more detail.

5.1 Category 1 – all commercial exploitation of the invention is considered immoral/against public policy

The first category identified concerns inventions the commercial exploitation of which would always be considered immoral or against public policy. Examples of this category in action have been discussed above, which will inform the discussion in this section related to the role the public interest plays in patent law.

Morality and public policy are first considered from the perspective of the general provision. The Opposition Division in *Howard Florey/Relaxin* cited an example in which Article 53(a) would be invoked – a letter bomb.[109] The context of this example is important because the Opposition Division stated, implementing a narrow approach to the interpretation of exceptions, that Article 53(a) would only be invoked in "rare and extreme cases".[110] In the case of a letter bomb, when considering the moral and ethical implications, the answer is clear. It is possible to distinguish between the morality of the invention and the morality of the commercial exploitation of the invention. In this case, it is likely that the invention itself is immoral but so would any possible commercial exploitation of it. Therefore, the criteria of Article 53(a) would be satisfied, that is, the possible commercial exploitation of this invention i.e. if it were to be put on the market, would be immoral. As a society, the overall consensus would likely be that selling letter bombs, for example, would be immoral.

However, considerations of morality and public policy are different when inventions are more complex and multi-layered. As expanded on above, morality has been playing a role in the case law of the Boards of Appeal of the EPO and the CJEU and is front and centre in these decisions, with the basis of these decisions being linked to human dignity. However, the role morality plays in these decisions is difficult to decipher. Both the Boards of Appeal and the CJEU appeared to have difficulty distinguishing between the morality of the creation of the invention and its commercial exploitation.

In the *WARF* and *Brüstle* decisions the general provision seemed to take on a new function. In *WARF*, it was determined that the invention was immorally made and therefore, any commercial exploitation of it was immoral. In *Brüstle*, it was determined that a human embryo ought to be widely defined and that any use that required the destruction of the human embryo was broadly condemned, that use being linked to its commercial exploitation by applying for a patent on it.

In both of these cases it was the invention that was deemed immoral and as a result any commercial exploitation of it was automatically immoral. The link to commercial exploitation

[109] *Howard Florey/Relaxin* [1995] EPOR 541 (EPO (Opposition Division)) 6.2.1.
[110] *Howard Florey/Relaxin* [1995] EPOR 541 (EPO (Opposition Division)) 6.2.1.

in these cases is tenuous. Neither the Boards nor the CJEU considered the potential uses of the invention. Nor did they consider scientific practice at the time in individual Member States.[111]

In *WARF*, the Enlarged Board of Appeal did not use a balancing test or a threshold test to determine whether the potential benefits of the invention (its commercial exploitation) would ever outweigh the destruction of the human embryo, or whether there was an overwhelming consensus against the possible use of the invention, as previous Board of Appeal practice established in relation to the exceptions to patentability as shown above. In *Brüstle*, the CJEU defined human embryo broadly without considering current day practice surrounding research restrictions on embryos in its Member States.

In both scenarios, it would have been relevant to identify and judge the potential uses of the inventions. This is because the legal requirement of the general provision is to determine whether the commercial exploitation of the invention would be immoral/against public policy. Instead, these examples show that the courts/tribunals tend to focus on the invention and then vaguely link that to commercial exploitation without discussing what the inventions could be used for and whether there would be any scenario in which this type of invention would be permitted.

It appears that it does not necessarily matter what the invention could be used for, if how it is made is immoral. This is even the case if the details on how the invention is made are not contained in the patent application. This is without doubt an expansion of the general provision, which is a huge step forward for human dignity considerations in patent law. However, despite that, we are not given an explanation as to why these inventions are immoral and why their commercial exploitation would thus always be immoral.

It can be concluded at this point that in current practice the public interest has a strong presence in patent law and the role it has taken on is beneficial from a human dignity perspective, but it is not optimal because there is very little detail in reasoning of courts as they apply the relevant concepts in patent cases.

5.2 Category 2 – some but not all commercial exploitation of the invention is considered immoral/against public policy or where some commercial exploitation of the invention raises public interest concerns

The inventions with which this section is concerned fall into two broad types. Firstly, there are inventions where some, but not all, commercial exploitation of the invention raises moral or ethical concerns. Such inventions might involve technology with a dual use for moral and immoral purposes, such as CRISPR technology, which could be used for both unacceptable germ line gene editing and acceptable gene editing for research purposes. The second type of invention is where the invention itself is not immoral but some commercial exploitation of the invention may raise public interest concerns.

At present, as discussed earlier, these types of invention fall outside the exception in Art 53(a) EPC. However, other provisions of patent law also offer opportunities to address balancing of the public interest. The majority of these provisions make no explicit reference to concepts of morality or human dignity, and the reasoning which is referred to in their application is more or less disconnected from discussions of the ethics or from human rights law concepts.

[111] For an overview on the differences in scientific practice in some Member States, see: Gerard Porter, 'The Drafting History of the European Biotechnology Directive' in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (OUP 2009) 23-26.

The most obvious links between the provisions of patent law and the types of invention included in this section are through the exceptions to patentability. Although Art 53(a) has been limited in scope to the extent that it is inapplicable to this category of inventions, Art 53(b) and (c) have ethical underpinnings and may also be linked to concepts of human dignity. Under Art 53(c), patents will not be granted for methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body, although this exception does not apply to products for use in any of these methods.

Prior to the EPC 2000, the prohibition on patenting of medical methods was found in Art 52(4), which provided inter alia that 'diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application'. This fiction of lack of industrial applicability was abandoned in EPC 2000, with the rationale for the exception is now clearly based on public health considerations.[112] However, the scope of this exception is very narrow, such that *in vitro* diagnostic method steps performed on isolated samples, do not satisfy the criterion of "practised on the human or animal body", and therefore are not excluded from patentability.[113]

Other patents in this category may be dealt with by means of the technical patentability criteria. In some cases, there is a reasonably obvious link to the public interest; for example, overly broad patents strain the patent bargain too far in favour of incentives for innovation against access. The most appropriate response to such overly broad patents is to narrow them by reference to the technical patentability criteria. The criteria of novelty, inventive step and industrial application are a "hybrid mix of technical and legal components encompassing economic and social considerations", and their application by patent offices, and ultimately by EPO tribunals and national courts, can have important social and economic effects.[114]

The "as such" limitations in the Art 52(2) exclusions can also serve to limit the patentability of inventions which may have unethical implications. Although examples are scarce in Europe, in other jurisdictions, the product of nature doctrine[115] and the interpretation of the requirement of manner of manufacture[116] have served to limit patents on human genes with the reasoning in the cases making extensive references to ethical and moral arguments.

Defences to infringement also work to avoid problematic outcomes of patents in this area. As infringement is (currently) a matter of national law,[117] questions of infringement and defences to infringement are also a matter of national law, although there is some consistency across Europe due to changes implemented into national law in light of the Community Patent Convention. Two defences which mitigate unethical or immoral effects of patents are the experimental use exception[118] and the extemporaneous preparation of medicaments exception.[119]

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[112] European Patent Office Administrative Council, 'Basic Proposal for the Revision of the European Patent Convention' (European Patent Organisation, Munich 2000) 45.
[113] Chartered Institute of Patent Agents, *CIPA Guide to the Patents Acts* (8th ed Sweet & Maxwell, London 2016) [4A.07]; UK Intellectual Property Office, 'Examination Guidelines for Patent Applications relating to Medical Inventions in the UK Intellectual Property Office' (UKIPO, Newport 2016) [62]; G1/04 *Diagnostic Methods* of 16.12.2005; T1197/02 *Australian National University/Glaucoma* of 12.7.2006.
[114] Aurora Plomer, 'The EPO as Patent Law-Maker in Europe' (2019) 25 European Law Journal 57, 61.
[115] Association for Molecular Pathology v Myriad Genetics Inc 133 S Ct 2107 (2013).
[116] D'Arcy v Myriad Genetics Inc [2015] HCA 35.
[117] Although the UPC may have implications should it come into force in the future.
[118] Section 60(5)(b) Patents Act 1977 (UK).
[119] Section 60(5)(c) Patents Act 1977 (UK).

In England and Wales, section 60(5)(b) of the Patents Act provides a defence to patent infringement for acts done for experimental purposes relating to the subject matter of the invention, and there are similar, although not uniformly applied, provisions in many other EPC member states.[120] The defence is recognized as having two limbs. An act will fall within the defence if its purpose is to discover something unknown or to test a hypothesis[121] but will not be for experimental purposes if it is carried out in order to demonstrate to a third party that a product works or in order to amass information to satisfy a third party, such as a customer or a regulatory body.[122] The second limb concerns whether the conduct relates to the subject matter of the invention. Here, "experimenting on" or "experimenting into" a patented invention is within the scope of the defence, whereas "experimenting with" or "experimenting using" the patented invention is usually outside the scope of the defence.[123]

Section 60(5)(c) of the Patents Act 1977 (UK) provides a defence to infringement for the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner.[124] This section is also justified on public health grounds ensuring that pharmacists are able to carry out their professional role and that patients obtain necessary medicines without obstruction caused by the necessity of having regard to patents.[125]

The final areas of patent law which work to mitigate outcomes contrary to the public interest in this category are compulsory licensing and crown use. Compulsory licences are often suggested as a possible solution to ameliorate the access problems potentially created by patents.[126] Compulsory licences permit individuals other than the patent owner to exploit the invention that is the subject of a patent when the patentee is unable or unwilling to do so. Although very few applications are made for compulsory licences, common wisdom provides that the mere prospect of the grant of such a licence may result in the working of an invention or willingness to license.[127]

Similar to the compulsory licensing provisions, under the Crown use provisions in ss 55-59 of the UK Patents Act a government department or a person authorized in writing by a government department may, for the services of the Crown, do certain acts in relation to a patented invention without the consent of the proprietor of the patent. These acts include, in

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[120] Community Patent Convention at Art 27(b). Geertrui van Overwalle et al, 'Models for Facilitating Access to Patents on Genetic Inventions' (2006) 7 Nature Reviews Genetics 143, 143; Trevor Cook, 'Responding to Concerns about the Scope of the Defence from Patent Infringement for Acts Done for Experimental Purposes Relating to the Subject Matter of the Invention' [2006] IPQ 193; Trevor Cook, *A European Perspective as to the Extent to which Experimental Use, and Certain Other Defences to Patent Infringement, Apply to Differing Types of Research: A Report for the Intellectual Property Institute* (Intellectual Property Institute, London 2006).

[121] Monsanto Co v Stauffer Chemical Co [1985] RPC 515 (CA) 542.

[122] Ibid 542.

[123] Trevor Cook, 'A European Perspective as to the Extent to which Experimental Use, and Certain Other Defences to Patent Infringement, Apply to Differing Types of Research: A Report for the Intellectual Property Institute' (Intellectual Property Institute, London 2006) 31.

[124] The corresponding provision of the Community Patent Convention is Art 27(c).

[125] Naomi Hawkins, 'An Exception to Infringement for Genetic Testing – Addressing Patient Access and Divergence between Law and Practice' [2012] IIC 641; Bengt Domeij, *Pharmaceutical Patents in Europe* (Stockholm Studies in Law, Kluwer Law International, The Hague 2000) 310.

[126] See for example William Cornish, Margaret Llewelyn and Mike Adcock, 'Intellectual Property Rights (IPRs) and Genetics: A Study into the Impact and Management of Intellectual Property Rights within the Healthcare Sector' (Public Health Genetics Unit, Cambridge Genetics Knowledge Park, Cambridge 2003) Section C(2)(c); Nuffield Council on Bioethics, *The Ethics of Patenting DNA: A Discussion Paper* (Nuffield Council on Bioethics, London 2002) 54-56.

[127] Lionel Bently et al, *Intellectual Property Law* (5th ed, OUP 2018) 684.

relation to a product, making and using the product, and, in relation to a process, using the process. Section 57A of the Patents Act provides that compensation for loss of profit must be paid for the Crown use. Nothing in these provisions requires that notice must be given to the patent proprietor prior to the Crown use or that attempts to license from the patent proprietor must be made. The making, use or importation of pharmaceuticals for supply to NHS patients on prescription is specifically mentioned within the terms of the provisions as falling within the ambit of Crown use.[128]

Some inventions give rise to moral and ethical concerns, whether that be where all commercial exploitation of the invention is clearly immoral/against public policy (category 1) or where some commercial exploitation of the invention raises public interest concerns (category 2). At present, the legal analysis and approach to inventions in category 1, as opposed to the inventions outlined in category 2, is separate and distinct, and lacks a coherent and connected framework. However, it is our contention that the concerns about the inventions in category 1 and category 2 are on the same continuum.

An approach to the public interest in patent law which is underpinned by the principle of human dignity will provide a cogent framework for legal analysis which will allow concerns about morality and public policy in patent law to be addressed in a consistent and coherent manner. We explore this further in section 6 below.

6 What role should morality and public policy play in patent law?

Morality, public policy and human dignity clearly have a significant role in European patent law. In practice, that role is currently being discussed in very narrowly defined areas. In other areas, it is only being considered implicitly.

The use of human dignity in interpreting existing provisions of patent law provides a legal and theoretical framework for the interpretation of existing provisions in a coherent manner in accordance with the public interest. It also opens up a broader range of case law for practitioners and judges looking to interpret these provisions, which arguably answers to some extent increasing calls for an interpretation of intellectual property law which integrates human rights considerations.[129]

Human rights supports both the private interest and the public interest components of patent law, and provides a consistent and coherent basis for the interpretation of patent law provisions which touch on questions of morality and ethics.[130] Moreover, the concept of human dignity is sufficiently flexible and the case law recognises a wide margin of defence and respect for the plurality of diversity of moral cultures in Europe.[131] Although the application of human dignity to patent law can be criticised for being too indeterminate[132] and for allowing the

[128] *Pfizer Corporation v Ministry of Health* [1965] AC 512 (HL); Patents Act 1977 s 55(1)(a)(ii), s 55(1)(c).
[129] See for example: Christophe Geiger, '"Constitutionalising" Intellectual Property Law? The Influence of Fundamental Rights on Intellectual Property in the European Union' (2006) 37 IIC 371, Duncan Matthews, 'Right to Health and Patents' in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015).
[130] Van Overwalle, 257.
[131] Aurora Plomer, 'Human Dignity, Human Rights, and Article 6(1) of the EU Directive on Biotechnological Inventions' in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (OUP 2009) 224.
[132] Aurora Plomer, 'Human Dignity, Human Rights, and Article 6(1) of the EU Directive on Biotechnological Inventions' 209.

importation of religious objections in a manner which lacks transparency,[133] whilst it may not be perfect, it adds legal content to concepts of morality and ethics in patent law which would otherwise be lacking.

At the same time, we recognise that the patent framework should not be the primary means of regulating the use of new technologies.[134] EU and national laws restrict the uses of new technologies on public safety grounds, such as those which regulate the clinical use of new pharmaceuticals. However, whilst patent law does not provide the only opportunity for regulation of new technologies, this does not mean that it should not more extensively accommodate public interest concerns. A state cannot discourage or prohibit a particular activity, for example, by prohibiting or restricting use, but, at the same time, encourage innovation in that activity by offering the opportunity of reward through the patent system; to do so is illogical and inconsistent. Full consideration of the ethical implications of particular technologies may more appropriately take place in contexts other than intellectual property law, but it does not follow that patent law should completely disregard these issues.

A patent application is frequently the first consideration of a new technology by any organ of a state and therefore, the first opportunity for an examination of the public interest issues arising from the commercial exploitation of the invention. Patent offices must not reject the opportunity to address the question of morality and public policy. The incorporation of reference to human dignity at relevant points in the patent life cycle would provide some appropriate safeguards to help rebalance the patent system in the public interest, and we explore this further below.

Section 5 has shown that in the identified categories the role of morality and public policy is limited. This section will make suggestions as to the role they should play in European patent law in both categories and beyond. We argue that for category one, the interpretation of morality/public policy should be more detailed and reasons should be given in the decisions of Boards and Courts to increase legal certainty. For category two, the recognition of the importance of human dignity in relevant cases, and interpretation of the relevant provisions of patent law in accordance with human dignity, will serve to better address concerns about ethics and morality. Finally, the public interest should be considered through the life cycle of the patent. We argue that these changes would not require a massive shift in practice and would bring about a more coherent approach to morality and public policy in patent law.

6.1 Category 1

The inventions in category 1 give rise to moral and ethical concerns relating to the subject matter of the invention and how the invention has been made.

In sections 3 and 5.1 above, it can be seen that references to morality, public policy and human dignity in patent law are rising. In the two most important cases in this area, *WARF* and *Brüstle*, morality and human dignity played a significant role. This practice is one that should continue in order to ensure that these fundamental rights are being taken into account in European patent law. However, we argue that this practice is not yet optimal and could be taken further.

Although the *WARF* and *Brüstle* cases came to similar decisions and were both significant steps forward for considerations of morality and human dignity in patent law, the

[133] Aurora Plomer, 'Human Dignity and Patents' in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property* (Edward Elgar 2015) 485.
[134] T356/93 *Plant cells* of 21.2.1995, Reasons, 18.4.

reasoning in each case focussed on different aspects. Both institutions implemented a broad understanding of human embryo and ensured that the destruction of a human embryo, even if not mentioned in the patent application, would mean that an invention would not be patentable. These decisions are extremely important and show the significance of morality and ethical considerations in patent law.

Although these decisions both represent an advance in the way in which morality, and human dignity in particular, are considered in patent law, we argue that these considerations should be developed further. The Enlarged Board in *WARF* did not find it necessary to view the practice in its Contracting Member States around the use of human embryos and whether the destruction of a human embryo was ever permitted. In fact, human embryonic stem cell research is permitted up to a point in many Contracting Member States.[135] In *Brüstle*, the CJEU defined human embryo quite broadly, which again, did not match with practice in many EU Member States.[136]

In both *WARF* and *Brüstle* the possible uses of the inventions were not given much consideration and it can be argued that they should have been. By linking commercial exploitation to the making of the invention (*WARF*), and linking the application for a patent to commercial exploitation (*Brüstle*), the potential benefits of the inventions were ignored. This is most perturbing in relation to the Board of Appeal decisions where previous practice with exceptions is to consider these potential benefits and weigh them against the consequences.

In these cases the immorality of the invention was assumed, which then influenced the final decision of the Board or Court in relation to the commercial exploitation of the invention. If the Boards of Appeal and the CJEU are going to expand morality considerations in patent law to asking whether the invention is immoral and thus all commercial exploitation of it is immoral, the reasoning behind this decision should be included.

By leaving out the reasoning behind questions relating to what is moral and what is not, there is an increase in legal uncertainty. Courts and Boards are abrogating their responsibility and shirking their duty to determine what is moral, what is not, and most importantly, how they came to that conclusion. Expanding the morality provision to an investigation as to the morality of the subject matter of the invention or how it is made places human dignity at the centre of the debate, but society is left without an explanation as to why the invention is immoral. The reasoning behind this is directly related to the final decision and should therefore be included in the final decision of the court.

Possible reasons against doing so must be taken into account. First, with regard to the Boards of Appeal of the EPO, panels consist of predominantly technical members. Given that the majority of case law at the EPO relates to very specific technological advances that are well understood by panellists who are familiar with the technology in question, the makeup of the panel is appropriate. However, when a moral or ethical concern is raised the same level of expertise is not present.

Leading on from that point, with regard to the CJEU, the Court may have been more willing to discuss matters of morality given their generalist legal perspective. [137] However, even with that generalist perspective a definition was given without having considered the practice in Member States and without providing clear reasons.

There are also some possible overarching reasons. First, it could be argued that considering possible uses of the invention is too speculative. However, numerous possible uses

[135] On the lack of consensus on the ethical acceptability of human embryonic stem cell research, see: Gerard Porter, 'The Drafting History of the European Biotechnology Directive' in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (OUP 2009) 23-26.
[136] Ibid.
[137] For multiple commentaries on generalist and specialist judiciaries in the European patent system, see: Christophe Geiger (ed), *Intellectual Property and the Judiciary* (Edward Elgar 2018).

of the invention are often contained in the patent application so that the patentee is given protection for an appropriate range. Looking at the potential uses of an invention is something that has been done previously in cases such as *Oncomouse*. Additionally, in *Euthanasia Compositions*, abuse of the invention was found not sufficient to deny patent protection if there was a use for the invention that would not fall under Art 53(a) EPC.[138]

Furthermore, by taking into account the potential uses of the invention and weighing that against the moral and ethical implications, the Courts and Boards of Appeal would be addressing some of the broader concerns that we have addressed above. However, it must also be said that questions of access to medicine, and indeed access to other technologies, might be better addressed by attention to the flexibilities in patent law around licensing and defences to infringement, rather than the blunt tool of invalidity. These are not morality specific, but they do have moral implications. The lack of appropriate opportunity to address specific moral and ethical concerns related to not knowing all iterations of use could be addressed at this later stage.

Second, given the differences in opinion on moral and ethical issues among EU Member States and Contracting Member States, general rulings could be preferred as these can be implemented in any Member State without the need to determine an overall consensus. This is a fair point, but it was not followed in the *Brüstle* decision, and generally, some guidance is required for Member States to follow.

Finally, all national patent laws in Europe and all European patent laws contain a morality/public policy provision. Therefore, it is the duty of the Board or the Court to interpret this legal provision and give reasons for their decisions, be they generalist or specialist.[139] If this practice were optimised, the role of the public interest in patent law would be significantly more important and better reflect the balance necessitated by the patent social contract.

6.2 Category 2

The inventions in category 2 give rise to concerns which relate less to the subject matter of the invention, and more to the way in which the patent is exploited. These concerns are in relation to particular immoral types of uses of the invention, or the exploitation of the patent in ways that disadvantage particular sectors of the public, or the public generally. Existing provisions of patent law offer opportunities to address these problematic patents, as outlined in section **Error! Reference source not found.** earlier. In many cases, these provisions provide an appropriate and adequate solution.

Moreover, in relation to some aspects by which the public interest is addressed, outlined in section **Error! Reference source not found.**, the scope for reference to human dignity is very narrow. Application of the technical patentability criteria is unlikely to draw on principles of human dignity without straining the interpretation of the legislation beyond breaking point. Similarly, it seems unlikely that principles of respect for human dignity will add anything to a consideration of whether the subject matter of the patent constitutes an invention under Art 52(2) EPC.

However, in some cases, the narrow, economically focused approach of patent law may be insufficient. The patent law bargain depends on the delicate balance between the private rights of the inventor and the public interest. There is more scope for reference to principles of human dignity in other existing patent law solutions which may be applied in relation to unethical inventions.

[138] T866/01 *Euthanasia Compositions/Michigan State*, Reasons 5.8.

[139] Even though both the Boards of Appeal and the CJEU have made statements indicating this was not something they had been tasked with, as elaborated on above.

Art 53(c) EPC exceptions of medical methods, defences to infringement, compulsory licensing and crown use all incorporate elements of the public interest, and all would be amenable to considerations of human dignity in relation to certain inventions. Although case law exploring these provisions is relatively limited, it is our contention that reference to principles of human dignity in the determination of these areas of patent law would provide a coherent link to appropriately weigh the public interest.

The obvious question which arises is then how human dignity might apply in these cases. Where there are exceptions to patentability the considerations of human dignity may arise both in the examination phase, before EPO tribunals, and potentially before the courts. In such cases, the analysis would potentially be similar to that in relation to the morality/public policy provisions as outlined above and could draw on the existing and developing case law. Art 53(c) EPC might be particularly amenable to this type of analysis, although current narrow interpretations of the provision leave very little scope for these types of arguments.

It is more complicated to conceive of the application of human dignity in relation to defences to infringement, which is a matter of national law and very rarely litigated. However, there is clear potential for the public health considerations which underlie the extemporaneous medicament defence to draw on a human dignity analysis, should such a case arise. The compulsory licence and crown use provisions are also very rarely applied in court cases. However, there is in these cases a clear relationship between the underlying principles in these areas and questions of human dignity.

In practical terms, there is very little litigation that proceeds to trial in these areas and therefore little hope that these questions will result in helpful precedent in this area. However, increasingly, charitable and public interest cases are being brought by these groups in relation to patents perceived by these groups to be contrary to the public interest. There is therefore potential for a human dignity approach to be ventilated in such a case. Moreover, even in its absence, there is scope for these arguments to be put forward in patent negotiations, although without legal authority supporting them perhaps there is little scope for them to be decisive. Finally, particularly where there is a potential compulsory licence or crown use, there will be significant governmental involvement in negotiations. In such cases, a human dignity legal analysis would be helpful to balance the economic arguments, in support of the public interest.

6.3 How the public interest should play a role in the rest of the patent life cycle

The failure of patent law to adequately respond to concerns about the moral and ethical implications of patents on particular inventions, and the wider problems of access to technologies is well recognised. Too often, patent law can be seen to be about the grant of patents in the context of economic rights and the commercialisation of inventions with scant attention paid to the broader public interest implications of those economic rights in practice.[140] However, as we have argued, importing a greater role for human dignity could help to rebalance patent law away from an excessive focus on trade, access to markets and economic incentives,[141] to more appropriately account for the public interest by addressing moral and ethical concerns.

Importantly, such rebalancing need not involve large changes in existing practice, for patent offices, patentees or patent users. The majority of patents do not raise public interest concerns and will therefore be entirely unaffected. Even in cases where patents do raise the concerns we have outlined above, the existing approach may be sufficient. However, an

[140] See for example: Aisling McMahon, 'Gene Patents and the Marginalisation of Ethical Issues' (2019) 41(2) EIPR 608.
[141] Van Overwalle.

additional consideration of whether the existing approach reflects the obligation to respect human dignity may assist in cases where there are difficult moral and ethical questions.

A significant obstacle to the operation of human dignity in European patent law is its enforceability. Although there is evidence that the Boards of Appeal are beginning to have regard to the principle of human dignity, at least with respect to Art 53(a) EPC, the applicability of EU instruments to the EPC is limited and there is no mechanism within the EPC to require the EPO and its institutions to take into account or respect rules beyond those contained in the EPC.[142] An important exception is the Biotech Directive, however, which has been incorporated into the EPC and explicitly references human dignity. However, as the EPO is structurally insulated from the national legal systems and the EU machinery, its willingness to take into account human dignity in its granting procedures, including opposition procedures, remains to be seen.

The EPO, through its role in granting patents, is highly influential in defining and applying policy and unless the EPO moves to situate human dignity more centrally in relation to the moral and ethical aspects of patent law, progress in this area is likely to be slow.[143] However, as individual member states of the EPC are, with few exceptions, subject to the EU Charter, there is potentially more scope for national court willingness to employ concepts of human dignity in their treatment of patent law at national level.

7 Conclusion

It is clear that morality and public policy have a significant role in European patent law. However, this paper has shown that although great strides have been taken to ensure that human rights concerns, especially human dignity, are taken into account when the morality and public policy provisions are an issue, more can be done.

Concerns about the public interest arise in a small but significant number of inventions, be it where all commercial exploitation of the invention is clearly immoral/against public policy (category 1) or where some commercial exploitation of the invention raises public interest concerns (category 2). It has been shown that morality and public policy are considered in both categories, but not optimally. The legal analysis of morality/public policy in European patent law should be considered in more detail and should not be separated off from questions of public interest relating to the operation of the patent system. More detailed reasoning in court decisions is required for category 1 and the scope for reference to human dignity in category 2 needs to be expanded.

We suggest that, in order to have a more coherent and connected approach to morality and public policy in patent law, attention needs to be drawn to the wider public interest implications of patents in practice and the potential uses of the inventions. Reference to the principle of human dignity draws these areas together and has the potential to make law more coherent across both areas. Consideration of the public interest implications of patents in this way should be applied at all relevant points in the patent life cycle. To do so would not require a huge change in practice and would help to ensure that the interests of society are balanced appropriately with those of the patentee.

[142] Plomer, 'The EPO as Patent Law-Maker in Europe' 65; *WARF*.
[143] Plomer, 'The EPO as Patent Law-Maker in Europe' 73.