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Abstract: For seventy years, debates in the European patent community have centred on the introduction of a unitary patent system. For an efficient and effective European patent system, there are two key aspects – the promotion of harmonisation and the consideration of wider societal implications. In considering these two key aspects, this article focuses on the role of the Court of Justice of the European Union (CJEU) in the Unitary Patent Package (UPP) and the added complication of Brexit. In doing so, it examines the relevant institutional issues that have arisen in the lead up to the finalisation of the UPP, which continue to cause issues as a result of Brexit, and proposes a new way forward for reconciliation. It is argued that the continued questioning of the role of the CJEU goes against the overarching goal of a harmonised patent system that still considers the wider implications of its decisions.

The Unitary Patent Package, the Court of Justice of the European Union, and Brexit: (Ir)reconcilable?

Karen Walsh¹

1. Introduction

For almost seventy years, debates in the European patent community have centred on the introduction of a unitary patent system, be it for the European Union (EU) or more inclusive. For an efficient and effective European patent system, there are two key aspects to consider – the promotion of harmonisation and the consideration of wider societal implications. The Unitary Patent Package (UPP) could be the first successful implementation of a unitary system. However, even if it only ends up being a chapter in the quest for unitary patent protection, there are major lessons we can learn from this attempt at harmonising the European patent system.

In considering these two key aspects, this article focuses on the role of the Court of Justice of the European Union (CJEU) in the UPP and the added complication of Brexit. In doing so, it examines the relevant institutional issues that have arisen in the lead up to the finalisation of the UPP, which continue to cause issues as a result of the United Kingdom's (UK) decision to leave the EU, and proposes a new way forward for the reconciliation of the UPP, the CJEU, and Brexit. It is argued that the continued questioning of the role of the CJEU goes against the overarching goal of a harmonised patent system that still considers the wider implications of its decisions.

The make-up of the UPP is unique. It consists of two EU Regulations: one creating the unitary patent and another implementing a new translation arrangement. The third and final element of the UPP is the international (non-EU) Agreement on a Unified Patent Court (UPCA), which will introduce a Unified Patent Court (UPC). One of the most unique aspects of this package is the EU nature of the unitary patent coupled with the jurisdiction of a non-EU court.

In the lead up to the finalisation of the UPP, great strides were taken by EU Member States in an attempt to restrict the CJEU from interpreting provisions of substantive patent law. However, questions remain as to the level of involvement the CJEU could and should have in substantive patent law and the UPP. This will have a major impact on how the patent system in Europe progresses and whether that progress will be at the expense of broader societal concerns. This question has added significance given the UK's decision to ratify the UPCA despite its imminent departure from the EU.

Much has been written about the UPP and some recent articles have discussed the question of the continued participation of the UK in the UPP post-Brexit.² Legally, there have been strong arguments on either side as to whether the UK can and should remain a part of the proposed unitary patent system after leaving the EU. However, this article takes a new approach by focussing solely on

¹ Lecturer, Law School, University of Exeter. The author would like to thank Stefan Luginbuehl, Dr Naomi Hawkins, Dr Mathilde Pavis, Dr Bríd Ní Ghráinne, and Professor Andrea Lista for their comments on earlier drafts of this paper, and Dr Justine Pila for her support and insight.

² See: Richard Gordon QC and Tom Pascoe, 'Re The Effect of "Brexit" on the Unitary Patent Regulation and The Unified Patent Court Agreement' [2016] <http://www.bristowsupc.com/assets/files/counsel_s%20opinion%20on%20effect%20of%20brexit%20on%20upc,%2012%20sept%202016.pdf> accessed 27 September 2018; Winfried Tilmann, 'The future of the UPC after Brexit' (2016) available at: < <http://www.theunitarypatent.com/the-unitary-patent-regulation-and-upc-agreement-after-brexit>> accessed 27 September 2018; Ansgar Ohly and Rudolf Streinz, 'Can the UK stay in the UPC system after Brexit?' (2017) 12(3) JIPLP 245; Thomas Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit' (2016) SSRN Discussion Paper; Maria Aránzazu Gandía Sellens, 'The Viability of the Unitary Patent Package After the UK's Ratification of the Agreement on a Unified Patent Court' (2018) 49 IIC 136; and Aisling McMahon, 'Brexit and the Unitary Patent Package: A Further Compromised Future?' (2018) 15(2) Scripted 175.

the continually threatened role of the CJEU in the UPP despite having shaped its form, how Brexit has added to that and its implications for a harmonised European patent system.

It begins with a summary of the main provisions of the UPP, followed by a review of the negotiations that led up to the final iteration of the UPP. One of the most significant aspects of this period, and something that has not been explicitly mentioned in literature thus far, is the contrast between the role of the CJEU in shaping the UPP and the attempts that were then made by EU Member States to limit the role of the CJEU in the interpretation of the UPP.

By investigating the reasons behind these attempts, this article illustrates that there is a level of distrust when it comes to the CJEU, especially from the UK, but also among stakeholders in the patent community. Through an analysis of key decisions by the CJEU in relation to supplementary protection certificates and biotechnological inventions, it is found that there is a valid reason for this scepticism, but the author argues that this is not sufficient reason to limit its role in patent law or in the UPP. It is argued that the CJEU should retain a key role over patent law in Europe given its generalist nature and consideration of wider societal concerns. Furthermore, the attempts that were made were not successful. Therefore, it is concluded that the CJEU will likely have a significant role in the UPP.

Another major complicating factor surrounding these debates is the decision of the UK government to leave the EU. Although previous attempts to limit the role of the CJEU have failed, Brexit may have that intended impact for the UK in a post-EU future, which goes against the purpose of a harmonised system.

The article will therefore also analyse the continued participation of the UK in the UPP following Brexit and the future role of the CJEU. Given the UK's staunch objection to the involvement of the CJEU versus their wanting to remain part of the unitary patent system,³ a key question arises as to whether the UK would be bound by CJEU judgments on the unitary patent system if it remains in that system, but outside the EU, and if that would be acceptable.

Despite the uncertainty surrounding the issue and calls to use this opportunity to re-draft a more inclusive unitary patent system, this paper argues a new way forward for the reconciliation of the UPP, the CJEU and Brexit by soft harmonisation through persuasive authority – that in any scenario, decisions of relevant courts, including the CJEU, can and should be taken into account. It is argued that despite attempts to limit the role of the CJEU and the added complication of Brexit, it will and still should have a role in the interpretation of substantive patent law, the UPP, and furthermore in UK patent law post-Brexit. To ensure that the European patent system becomes more harmonised and continues to take into account societal concerns, it is imperative that the CJEU retains its role and has a say in the interpretation of the substantive patent law of the UPP, but also that those outside the EU (soon to include the UK) take heed of its decisions, given the harmonising effect that this would have for the patent system as a whole.

2. The Unitary Patent Package

The unitary patent package is a legislative package containing two EU regulations and an international agreement: EU Regulation 1257/2012 implementing enhanced cooperation in the area of unitary patent protection (Regulation 1257), EU Regulation 1260/2012 implementing enhanced cooperation in the

³ For the UK's staunch objection to the involvement of the CJEU, see: Matthias Lamping and Hanns Ullrich, 'The Impact of Brexit on Unitary Patent Protection and its Court' (2018) Max Plank Institute for Innovation and Competition, Research Paper No. 18-20 citing Theresa May, House of Commons Official Report, Parliamentary Debates, 29 March, Volume 624, Column 252. For indication that the UK want to remain part of the proposed system see: Brexit White Paper, 'The Future Relationship between the United Kingdom and the European Union' (July 2018) available at: <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/725288/The_future_relationship_between_the_United_Kingdom_and_the_European_Union.pdf> accessed 11 October 2018, paragraph 151; and this can also be implied from its ratification of the UPCA, despite Brexit.

area of the creation of unitary patent protection with regard to the applicable translation arrangements (Regulation 1260), and Agreement 2013/C on a Unified Patent Court (UPCA).⁴

If it enters into force, the UPP will introduce a unitary patent for participating EU Member States and the UPC to deliver cross-border judgments on unitary patents and non-unitary European (European Patent Convention EPC) patents validated in those Member States.⁵ The UPP aims to address issues relating to the prohibitive cost of the current patent systems and the problems related to parallel patent litigation.

Regulation 1257 establishes unitary patent protection for all participating Member States of the EU on the basis of Article 118(1) of the Treaty on the Functioning of the European Union (TFEU) and applies Council Decision 2011/167/EU, authorising enhanced cooperation.⁶ The substantive features of the European patent with unitary effect have been agreed in that patentability and revocation will be governed by the rules of the EPC and Regulation 1257, and the post-grant life of the unitary patent will be predominantly governed by the UPCA.⁷

Article 3 Regulation 1257 establishes the European patent with unitary effect.⁸ Uniform protection is guaranteed by Article 5 Regulation 1257, which states that the European patent with unitary effect confers a right to prevent third parties from committing acts against which that patent provides protection throughout participating Member States.⁹

It states that those acts against which the patent provides protection are defined by the law applied to European patents with unitary effect in the participating Member States whose national law is applicable to the European patent with unitary effect as an object of property.¹⁰ Prohibited acts are not defined directly in Regulation 1257.

Regulation 1260 establishes the translation arrangements for the proposed European unitary patent system on the basis of Article 118(2) TFEU and also applies Council Decision 2011/167/EU, authorising enhanced cooperation. The aim of the compromise in Regulation 1260 is to reduce the number of translations that are necessary by means of a uniform and simple translation regime for European patents with unitary effect.

The UPCA establishes the UPC: a specialised patent court common to the Member States of the EU, for the settlement of disputes relating to European patents with unitary effect, European (EPC) patents and applications, and supplementary protection certificates (SPCs). Its purpose is to remedy

⁴ Council Regulation (EU) 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L 361/1 (Regulation 1257); Council Regulation (EU) 1260/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements [2012] OJ L 361/89 (Regulation 1260); Agreement 2013/C on a Unified Patent Court [2013] OJ L 175/01 (UPCA).

⁵ To enter into force, the UPCA is subject to ratification by thirteen participating Member States, including France, Germany and the United Kingdom. To date, sixteen Member States, including France and the UK, have ratified the UPCA, leaving its entry into force dependent on the ratification of Germany. This is currently dependant on a decision of the German Constitutional Court on the legality of the UPP, which will be discussed below. Also discussed below is the possibility of continued participation of the UK in the UPP post-Brexit.

⁶ Council Decision (EU) 2011/167/EU of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection [2011] OJ L 76/53.

⁷ Thomas Jaeger, 'Is it Back to Square One? An Assessment of the Latest Proposals for a Patent and Court for the Internal Market and Possible Alternatives' (2012) 43(3) IIC 286, 287.

⁸ The procedure involved in applying for a European patent with unitary effect under Regulation 1257 is quite simple. A patent applicant must follow the procedure for obtaining a European patent under the EPC, including by filing an application with the EPO. The EPO will then conduct the necessary search and examination and issue a decision. If successful, the patentee has one month after grant from which they can submit a request for unitary effect. If the formal requirements for registration are met a European patent with unitary effect must be registered by the EPO. For more on the rules relating to the unitary patent see: Decision of the Select Committee of the Administrative Council of 15 December 2015 adopting the Rules relating to Unitary Patent Protection (SC/D 1/15), available at: <<https://www.epo.org/law-practice/legal-texts/official-journal/2016/05/a39.html>> accessed 8 October 2018.

⁹ Article 5(1) Regulation 1257.

¹⁰ Article 5(3) Regulation 1257.

the significant variations between national court systems that are detrimental to innovation, by setting up the UPC, which has been devised to ensure cross-border, expeditious, and high-quality decisions that strike a fair balance between the interests of right holders and other parties.¹¹

It contains provisions on substantive patent law, defining the rights of the proprietor of a European patent with unitary effect or European patent, to prevent the direct and indirect use of the invention.¹² This includes making, offering, placing on the market or using a product which is the subject matter of the patent, or importing or storing the product for those purposes.

Regarding applicable law, under Article 24 UPCA, the UPC will be required to base its decisions on Union law, the UCPA (including its Statute¹³ and Rules of Procedure¹⁴), the EPC, and other international agreements applicable to patents that are binding on all the Contracting Member States.¹⁵ The Court can also apply the national law of a Member State, for example, when dealing with rights of prior use or the unitary patent as an object of property.¹⁶

EU law shall have primacy¹⁷ and the UPC must cooperate with the CJEU in properly interpreting Union law by relying on its jurisprudence and by requesting preliminary rulings in accordance with Article 267 TFEU.¹⁸

Following a transitional period of at least seven years, the UPC will have exclusive jurisdiction for the Contracting Member States of the UPCA. Therefore, if a European patent with unitary effect, or a European (EPC) patent (unless opted out¹⁹), is subject to an action outlined in Article 32 UPCA the case will be taken before the UPC.²⁰

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3. Five-year lead up to the UPP: 2009 – 2013

Attempts at a unitary patent system date back to 1949 when French Senator, Henri Longchambon, proposed a type of unitary patent system for Europe. Since then, a number of attempts have been made to implement such a system.²² In recent history, a long period of negotiation occurred between 2000-2008, however, that eventually stagnated.²³

In 2009, the development of an EU patent picked up momentum once again, fuelled by a sense of urgency among politicians and EU law makers after over forty years of previous failed attempts.²⁴

¹¹ UPCA, Preamble.

¹² Article 25 and 26 UPCA.

¹³ Agreement 2013/C on a Unified Patent Court [2013] OJ L 175/01, Annex I, Statute of the Unified Patent Court.

¹⁴ Preliminary set of provisions for the Rules of Procedure ('Rules') of the Unified Patent Court, 18th draft of 19 October 2015.

¹⁵ Article 24(1) UPCA.

¹⁶ Article 24(2) UPCA.

¹⁷ Article 20 UPCA.

¹⁸ Article 21 UPCA.

¹⁹ Article 83 UPCA outlines that unless an action has been brought before either the UPC or a relevant national court, the patentee is given the option to opt out of the jurisdiction of the UPC.

²⁰ A patent mediation and arbitration centre is available under Article 35 UPCA at centres in Ljubljana and Lisbon.

²¹ Article 84 UPCA.

²² For more on this see: Justine Pila, 'An Historical Perspective I: The Unitary Patent Package' in Justine Pila and Christopher Wadlow (eds), *The Unitary EU Patent System* (Hart Publishing 2014) and Christopher Wadlow, 'An Historical Perspective II: The Unified Patent Court' in Justine Pila and Christopher Wadlow (eds), *The Unitary EU Patent System* (Hart Publishing 2014).

²³ For more detail on this period and the lead up to the UPP see: Hugh Dunlop, *European Unitary Patent and Unified Patent Court* (2nd edition, CIPA 2014); and Alfredo Iardi, *The New European Patent* (Hart Publishing 2015).

²⁴ This sense of urgency was captured by many online blogs such as (but not limited to) IPKat, Managing IP, and EPLAW Blog, as well as the Max Planck Institute in their report: Reto M. Hilty, Thomas Jaeger, Matthias Lamping and Hanns

However, it would be another five years before the UPP was finalised,²⁵ and another five years (and counting) passing since then without the UPP entering into force.

The five-year lead up to the finalisation of the UPP was marked by a number of key developments. One of the most significant developments related to the role of the CJEU. As will be analysed below, despite shaping the UPP through its official opinions and judgments, essentially having the final say on whether or not it was compatible with EU law and therefore viable, a number of attempts were made to limit the jurisdiction of the CJEU over substantive patent law provisions in the final iteration of the UPP.

3.1 How the CJEU shaped the UPP

In 2009, the EU Council requested an opinion from the CJEU on the compatibility of the then most recent attempt at implementing a European patent court, the European and Community/European Union Patent Court (EEUPC) Agreement, with the EU Treaties. In 2011, the CJEU issued its opinion (Opinion 1/09)²⁶ where it was held that the draft agreement was incompatible with EU law:

[T]he envisaged agreement, by conferring on an international court which is outside the institutional and judicial framework of the European Union an exclusive jurisdiction to hear a significant number of actions brought by individuals in the field of the [European Union] patent and to interpret and apply European Union law in that field, would deprive courts of Member States of their powers in relation to the interpretation and application of European Union law and the Court of its powers to reply, by preliminary ruling, to questions referred by those courts and, consequently, would alter the essential character of the powers which the Treaties confer on the institutions of the European Union and on the Member States and which are indispensable to the preservation of the very nature of European Union law.²⁷

The Court expressed that the Member States are the ‘guardians’ of the EU legal order and so removing their right to refer questions to the CJEU was incompatible with the EU Treaties.²⁸ Furthermore, as there would be no way to ensure the EEUPC would refer questions to the CJEU on matters of EU law, and without remedies for individuals against breaches of EU law,²⁹ the agreement was not in line with the Treaties.³⁰ The implementation of a unified litigation system for patents in Europe was consequently prolonged once again.

In the meantime, disagreements over the proposed translation requirements remained at the centre of the EU patent debate. The EU Council eventually decided to launch enhanced cooperation in

Ullrich, ‘The Unitary Patent Package: Twelve Reasons for Concern’ [2012] Max Planck Institute for Intellectual Property & Competition Law Research Paper No. 12-12 <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2169254> accessed 27 September 2018.

²⁵ The Agreement on a Unified Patent Court was signed in December 2013.

²⁶ Opinion 1/09 ECLI:EU:C:2011:123 (Opinion 1/09).

²⁷ Opinion 1/09, para 89.

²⁸ Opinion 1/09, para 66.

²⁹ Thomas Jaeger, ‘What’s in the Unitary Patent Package?’ [2014] Max Planck Institute for Intellectual Property & Competition Law Research Paper No. 14 – 08 <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2435125> accessed 27 September 2018, 12.

³⁰ Opinion 1/09, para 89.

the area of unitary patent protection.³¹ This was requested by twelve Member States, and eventually followed by all remaining Member States with the exception of Italy and Spain.³²

The European Parliament granted consent to the use of enhanced cooperation in February, and on 11 March 2011, the Council adopted a decision authorising said enhanced cooperation.³³ The Commission then proposed two regulations. The first contained a framework for conferring unitary patent protection, and the second contained translation arrangements, both of which the Council approved in June 2011, after much debate and deliberation by Member States.³⁴

In a joint statement by Commissioner Michel Barnier and Minister of State Zoltán Cséfalvay it was announced that:

[By w]orking closely with the European Parliament, the final objective – the creation of unitary patent protection – is within reach. If we maintain our present momentum and cooperative spirit, a unitary patent in Europe could be a reality within the next two years.³⁵

Undetectable in this optimistic statement was the reality of a situation in which Spain and Italy had, only one month previously, brought an action against the Council to the CJEU for its unlawful implementation of enhanced cooperation in the area of the creation of unitary patent protection,³⁶ essentially putting the success of the lengthy negotiations at risk. It was argued that by authorising enhanced cooperation, the Council had circumvented the requirement for unanimity and unduly dismissed their objections regarding translation requirements.

Again, the CJEU had a say in whether the UPP was compatible with EU law. This case was dismissed by the CJEU just under two years later, as well as another case brought by Spain alone.³⁷ Here, the CJEU had the opportunity to further shape the unitary patent Regulations. It had been argued, amongst other issues, that the enhanced cooperation procedure was not a last resort as required. If the CJEU had agreed with the arguments made by Spain, negotiations may have continued and perhaps the enhanced cooperation procedure would not have been necessary, resulting in a more inclusive unitary patent system (for the EU at least). However, the CJEU did not find that any of the issues raised by Spain were valid and so the Regulations remained the same and were implemented by enhanced cooperation.

Meanwhile, the Hungarian Presidency of the EU proposed that negotiations should be resumed on the creation of the unified patent litigation system based on a Commission non-paper containing potential solutions to the problems identified in Opinion 1/09.³⁸ In June 2011, a full amendment of the

³¹ Proposal for a Council Decision (EU) 2010/0384 (NLE) authorising enhanced cooperation in the area of the creation of unitary patent protection [2010] COM(2010) 790 final.

³² Enhanced cooperation is a procedure that allows a minimum of nine EU Member States to cooperate in a certain area without the participation of all Member States. The aim of this procedure is to overcome deadlock, to be used only as a last resort.

³³ Council Decision (EU) 2011/167/EU of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection [2011] OJ L 76/53.

³⁴ Council General Approach (EU) 11328/11 on the Proposal for a Regulation of the Council and the European Parliament implementing enhanced cooperation in the area of the creation of unitary patent protection and on the Proposal for a Council Regulation implementing enhanced cooperation in the area of unitary patent protection with regard to the applicable translation arrangements [2011] PI 67 CODEC 995.

³⁵ European Commission Press Release (EU) MEMO/11/463 Joint Statement of Commissioner Michel Barnier and Minister of State Zoltán Cséfalvay, Chairman of the Competitiveness Council, on unitary patent protection [2011] MEMO/11/463.

³⁶ Joined Cases C-274/11 and C-295/11 *Kingdom of Spain and Italian Republic v Council of the European Union* ECLI:EU:C:2013:240.

³⁷ Case C-146/13 *Kingdom of Spain v European Parliament and the Council of the European Union* ECLI:EU:C:2015:298 and Case C-147/13 *Kingdom of Spain v Council of the European Union* ECLI:EU:C:2015:299.

³⁸ Council Orientation Debate (EU) 10630/11 creating a Unified Patent Litigation System [2011] PI 54 COUR 28.

now UPCA was put forward for deliberation.³⁹ In September 2011, the Polish Presidency of the EU submitted an amended text.⁴⁰ The text was debated extensively in the following months and in the face of opposition to the agreement from practitioners and others who believed that the proposals were being rushed through, the text was rejected. In October 2011, the agreement was further examined for compatibility with Opinion 1/09.⁴¹

Draft after draft of the agreement was released, each one attempting to rectify certain issues with the last. These issues included opposition to the translation arrangements, the role that the CJEU would take in the proposed system, and the location of the central division of the proposed UPC. The draft regulations and the agreement became known as the unitary patent package.

3.2 Attempts to limit the role of the CJEU

In December 2011, the momentum to reach an agreement on the package reached its height, though with negotiations and deliberations happening *in camera*, the public were left unaware as to what was happening.⁴² The European Parliament issued a press release⁴³ with news that political agreement had been reached on the UPP (which took many by surprise) and it would now only require approval by Parliament and Council to take effect.⁴⁴ This gave the impression to some that there was an unnecessary push behind the implementation of the package.⁴⁵ For practitioners and patent applicants alike, who were prevented from commenting because of the secrecy of negotiations, there was a sense that the process had become unduly politicised and undemocratic.⁴⁶

With the meetings still being held *in camera*, information about their progress was difficult to obtain, and the information that was offered to the public was not always clear. According to Poland's European Affairs Minister, Mikolaj Dowgielewicz, at the time:

Essentially the whole package is negotiated, it's final. Nevertheless, due to the resistance to compromise of one or two member states, we will not decide this year on the seat of the court... This is an issue where we have just hit the wall.⁴⁷

Having hit this wall it took twelve months of deliberations to resolve the central division dispute, as well as other important issues, including the role of the CJEU in the proposed European unitary patent system. The issue regarding the role of the CJEU related to the extent to which it would have a say in the interpretation of the substantive provisions applicable to the unitary patent.

³⁹ Presidency Text (EU) 11533/11 on a Draft agreement on a Unified Patent Court and draft Statute [2011] PI 68 COUR 32.

⁴⁰ Revised Presidency Text (EU) 13751/11 on a Draft agreement on a Unified Patent Court and draft Statute [2011] PI 108 COUR 48.

⁴¹ Opinion of the Legal Service (EU) 15856/11 on the compatibility of the draft agreement with the Opinion 1/09 [2011] PI 138 COUR 61.

⁴² Since this period of time, Ingve Björn Stjerna has published translations of meetings from the European Parliament and its Legal Affairs Committee. See: Ingve Björn Stjerna, *The Parliamentary History of the European 'Unitary Patent': Verbatim protocol of selected meetings in the European Parliament and its Legal Affairs Committee* (Tredition 2015).

⁴³ European Parliament, 'Done deal on the EU patent?' [2011] <http://www.europarl.europa.eu/pdfs/news/expert/infopress/20111201IPR33061/20111201IPR33061_en.pdf> accessed 27 September 2018.

⁴⁴ These views were expressed in: <<http://ipkitten.blogspot.co.uk/2011/12/recap-update-unitary-patent-system-and.html>> accessed 27 September 2018.

⁴⁵ These views were expressed in: <<http://ipkitten.blogspot.co.uk/2011/12/recap-update-unitary-patent-system-and.html>> accessed 27 September 2018.

⁴⁶ These views were expressed in: <<http://ipkitten.blogspot.co.uk/2011/12/recap-update-unitary-patent-system-and.html>> accessed 27 September 2018.

⁴⁷ Competitiveness Council of the EU, Press Conference of 5 December [2011] <<http://video.consilium.europa.eu/webcast.aspx?ticket=775-979-10496>> accessed 27 September 2018.

Originally, Regulation 1257 contained substantive patent law provisions on prohibiting use, injunctions following a finding of validity and infringement, and provisions on limitations (Articles 6-8⁴⁸). Fronted by the UK, it was argued that if the Regulations were to contain these provisions, the CJEU would play too significant a role in substantive patent law.

A compromise was reached, resulting in the deletion of Articles 6-8 from Regulation 1257 and their transfer into the UPCA.⁴⁹ This compromise meant that the substantive law provisions of the package that related to the rights conferred by the unitary patent were moved from the EU Regulation, wherein they would fall within the jurisdiction of the CJEU, to the non-EU draft agreement, in which they would be outside that jurisdiction. However, whether those provisions are outside the jurisdiction of the CJEU is questionable, which will be addressed below.

This debate and decision caused much of the initial controversy surrounding Regulation 1257 and has created a degree of legal uncertainty regarding the role of the CJEU in the proposed unitary patent system. While the compromise enabled the package to be concluded, it also caused further concerns amongst commentators who again believed that the proposals had been rushed through without proper evaluation of their implications.⁵⁰ The central division dispute was resolved by splitting the division in three, with the seat in Paris and clusters in London and Munich⁵¹

In December 2012, agreement was achieved and the unitary patent package was finally approved. The regulations on the creation of unitary patent protection⁵² and the applicable translation arrangements⁵³ were adopted.⁵⁴ In February 2013, the text of the Agreement on a Unified Patent Court⁵⁵ was finalised; twenty-five out of twenty-seven (at the time) EU Member States' signatures were collected;⁵⁶ and the process of ratification and implementation began, which is yet to be completed.

4. Possible reasons for attempting to limit the role of the CJEU and the result of those efforts

One of the most significant aspects from this five-year lead up was the contrast between the involvement of the CJEU in framing and shaping the content of the UPP and the subsequent attempt to remove any potential for CJEU involvement in the system once it was up and running.

⁴⁸ Based on Articles 29-31 Convention for the European Patent for the Common Market (15 December 1975) (Community Patent Convention) (CPC) or Articles 25-27 Council Agreement 89/695/EEC of 15 December 1989 relating to Community Patents [1989] OJ L 401/1 (Community Patent Agreement).

⁴⁹ European Parliament, 'Parliament approves EU unitary patent rules' [2012] <<http://www.europarl.europa.eu/news/en/news-room/20121210IPR04506/parliament-approves-eu-unitary-patent-rules>> accessed 27 September 2018.

⁵⁰ This opinion and other concerns have been expressed by many online blogs such as (but not limited to) IPKat, Managing IP, and EPLAW Blog, as well as the Max Planck Institute in their report: Reto M. Hilty, Thomas Jaeger, Matthias Lamping and Hanns Ullrich, 'The Unitary Patent Package: Twelve Reasons for Concern' [2012] Max Planck Institute for Intellectual Property & Competition Law Research Paper No. 12-12 <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2169254> accessed 27 September 2018.

⁵¹ Michael Cross, 'City: Three Way Split for European Patent Court' [2012] 27 LS Gaz 6(3).

⁵² Council Regulation (EU) 1257/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L 361/1.

⁵³ Council Regulation (EU) 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements [2012] OJ L 361/89.

⁵⁴ The Regulations were adopted by: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Sweden and United Kingdom. This includes all EU Member States with the exception of: Spain, Croatia, and Italy. Italy has since adopted the Regulations.

⁵⁵ Agreement 2013/C on a Unified Patent Court [2013] OJ L 175/01.

⁵⁶ The Agreement was signed by: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Romania, Slovakia, Slovenia, Sweden, and United Kingdom. This includes all EU Member States with the exception of Croatia, Poland, and Spain.

The compromise achieved, elaborated on above, was essentially due to a demand by the UK which would not participate in the proposed system if the CJEU had jurisdiction over substantive patent law.⁵⁷ Besides the political reasons set against the CJEU, its position as leading institution in a European-wide patent framework has also been weakened by its controversial jurisprudence in patent law matters. It is perceived by some that the CJEU has not had the best record in its decisions concerning patent law,⁵⁸ however, this article questions whether this is a valid presumption and/or reason to limit its jurisdiction.

The CJEU has not had the opportunity to interpret patent law in many cases, however, when it has, controversy and criticism has followed. In two areas specifically the CJEU has been especially controversial in its decisions: the exception to patentability regarding the use of human embryos for industrial or commercial purposes as well as the regulation of supplementary protection certificates (SPCs).

In both of these areas, the EU has introduced legislation in order to harmonise the approach taken towards these issues across all EU Member States.⁵⁹ First, regulations on SPCs were implemented in order to ensure that across all Member States a protection mechanism was in place to make up for any lost patent protection time because of market authorisation delays. Second, the Biotech Directive was implemented in order to encourage a strong biotechnology industry in Europe by introducing effective and harmonised protection throughout the Member States, as well as to protect fundamental rights, such as human dignity.⁶⁰

Given the existence of EU law in these areas of patent law, EU Member States have a duty to refer questions to the CJEU if there are uncertainties regarding the correct interpretation of these provisions.⁶¹ Furthermore, despite the criticism surrounding the decisions in these areas, there would be significant implications if the CJEU were to be restricted from interpreting these patent law matters. First, the generalist overview that is necessary to take the wider societal implications of patent law decisions into account would no longer exist. Second, the harmonisation that follows from CJEU decisions would also be lost.

4.1 The Controversial Case Law – SPC Regulations

The EU first became involved with patents through the implementation of two regulations; one concerning SPCs for medicinal products and another for plant protection products.⁶²

⁵⁷ Winfried Tilmann, 'The compromise on the uniform protection for EU patents' (2013) 8(1) *JIPLP* 78.

⁵⁸ See for example: Robin Jacob, 'The Relationship between European and National Courts in Intellectual Property Law' in Ansgar Ohly and Justine Pila (eds), *The Europeanization of Intellectual Property Law: Towards a European Legal Methodology* (OUP 2013) 198; Tuomas Mylly, 'A Constitutional Perspective' in Justine Pila and Christopher Wadlow (eds), *The Unitary EU Patent System* (Hart Publishing 2014); Thomas Jaeger, 'What's in the Unitary Patent Package?' [2014] Max Planck Institute for Intellectual Property & Competition Law Research Paper No. 14 – 08 <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2435125> accessed 27 September 2018, 8.

⁵⁹ Council Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (codified version) [2009] OJ L 152/1; Council Regulation (EC) 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products [1996] OJ L 198/30; Council Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions [1998] OJ L 213/13 (Biotech Directive).

⁶⁰ Recital 3, Biotech Directive.

⁶¹ This duty is under Article 267 TFEU.

⁶² Council Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (codified version) [2009] OJ L 152/1 and Council Regulation (EC) 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products [1996] OJ L 198/30 (SPC Regulations).

An SPC is distinct from a patent; it is a *sui generis* right that extends the protection afforded to a patented product, in certain circumstances, for a limited period of time.⁶³ It was deemed necessary by the EU to implement a uniform solution at Community level to provide for situations where ‘the period that elapses between the filing of an application for a patent for a new medicinal or plant product and the authorisation to place that product on the market, makes the period of effective protection under the patent insufficient to cover the investment put into research’.⁶⁴

A uniform solution, in the form of an SPC was implemented to harmonise and promote the functioning of the internal market in order to remove the risk of discrepancies arising that would incite the relocation of research to countries offering greater protection.⁶⁵

The interpretation of the Regulations by the CJEU, especially with regard to medicinal products, has been the subject of considerable controversy.⁶⁶ The CJEU has been criticised for failing to clearly answer the questions referred to it by domestic courts.⁶⁷ However, that there have been so many cases referred to the CJEU on the content of these Regulations is often down to the legislation itself being particularly vague. Furthermore, the CJEU has also been criticised for going too far in other rulings (see below for example, in relation to ‘human embryos’) and so a fine balance is required between decisions that are detailed enough and those having too much detail, a balance that is difficult to find in all decisions.

In reference to the SPC Regulations, a relatively high number of cases have been referred to the CJEU on the interpretation of Article 3 Regulation 469/2009. Article 3 states that an SPC will be granted if ‘the product is protected by a basic patent in force’. There have been some issues with SPCs relating to inventions claiming active ingredients/combinations of active ingredients and the criteria required to decide whether ‘the product is protected by a basic patent in force.’

A number of referrals have been attempted to gain clarity on the interpretation of this vague provision, including (but not limited to) *Medeva*, *Eli Lilly*, and *Actavis v Boeringher*.⁶⁸ Additionally, *Teva v Gilead*, decided in 2018, has added some more detail to the discussion.⁶⁹

In *Medeva*, the referring court asked what was meant by ‘protected by a basic patent in force’ and what were the determining criteria in a number of different circumstances, such as when a medical product contains more than one active ingredient. The CJEU ruled that the active ingredient had to be ‘specified in the wording of the claims of the basic patent relied on in support of the application’ to be granted an SPC.⁷⁰ However, the Court did not specify how ‘specified’ should be interpreted and so questions remained over how specific the claims needed to be for an SPC to be granted over a number of active ingredients.

⁶³ Article 13 Regulation 469/2009.

⁶⁴ Recital 4 Regulation 469/2009.

⁶⁵ Annette Kur and Thomas Dreier, *European Intellectual Property Law: Text, Cases & Materials* (Edward Elgar 2013) 145.

⁶⁶ For an extensive study on the legal aspects of the SPCs, see: European Commission Report, ‘Study on the Legal Aspects of Supplementary Protection Certificates in the EU’ (2018) available at: <<https://publications.europa.eu/en/publication-detail/-/publication/6845fac2-6547-11e8-ab9c-01aa75ed71a1/language-en>> accessed 8 October 2018.

⁶⁷ Darren Smyth, ‘Two gaps instead of one: the CJEU’s effect on Supplementary Protection Certificate jurisprudence’ (2014) 9(6) *JIPLP* 445. See also the Swiss Federal Patent Court judgment in *Teva v Gilead* (https://www.bundespatentgericht.ch/fileadmin/entscheide/O2017_001_Urteil_2017-10-03.pdf) wherein the court summarised CJEU case law on SPCs and refused to follow its rulings as they were unclear – reported in English by Lexology, available at: <<https://www.lexology.com/library/detail.aspx?g=c361ffe8-bbe6-4514-822e-8b08f2629261>> accessed 8 October 2018. In the spirit of harmonisation, on appeal, the Federal Supreme Court in Switzerland has since ruled that for new SPCs, the CJEU *Medeva* test will apply.

⁶⁸ Case C-322/10 *Medeva v Comptroller General of Patents, Designs and Trade Marks* ECLI:EU:C:2011:773; Case C-493/12 *Eli Lilly v Human Genome Sciences* ECLI:EU:C:2013:835; and Case C-577/13 *Actavis v Boeringher* ECLI:EU:C:2015:165.

⁶⁹ Case C-121/17 *Teva UK v Gilead Sciences Inc* ECLI:EU:C:2018:585.

⁷⁰ Case C-322/10 *Medeva v Comptroller General of Patents, Designs and Trade Marks* ECLI:EU:C:2011:773, para 43.

Owing to the uncertainty created, in *Eli Lilly*, the CJEU was asked what the criteria are for determining whether ‘the product is protected by a basic patent in force’ in relation to a combination product – Eli Lilly had claimed that an antibody relating to the invention contained in the SPC owned by Human Genome Sciences was not ‘specified’. The Court ruled that it was not necessary for the active ingredient to be identified in the claims but that was on the condition that where the active ingredient is covered by a functional formula in the claims, it was possible to conclude that the claims related ‘implicitly but necessarily and specifically’ to the active ingredient.⁷¹ That decision was seen as not being detailed enough and did not add much to the previous case law – the CJEU ruling was found to be ‘disappointing’ by the implementing court because although the CJEU gave some indication as to how active ingredients ought to be specified, there was no express guidance.⁷²

A question on Article 3 was again referred in *Actavis v Boehringer*. The case concerned Boehringer’s attempt to gain an SPC over their patented product (on which they already had an SPC) combined with another active ingredient, which was detailed in a subsequent claim. The CJEU held that if an SPC had already been obtained on the first claimed active ingredient which was the ‘sole subject matter of the invention’, it was not possible to have another SPC on that product combined with another active ingredient.⁷³ This reflected an earlier decision in *Actavis v Sanofi* that rejected a combo-SPC where the ‘core-inventive advance’ had already been subject to a SPC.⁷⁴

Most recently, in 2018, the CJEU once again handed down a ruling following another referral that asked what the criteria were for deciding whether ‘the product is protected by a basic patent in force’ relating to combinations of active ingredients.⁷⁵ In its answer, the Court stated that ‘a product composed of several active ingredients with a combined effect is ‘protected by a basic patent in force’ within the meaning of that provision where, even if the combination of active ingredients of which that product is composed is not expressly mentioned in the claims of the basic patent, those claims relate necessarily and specifically to that combination’ and gave more detail by stating that ‘the combination of those active ingredients must necessarily, in the light of the description and drawings of that patent, fall under the invention covered by that patent, and each of those active ingredients must be specifically identifiable, in the light of all the information disclosed by that patent.’⁷⁶

Although the Court did not provide any further guidance on for example, what is meant by ‘specifically identifiable’, or what is meant by active ingredients having to ‘fall under the invention covered by that patent’ it is more detail than what has previously been provided and can be applied more generally. It appears that an attempt has been made to be more detailed in this response, which should also be carried out for future cases to further clarify the uncertainties that remain in this area.

It is clear from the number of cases relating to inventions concerning active ingredients/combinations of active ingredients that have been referred to the CJEU asking what the criteria are to determine if ‘the product is protected by a basic patent in force’ that the answers previously returned were unsatisfactory and unclear. The result of this is confusion, uncertainty, and a level of distrust in the CJEU when it comes to giving clear guidance on issues relating to the protection of inventions. Attempts in *Teva v Gilead* have arguably assisted to a certain degree, however, two further cases are awaiting judgment.⁷⁷ For the distrust that exists to dissipate, the CJEU must further clarify this area and give more detailed guidance.

Owing to the time, effort and cost of referring a question to the CJEU, coupled with the unclear guidance that returns, it has been proposed that national courts should stop referring these questions to

⁷¹ Case C-493/12 *Eli Lilly v Human Genome Sciences* ECLI:EU:C:2013:835, para 45.

⁷² *Eli Lilly v Human Genome Sciences* [2014] EWHC 2404 (Pat), para 63.

⁷³ Case C-577/13 *Actavis v Boehringer* ECLI:EU:C:2015:165, para 42.

⁷⁴ Case C-443/12 *Actavis v Sanofi* ECLI:EU:C:2013:833.

⁷⁵ Case C-121/17 *Teva UK v Gilead Sciences Inc* ECLI:EU:C:2018:585.

⁷⁶ Case C-121/17 *Teva UK v Gilead Sciences Inc* ECLI:EU:C:2018:585, para 58.

⁷⁷ Case C-650/17 *Request for a preliminary ruling from the Bundespatentgericht lodged on 21 November 2017* 2018/C 052/28 and Case C-114/18 *Request for a preliminary ruling from Court of Appeal (England & Wales) (Civil Division) made on 14 February 2018 – Sandoz Ltd, Hexal AG v GD Seale LLC, Jansses Sciences Ireland* 2018/C 152/20.

the CJEU and decide on them in a manner that is as consistent as possible.⁷⁸ In general, national courts continue to refer questions to the CJEU even when it takes a long time to get an answer and those answers remain unclear.⁷⁹ However, it must be borne in mind that the CJEU has to find a balance between guiding Member States on the correct general interpretation of certain provisions that are often quite vague to begin with on the one hand, and going too far/getting too detailed on the other hand. Rulings from the CJEU need to be somewhat vague given their future application to all cases related to the particular provision in question at the time.

4.2 The Controversial Case Law – Biotech Directive

The most significant example of the involvement of the EU in the European patent system is the implementation of the Biotech Directive in 1998. The Directive seeks to achieve its aims by setting out the conditions for patentability of biotechnological inventions and the subject matter that is excluded from patentability. In doing so, it restates the core provisions of the EPC and explains how they relate to biotechnological inventions. In 1999, only one year after its introduction, the provisions of the Directive were incorporated into the Implementing Regulations to the EPC.⁸⁰

One of the most controversial and therefore most relevant aspects of the Biotech Directive for this article has been the interpretation of Article 6(2)(c), which excludes from patentability inventions whose commercial exploitation would be contrary to *ordre public* or morality, and specifically the use of human embryos for industrial or commercial purposes.

In Case C-34/10, also known as the *Brüstle* decision, a reference for a preliminary ruling was requested by the German Supreme Court⁸¹ under Article 267 TFEU.⁸² The case concerned a patent relating to neural precursor cells and the processes for their production from embryonic stem cells, as well as their use for therapeutic purposes. The German court, amongst other questions, asked the CJEU what was meant by the term ‘human embryo’ in Article 6(2)(c) of the Biotech Directive.⁸³

The CJEU was of the opinion that the term must be regarded ‘as designating an autonomous concept of EU law’ for the purposes of the application of the Directive, which must be ‘interpreted in a uniform manner throughout the territory of the Union’.⁸⁴ It went on to define ‘human embryo’ – having regard to the fundamental rights underpinnings of the patentability exclusion in which the term appeared – as:

[A]ny human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis.⁸⁵

In doing so, the CJEU ensured that the term ‘human embryo’ was given a significantly broad definition, which had the effect of restricting the commercialisation of innovation in this area, but also closely harmonised this area of patent law.

⁷⁸ Smyth, Two gaps instead of one, 445.

⁷⁹ Cases such as: Case C-567/16 *Merck Sharp & Dohme Corporation v Comptroller General of Patents, Designs and Trade Marks* ECLI:EU:C:2017:948; and Case C-121/17 *Teva UK v Gilead Sciences Inc* ECLI:EU:C:2018:585. These recent cases have been subject to criticisms on many blogs online such as (but not limited to) Lexology and IPKat.

⁸⁰ Chapter V, Rule 26(1) Implementing Regulations to the EPC 2000.

⁸¹ Decision of the Bundesgerichtshof, 17 December 2009 (Xa ZR 58/07) – ‘Neurale Vorläuferzellen (*Neural precursor cells*).’

⁸² Case C-34/10 *Oliver Brüstle v Greenpeace eV*. ECLI:EU:C:2011:669.

⁸³ For more detailed commentary on the CJEU ruling in this case, see, for example: Martine Ines Schuster, ‘The Court of Justice of the European Union’s ruling on the patentability of human embryonic stem-cell-related inventions (case C-34/10)’ (2012) 43(6) IIC 626.

⁸⁴ *Brüstle*, para 26.

⁸⁵ *Brüstle*, para 38.

Brüstle may have closely harmonised the area, however, it has been questioned by commentators whether this was appropriate or progressive.⁸⁶ Although the CJEU has considered the intention of the legislator to protect fundamental rights and human dignity, the decision has been criticised⁸⁷ as one that has gone too far by overly simplifying and giving an ‘incomplete analysis of the human rights situation’.⁸⁸ By defining ‘human embryo’ expansively and as an autonomous concept of EU law, the CJEU has ignored the fact that various definitions existed in many Member States and in doing so, has ignored considerations of national diversity.⁸⁹

This case first raises a question as to whether the identification of terms as autonomous concepts of EU law is an appropriate action for the CJEU to take in circumstances involving morality in patent law, but also morality in general. It could be argued that in doing so, the CJEU is moving from the realm of judicial interpretation into that of judicial activism.⁹⁰ However, the reason for referring questions to the CJEU is to clear up areas where the correct interpretation of a provision is unclear. The expectant result is an answer that applies across the EU for all Member States to consider in future. In patent law, the CJEU is better placed to give a generalist answer on morality rather than one that would possibly disregard wider societal implications.

Second, Aurora Plomer argues that by imposing uniform exclusions based on human dignity where reality points to diversity threatens not only the sovereignty of Member States but also the integrity of the CJEU.⁹¹ Previously, in the *Omega* case, the CJEU had emphasised the need to ensure a margin of appreciation to EU Member States regarding the meaning and requirements of human dignity.⁹² Furthermore, the CJEU had previously held in the *Netherlands* case that provisions of the Biotech Directive should allow Member States a wide scope of manoeuvre and discretion in their application.⁹³ If the CJEU had followed its own case law and displayed restraint in *Brüstle*, it could have left some room to manoeuvre for national courts. Requiring Member States to by-pass the legislature by adopting a definition of ‘human embryo’ that is different from the definitions supported by the majority of EU Member States, has important implications for other areas of law and social policy.⁹⁴

⁸⁶ Shane Burke, ‘Interpretative clarification of the concept of “human embryo” in the context of the Biotechnology Directive and the implications for patentability: *Brüstle v Greenpeace eV* (C-34/10)’ (2012) 34(5) EIPR 346, 349. For more commentaries on this, see footnotes below.

⁸⁷ For a brief outline of the criticisms of *Brüstle*, see: Scott Parker and Paul England, ‘Where now for stem cell patents?’ (2012) 7(10) EIPR 738, 743.

⁸⁸ 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) 159.

⁸⁹ As mentioned in: Justine Pila, ‘A Constitutionalized Doctrine of Precedent and the *Marleasing* Principle as a Basis for a European Legal Methodology’ in Ansgar Ohly and Justine Pila (eds), *The Europeanization of Intellectual Property Law: Towards a European Legal Methodology* (OUP 2013) 236. This was also one of the reasons of the European Court of Human Rights when it decided not to define when the right to life begins. It was stated that the issue of when the right to life begins comes within the margin of appreciation which the Court generally considered that States should enjoy themselves: *Vo v France* App no 53924/00 (ECtHR 8 July 2004), para 82; *Evans v UK* App no 6339/05 (ECtHR, 7 March 2006), para 46.

⁹⁰ Andrea Faeh, ‘Judicial activism, the Biotech Directive and its institutional implications: is the court acting as a legislator or a court when defining the “human embryo”?’ (2015) 40(4) EL Rev 613.

⁹¹ Aurora Plomer, ‘After *Brüstle*: EU accession to the ECHR and the future of European patent law’ (2012) 2(2) Queen Mary Journal of Intellectual Property 110, 125.

⁹² Case C-36/02 *Omega Spielhallen- und Automatenaufstellungs-GmbH v Oberbürgermeisterin der Bundesstadt Bonn* ECLI:EU:C:2004:614 (*Omega*).

⁹³ This point seemed to have been forgotten in *Brüstle*, as noted in the following article: Shawn HE Harmon, Graeme Laurie and Aidan Courtney, ‘Dignity, plurality and patentability: the unfinished story of *Brüstle v Greenpeace*’ (2013) 38(1) EL Rev 92.

⁹⁴ Justine Pila and Paul Torremans, *European Intellectual Property Law* (OUP 2016) 107.

However, the CJEU backtracked on its decision in *Brüstle* only three years later when a question on the interpretation of Article 6(2)(c) of the Biotech Directive, specifically regarding the previous interpretation of the term ‘human embryo’, was referred to the CJEU by the UK.⁹⁵

In Case C-364/13 *International Stem Cell Corporation (ISCC)*⁹⁶ the CJEU clarified its earlier decision in *Brüstle* and decided that an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a ‘human embryo’ if it does not, in itself, ‘have the inherent capacity of developing into a human being’.⁹⁷ The effect of the decision is that rather than the definition of ‘human embryo’ concerning the capability of the ovum to *commence* the development into a human being (*Brüstle*), it must have the inherent capacity of *developing into* a human being (*ISCC*). This opened up the doors that *Brüstle* closed for patents on inventions using ova stimulated by parthenogenesis, which would never have the capacity to develop into a human being but commences that process.

The reason behind this clarification was because the CJEU in the *Brüstle* case based its findings on observations that considered that the non-fertilised ovum stimulated by parthenogenesis would be capable of full development, which was inaccurate.⁹⁸ This type of misunderstanding is one of the causes for concern amongst those who believe that the CJEU should not have a say in the interpretation of substantive patent law matters as a technically qualified court may have realised this inaccuracy. However, this inaccuracy was presented to the Court as fact and there would have been no reason for the CJEU to question this information at the time. As can be seen from the *ISCC* decision, had the CJEU known that this information was inaccurate, they arguably would not have come to same conclusion in *Brüstle*.

Overall, the *ISCC* decision has been welcomed and has somewhat reopened the doors of commercialising research in this area.⁹⁹ Some commentators are of the opinion that this is a step in the right direction, but that it does not take away from the fact that the CJEU has defined subject matter that, in this case, it ought to have left to the discretion of national courts in the first place¹⁰⁰ and so a distrust remains.

4.3 The CJEU has a poor track record in patent law, but should that be a reason for limiting its jurisdiction?

From the above examples, it can be seen that in patent law the CJEU has delivered decisions that have been controversial, albeit in the relatively few relevant cases. In certain instances, the CJEU has arguably gone too far in its interpretation of substantive patent law and in others it has caused significant confusion, so the presumption that the CJEU has a poor track record in patent law is valid, albeit with qualification.

The overarching problem that has been expressed regarding the jurisdiction of the CJEU over the UPP and patent matters in general is the fact that as a generalist court, it does not have the expertise

⁹⁵ *International Stem Cell Corporation v Comptroller General of Patents* [2013] EWHC 807 (Ch).

⁹⁶ Case C-364/13 *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks (ISCC)* ECLI:EU:C:2014:2451.

⁹⁷ *ISCC*, para 28.

⁹⁸ *ISCC*, para 31 and 32.

⁹⁹ See for example: Sebastian Moore and Andrew Wells, ‘Clarification of European law relating to stem cell patents’ (2015) 37(4) EIPR 258; and 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. O’Sullivan welcomes this clarification but questions whether it entirely opens the doors for the patentability of inventions involving parthenotes.

¹⁰⁰ Timo Minssen and Ana Nordberg, ‘The evolution of the CJEU’s case law on stem cell patents: Context, outcome and implications of Case C-364/13 *International Stem Cell Corporation*’ [2015] 5 Nordic Intellectual Property Law Review 493; 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.

necessary to deliver judgments on patent law.¹⁰¹ As seen, not many patent cases have been decided, but those that exist have resulted in controversy. For example, the *Brüstle* ruling that went too far by defining the term ‘human embryo’ as it did,¹⁰² and the rulings on the SPC Regulations that have caused legal uncertainty in the area. A lack of expertise in patent law on the part of the CJEU is said to have been one of the causes of these issues in patent law judgments.

However, in both instances there have been external circumstances that have led to this apparent poor record in patent law. For decisions relating to the SPC Regulations, the Regulations themselves are very vague. For decisions relating to ‘human embryos’ the concerning misunderstandings of the Court were based on factual evidence submitted to the Court.

The CJEU’s interpretation of substantive patent law, especially EU patent law, remains entirely necessary. In general, other EU principles need to be considered and, in a reversal of the argument above, it is argued that specialised patent courts will not necessarily have the expertise or inclination to do so adequately.

This question of whether the CJEU should have jurisdiction in this area is of especial importance moving forward given the nature of the proposed unitary patent system. Many commentators also argue that this poor track record should not be a reason to limit CJEU jurisdiction. For example, it is said that the generalist nature of the CJEU is what is necessary in patent law in order to ensure that not only patent rights are considered, but also fundamental rights:

Patent law does not belong exclusively to the worlds of commerce, industry, and technology, but rather has other social and cultural dimensions which must be considered by the legislature and courts when developing and applying it.¹⁰³

The advocates of this argument take the view that if the CJEU does not have jurisdiction over the proposed unitary patent system, that the UPC could become too specialised. Observers have suggested that these generalist interests are and should be shaping core issues of intellectual property through proportionality, a trend that should be applauded.¹⁰⁴ It has therefore been suggested that the CJEU is better equipped to interpret these general provisions and should maintain a generalist role over the UPC.¹⁰⁵

According to Rochelle Dreyfuss, an emphasis on experienced patent judges, experts in all fields of technology, and training for those who are not experts, may actually have a negative effect on the ability of the UPC to see patent law in context, and not as the ‘be all and end all’ of issues.¹⁰⁶

Furthermore, a bias may develop towards technology-based values as a result of this highly specialised judiciary. There is the possibility, as mentioned above, that there will be a lack of consideration for fundamental rights such as human dignity, health, and welfare. A ‘tunnel-vision’ or

¹⁰¹ Jan Smits and William Bull, ‘The Europeanization of Patent Law: Towards a Competitive Model’ in Ansgar Ohly and Justine Pila (eds), *The Europeanization of Intellectual Property Law: Towards a European Legal Methodology* (OUP 2013), 52.

¹⁰² For criticisms on the *Brüstle* ruling, see: Shane Burke, ‘Interpretative clarification of the concept of “human embryo” in the context of the Biotechnology Directive and the implications for patentability: *Brüstle v Greenpeace eV* (C-34/10)’ (2012) 34(5) EIPR 346; Scott Parker and Paul England, ‘Where now for stem cell patents?’ (2012) 7(10) EIPR 738; and 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). The same could be said for the *Monsanto* decision on modified genes in plants (Case C-428/08 *Monsanto Technology v Cefetra* ECLI:EU:C:2010:402), which limited the scope of patentability in that area.

¹⁰³ Justine Pila, ‘A Constitutionalized Doctrine of Precedent and the *Marleasing* Principle as Bases for a European Legal Methodology’ in Ansgar Ohly and Justine Pila (eds), *The Europeanization of Intellectual Property Law: Towards a European Legal Methodology* (OUP 2013) 228.

¹⁰⁴ Strowel and Kim, 142.

¹⁰⁵ Pila, Historical Perspective, 21.

¹⁰⁶ Rochelle C Dreyfuss, ‘An International Perspective I: A View from the United States’ in Justine Pila and Christopher Wadlow (eds), *The Unitary EU Patent* (Hart Publishing 2014), 157.

‘closed pro-protection perspective’ might emerge, wherein all UPC judgments are based on pure substantive patent law and promoting the grant of patents without regard for more general laws and issues.¹⁰⁷ It is argued that this problem could be remedied quite efficiently by the CJEU and it is therefore necessary for the UPC to respect and use this institution to its benefit so that the European patent system continues to consider the wider implications of its decisions.

Some commentators have compared the situation to that in the US.¹⁰⁸ The Supreme Court of the US, acting as Court of Appeal in patent matters, puts an emphasis on common sense and views issues that come before it in a broader and more general perspective than the Federal Circuit.¹⁰⁹ This has arguably brought patent cases into line and back from the extreme specialisation towards which they were headed.¹¹⁰ The CJEU could effectively do the same for the European patent system.

As pointed out by Alain Strowel and Hee-Eun Kim, the CJEU case law highlights the need for a balance between intellectual property rights and other interests.¹¹¹ While it is admitted that the *Brüstle* judgment went too far by defining human embryo as it did, proponents of its involvement suggest that the CJEU was correct in considering constitutional values¹¹² and that there can be ‘no doubt’ that the courts must take fundamental rights into account.¹¹³

There have been strong arguments made both against and in favour of the role that the CJEU could play alongside the UPC by many commentators – on the one hand that a specialist court is necessary to deal with the technical nature of patent law, and on the other hand that patent law cannot be defined restrictively, without balancing all rights concerned.¹¹⁴

Overall, limiting the role of the CJEU would be highly problematic and effectively create a patent system that is highly specialised and pro-patent, but possibly one that would disregard other important factors. This can already be seen in the extensions and attempted extensions that have been made to allow for the granting of more patents. For example, second use patents have been expanded and allowed for quite some time, and until the European Commission stepped in, the EPO was also set (and possibly still is set) to allow patents on products that are the result of non-patentable essentially biological processes.¹¹⁵ This extension of patent protection is set to continue as technology continues to develop, and in a field such as biotechnology, it is imperative to keep fundamental rights considerations in view.

Additionally, the harmonising nature of CJEU judgments cannot be disregarded. By handing down decisions on the appropriate interpretation of certain provisions for all EU Member States soft harmonisation follows, which has a significant impact.

¹⁰⁷ Ansgar Ohly, ‘Concluding Remarks: Postmodernism and Beyond’ in Ansgar Ohly and Justine Pila (eds), *The Europeanization of Intellectual Property Law: Towards a European Legal Methodology* (OUP 2013), 264; and Jens Schovsbo, Thomas Riis and Clement Salung Petersen, ‘The Unified Patent Court: pros and cons of specialization – is there a light at the end of the tunnel (vision)?’ (2015) 46(3) IIC 271, 273.

¹⁰⁸ Dreyfuss, *International Perspective*, 157.

¹⁰⁹ Clement Salung Petersen and Jens Schovsbo, ‘On Law and Policy in a European and European Union Patent Court (EEUPC) – What Will it do to Patent Law and What Will Patent Law do to it?’ [2010] <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1572521> accessed 27 September 2018, 11.

¹¹⁰ However, the Supreme Court of the United States has also been criticised along the same lines as the CJEU.

¹¹¹ Alain Strowel and Hee-Eun Kim, ‘The Balancing Impact of General EU Law on European Intellectual Property Jurisprudence’ in Ansgar Ohly and Justine Pila (eds), *The Europeanization of Intellectual Property Law: Towards a European Legal Methodology* (OUP 2013) 122.

¹¹² 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) 159.

¹¹³ Ohly, *Fundamental Rights in IP*, 146.

¹¹⁴ Pila, *Historical Perspective*, 23.

¹¹⁵ On expanding liability to do with second medical use patents, see: Kai Rütting, ‘A New Scenario for Infringement of Second Medical Use Patents: Are Generics Liable when They Participate in Discount Contract Tenders?’ [2016] 1 epi Information 25. For the EPO press release considering the Notice from the European Commission, see: <<https://www.epo.org/news-issues/news/2017/20170629.html>> accessed 19 October 2018. Subsequently, the EPO Boards of Appeal found that this Notice was not legally binding in T 1063/18 and so the EPO may in future still allow for this type of patent.

Rather than force the CJEU out, there are alternative ways in which the issues faced in the past could be rectified. For example, independent technical experts could be appointed more regularly to give specialist information to the CJEU, which could rectify the tarnished view of those that are opposed to the CJEU having a say in these matters. Having relevant independent experts available to the generalist panel would ensure that the correct technical information is relayed to the Court, which will add the necessary level of specialism. The CJEU could also attempt to give more detailed guidance on what is meant by a particular word or phrase in its judgments.

It is clear from the provisions of the UPCA that EU law has primacy and questions shall be referred to the CJEU in matters of EU law. The CJEU will surely have a role to play in the proposed unitary patent package, but the extent of that role is unsure.

4.4 Did the attempts to limit CJEU jurisdiction work?

Despite the criticisms against CJEU decisions in patent law matters, its generalist nature remains essential in considering the wider implications of patents on society and in promoting a harmonised approach towards patent law. However, whether the role of the CJEU has been limited in the UPP, as attempted, can and has been questioned.

As seen, the substantive provisions of the UPP were moved from the EU Regulations to the non-EU UPCA. The reasoning behind this was that those provisions would then no longer be a part of EU law, and so it would not be possible for the CJEU to interpret them.

Although seen as a political success for the UK (leading the charge on this front), this compromise may not achieve the intended result. The CJEU could still have jurisdiction over the provisions of the UPCA. Rather than clarifying the CJEU's jurisdiction with respect to substantive patent law matters, the move to delete Articles 6-8 has resulted in uncertainty regarding the scope of that jurisdiction.

Some commentators believe that it would be naïve to think that the CJEU will not fill in any blanks in substantive patent law that have been left by Regulation 1257¹¹⁶ and could go so far as to deem the entire package unconstitutional if referred a question on its interpretation.¹¹⁷ It is likely that the CJEU will fill in the blanks and it has sometimes taken an aggressive stance when its own role and jurisdiction are challenged;¹¹⁸ however, it must be recalled that the CJEU has had the opportunity to shape the Regulations, and had the opportunity to deem their implementation by enhanced cooperation unlawful. It is therefore unlikely that it would go so far as to deem the entire package unconstitutional, but likely that if referred a question on the interpretation of the UPP provisions, it would not limit itself to those contained in the Regulations.

Another commentary has stated that the livelihood of the Regulation will 'depend on how far the CJEU will be willing to go – either the CJEU construes the Regulation as incorporating the UPCA provisions or as authorising the development of an entirely new body of law'.¹¹⁹ This is an interesting point and raises an argument that has been made, by those such as Winfried Tilmann, that the CJEU could have jurisdiction over the UPCA through the loop-hole of an 'incorporating referral' from the Regulations.¹²⁰

¹¹⁶ Thomas Jaeger, 'Shielding the unitary patent from the ECJ: a rash and futile exercise' (2013) 44(4) IIC 389, 391.

¹¹⁷ Mylly, 79.

¹¹⁸ See, for example: Opinion 1/91 ECLI:EU:C:1991:490; Opinion 2/94 ECLI:EU:C:1996:140; Opinion 2/13 ECLI:EU:C:2014:2454; and Joined cases C-402/05 P and C-415/05 P *Yassin Abdullah Kadi and Al Barakaat International Foundation v Council of the European Union and Commission of the European Communities* ECLI:EU:C:2008:461.

¹¹⁹ Katharina Kaesling, 'The European patent with unitary effect – a unitary patent protection for a unitary market?' (2013) 2(1) UCL JL and J 87, 100.

¹²⁰ Winfried Tilmann, 'The compromise on the uniform protection for EU patents' (2013) 8(1) JIPLP 78, 81.

Having previously argued that the deletion of Articles 6-8 was not necessary,¹²¹ Tilmann maintains that the provisions of the UPCA are now part of the Article 5 rule on uniform protection. Article 5(3) states that ‘the acts against which the patent provides protection... [are] defined by the law applied to European patents with unitary effect in the participating Member State whose national law is applicable to the European patent with unitary effect as an object of property’.¹²²

With the incorporating referral argument, it is said that the national law referred to in Article 5(3) will be the UPCA once it enters into force. Taking that argument further, Tilmann convincingly argues that the UPCA provisions therefore belong to Union law and so, the CJEU could have scope over the entire package.¹²³

This argument is compelling, especially coupled with the previous activity of the CJEU in the UPP development. It is entirely likely that the CJEU will continue to shape the UPP, once/if it enters into force, and once/if important questions regarding interpretation arise.

Following Opinion 1/09 and the redrafting of the UPCA, it is also clear that Union law has primacy within the proposed unitary patent system. It is therefore argued that the CJEU will likely be referred questions on the interpretation of UPP provisions. What is likely is that the CJEU will have a say in the interpretation of the entire UPP, but that will entirely depend on the questions that it is referred.

Finally, it can be assumed that CJEU referrals will have the same impact as they currently do in national courts. Therefore, it will be up to the referring division of the UPC (likely the UPC Court of Appeal) to interpret the ruling of the CJEU. The interpretation of the referring division will then become the interpretation for the entire UPC, partly ensuring the harmonisation that it promises.

Overall, that the CJEU will more than likely have a say in not only the interpretation of the Regulations but also the UCPA provisions will be of benefit to the UPP. As mentioned, the CJEU can maintain a generalist court perspective over the highly specialised UPC, providing a level of assurance against the concern relating to tunnel-vision and ensure that fundamental rights are taken into consideration, as well as promoting a harmonised approach towards interpretation.

However, although attempts to limit CJEU jurisdiction in this way have arguably failed, since the UK have now decided to leave the EU questions arise once more as to the involvement that the CJEU should have in patent law, especially in the UK and furthermore, whether this will lead to the end of the UPP. The question relating to the harmonising role of the CJEU over patent law therefore has refreshed significance and could be ultimately affected by Brexit.

5. Brexit, the continued participation of the UK in the UPP, and the role of the CJEU

Since Brexit, the question of the role of the CJEU in the UPP and over substantive patent law needs to be analysed from this new perspective. Associated questions relate to the future of the UPP and the participation of the UK in it. At the centre of these concerns is whether the UK will be required to implement decisions of the CJEU in matters relating to the proposed unitary patent system following its departure from the EU if it remains in the unitary patent system. If it is not required to do so, the resulting impact could be divergence in the interpretation of patent law provisions to the detriment of an efficient and effective European patent system.

¹²¹ Winfried Tilmann, ‘The Battle about Article 6-8 of the Union Patent Regulation’ [2012] European Scrutiny Committee Written Evidence, available at: <<http://www.publications.parliament.uk/pa/cm201012/cmselect/cmeuleg/1799/1799vw06.htm>> accessed 28 September 2018. For further arguments about the deletion of Articles 6-8 see: Christopher Wadlow, ‘“Hamlet without the Prince”’: Can the Unitary Patent Regulation strut its stuff without Articles 6 – 8?’ (2013) 8(3) *JIPLP* 207; and Hanns Ullrich, ‘Select from within the System: The European Patent with Unitary Effect’ [2012] Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 12-11, available at: <http://www.rzeczniapatentowy.org.pl/nie_dla_pat_jed/SSRN-id2027920.pdf> accessed 18 September 2018.

¹²² Article 5(3) Regulation 1257.

¹²³ Winfried Tilmann, ‘The compromise on the uniform protection for EU patents’ (2013) 8(1) *JIPLP* 78, 81.

5.1 Ratification of the UPCA

For the UPP to enter into force, the UPCA must be ratified by thirteen Member States, including France, Germany and the UK. Before Brexit, ratification of the Agreement was picking up momentum and the UK was making progress in Parliament. France had already ratified the Agreement and Germany were also moving forward. However, progress was prolonged when the UK decided, by referendum, to leave the EU.

Following Brexit, the fate of the UPP was once more thrown into question. If the UK were to leave the EU, what would become of the UPP? Would and could the UK continue to participate in the system? Could the CJEU still have a role over the UPP in relation to the UK?

If the UK do not or cannot participate in the UPP, it would be a significantly less attractive system to the other states concerned. There are a number of reasons for this. The UK has one of the highest number of patents in force in the EU¹²⁴ and in 2017, the UK was in the top ten countries for patent applications to the EPO with 5,313 applications.¹²⁵ More strikingly, however, is that UK applicants only amount to 3% of applications made to the EPO. It can be concluded from those statistics that patentees in countries outside the UK own the majority of patents in force in the UK.

Furthermore, patent litigation in the UK is not necessarily common, but it receives a lot of attention as courts are known to be thorough and costly.¹²⁶ It can be foreseen that if the UPP were to go ahead without the UK, it may lose the expertise of the UK courts, and a reassessment of UPC court fees would have to be undertaken.

This would make the system less attractive, first, because judges with experience in adjudicating on patent law cases (like those from the UK courts) would be very important in the development of the new system. This would be especially so in the early days of the system because that experience could give users more confidence in the system.

Second, if the UK is not involved, when deciding on whether to litigate across Europe, users would have to consider the cost of the UPC (which would have to be renegotiated) plus the significantly high cost of litigation in the UK when deciding whether they should litigate and where they should litigate.

An extensive opinion by Richard Gordon QC and Tom Pascoe on the effect of Brexit on the UPP was published in 2016. In that opinion, it was concluded that from a legal perspective the UK could remain part of the UPP after Brexit as long as an agreement was entered into with the EU and Member States regarding the unitary patent, and the UK agreed to the provisions of the UPCA.¹²⁷ Referring the matter to the CJEU was found to be impossible as the EU is not a party to the UPCA.¹²⁸

In a response, one commentator, Ingve Björn Stjerna argued that this opinion was essentially one sided and not truly objective.¹²⁹ In his response, he concluded that it is possible for the CJEU to rule on the compatibility of the UPCA with Union law – the opportunity lay in the German ratification proceedings.¹³⁰

¹²⁴ The reason that the UK is one of three countries that must ratify the UPCA for it to enter into force.

¹²⁵ EPO Statistics, available at: <<https://www.epo.org/about-us/annual-reports-statistics/statistics.html#applicants>> accessed 24 August 2018.

¹²⁶ Christian Helmers and Luke McDonagh, 'Patent Litigation in the UK' Law Society Economy Working Papers 12/2012 <https://www.lse.ac.uk/collections/law/wps/WPS2012-12_Mcdonagh.pdf> accessed 27 September 2018.

¹²⁷ Richard Gordon QC and Tom Pascoe, 'Re The Effect of "Brexit" on the Unitary Patent Regulation and The Unified Patent Court Agreement' [2016] <http://www.bristowsupc.com/assets/files/counsel_s%20opinion%20on%20effect%20of%20brexit%20on%20upc,%2012%20sept%202016.pdf> accessed 27 September 2018, 38 and 39.

¹²⁸ Gordon and Pascoe, 38 and 39.

¹²⁹ Ingve Björn Stjerna, "'Unitary Patent' and court system – The Gordon/Pascoe Opinion and the UPCA's incompatibility with Union law' available at: <<https://www.stjerna.de/gp-opinion/?lang=en>> last accessed 21 September 2018, 8.

¹³⁰ Stjerna, 8.

It was contended that any individual affected had the possibility to complain to the German Constitutional Court that the UPCA was not compatible with the German Constitution as it contradicted Union law and it should therefore not be ratified.¹³¹ If that were to happen, it was argued that the German Constitutional Court could refer the matter to the CJEU owing to the potential EU law violation.¹³²

This opportunity was taken by Stjerna, who brought a complaint to the German Constitutional Court on the basis (amongst other things) that the Agreement was in violation of EU law, and its ratification would not be compatible with the German Constitution.¹³³ A decision from the German Constitutional Court is expected in 2019.

Whether the case is referred to the CJEU, as is Stjerna's apparent intention, is yet to be seen. If it were referred, the CJEU would once again have the opportunity to shape the direction of the UPP. However, this would further delay the entry into force of the UPP but could ensure its compatibility with EU law.

More recently, a convincing study by Ansgar Ohly and Rudolf Streinz asked whether the UK could remain a part of the unitary patent and the UPC.¹³⁴ It was concluded that in both situations it was possible. It was also argued that 'once the UK ratified the UPCA it will not need to accept the supremacy of EU law or the possibility of preliminary references from the UPC to the CJEU by separate agreement,' as the UK will remain a member of the UPCA unless membership is terminated, a departure from the Gordon and Pascoe opinion.¹³⁵

Since these discussions, the UK has indeed ratified the UPCA, has approved the Protocol on Privileges and Immunities and had previously deposited the document required to apply the Protocol on Provisional Application of the UPCA.¹³⁶ There are now two potential ways forward.

First, before the UK officially leave the EU, Germany could ratify the agreement, and the required approvals of the Protocols could take place therein and elsewhere. The UPP would then enter into force and the UK would officially be party to the new system. If this were the case, a question arises as to whether the UK can remain in the unitary patent system once it leaves the EU, which is a question of treaty interpretation.

The second possibility is that the entry into force of the UPP is delayed until after the UK officially leave the EU. The same question then arises as to whether the UK can be a part of the unitary patent system having left the EU.

5.2 Post-Ratification and post-Brexit

The question of continued participation only arises once the UK leaves the EU. The reason for this is because post-ratification and pre-Brexit the situation is the same as if the UK were remaining in the EU. It is only after the UK leave that the question of continued participation becomes relevant.

¹³¹ Stjerna, 8.

¹³² Stjerna, 8.

¹³³ A complaint (2 BvR 739/17) made to the German Constitutional Court will apparently be decided upon in 2019, as evidenced by the Court's list of cases at: <https://www.bundesverfassungsgericht.de/EN/Verfahren/Jahresvorausschau/vs_2019/vorausschau_2019_node.html> last accessed 25 February 2019.

¹³⁴ Ansgar Ohly and Rudolf Streinz, 'Can the UK stay in the UPC system after Brexit?' (2017) 12(3) *JIPLP* 245. For further opinions on the UPP post-Brexit see: Thomas Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit' (2016) SSRN Discussion Paper; María Aránzazu Gandía Sellens, 'The Viability of the Unitary Patent Package After the UK's Ratification of the Agreement on a Unified Patent Court' (2018) 49 *IIC* 136; and Aisling McMahon, 'Brexit and the Unitary Patent Package: A Further Compromised Future?' (2018) 15(2) *Scripted* 175.

¹³⁵ Ohly and Streinz, 258.

¹³⁶ UK Government News Story, 'UK ratifies the Unified Patent Court Agreement' available at: <<https://www.gov.uk/government/news/uk-ratifies-the-unified-patent-court-agreement>> accessed 27 September 2018.

Examining the Ohly and Streinz study, which considers a situation in which the UK ratifies the UPCA, the most relevant point for this article is their claim that the UK ‘will not have to accept the supremacy of EU law or the possibility of preliminary references from the UPC to the CJEU by separate agreement’.¹³⁷ It seems clear that only the divisions of the UPC that would exist in the UK would be bound by EU law. These divisions are not UK courts, they are divisions of the Court of First Instance of the UPC. For example, the UK local division/s, as well as the London based central division, are a part of the UPC Court of First Instance. They therefore owe obligation to the UPCA and as Ohly and Streinz remind, the cooperation between the UPC and the CJEU is as a result of the UPCA, not EU law.¹³⁸ It can be concluded from these points that the divisions of the UPC that would exist in London could continue to operate once the UK leave the EU and would have to consider decisions of the CJEU.

However, the remaining national courts in the UK would no longer need to refer questions to the CJEU as EU law would no longer apply in that way – this would also be the case for the Biotech Directive and SPC Regulations mentioned above, for example. However, a related point here is that the UK might still have to consider judgments from the CJEU on matters relating to the Biotech Directive given the Directive’s provisions being incorporated into the Implementing Regulations of the EPC and the UK’s continued membership of the EPC.

However, this paper argues for the first time that the UK national courts, whether or not they would remain bound by CJEU decisions in this area, should still view the judgements of the CJEU on patent law as a persuasive authority (at least) given the benefits of a harmonised European patent system; a benefit that UK courts deciding on patent law cases strive for in current practice.¹³⁹

This recommendation is even more powerful when considering that the substantive patent law provisions that the CJEU could potentially rule on (contained in the UPCA) are akin to the provisions implemented into many individual countries national patent laws (including the UK) as a result of the un-ratified Community Patent Convention.¹⁴⁰

In the same way that national courts currently see the rulings of the Boards of Appeal of the European Patent Office as persuasive,¹⁴¹ that practice could emerge with the judgments of the CJEU. This could also be encouraged in non-participating Member States such as Spain, who could view any decisions of the CJEU on the UPP as persuasive, as well as decisions from the UPC. Although not an ideal situation, it would be for the benefit of harmonisation if the proposed system enters into force. In this way, the CJEU would continue to have a role over all aspects of patent law in the UK.

Against this suggestion for the UK, however, is the political reality that the UK government want nothing to do with the CJEU.¹⁴² However, in this suggested scenario, judgments would not be binding on the UK, but of persuasive authority only. Thus, if there were a situation in which there was a serious disagreement on interpretation or outcome, the UK court would not have to implement that interpretation or decision (in its national courts). This would also fit with current practice as the UK currently do the same with decisions of the Boards of Appeal of the EPO.¹⁴³

It is important to note here, that the EU may nevertheless insist that the answers from referrals to the CJEU will be binding on the UK as members of the UPCA.¹⁴⁴ This suggested approach would

¹³⁷ Ohly and Streinz, 245.

¹³⁸ Ohly and Streinz, 258.

¹³⁹ One of the most recent examples of this being *Actavis v Eli Lilly* [2017] UKSC 48.

¹⁴⁰ Although the CPC was not ratified, its provisions were implemented into many national laws in preparation. The substantive provisions in the UPCA are based on those same CPC provisions.

¹⁴¹ *Merrell Dow Pharmaceutical Inc v Norton & Co Ltd* [1996] RPC 76, 82; *Genentech Inc. 's Patent* [1989] RPC 147, 197; and *Biogen Inc. v Medeva* [1996] UKHL 18.

¹⁴² Matthias Lamping and Hanns Ullrich, ‘The Impact of Brexit on Unitary Patent Protection and its Court’ (2018) Max Plank Institute for Innovation and Competition, Research Paper No. 18-20 citing Theresa May, House of Commons Official Report, Parliamentary Debates, 29 March, Volume 624, Column 252.

¹⁴³ *Human Genome Sciences Inc v Eli Lilly* [2011] UKSC 51, [87].

¹⁴⁴ This conclusion can also be drawn from Opinion 1/09.

therefore require great flexibility from the EU. On the other hand, in spite of the staunch objection to the involvement of the CJEU, given the benefits of a unified patent system, the UK may accept the patent policy of the EU so that it can remain in the proposed unitary patent system. Again, this will come down to politics.¹⁴⁵

Despite the persuasiveness of the Ohly and Streinz study and others, the Max Plank Institute published a comprehensive study on the implications of Brexit on unitary patent protection and argued that continued participation by the UK would be undesirable.¹⁴⁶ In it, Matthias Lamping and Hanns Ullrich argue that the extension of unitary protection to the UK is outside the objective of unitary patent protection and would cause numerous issues, such as frustrating the UK's sovereign interests and affecting the EU's autonomy.¹⁴⁷ They also state that the continued UK participation in the UPCA is not possible due to a lack of legal basis in relation to courts outside the EU legal order cooperating with the CJEU, that third countries would have a say in UPC policy including Union law and policies, and the different principles that will be applied in the interpretation of the UPC.¹⁴⁸ In this study, participation is deemed to be against the objectives of the project and undesirable because of the implications it will have.

The points made are compelling, however, whether the UK remains a part of the proposed unitary patent system will come down to the political situation. If it wants to stay in the system there are ways it can do so, as long as it accepts that the CJEU will have a role to play in at least the UK based divisions of the UPC.

Relevantly, in September 2018 the UK government released a guidance note on the implications of a 'no deal Brexit' on the UPP. It was stated that the 'UK will explore whether it would be possible to remain within the Unified Patent Court and unitary patent systems in a 'no deal' scenario'.¹⁴⁹ The note also pointed out some potential implications if the UK were to have to withdraw from the UPP, which implies that this could be a real possibility. Rather than clarify matters, this note leaves the situation uncertain.

If it is decided that the UK will/must withdraw from the UPP, the suggestion above regarding persuasive authority can still apply if the UPP goes forward. The UK will still participate in the discussion of European patent law, given its continued membership of the EPC. Even outside the EU and the UPP, it can and would continue to deliver authoritative decisions on patent law, and it is suggested that it should and will continue to take decisions from other jurisdictions, including the CJEU, into account.

A final question must also be asked at this point as to whether or not making any concessions would be beneficial to the proposed system, which has already faced severe criticism for not being entirely complete, and further fragmenting the system that it attempting to integrate. Instead, Jaeger and McMahon suggest that this opportunity should be taken to redraft/reconfigure the UPP to ensure that it is as fully fledged and inclusive as it can be.¹⁵⁰ Whether or not the UPP enters into force, with or without the UK, an opportunity could be taken to make the unitary patent system more inclusive and have a wider impact on the European patent system.

For example, if the UPP goes ahead with the UK, perhaps other non-EU Member States, such as Switzerland, could also join. If it does not or cannot go ahead, the package could be renegotiated to be more inclusive and thus truly unitary.

¹⁴⁵ It is worth noting that under the current draft of the Withdrawal Agreement, the UK must have due regard to the relevant case law of the CJEU with regard to the Withdrawal Agreement following the transitional period and so the CJEU will not be cut out of the UK completely.

¹⁴⁶ Lamping and Ullrich 2018.

¹⁴⁷ Lamping and Ullrich 2018, 18.

¹⁴⁸ Lamping and Ullrich 2018, 20.

¹⁴⁹ UK Department for Business, Energy & Industrial Strategy, 'Guidance: Patents if there's no Brexit deal', 24 September 2018, available at: <<https://www.gov.uk/government/publications/patents-if-theres-no-brexite-deal/patents-if-theres-no-brexite-deal>> accessed 27 September 2018.

¹⁵⁰ Jaeger, 2016; McMahon, 2018.

Ideally, this suggestion should be taken on board. However, in October 2018, Kevin Mooney (who has been heavily involved in the UPP) and Stephen Jones (current President of the Chartered Institute of Patent Attorneys) gave evidence to the House of Lords on the effect of Brexit on the UPP.¹⁵¹ The presentation focussed on how to make the system work despite the potential issues discussed above, and particularly with regard to the transitional period of Brexit or a no deal Brexit. This indicates the strong desire for the UK to remain a part of the UPP with Mooney also stating that ‘there is the political will to do it’ basing that opinion on the recent guidance note mentioned above and the decision to ratify the UPCA.¹⁵² It may therefore be the case that the UPP is implemented by all means necessary, despite what it ends up as and that reality should be prepared for.

From the examination of the continued participation of the UK in the UPP it is argued that in the case that the UPP goes ahead with the UK involved, which appears to be the intention of the UK and more importantly possible, the CJEU should continue to play a role in European patent law, and in most potential cases it will. Overall, there should be a greater involvement of the CJEU in the UPP and patent law generally to ensure a harmonised European patent system, but also one that takes societal concerns into account.

6. The way forward: a hypothetical scenario

The next potential change in the European patent system is the UPP. Standing in the way of that system and set to have an impact on the development of a harmonised patent system is Brexit. Each of these developments have threatened/threaten the role of the CJEU in patent law matters. It was therefore necessary to determine whether the three were (ir)reconcilable.

As has been shown, in general, in order to develop a more efficient and effective European patent system the role of the CJEU is essential. This is for two reasons: first, its generalist overview which ensures that matters outside the patent system are taken into account, such as fundamental rights; and second, its harmonising effect on EU patent law interpretation. The constant threat to the role of the CJEU over patent law goes against the development of such a system.

In the lead up to the finalisation of the UPP, the CJEU played a key role in ensuring its compatibility with EU law and thus its viability. However, attempts were then made to restrict the role of the CJEU over the substantive patent law contained therein. Politics aside, one of the reasons behind such attempts was due to the controversial case law that the CJEU has handed down on patent law matters.

In relation to SPCs and biotechnological inventions, the decisions of the CJEU have been criticised for being confusing and for going too far. However, external factors (vague laws and incorrect scientific evidence) had an impact on those controversial decisions. Nevertheless, a distrust remains regarding the CJEU given its generalist nature. Criticisms suggest that a specialist court is necessary for making decisions on patent law given the technical nature of the subject.

However, despite the results of CJEU decisions thus far, maintaining its generalist nature is essential in patent law to ensure that wider societal concerns are taken into account. When it comes to patent law, there exists a risk that in the spirit of innovation and further development, fundamental rights and values may not be given full consideration. If that were to become a reality, the resultant patent system would not be as effective because it would be ignoring these important factors. The CJEU will likely retain its role in the new system and importantly, over relevant substantive patent law.

Brexit may also have an impact on the role of the CJEU as a harmonising agent in the European patent system. Once the UK leaves the EU, whether it remains in the UPP will come down to political realities. If it does stay in the UPP, UPC divisions in the UK will have to consider the case law of the

¹⁵¹ EU Justice Sub-Committee Recording available at: <<https://parliamentlive.tv/event/index/123eb9d5-2500-47c6-bd9f-ee54fd1784f1>> accessed 11 November 2018.

¹⁵² EU Justice Sub-Committee Recording, at 11:27:41.

CJEU on the relevant laws. However, it is not clear whether UK national courts will have to do the same. If they do not take CJEU jurisprudence into account, this could result in areas of divergence in the interpretation of patent law between the UK and EU Member States that follow CJEU rulings. This would go against the long standing goal of a harmonised European patent system (especially one that goes beyond the EU) and would have an impact on its efficiency.

In an ideal scenario, the opportunity would be taken to renegotiate the proposed unitary patent system so that it would be more inclusive. However, it seems as though all attempts are being made to make the current iteration work with the UK remaining involved post-Brexit. To prepare for that situation, it is suggested that national courts in the UK should consider the rulings of the CJEU (and the UPC) as persuasive and consider the reasonings of the Court in their decisions on similar matters. In doing so, a harmonised approach can still emerge. By implementing this suggestion, the UPP, the CJEU and Brexit could be reconciled. Therefore, in the event that this system goes ahead and the UK leaves the EU, the patent system could still move forward.

Given the hypothetical nature of this suggestion, it is useful to consider how it could work in practice. Two questions must be considered in this example: one, the necessary nature of the role of the CJEU in considering the wider societal implications of patent law decisions; and two, the impact of Brexit on harmonisation in the European patent system.

Take for example a hypothetical invention relating to processes for cloning human organs. Under Schedule 2A of the Patent Act 1977 (UK), Article 6 of the Biotech Directive, and Rule 28 of the EPC, ‘processes for cloning human beings’ are excluded from patentability. The reason behind this exception is due to concerns with eugenics. This exception does not however specify whether processes for cloning human organs would also be an exception to patentability. Given developments in technology, it is relevant to consider possible advances and the implications that could result.

If an inventor were to apply to the EPO for a patent on this process for cloning human organs, given the narrow interpretation that is often implemented by the EPO when it comes to exclusions and exceptions to patentability, it may be the case that a patent is granted on that invention as it is not specifically a process for cloning a human being. It also may not fall under the general morality provision in Article 53 EPC as that would require the existence of an overwhelming consensus against such an invention.

However, it would also be likely that either an opposition action would be taken before the EPO, or a national court action could be raised in an attempt to have the patent revoked if granted based on questions of morality. In the latter case, given there is an exception to ‘processes for cloning human beings’ it may not be clear if ‘processes for cloning human organs’ would fall within that exception. As the provision exists in the Biotech Directive, an EU Member State might have to refer this question of interpretation to the CJEU.

In this case, the decision of the CJEU would be essential. Given its generalist expertise and its concern with the wider societal implications of patent law decisions, it may consider that ‘processes for cloning human organs’ should fall under the specific exception or the general exception on morality given similar concerns with eugenics, for example.

If that were the case, all relevant national courts would have to take that decision into account.¹⁵³ Furthermore, a UPC division could also request an opinion on this matter from the CJEU and in that case, all UPC divisions would also have to take that decision into account (including the UK divisions). Even if the UPC had not requested an opinion, it would be advisable that they take the CJEU decision into account. The result would be the wide-spread consideration of a decision that has been made taking into account the wider implications of technological developments and thus, a harmonised approach to this issue.

¹⁵³ In this specific scenario, the EPO Boards of Appeal could also consider the decision of the CJEU given the provisions of the Biotech Directive have been incorporated into the EPC Implementing Regulations.

However, once the UK leaves the EU, national courts may not have to take CJEU decisions on patent law matters into account. If that were the case in this scenario, the UK may take a different approach to the patentability of processes for cloning human organs. As a result, divergence in interpretations could emerge, not just in this hypothetical scenario, but in the event of any CJEU referral. This would go against the long-standing goal of a harmonised European patent system.

On the other hand, if the UK national courts saw CJEU decisions as a persuasive authority and considered its reasoning sound, there would be no reason for the UK national court to detract from that interpretation. This also leaves room for the UK national court to disagree with the reasoning of the CJEU and to put forward an interpretation that they favour from a moral standpoint.

Overall, it can be seen that this suggestion could have the effect of promoting harmonisation in the European patent system in the numerous situations that could emerge in future, for example if the UPP is implemented and/or post-Brexit.

7. Conclusion

It is clear that the situation regarding the UPP and the CJEU has been and continues to be a complicated one. Significantly adding to the complication was the decision of the UK to leave the EU and then to ratify the UPCA. The continued questioning of the role of the CJEU goes against the overarching goal of a harmonised patent system that still considers the wider implications of its decisions. It was therefore necessary to examine in detail the role of the CJEU and whether the UPP, the CJEU and Brexit are (ir)reconcilable from this institutional perspective.

From the initial development of the UPP, the CJEU has had a say. Not only has it had a say, it has been instrumental in the shaping of the UPCA through Opinion 1/09 and has examined the Regulations in detail to ensure their legality in Cases C-274/11, C-295/11, C-146/13, and C-147/13. However, attempts have also been made to limit its jurisdiction.

Yes, the CJEU currently has a poor record in patent law but limiting its jurisdiction in the area may result in unforeseen legal and societal consequences. Despite the poor record, which has been qualified by external factors, the CJEU should still have a place in the patent system by having a generalist overview, ensuring that all factors and fundamental rights are taken into consideration when determining patent law matters. Adding to that argument is the resulting harmonising nature of CJEU decisions.

It is also clear that despite the attempts to keep it out, the CJEU could retain jurisdiction over the provisions of the UPCA through an incorporating referral in Article 5 Regulation 1257. Its decisions will entirely depend on the questions that it is referred but it is likely that it will have a say in the matter if it so chooses.

When adding the question of Brexit, the situation becomes even more complicated. Although previous attempts to limit the role of the CJEU have failed, Brexit could limit its harmonising role over patent law in the UK. However, the UK have now ratified the UPCA, and as concluded, the CJEU will likely have a say in the interpretation of the entire UPP. A question was asked as to whether the UK would have to take CJEU decisions into account post-Brexit. The end result will depend significantly on the political reality of the situation from both a UK and EU point of view.

However, despite the uncertainty surrounding the continued participation of the UK in the UPP and the role of the CJEU, it has been argued for the first time in this paper that in either scenario, decisions of relevant courts (including the CJEU) can and should be taken into account by the UK courts to ensure an effective and efficient European patent system. If the UK remains in the UPP, decisions of the UPC and the CJEU will have to be taken into account by the divisions of the UPC in the UK. Furthermore, in relation to national courts, just as they currently see the decisions of the Boards of Appeal of the European Patent Office as persuasive, so too could they see decisions of the CJEU and UPC. Finally, if the UK withdraws from the UPP, decisions from other courts can remain persuasive.

By doing so, the long-standing goal of an effective and efficient, harmonised European patent system will come closer, with or without the UK in the EU or the UPP. As a result, and although perhaps it is not the most ideal scenario, it can be argued that the UPP, CJEU and Brexit are reconcilable.