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THE MORALITY PROVISIONS IN THE 'EUROPEAN'
PATENT SYSTEM
AN INSTITUTIONAL EXAMINATION

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Abstract

This thesis analyses the supra-national application of the morality provisions in the ‘European’ patent system by the judicial/quasi-judicial decision-making in the European Union (“EU”) and European Patent Organisation (“EPOrg”). In doing so, it focuses specifically on Article 53 of the European Patent Convention and Article 6 of Directive 98/44/EC on the legal protection of biotechnological inventions, with particular reference to the overlapping institutional matrix within which these legislative provisions are applied.

The intended contribution of this research is in relation to how these decision-making entities of the EPOrg and the EU interpret and apply the morality provisions in the ‘European’ patent system *as a feature of their operation as institutions*. The research investigates specifically: to what extent and in what ways does an analysis of the institutional framework for the application of the morality provisions by the various institutions implicated in the ‘European’ patent system reveal new insights into the current position and suggest defensible approaches to the future development of these provisions. This has particular relevance in the current context, in light of the developing unitary patent scheme examined through an institutional lens in chapter six.

Importantly, the contribution of this research will *not* be in relation to the specific principles or tests which should be used in applying the morality provisions *per se* in the ‘European’ patent system, nor does it seek to contribute specifically to the normative questions in relation to what morality should mean in this context or whether the morality provisions should exist within the patent system. Such matters have been explored extensively in the literature. Instead, this thesis uses doctrinal methods to build a theoretical framework by drawing specifically on institutional theories within law and sociology, which are used to devise a novel framework for *assessing institutional influences* on decision-makers. This framework is then applied to the EPOrg and EU with the aim of demonstrating the differing institutional pulls on each body in their application of the morality provisions, which is used as a single exemplar to achieve this kind of institutional analysis. The overall aim of this research is to contribute to an understanding of decision-making in this specific context by reference to understandings of how institutional contexts can have profound effects upon

the end outcomes of decision-making. This reveals a hitherto un-exposed perspective not only on what is happening within patent law with respect to the morality provisions, but also novel insights that may help to explain the legal landscape that has emerged, and which can inform its future development.

Lay Summary

This thesis explores the application of the morality provisions in the ‘European’ patent system for biotechnological inventions. These provisions provide that patents will not be granted for any invention if its commercial exploitation would be contrary to morality or ‘ordre public’. The term ‘European’ is used as there is no single European legal framework which governs patents on biotechnology, instead at the supranational level this is governed by both the European Patent Organisation (“EPOrg”) and also the European Union (“EU”). These bodies have their own separate legal provisions in relation to morality which are almost identical in wording. However, despite the fact that the wording of these provisions largely mirror each other, it is questionable if the judicial/quasi-judicial decision-making bodies of the EPOrg and EU are delivering a similar interpretation of these provisions when called upon to apply them. In this context, the thesis will use institutional theories drawn from the fields of law and sociology - which look at how the applicable institutional framework can influence decision making processes- in order to investigate whether and in what way the features of the EPOrg and EU may influence the decision-making bodies situated within them in their application of the morality provisions.

The issues of whether the patent system is the appropriate place for the morality provisions, how morality should be interpreted in this context, or which tests should be used in interpreting the morality provisions will not be examined in the thesis. These aspects have already been examined extensively in the literature in this area. Instead, the focus of the thesis is in relation to how the *characteristics of the institutions* within which the decision-makers interpreting these provisions are situated, will influence their decisions. The thesis hopes to reveal new insights which may help to explain how the morality provisions have been developed to date, and which will also suggest lessons for the future development of these provisions. This research is of particular contemporary relevance in light of the planned unitary patent scheme which will add another layer to the existing overlapping frameworks which exist in the ‘European’ patent system.

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Declaration

I confirm that this thesis has been composed by me, that the work contained in this thesis is my own and has not been submitted for any other degree or professional qualification.

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23 July 2015.

Chapter one: Biotech Patents, Morality and Institutional Tensions: An Introduction

1.1 Introduction

This thesis examines the supra-national judicial/quasi-judicial¹ framework for the application of the morality provisions in the ‘European’² patent system for biotechnological inventions. In doing so, it focuses specifically on the application of: Article 53(a) of the European Patent Convention (EPC)³ which is applied by the quasi-judicial bodies of the European Patent Office (EPO) - a branch of the European Patent Organisation (EPOrg); and Article 6 of the European Biotechnology Directive⁴ (the Directive) whose application is monitored by the Court of Justice of the European Union (CJEU).⁵ The former provision is supplemented by the Implementing Regulations⁶ to the EPC, which are also examined.

¹ ‘Quasi-judicial’ describes the amalgamation of administrative and judicial functions within the European Patent Office (EPO), the adjudicative branch of the EPOrg; discussed in chapter four. See, P Leith, ‘Judicial or Administrative Roles: the patent appellate system in a European context’ [2001] IPQ 50. For a discussion of the meaning of ‘quasi-judicial’ see, H Wade, ‘‘Quasi-Judicial’ and its background’ (1949) 10(2) The Cambridge Law Journal 216.

² The term ‘European’ is used to denote the system created by the European Patent Convention (EPC), with particular reference to the overlapping decision-making functions of the EPOrg and EU and relevant institutional frameworks which arise at a supranational level within these countries. This is discussed in section 1.2.

³ Article 53(a) states: “European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some, or in all of the Contracting States.”

⁴ 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. Article 6 states: “1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation. 2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.”

⁵ This is the collective term describing the judicial authority of the EU, which comprises of three courts, namely: the Court of Justice, the General Court and the Civil Service Tribunal. The composition and workings of the CJEU are discussed in chapter four.

⁶ Rule 28 and 29 of the Implementing Regulations. Rule 28 states: “Under Article 53(a) European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.”; Rule 29 states: “The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. (2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is

The effect of the morality provisions is to render unpatentable inventions whose commercial exploitation is against “ordre public” or morality.

At the outset, it should be noted that the intended contribution of the research is in relation to how the judicial/quasi-judicial decision-making entities of the EPOrg and EU interpret and apply the morality provisions in the ‘European’ patent system *as a feature of their operation as institutions*. In particular, it will examine whether and to what extent the characteristics of the overarching institutions where these decision-making bodies are situated influence the way in which the moral exclusions are applied. Importantly, the contribution of this research will *not* be directed at which principles or tests should be used in applying the provisions, or at normative questions surrounding the place for morality in the patent system. In the course of the analysis relevant insights arise in this context, however, these normative questions are not the central focus of this work *per se*. Furthermore, whilst institutional theories will be employed to support the hypothesis proposed, this thesis *does not* seek to make a contribution to theory. Instead, it draws on elements of institutional theory to explain what is happening in the patent system, with the overall aim of contributing to the understanding of judicial/quasi-judicial decision-making in this context.

The morality provisions were chosen as the focus, because of the overlapping functions of the adjudicative branches of the EPOrg/EU, and the fact that despite the identical wording of the provisions, these provisions concern open-textured and malleable terms such as ‘morality’ and ‘ordre public’ which means that decision-making bodies have a significant role in shaping their interpretation. This in turn means that the morality provisions provide an ideal exemplar for investigating the *institutional* influences on the interpretative functions of the CJEU and adjudicative bodies in the EPO. This institutional analysis reveals a hitherto un-exposed perspective not only on what is happening within patent law with respect to its morality provisions, but also leads to novel insights that help to explain the legal landscape that has emerged to date, and which can inform its future development. Moreover, relevant insights can be gleaned in relation to other facets of the ‘European’

identical to that of a natural element. (3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.”

patent system where open-textured terms, e.g., novelty, inventive step etc. are evident and thereby susceptible to institutional influence.

This introductory chapter sets the foundations for the analysis conducted. Part two outlines the institutional framework in the ‘European’ patent system and highlights the overlapping functions of the judicial/quasi-judicial branches of the EPOrg and EU which lead to the tensions explored in this thesis. It then identifies a number of avenues which exist to maintain convergence between the EPOrg and EU on the application of the morality provisions at a legislative level. However, it will demonstrate that despite avenues for convergence at a legislative level, this may not necessarily result in converging interpretations at an adjudicative level and it is this particular tension which this work explores. Part three provides an overview of the research project, highlighting the central research question, hypothesis proposed and the methodology adopted. Following this, Part four justifies the need for this research by highlighting: (1) The contemporary relevance of the issues explored; (2) The gap in the literature in relation to institutional influences on judicial/quasi-judicial decision-making; and (3) How this project can be clearly distinguished from some developing literature responding to similar issues to the ones that prompted this thesis. The chapter concludes by offering an overview of the specific dimensions of the original contributions claimed.

1.2 The Institutional framework for the application of the morality provisions in the ‘European’ patent system

The supranational framework in the ‘European’ patent system is a complex one. Applicants can apply for a patent individually in each of the national intellectual property offices. Alternatively, although there is no unitary ‘European’ patent – as will be discussed in chapter six a unitary patent system has recently been adopted which will offer a unitary patent for participating EU countries once it comes into effect - under the EPC applicants may currently make a single patent application to the EPO designating as many EPC States as they wish to have a patent granted in. This classical European Patent (EP) process provides a single grant application route for applicants seeking a patent in a number of Contracting States to the EPC. The functions of the quasi-judicial

branches of the EPO are examined in chapter four. Notably, when the EPC was signed in 1973 there were only sixteen Contracting States to the EPC, but this number has expanded and at the time of writing it has thirty eight Contracting States:⁷ including all the twenty eight EU Member States (MSs) and ten non-EU States. Having said this, the EU is not itself a party to the EPC, a point which will be returned to.

All applications via this classical EP route are considered by the EPO and if successfully granted, are then refracted into a bundle of national patents for the States designated in the application.⁸ Therefore, whilst the EPO is responsible for patent grant and validity proceedings; issues of infringement, enforcement, revocation etc. of granted patents are dealt with individually under the relevant national laws.⁹ This single EP application route is a more cost effective and convenient mechanism of applying for patents in multiple European jurisdictions. Hence, the application of the patentability criteria in Europe, including whether the exclusionary morality provisions should apply, is often at first instance a matter for the EPO, as granting body, to decide.¹⁰

As an aside, the fact that post-grant aspects are dealt with by national jurisdictions, increases the institutional complexity.¹¹ However, given restrictions as to time and space and because this is ancillary to the main focus, the difficulties posed by this, including issues in relation to the potential for national divergences on the interpretation of the morality provisions, are not examined in this thesis.¹² Instead, this project is confined to an examination of the supra-national framework for the application of the morality provisions.

⁷ This is correct at the time of writing, 16th July 2015. For a list of Contracting States, see <<http://www.epo.org/about-us/organisation/member-states/date.html>> accessed 16th July 2015.

⁸ A Bakardjieva Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting in Europe (EC and EPO): Tensions and Prospects' in A Plomer and P Torremans (eds) *Embryonic Stem Cell Patents in Europe: European Law and Ethics* (OUP 2009) 229.

⁹ L Bently and B Sherman, *Intellectual Property Law* (4th Edition, OUP 2014) 383.

¹⁰ In 2014, there were 151,981 patent applications filed with the EPO. See <<http://www.epo.org/about-us/annual-reports-statistics/annual-report/2014/statistics/patent-applications.html>> accessed 16 July 2015.

¹¹ Bently and Sherman, *Intellectual Property Law*, note 9, 383.

¹² For a discussion of these aspects, see: Bakardjieva Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting', note 8; A Hellstadius, 'A comparative Analysis of the National Implementation of the Directive's Morality clause' in A Plomer and P Torremans (eds.), *Embryonic Stem Cell Patents in Europe: European Law and Ethics* (OUP 2009) 117-139.

1.2.1 Entry of the EU into the decision-making framework for the application of the morality provisions

The EU's role in the patenting of biotechnological inventions was crystallised with the adoption of the Biotechnology Directive (the Directive) in 1998. This clarified substantive patent issues but complicated the picture institutionally.¹³ The primary rationale for the introduction of the Directive was to address economic concerns, as the biotechnological industry was seen as poised for substantial growth which the EU should capitalise upon.¹⁴ Moreover, it was felt this would be facilitated by having clearer intellectual property protections for biotechnological inventions.¹⁵ The EU was perceived as lagging behind Japan and the United States (US) due to the uncertain intellectual property rights in comparison to more liberal systems in Japan and the US, which had readily adapted to protect biotechnological inventions.¹⁶

Thus, the main purpose of the Directive was to harmonise and clarify existing law in terms of its application to biotech inventions.¹⁷ Nonetheless, its drafting was by no means straightforward and instead it involved over ten years of debate. The first draft was introduced in 1988¹⁸ and considerable debate thereafter revolved around the moral and ethical aspects of biotech patents¹⁹ - this is discussed further in chapter four, section 4.5.1. The drafting of the Directive also occurred against the backdrop of the EPO's decision in *Oncomouse*²⁰ which involved the patentability of a transgenic mouse genetically

¹³ Bakardjieva Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting', note 8, 247.

¹⁴ G Porter, 'The Drafting History of the European Biotechnology Directive' in A Plomer and P Torremans (eds.) *Embryonic Stem Cell Patents in Europe: European Law and Ethics* (OUP 2009) 7.

¹⁵ R Gold and A Gallochat, *The European Directive on the Legal Protection of Biotechnological Inventions: History, Implementation and Lessons for Canada* (Canadian Biotechnology Advisory Committee, 2001) as cited in Porter, 'The Drafting History of the European Biotechnology Directive', note 14, 7.

¹⁶ The EU Commission noted that "[W]hereas the two leading nations in biotechnology, the United States of America and Japan, have been able continuously to adapt their patent protection according to the latest needs of industry, science and consumers, the Member States, representing, comparable potential of intellectual manpower and capital, are immobilised by a not yet completed and... in part outdated legal framework", EC, "Proposal for a Council Directive on the legal protection of biotechnological inventions" COM (88) 496 final, 17 October 1988, as cited in Porter, 'The Drafting History of the European Biotechnology Directive', note 14, 9.

¹⁷ Porter, 'The Drafting History of the European Biotechnology Directive', note 14, 10. For a discussion of the legal basis of the Directive, see Case C-377/98 *The Kingdom of the Netherlands v European Parliament and Council* [2001] ECR I-07079.

¹⁸ The first draft was introduced by the Commission on 17th October, 1988; EC, Proposal for a Council directive on the legal protection of biotechnological Inventions' COM (88) 496 final/EYN 159 of 17 October 1988, OJ C10/3, see, Porter, 'The Drafting History of the European Biotechnology Directive', note 14, 7.

¹⁹ Porter, 'The Drafting History of the European Biotechnology Directive' note 14, 10

²⁰ *Harvard/Oncomouse* (1990) OJ EPO 476; (1992) OJ EPO 589.

modified to be used in cancer research.²¹ This case and issues it raised were particularly controversial and led to a questioning of ‘patents on life’ which came to form part of the broader debate on the patentability of biotech inventions.²² The first draft of the Directive was eventually rejected by the European Parliament in March 1995.²³ However, it was subsequently amended by the Commission, placing greater emphasis on the ethical issues, and a revised proposal was submitted in December, 1995 which was approved in May 1998.²⁴

The final Directive contained a general morality provision in Art. 6(1) which was almost identical to the provision already contained in the EPC. Alongside this, four specific exclusions to patentability under the morality criteria were adopted in Art. 6(2) of the Directive, rendering the following unpatentable:

“(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.”

In light of the introduction of Art. 6(2), the Biotech Directive and the EPC had differently composed morality provisions which may have resulted in uncertainty for patents granted by the EPO under the EPC in respect of Contracting States to the EPC who were also EU MSs. Arguably, such patents could have been vulnerable to subsequent challenge under EU law on the basis that the morality provisions applied by the EPO under the EPC were differently composed to those set out under the Biotech Directive which was applicable in the EU. However, this possibility was quickly averted, as following the adoption of the Directive in 1998, the EPOrg voluntarily adopted the specific list of exclusions contained in Art. 6(2) of the Biotechnology Directive into the EPC on 16th June 1999. This was achieved through a decision of the Administrative Council amending the

²¹ Porter, ‘The Drafting History of the European Biotechnology Directive’, note 14, 12

²² Ibid 12.

²³ Ibid 13.

²⁴ Ibid 14.

Implementing Regulations.²⁵ Alongside these provisions, a further alignment of provisions was secured through the adoption of Regulation 26(1) of the Implementing Regulations which states that the Directive should be used as a supplementary means of interpretation for patents on biotechnological inventions. However, this in turn created a curious institutional scenario where provisions of an intergovernmental treaty, the EPC, are being interpreted using an EU treaty as guidance, in circumstances where not all of the EPC Contracting States are EU MSs.

As an aside, these legislative developments justify the focus of this research specifically in relation to the application of the morality provisions to *biotechnological* inventions relating to their potential *exclusion* from patent protection. Whilst the general morality provision contained in Art. 53(a) EPC applies to all inventions, including but not limited to biotechnological inventions, the EU Biotech Directive only applies to this latter category, and it is the resulting overlapping supranational decision-making frameworks; caused by the existence of both the Directive and EPC which is the focus of this research. Biotechnological inventions are defined in the EPC as “...inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used”.²⁶ Patents can be applied for in this context in respect of a product or a process, provided they fulfil the three step criteria of novelty, inventive step, and technical application; and provided they do not fall into the excluded categories of subject matter,²⁷ or fall within the morality exclusion.

²⁵ The mechanism for adopting these provisions has been criticised as democratically deficient, see I Schneider, ‘Governing the patent system in Europe: the EPO’s supranational autonomy and its need for a regulatory perspective’ (2009) 36(8) *Science and Public Policy* 619, 623. This is discussed, at 1.2.2(b).

²⁶ Rule 26(2)-(3), Implementing Regulations to the EPC. See, also Art. 3(1) and Art. 2(1) of the Biotechnology Directive. For a general discussion of the nature of biotechnologies, see, Nuffield Council, “*Emerging Biotechnologies: Technology, Choice and the Public Good*” (December, 2012) xviii; S Jansanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press 2011); For an overview of biotechnologies in the context of the patent system, see : Warren Jones, ‘Taming Scary Monsters with morality’ note 26, 12-23; O Mills, *Biotechnological Inventions: Moral Restraints and Patent law* (Revised Edition) (Ashgate Publishing 2010) 7-10.

²⁷ See, C Waelde, G Laurie, A Brown, S Kheria, J Cornwell, *Contemporary Intellectual Property: Law and Policy* 3rd Edition (OUP 2014) 12.24-12.42; Intellectual Property Office, *Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the Intellectual Property Office* (2013) <<http://www.ipo.gov.uk/biotech.pdf> > accessed 16 July 2015.

1.2.2 Interaction of the EU and EPOrg in the application of the morality provisions: Convergence at a Legislative Level

Importantly, the legislative convergence described above between the EPOrg and EU on the development of the morality provisions is entirely voluntary in nature;²⁸ neither party is bound to adopt a converging position with the other - the EU is not a party to the EPC and the EPOrg is not an EU institution. Having said this, convergence is facilitated by two main sites of interaction between the EPOrg and EU, namely, through the President of the EPOrg and the Administrative Council. The Administrative Council is the supervisory body over the EPO, and is often considered as akin to its 'legislative' branch - although this classification can be called into question, as examined in 1.2.2 (b) below. This section outlines the links between the EPOrg/EU and also highlights the limitations of these links should conflicting views arise. More importantly, it demonstrates why these links, at a legislative level, do not necessarily mean, that similar convergence will be translated to the adjudicative level. This in turn leads us to the central research question examined.

a) Role of the President of the EPOrg

The President of the EPOrg has a number of functions which can be used to facilitate convergence at a legislative/policy level between the EPOrg and EU. First s/he, with the authorisation of the Administrative Council can negotiate, and subject to the Council's approval can conclude agreements on behalf of the EPOrg with States and intergovernmental organisations such as the EU.²⁹ Second, s/he can issue comments³⁰ in proceedings under Art 112 EPC, whereby the Enlarged Board of Appeal may at its own initiative or at the written reasoned request of the President request that s/he comment on questions of general interest in proceedings arising before it.³¹ This procedure could be used to advocate that the EPO follow a particular interpretation of the morality provisions to align itself with the EU approach. However, this mechanism only arises in cases where a patent has been brought to the attention of the President by virtue of a challenge to its grant. Only a limited number of cases have been taken challenging patents on the basis of

²⁸ Waelde et al, *Contemporary Intellectual Property*, note 27, 10.27.

²⁹ Art. 33(4) EPC, 1973, as amended.

³⁰ Art. 9 of Rules of Procedure of the Enlarged Board of Appeal <http://www.epo.org/law-practice/legal-texts/html/caselaw/2013/e/clr_rpeba.htm> accessed 16 July 2015.

³¹ Ibid.

the morality provisions and out of these there has only been one opinion issued by the President concerning the morality provisions to date.³² This highlights the limited role this mechanism plays in practice.

Thirdly, the President of the EPOrg has a ‘declaratory’ role; in cases where the Boards of Appeal have issued different opinions s/he can refer the decision to the Enlarged Board of Appeal.³³ This ensures internal consistency.³⁴ Finally, s/he also has the power to submit proposals to the Administrative Council to amend the EPC, or to submit proposals for general regulations.³⁵ This could be used to submit proposals for amendments in instances where EPO practices differ from EU law or the laws of other regional bodies. These mechanisms offer avenues to gain convergence on patent law amongst the EPOrg and other organisations, including the EU.

b) Role of the Administrative Council

Turning to the Administrative Council,³⁶ this arguably offers the main bridge between the EPOrg and other institutions such as the EU, for two reasons: (1) it facilitates interaction and discussion amongst the EPOrg and regional bodies, such as the EU, and its own Contracting States; and, (2) it has powers to amend legislation to align EPOrg guidance/legislative instruments with that of the EU and other international bodies.

In terms of facilitating multi-governmental/organisational interaction, the Administrative Council has a number of mechanisms to achieve this. Firstly, intergovernmental organisations charged with the implementation of international procedures in the patent field which the EPOrg has concluded an agreement with are represented at meetings of the Administrative Council.³⁷ Similarly, intergovernmental and international non-governmental organisations involved in activities of interest to the EPOrg may be invited by the Administrative Council to send a representative as an observer to Council meetings

³² G2/06 Comments by the President of the European Patent Office (September, 2006).

³³ Art. 112(1)(b) EPC. See Waelde et al, *Contemporary Intellectual Property*, note 27, 10.24.

³⁴ Art. 112(1)(b) EPC.

³⁵ Art. 10(2)(c) EPC.

³⁶ The details on the operation of the Administrative Council are set out in Part IV of the EPC.

³⁷ Art. 30(2) EPC.

concerning matters of mutual interest.³⁸ The EU is listed as a current observer to the Administrative Council.³⁹

Another means of interaction amongst national Contracting States and the EPOrg arises as a result of the fact that the Administrative Council is composed of two representatives - a main and alternative representative - from each Contracting State to the EPC⁴⁰ thereby offering a forum for the discussion of national interests. The current thirty eight Contracting States to the EPC are as follows: all the EU states together with Albania, the Former Yugoslav Republic of Macedonia, Iceland, Liechtenstein, Monaco, Norway, San Marino, Serbia, Switzerland and Turkey.⁴¹ Arguably, because the twenty eight EU Member States make up a substantial majority of the total thirty eight Contracting States, this implies a considerable lobby of EU representatives within the EPOrg. However, members are representing national interests which are not necessarily the same as EU interests. Alongside this, national representatives are generally the head of the national intellectual property offices, so rather than getting a general view on patenting issues, one is gaining a patent community insider's perspective,⁴² a point which is returned to in chapter three.

The second means of facilitating convergence between the EPOrg and the EU is through some of the "legislative" functions of the Administrative Council. As noted, the Council is often described as the legislative branch⁴³ of the EPOrg although technically it does not have formal legislative powers recognised in the EPC.⁴⁴ Nonetheless, the Administrative Council has powers to amend patent policy, set out in Article 33 EPC which includes the power to amend the Implementing Regulations to the EPC. This requires a decision to be taken with a qualified majority of three quarters of the votes of Contracting States

³⁸ Art. 30(3) EPC.

³⁹For a full list, see <<http://www.epo.org/about-us/organisation/administrative-council/composition.html>> accessed 16 July 2015.

⁴⁰ Art. 26 EPC.

⁴¹See <<http://www.epo.org/about-us/organisation/foundation.html>> accessed 16 July 2015.

⁴² Schneider has argued that democratic accountability can only be obtained through publicly elected actors, which Presidents of the patent offices are not. In the EPO apart from when Diplomatic Conferences are convened, publicly elected representatives do not generally represent Contracting States. See, I Schneider, 'Governance of the European Patent System' in EPO (ed.) 'Interview Dr Ingrid Schneider', Scenarios for the Future (Munich 2007) <[http://documents.epo.org/projects/babylon/eponet.nsf/0/F172DE5BB2B9B15BC12572DC0031A3CB/\\$File/Interview_Schneider.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/F172DE5BB2B9B15BC12572DC0031A3CB/$File/Interview_Schneider.pdf)> accessed 16 July 2015, 603.

⁴³ Schneider, 'Governing the patent system in Europe', note 25, 622.

⁴⁴ Bakardjieva Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting', note 8, 249.

represented and voting.⁴⁵ This procedure proved instrumental to the development of the morality provisions as it was used to adopt the exclusions concerning Art. 6(2) of the EU's Biotechnology Directive into its Implementing Regulations.

However, the mechanism used to adopt these provisions has been strongly criticised,⁴⁶ giving rise to the suggestion that it was "legislation in disguise".⁴⁷ The main procedural criticism of the mechanism was that the act over-stretched EPC rules by amending patent law contained in the EPC using the Implementing Regulations. At the time, if one wished to amend the EPC or amend substantive patent law, this required a Diplomatic Conference.⁴⁸ Nonetheless, the Implementing Regulations or rather the method of their adoption was given retrospective legality⁴⁹ by the Diplomatic Conference of the EPOrg in 2000. This revised Articles 33-34 of the EPC which granted the Administrative Council the power to amend the EPC directly subject to unanimous decision of Council⁵⁰ to align itself with EU law or international treaties relating to patents. Article 33(1)(b), as amended, reads:

"(1) The Administrative Council shall be competent to amend:... (b) *Parts II to VIII and Part X of this Convention, to bring them into line with an international treaty relating to patents or European Community legislation relating to patents;...*"
[Emphasis added]

As Article 53(a) EPC is contained in Part II of the EPC it can be amended by the Administrative Council to take account of any changes in EU law. The mechanism avoids having to go through the lengthy and uncertain process of EPC revisions when there is full agreement amongst Contracting States on incorporating such changes into the EPC framework, even if this agreement was achieved in a different forum.⁵¹ However, it is not

⁴⁵ Art. 35(2) EPC.

⁴⁶ O Bossung, 'A Union Patent instead of the community patent' (2003) 34(1) *International Review of Intellectual Property and Competition Law* 1-30; H Ulrich, 'Patent Protection in Europe: Integrating Europe into the Community or the Community into Europe?' (2002) 8 *EL Rev* 433.

⁴⁷ Report for the European Commission, A. Plomer (co-ordinator) *Stem Cell Patents: European Patent Law and Ethics* (Nottingham, 2006) 97, footnote 327.
<<http://www.nottingham.ac.uk/~ilzwww/StemCellProject/project.report.pdf>> accessed, 16th July, 2015.

⁴⁸ Schneider, 'Governing the patent system in Europe', note 25, 623.

⁴⁹ *Ibid* 623.

⁵⁰ U Schatz, 'Recent changes and expected developments in patent regimes: A European Perspective' *Patents, Innovation and Economic Performance*, OECD Conference Proceedings (OECD 2004) 165.

⁵¹ *Ibid* 165.

necessarily the case that all EPC states who are non-EU members would wish to follow the EU in terms of the morality provisions. Furthermore, the strength of this mechanism is diminished when one examines the voting procedure required to effect such an amendment governed by Art. 35(3) EPC which requires unanimity amongst Contracting States. Furthermore, States have up to twelve months from the decision to declare they do not wish to be bound by it and if one State does so, the decision is rendered ineffective. Arguably, in a situation of conflicting views on the morality provisions this mechanism would be of little, if any, aid.

1.2.3 Reflections on the Institutional Framework and Research Problem.

The President and the Administrative Council have a number of mechanisms to encourage convergence on patent law principles between the EPOrg and EU. Moreover, in spite of the limitations on some of the mechanisms for securing convergence, this convergence is likely to be maintained at a legislative level as it would be a questionable political move for the EPOrg to diverge from the EU, or *vice versa*, on these provisions given that the twenty eight EU States form a majority of its thirty eight members. If it were to do so, it could put the EPO's role as patent granting body for the EU territories in jeopardy⁵² which would be seriously financially adverse⁵³ to this body.

Nonetheless, even if convergence is desired and being actively encouraged at a legislative level between the EPOrg and EU, this does not mean that the adjudicative bodies are delivering converging interpretations on the morality provisions. Indeed, this thesis argues that despite legislative intentions aimed at convergence the adjudicative bodies are *institutionally* configured in a manner which simply cannot deliver converging interpretations at an adjudicative level. This is because the adjudicative bodies are situated within two very distinct institutions with differing Contracting State memberships, and these bodies have differing values/purposes/functions as set out in their relevant legislative instruments, the EPC and the Biotech Directive together with relevant EU Treaties. Furthermore, these adjudicative bodies are being called upon to interpret provisions concerning morality, a malleable concept which as will be argued in 1.3 increases the scope for institutional influences in this context. The 'separateness' of the interpretative roles of

⁵² See also J Pila, 'An Historical Perspective I: The Unitary Patent Package' in J Pila and C Wadlow (eds) *The Unitary EU Patent System* (Hart Publishing 2015) 24.

⁵³ The financial incentives of the EPOrg are discussed in chapter three.

the adjudicative bodies of the EPOrg and EU was also expressly confirmed in the EPO's 2008 decision in *WARF*⁵⁴. This confirmed that the EPO could not refer a question to the CJEU in relation to the morality provisions, nor did the EPO have the power to bind itself to follow a ruling of the CJEU⁵⁵- this is discussed further in chapter three.

Moreover, when the Directive was adopted it was unclear initially whether and to what extent the interpretation of the provisions by the CJEU, if called upon to examine these provisions, would align with the restrictive application evident within the EPO cases issued pre-Directive,⁵⁶ or if the EPO would align itself at an adjudicative level with the CJEU should it adopt a broader interpretation of the provisions. Arguably, this tension remains, and is demonstrated most vividly in recent cases surrounding the patentability of human embryonic stem cell (hESC) technology - discussed in chapters three and four - where again it was unclear if the EPO approach in *WARF*⁵⁷ would be followed by the CJEU and then following the CJEU's decision in *Brüstle*⁵⁸ questions arose as to whether this approach would be mirrored by the EPO. It is this uncertainty in terms of how these cases are decided within each institution and the extent to which such interpretations will/can be assimilated within and aligned with by the other institution that sits at the heart of this thesis and forms the central problem explored. The word 'can' is used in this context because as will be discussed in chapter two, there are both differing external influences on the adjudicative bodies which may predict differences in how they will interpret the morality provisions, and also differing legal constraints on these adjudicative bodies in their interpretations of these provisions. These legal constraints arise for instance, because of the differing legislative instruments underlying the morality provisions in the EPOrg and EU context, and the differing legal relationships these institutions and in turn their adjudicative bodies have with the relevant Contracting States. These legal constraints limit the way in which such adjudicative bodies can apply the morality provisions as they must do so within the scope of their legal functions in their situated institutional context.

⁵⁴ *Wisconsin Alumni Research Foundation (WARF)* (G002/06), Decision of the Enlarged Board of Appeal of 25 November 2008.

⁵⁵ *Ibid*, para. 7.

⁵⁶ These include: *Harvard/Onco-Mouse* [1991] EPOR 525; *Lubrizol/hybrid plants* [1990] EPOR 173; *Plant Genetic Systems/Glutamine Synthetase Inhibitors (Opposition by Greenpeace)* [1995] EPOR 357; *Howard Florey/Relaxin* [1995] EPOR 541.

⁵⁷ *WARF*, note 54.

⁵⁸ Case C-34/10 *Brüstle v Greenpeace eV*, Judgment of the Court (Grand Chamber), 18th October, 2011, [2011] E.C.R. I-9821.

1.3 Overview of Research

1.3.1 Research Question

In light of the complex institutional matrix within which the morality provisions are interpreted, the thesis pursues the following central question: To what extent, and in what ways, does an analysis of the institutional framework for the application of the morality provisions at a supranational level, in the ‘European’ patent system by the judicial/quasi-judicial decision-making organs of the EPOrg and EU, reveal insights into the current position, and suggest defensible approaches to the development of these provisions?

It is important to clarify what is meant by ‘defensible’ in this context. Defensible, used as an adjective, is defined as “capable of being defended (in argument), maintained, or vindicated; justifiable”.⁵⁹ A crucial element of defensibility is that the decision-making framework would be justifiable or coherent as a whole. The meaning of coherence within law is explored by Neil MacCormick⁶⁰ who states that:

“...the coherence of norms is a matter of their ‘making sense’ by being rationally related as a set, instrumentally or intrinsically, either to the realisation of some common value or values; or to the fulfilment of some common principle or principles”.⁶¹

The distinction between coherence and consistency must also be noted: consistency suggests a repetitive pattern, whereas coherence from MacCormick’s above definition suggests an understanding that makes sense, or is justifiable as a whole. A decision need not necessarily be consistent or the same as previous results in order to be coherent; in fact, in some cases, changing requirements may be justified if this is in furtherance of the common values sought. Thus, defensibility in the context of the thesis seeks to examine whether the current application of the morality provisions is conducted in a

⁵⁹ Oxford English Dictionary, 3rd Edition (Oxford University Press 2013)

⁶⁰ N MacCormick, ‘Coherence in Legal Theory’ in A Peczenik, et al (eds.), *Theory of Legal Science* (Springer 1984) 235-251.

⁶¹ Ibid 238.

manner which is justifiable and leads to coherent results, both within and also across the institutional frameworks where such decisions are made.

1.3.2 Hypothesis

This thesis argues that the decision-making bodies of the EPOrg and EU are predisposed to give an *institutionally*-tailored interpretation of the morality provisions which aligns with the respective purposes/final causes, competences and characteristics of the institutions within which the decision-making bodies are situated. Moreover, in light of the differences between the institutional frameworks within which each adjudicative body sits, regardless of any intention at a legislative level to generate an interpretation of the morality provisions which corresponds to the other institution's interpretation, divergence is likely to be perceived at a decision-making level. In essence, these adjudicative organs are embedded within distinct institutional frameworks and these frameworks are integral to how they refract, internalise and eventually give an interpretation to the morality provisions in their adjudicative processes. This hypothesis is developed by drawing on institutional theories which are detailed in chapter two. However, there are two foundational arguments which highlight the potential for influence in this context, namely: (i) the open-textured nature of the legislative provisions and (ii) the malleable and subjective nature of morality.

a) Open-textured nature of the morality provisions

H.L.A. Hart stated that "...statutes may be a mere legal shell and demand by their express terms to be filled out with the aid of moral principles...".⁶² This statement aptly applies to the general morality provision in the patent system under both the EPC and the Biotech Directive. Indeed, Hart's statement has been employed by Amanda Warren-Jones in this context, who noted that in instances where the source of morality applicable and the standards which should apply are not specifically set out, the patent system (or as this thesis argues any adjudicative body called upon to interpret these provisions) is forced to act as legislator in "formulating the deficit in the legislation".⁶³ In essence, the morality provisions at a legislative level are drafted in an open-textured manner, and aside from

⁶² HLA Hart, *The Concept of Law* (OUP 1961) 199-200.

⁶³ Warren Jones, 'Taming Scary Monsters with morality', note 26, 50.

the list of four inventions excluded from patentability in Art. 6(2) of the Biotech Directive, replicated in the relevant Implementing Regulations of the EPC - although these have also required judicial interpretation, discussed in section 1.4.2(c) - there is little by way of guidance⁶⁴ for decision-makers on the scope which these provisions should take or the tests/standards that should be used to assess the application of the exclusionary morality provisions.⁶⁵ These aspects are discussed further in chapters three and four.

For now it can be noted that in light of the open-textured nature of these provisions, decision-making bodies are left in the unenviable position of having to decipher the appropriate tests which should apply and also the scope these legislative provisions should take. They are essentially given the bare bones upon which they must put flesh on the contours of the morality provisions. In doing so, the thesis argues that decision-makers must act within the legal constraints on them and also are likely to be conscious to ensure any decisions adopted by them will be accepted by the community which the institution speaks to or serves.⁶⁶ In order to do so, they will seek to offer an interpretation which fits with the overall institutional framework within which it acts, thereby delivering institutionally tailored interpretations of the morality provisions.

b) The malleable and subjective nature of morality

Secondly and relatedly, the nature of the general morality provision provides significant scope for institutional influence. Arguably, in deciding on the morality of a specific act, we as individuals will internalise the issue and, based on our individual values and experiences, decide whether we deem an act moral or not. However, in this context, decision-makers are asked to decide upon the morality of the grant of a patent not in their capacity as individual actors, but as representatives of a court/quasi-judicial body which in turn speaks for the

⁶⁴ Some guidance is given in EPO, 'Guidelines for Examination', Part G, (September, 2013) para 4.1 <http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_1.htm> accessed 16 July 2015. These guidelines are discussed in chapter three, however, these do not mention an ethical framework or principles which should be applied in the application of the morality provisions.

⁶⁵ For discussion, see A Warren Jones, 'Vital parameters for patent morality- a question of form' (2007) 12(2) *Journal of Intellectual Property Law and Practice* 832, 832; Warren Jones 'Taming Scary Monsters with morality' note 26.

⁶⁶ For support of this view see C.W. Clayton and D.A. May, 'A Political Regimes Approach to the Analysis of Legal Decision' (1999) *Polity* 233-252 as reproduced in G Peters and J Pierre, *Institutionalism*, Volume 3 (Sage Library of Political Science 2007) 6.

overarching institution, i.e. the EU/EPOrg. It will be argued that in deciding on this, decision-makers will consider the decision by internalising it not individually but through the eyes of the sub-institution (the judicial/quasi-judicial body) and in cognisance of the overarching institution (EU/EPOrg) in which they are situated: an institutionally-subjective application of morality results. Seen in this light, the institutional framework acts as a prism through which moral questions are considered and filtered, in order to reach a decision which is deemed most appropriate for decision-makers representing a particular institution. The thesis relies particularly on the work of Neil MacCormick which is explored in chapter two in order to build this argument.⁶⁷

c) Consequence of hypothesis: A question of defensibility?

If the hypothesis is borne out, it suggests not merely that decision-makers are legally constrained by the differing institutional contexts in which they apply the morality provisions, but rather also that they are pre-disposed or conditioned to apply the morality provisions in specific manner because of their institutional contexts. This suggests that regardless of the convergence on the specific morality provisions evident at the legislative level, this could still result in divergence at the decision-making level. Indeed, it will be argued that the EPO is institutionally predisposed to interpret the morality provisions as restrictively as possible whereas the CJEU demonstrates a broader interpretation in line with the broader values such as ‘human dignity’ evident in the Biotech Directive and as found in the constitutional groundings of the EU itself. There will no doubt be exceptions to this, and in particular, the thesis will consider situations such as in *WARF*⁶⁸ where the EPO adopted a somewhat broader interpretation of the morality provisions than other cases. However, even in this case, its interpretation was narrower than that adopted by the CJEU in *Brustle*.⁶⁹ It will also be suggested that in this particular context, given the controversy which arose in relation to hESC patents, the EPO deliberately sought to align itself with its perception of what the CJEU position might be, thereby inter-institutional factors were at play.

⁶⁷ N MacCormick, *Practical Reason in Law and Morality* (OUP 2008) 172.

⁶⁸ *WARF*, note 54.

⁶⁹ *Brüstle*, note 58.

On a practical level, this causes difficulty as when applicants apply for a classical EP, it is granted by the EPO, and as all EU States are party to the EPC, a patent can be applied for in any/all of the EU MSs using this process. When this happens, the EPO is assessing patentability and so the application of the morality provisions. However, if the EPO's interpretation of the morality provisions differs from the interpretation the CJEU might give, then it is questionable whether the 'European' patenting system is offering a defensible framework for the application of the morality provisions. This is because if the underlying values and interpretative principles of the two institutions charged with the interpretation of these provisions differ such that they are arguably providing differing interpretations in their overlapping spheres of competence, then it is questionable whether a coherent application of the morality provisions is being delivered across and between these institutions in the 'European' patent system.

1.3.3 Methodology and chapter outline

The thesis employs a first-principles doctrinal approach to investigate the central research question. In doing so, it commences in *chapter two* by setting out a theoretical framework drawing on institutional theories to examine how institutions may influence decision-makers in their adjudicative capacity. This chapter sets out relevant institutional theories and uses these to design a template for assessing institutional influences in a judicial/quasi-judicial decision-making context. This template is then applied to the decision-making framework within the EPOrg and EU, in *chapters three* and *four* respectively, in order to investigate the central hypothesis proposed investigating how institutional features may influence the application of the morality provisions. In doing so, it examines the legal frameworks governing the internal decision-making processes within these institutions, and the rules governing their interactions with external institutions. It also explores, and contrasts decisions of these bodies on the morality provisions, in order to build a picture of the differing influences on each.

Following this, in *chapter five* the thesis examines the role of the European Court of Human Rights (ECtHR) in this context with the objective of assessing whether it could form a bridge between the EPOrg and EU in their application of the morality provisions by looking at legal instruments and case law to build a picture of the relationship between the EPOrg/EU and the ECtHR. Finally, *chapter six* looks to the future and examines how the

institutional features of the unitary patent system may influence the application of the morality provisions. The thesis concludes by reflecting on these aspects and offering a brief set of recommendations from the research in relation to how institutional aspects should be accounted for in the application of the morality provisions and particularly in future legislative initiatives in this context, in order to increase the defensibility of these provisions.

1.3.4 Exclusion of Art. 27(2) TRIPS from research

It should be clarified that whilst another supranational morality provision is contained in Art. 27(2)⁷⁰ of the *Trade Related Aspects of Intellectual Property Rights Agreement* (TRIPS) administered by the World Trade Organisation (WTO) and hence applicable to the majority of Contracting States to the EPC as these are also party to the TRIPS,⁷¹ however, this will not be examined in this thesis as it is not directly relevant to the core questions under investigation for the following reasons: Firstly, the morality provision contained in Art. 27(2) TRIPS is not a mandatory exclusionary provision; it states that Members “may” exclude from patentability certain inventions. This allows Members to derogate from the general requirements of patentability in TRIPS to exclude inventions on the grounds of morality, but does not mandate the exclusion on such basis. This contrasts

⁷⁰ It states that: “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.” For a discussion, see: G Porter, ‘Human Embryos, Patents and Global Trade: Assessing the Scope and contents of the TRIPS Morality exception’ in A Plomer and P Torremans, (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (OUP, 2009) 344-345; R Ford, ‘The morality of biotech inventions: differing legal obligations in Europe?’ (1997) *EIPR* 315- 318; P Van Den Bossche, *The Law and Policy of the World Trade Organisation: Texts, Cases and Materials*, 2nd Edition (CUP 2008) 785; N Pires de Carvalho, *The TRIPS Regime of Patent Rights* (Kluwer Law International, 2002) 170-171; P Fitzgerald, ‘Morality” May Not be Enough To Justify the EU Seal Products Ban: Animal Welfare Meets International Trade Law’ (2011) 14 *Journal of International Wildlife Law and Policy* 85; N Diebold, ‘The Morals and Order Exceptions in WTO Law: Balancing the Toothless Tiger and Undermining Mole’ (2008) 11(1) *Journal of International Economic Law* 43; D Gervais, *The TRIPS Agreement: Drafting History and Analysis* (3rd edition, Sweet and Maxwell 2008) 223.

⁷¹ All EPC States are also WTO Members except: Monaco, San Marino and Serbia. This is correct at the time of writing, 16 July 2015. However, the EPOrg and EU are not parties to TRIPS. For the EPO guidance see EPO, Case Law of the Boards of Appeal of the European Patent Office (7th edition, 2013) III(H)(2) <http://www.epo.org/law-practice/legal-texts/html/caselaw/2013/e/clr_iii_h_2_1.htm> accessed 16 July 2015. For a discussion of the EU’s relationship with the TRIPS Agreement in its judicial interpretations, see A Dimopoulos and P Vantsiouri, ‘Of TRIPs and traps: the interpretative jurisdiction of the Court of Justice of the EU over patent law’ (2014) 39(2) *EL Rev* 210; S Subramanian, ‘EU Obligation to the TRIPS Agreement: EU Microsoft Decision’ (2011) 21(4) *European Journal of International Law* 997; R Ford, ‘The morality of biotech inventions’ note 70.

to the wording of the EPC and Biotech Directive, both of which use the word “shall” highlighting the mandatory nature of the exclusion in these contexts.

Secondly, and most importantly, the contribution of this research is in relation to the institutional influences on judicial/quasi-judicial bodies of the ‘European’ patent system in the interpretation of the morality provisions. This is of significance in the ‘European’ patent system given the peculiar overlap of functions of the EPORG/EU and the fact that the EPO is charged with granting patents for EU MSs who are bound primarily by the EU’s Biotech Directive which can also be interpreted by the CJEU. The overlapping functions of the EPORG/EU gives rise to an intricate network of inter-institutional influences but also a potential for conflicting interpretations on the morality provisions at a judicial/quasi-judicial level. It is this institutional tension across and between the supranational bodies in the ‘European’ context which the thesis is interested in. The TRIPS Agreement sits as a peripheral backdrop but its influence to date has been negligible. Indeed, at the time of writing, there have been no cases where a WTO panel or Appellate body has been called upon to interpret Art. 27(2) of the TRIPS Agreement in this context. In light of this, and given the constraints as to time and space, Art. 27(2) will not be considered. Nonetheless, the understandings developed in the thesis will reveal insights applicable to the Art. 27(2) provision should it be decided upon in future. It is also hoped that future work will look further into this aspect.

1.4 Need for this Research

Turning to the need for this research, this is justified in light of: (1) its contemporary relevance, and (2) the gap in the literature in relation to institutional influences on the application of the morality provisions.

1.4.1 Contemporary Relevance

Two developments make this research of significant contemporary relevance, namely: the planned unitary patent system and the planned accession of the EU to the ECHR.

Firstly, the unitary patent system which has recently been adopted⁷² and is expected to come into effect in 2017 (the timeline is discussed in chapter six), will add a third supranational decision-making body the Unified Patent Court (UPCt) thereby exacerbating the institutional complexity within the ‘European’ patent system. Following its adoption, there will be three supranational fora for the adjudication of the morality provisions, and although the UPCt will have a link with the CJEU, the establishment of this court will introduce another decision-making framework for the morality provisions. In light of these changes, it seems incumbent upon us to be aware of how institutional frameworks may influence the application of the morality provisions and to factor this into the creation of this new decision-making framework. The unitary patent system and its potential influence in this context will be examined in chapter six, which therefore provides a timely look at this issue.

Secondly, the institutional framework will also be complicated by the planned accession of the EU to the European Convention on Human Rights (ECHR). This suffered a recent setback in light of the CJEU’s rejection of the draft accession agreement⁷³ which suggests there may be significant delays in the accession process. Nonetheless, given the duty prescribed in Art 6(2) TEU for the EU to accede to the ECHR, this thesis proceeds under the enduring assumption that accession will occur at some point. As yet, the potential effect of accession on the morality provisions is unknown and has been described as “unchartered legal territory”.⁷⁴ Relatedly, the relationship between the EPOrg and ECtHR in the application of the morality provisions has never been settled nor has it been scrutinised in detail in recent literature. The thesis offers an analysis of this interaction and also investigates the potential institutional influences which the ECtHR may exert on the morality provisions. Again, this is a timely addition to the law in this area and is relevant in light of current developments.

⁷² Regulation 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, OJ L 361/1 of 31.12.2012 (Regulation 1257/2012); Council Regulation 1260/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to applicable translation arrangements (Regulation 1260/2012).

⁷³ Opinion 2/13 *Accession of the European Union to the European Convention for the Protection of Human Rights and Fundamental Freedoms* ECLI:EU:C2014:2454.

⁷⁴ A Plomer, ‘After Brüstle: EU accession to the ECHR and the Future of European Patent Law’ (2012) 2(2) QMJPL 110.

1.4.2 Literature Review: Morality Provisions and Biotech Patents

Turning to the literature in the area, it is conceded that the morality provisions have been the subject of considerable debate and extensive literature. However, this literature has focused primarily on four main strands, namely: (1) whether moral considerations are appropriate within the patent system;⁷⁵ (2) the form and scope which the morality provisions should take - looking particularly at what morality should be directed at and the tests that should be used in applying these provisions;⁷⁶ relatedly, (3) the definitional questions surrounding the application of the specific morality exclusions outlined in Art. 6(2) of the Directive and their equivalents in the EPC framework⁷⁷ which has looked particularly at the application of Art. 6(2)(c) to patents on products/processes involving hESCs;⁷⁸ and finally, (4) the literature has compared the European and the United States⁷⁹ systems, as the latter patent system does not have any express provisions on morality.

Notwithstanding the extensive literature, the focus has been primarily on the normative questions surrounding the morality provisions – particularly, the place for these provisions within the patent system and the form they should take. The overlapping institutional framework involving the EU and EPOrg and the significance of this for the application of the morality provisions has been largely side-lined.⁸⁰ This is not to suggest

⁷⁵ See: Mills, *Biotechnological Inventions*, note 26; M Bagley, 'Stem Cells, Cloning and Patents: What's Morality Got to do With it?' (2004) 39 *New England Law Review* 501; D Beyleveld and R Brownsword, *Mice, Morality and Patents* (Common Law Institute of Intellectual Property 1993); S Sterckx 'The Ethics of Patenting – Uneasy Justifications' in P Drahos (ed.) *Death of Patents* (Lawtext Publishing 2005).

⁷⁶ A Warren-Jones, 'Morally Regulating Innovation: What is 'Commercial Exploitation'?' [2008] *IPQ* 193; Warren Jones, 'Vital Parameters for Patent Morality', note 65; Warren-Jones, 'Finding a 'Common Morality Codex' for Biotech: A question of substance' (2008) 6(39) *International Review of Intellectual Property and Competition Law* 638; Warren-Jones, 'Identifying European Moral Consensus: why are the patent courts reticent to accept empirical evidence in resolving biotechnological cases?' (2006) 1 *EIPR* 26.

⁷⁷ Rules 28 and 29 of the Implementing Regulations to the EPC.

⁷⁸ A Plomer and P Torremans (eds.) *Embryonic Stem Cell Patents in Europe: European Law and Ethics* (OUP 2009).

⁷⁹ M Abraham, 'Morality and the Patent System: An Analysis of Article 53(a) of the European Patent Convention and the US Patent System' (2009) 10(3) *Bio-Science Law Review* 95; Mills, *Biotechnological Inventions*, note 26.

⁸⁰ This is alluded to in some texts; in the context of stem cell patents, see Bakardjieva Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting', note 8, 227; T Jaeger, 'All back to square one? An assessment of the latest proposals for a patent and court for the internal market and possible alternatives' *Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 12.01*; S Luginbuehl, *European Patent Law: Towards a Uniform Interpretation*, (Edward Elgar 2011); A Ottolia, 'Moral limits to biotech patents in Europe: a quest for higher harmonisation' in E Arezzo and G Ghidini

that the normative questions addressed are unimportant.⁸¹ On the contrary, this work acknowledges the significance of, and need for thorough debate on the role and content of morality *per se* in the patent system. However, it argues that to date, the literature has been largely blinkered to the institutional issues which are equally important as the institutional framework provides the structural scaffold upon which the morality provisions hinge and operate.

In order to demonstrate this gap and to support the need for the analysis conducted, this section gives an overview of the main strands in the literature listed above, with the exception of the literature comparing the European and US systems.⁸² This latter aspect is not examined as this aspect does not relate to the central research question of this thesis which focuses specifically on the 'European' patent system. Hence, in the interests of brevity it is considered outside the scope of this project. The overview of the other three strands provides necessary background for the research that follows and also highlights how the institutional analysis conducted reframes questions previously considered, adding an important contribution to the field. Following this, the chapter outlines some recent developing literature which has started to delve into institutional aspects. These works respond to similar concerns as this thesis, but as will be demonstrated, they can be clearly distinguished from this project.

a) Suitability of the patent system for the application of the morality provisions

One of the central themes of the literature has been to question the place for the morality provisions within the patent system. Prior to the advancement of biotechnological

(eds), *Biotechnology and Software Patent Law: Comparative Review of New Developments* (Edward Elgar 2011) 309.

⁸¹ The significance of such questions has been acknowledged by S Thambisetty, 'The learning needs of the patent system and emerging technologies: a focus on synthetic biology' [2014] IPQ 13-39, 15.

⁸² See, M Bagley, 'Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law' (2003-2004) 45 William and Mary Law Review 469- 547, 474; M Bagley, 'Global Controversy: The Role of Morality in Biotechnology Patent Law' in P Yu, (ed), *Intellectual Property and Information Wealth: Issues and Practices in the Digital Age*, Volume 2 (Praeger Publishers 2007); M Llewelyn, 'Schrodinger's Cat: An Observation on Modern Patent Law' in P Drahos (ed.), *Death of Patents* (LawText Publishing 2005). For a discussion of the patentability of biotechnological inventions in the US, see Mills, *Biotechnological Inventions*, note 26, 115-131.

inventions, patent law was seen as relatively separate from politics or ethics,⁸³ viewed as a technical, neutral system which was “hermetically sealed, closed off from external considerations”.⁸⁴ Nonetheless, others such as Peter Drahos have argued that the patent system is, and has always been, linked to moral standards as the very grant of a patent which is not an automatic right, presumes that an invention is worthy of patentability thereby giving a limited monopoly right to the inventor in return for the information in relation to the development/use of the invention. Hence, the decision to grant a property right is in and of itself a moral judgement.⁸⁵

The advent of biotechnological inventions brought such questions to the fore and much of the early literature on morality and the biotechnological inventions focused on whether the patent system was a suitable vehicle to filter ethical considerations. A number of arguments were put forward questioning its suitability.⁸⁶ The main, often overlapping claims are as follows: Firstly, the futility argument,⁸⁷ whereby commentators refer to the limitations of the patent system and particularly, its inability to prohibit the use of products/processes through the denial of a patent⁸⁸ on moral grounds. This argument is generally framed around the idea that a patent is not a positive right, and its grant does not allow a patent holder to use a patent. The use of an invention is instead governed by other areas of law/regulation. Conversely, the denial of a patent does not prohibit the use of a product or the commercial exploitation of the same, it merely prevents a monopoly right arising over an invention. Thus, it has been argued that it is futile to deny patents on the basis of the morality provisions as this will neither stop the use of an invention nor its exploitation. Secondly and relatedly, an ‘appropriateness’ argument features in the literature, whereby it is claimed that the patent system is not the appropriate forum,

⁸³S Crespi, ‘The Morality of Patenting’ in S. Sterckx (ed), *Biotechnology, Patents and Morality* (Ashgate Publishing, 1997) 220. For further discussion, see: L Bently and B Sherman, ‘The Ethics of Patenting: Towards a Transgenic Patent System’ (1995) 3 *Medical Law Review* 275, 275.

⁸⁴B Sherman and L Bentley, ‘The Question of Patenting Life’ in L Bently and S Maniatis (eds.), *Perspectives on Intellectual Property: Intellectual Property and Ethics* (Sweet and Maxwell 1998) 111.

⁸⁵P Drahos, ‘Biotechnology Patents, Markets and Morality’ (1999) 21(9) *EIPR* 441, 441.

⁸⁶See Beyleveld and Brownsword, *Mice, Morality and Patents*, note 75, 24-30; Mills, *Biotechnological Inventions*, note 26, 10-14.

⁸⁷See: Mills, *Biotechnological Inventions*, note 26, 1; G Laurie, ‘Biotechnology: Facing the Problems of Patent Law’ in H MacQueen and B.G. Main (eds.), *Innovation, Incentive and Reward: Intellectual Property Law and Policy* (Edinburgh University Press 1997) (Hume Institute: Hume Papers on Public Policy Vol. 5(3)) 46-63; A Inch, ‘The European Patent Convention; A Moral Roadblock to Biotechnological Innovation in Europe’ (2007-2008) 30 *Houston Journal of International Law* 203.

⁸⁸See Recital 14 of the Biotechnology Directive.

nor is it properly constituted, to make assessments on the morality of science/technology.⁸⁹ Instead, it has been claimed that such assessments should be fulfilled by other regulatory instruments/bodies, ethics committees or through democratically elected actors, such as national governments.⁹⁰

These arguments centre on whether patents are a suitable regulatory tool to express moral concerns in relation to a particular invention and relatedly, whether the patent system is the appropriate forum to adjudicate such issues. This has resonance with institutional questions. However, the literature to date has looked primarily at the normative questions such as whether morality provisions should be in the patent system. Instead, this thesis takes as a given that morality provisions are currently embedded within the patent system, and questions how they are operating in this context. In doing so, it focuses specifically on whether and to what extent their current application reflects legal constraints, goals and institutional tensions within the EPOrg and EU, whose decision-makers are charged with the application of the morality provisions and then considers the consequence of this. From this perspective, it is not a question of whether the patent system should incorporate moral concerns, rather it is a question of what each institution within the patent system, i.e. the EPOrg and EU, perceive as being the function of the morality provisions and how this and other institutional factors may influence and constrain their interpretations of these provisions. These questions have not been assessed in this deliberately institutional manner to date.

Reverting to the literature, a third avenue has questioned the suitability of these provisions in an economic sense focusing on the risk such exclusions pose to maintaining commercial certainty within the patent system. The argument generally runs as follows: If one considers that a justification for the patent system is based on reward/incentive

⁸⁹ See: S Sterckx, 'European Patent law and Biotechnological inventions' in S Sterckx, (ed.) *Biotechnology, Patents and Morality* (Ashgate, Aldershot Publishing, 1997) 1, 8-11.

⁹⁰ One expression of this argument is demonstrated by Prof. Dworkin who stated in his evidence to the House of Lords Select Committee on the European Communities, that: "Few would deny that there are major ethical; issues relating to the development of biotechnology and genetic engineering; that there is a need to ensure that such ethical issues are properly addressed; that there should be adequate controls and monitoring of undesirable or questionable developments...[t]he real question, though, is whether such control should be exercised in any significant way through the patent system. A rational answer must be 'no'." See HL Paper 28, HMSO, 1 Mar 1994, as cited in: Mills, *Biotechnological Inventions*, note 26, 139.

theories,⁹¹ under which researchers/investors are seen as willing to invest time and money into the development of inventions on the understanding that their efforts will be rewarded with a patent and that they will gain profits in this manner. In turn, it is claimed that the patent system should offer some level of certainty as researchers should know at the outset of the likelihood or at least the possibility of a patent arising from a particular project. It is said to follow⁹² that if the morality provisions are applied in a broad or uncertain way in the patent system, this would reduce the incentive to innovate. These arguments have been extended to considering the potential difficulties which the provisions pose for the 'European' patent system in keeping abreast with the development of the biotechnological industry in Japan and the US, whose patent systems do not contain any express provisions on morality.⁹³ A number of counter arguments to this have been raised in the literature, including: that there is no clear evidence of the extent to which research and development would suffer if the incentives offered by the patent system were withdrawn;⁹⁴ that in any case there is no guarantee of a patent for all inventors because often similar research is undertaken by a number of organisations simultaneously, hence, there is often a race to finish and therefore it is never the case that all inventors are rewarded by a patent.⁹⁵

Regardless of the force or conclusiveness of these arguments, the institutional examination conducted reframes such questions by examining what institutional pulls may tilt the balance of a decision-maker's judgment in favour of economic necessity or safeguarding morality/rights in any particular context. It views such options as existing in a continuum i.e., patentability standards may change depending on the institutional influences which are applied.

⁹¹ Other justifications include: moral right theory, social contract theory, rent dissipation theory. See, Warren Jones, 'Taming Scary Monsters with morality' note 26, 29-39.

⁹² This argument is discussed in Mills, *Biotechnological Inventions*, note 26, 11-12.

⁹³ See, D Manspeizer, 'The Cheshire Cat, the March Hare, and the Harvard Mouse: Animal Patents open up a new genetically engineered Wonderland' (1991) 47 Rutgers Law Review 417, 449. For a general discussion on patents and predictability in the US see, J Bessen, and M.J. Meurer, *Patent Failure: How Judges, Bureaucrats and Lawyers put innovators at risk* (Princeton University Press, 2009).

⁹⁴ Mills, *Biotechnological Inventions*, note 26, 12

⁹⁵ Warren Jones, 'Taming Scary Monsters with morality' note 26, 32-36.

b) Shaping the Contours of morality: A questions of standards and scope

Turning to the second strand in the literature, Hart's discussion⁹⁶ of the role of decision-makers in relation to open-textured provisions to fill in the gaps and derive meaning from the legislation has been used by others, including Amanda Warren Jones,⁹⁷ to enter into a discussion on the scope and tests which are currently applied and which ought to be applied in the application of the morality provisions.⁹⁸ This research departs from this aspect, instead it focuses on how the open-textured nature of the morality provisions lends these provisions to being particularly susceptible to institutional influence, such that even if guidance is issued on the application of these provisions, the extent to which this will be implemented at a decision-making level will be highly dependent on how this guidance fits within the broader goals of the institutions and how it is refracted through the institutional framework.

To demonstrate this point, it may be useful to imagine the institutional frameworks in the EU and EPOrg within which the decision-makers sit as two coin machines at an amusement centre. When one inserts a coin, depending on how the machine is internally configured and the previous coins which have been inserted into each, the outcome will be altered. Similarly, this thesis argues that the application of the morality provisions is affected by the institutional set up within which the adjudicative bodies in the EU/EPOrg sit, including, the purposes/goals of that broader institution and the previous decisions it has made in this context. Adding a guidance document is the equivalent of moving a pin within the coin machine, and its effect on the outcome is dependent on the broader set up of the machine or institutional framework in the context of the morality provisions. This argument is expanded upon in chapter two. However, it is relevant here as it highlights a central point of this thesis, which is that proposals on reform, even if accepted by legislative bodies, may not necessarily give rise to the desired outcome at the adjudicative level. Indeed, arguably even if the same guidance is issued in the

⁹⁶ Hart, note 62, 199-200.

⁹⁷ Warren Jones, 'Taming Scary Monsters with morality' note 26, 50

⁹⁸ See: Warren Jones, 'Vital parameters for patent morality', note 65; Warren-Jones, 'Finding a "common morality codex for biotech' note 76; A Warren Jones, *Human and Animal Biotechnology in the United Kingdom and Europe* (Law text Publishing 2001) Chapter 4; Warren Jones, 'Taming Scary Monsters with morality' note 26; Mills, *Biotechnological Inventions*, note 26, chapter 4, 53-80; Bently and Sherman, 'The Ethics of Patenting: Towards a Transgenic Patent System', note 83; E Toumi, 'Case Comment: EC – Patents - Biotech Patents – Question of Morality' (2004) 26(2) EIPR 15; Beyleveld and Brownsword, *Mice, Morality and Patents*, note 75, chapter 3.

EPOrg/EU on the morality provisions, this will not necessarily lead to the same interpretations by their respective decision-making bodies, as the thesis argues that these decision-makers are predisposed and legally constrained in differing manners which will result in *institutionally* configured interpretations of the morality provisions.

Also, of relevance in this context, is the interpretation of the provisos contained within the morality provisions. The definitional aspects in relation to the specific morality provisions contained in Art. 6(2) of the Directive are discussed in the next section, however a number of provisos exist within the general morality provision in Art. 6(1) of the Directive, and Art. 53(a) EPC. Art. 53(a) EPC (mirrored to a large extent in Art. 6 of the Biotech Directive) can be recalled to highlight these, this states:-

“European patents shall not be granted in respect of: (a) inventions the *commercial exploitation* of which would be contrary to "*ordre public*" or *morality*; such exploitation shall not be deemed to be so contrary merely because it is *prohibited by law or regulation in some or all of the Contracting States.*” [Emphasis added]

The italicised provisos ‘commercial exploitation’, ‘ordre public or morality’ and ‘prohibited by law or regulation in some or all of the Contracting States’ have been the most contentious. The interpretation of these terms is important as they dictate the breadth of the application of the morality provisions by acting as funnels, as through expanding or narrowing these provisos the contours of moral decisions may be stretched thereby demarcating the bounds on decision-makers discretion. For instance, depending on the interpretation of “commercial exploitation” decision-makers may need to look at the development of the invention. This relates to the idea of bounded decision-making as discussed by MacCormick⁹⁹ where the interpretation of provisos within legislation sets the parameters for adjudication - this aspect is examined in chapter two. This thesis seeks to contribute to understandings in this context by providing a deeper understanding of how differing institutional frameworks may lead to differing interpretations of provisos

⁹⁹ N MacCormick, *Institutions of Law* (OUP 2007) 30.

such as these. For the purposes of background an overview of the literature on these terms should be noted.

i. Commercial Exploitation

Firstly, “commercial exploitation” has been interpreted as including an assessment of “the morality of the publication of the information contained within the patent application, the development of the invention, and the way in which the innovation is used in a social context.”¹⁰⁰ The phrase has also been discussed as suggesting that it would not be justifiable to withhold patentability for an invention where the immorality only occurs in its initial creation,¹⁰¹ but not in the technical teaching of the invention. However, more recent CJEU case law pertaining to the patentability of technology involving hESCs albeit in the context of Art. 6(2) appears to run contrary to this interpretation,¹⁰² requiring examiners to look deeper into the development of the invention in assessing patentability¹⁰³ - this will be discussed further in chapters three and four.

ii. Ordre Public/Morality

Secondly, what is meant by ‘ordre public’ and morality, and the relationship between these terms has been subject to considerable examination.¹⁰⁴ In assessing the meaning of this provision commentators have looked to the historical background of the provision to its roots in the Strasbourg Convention¹⁰⁵ where it was adopted to assuage fears of an invention being “obscene or...blasphemous [or] which would lead to a breach of the

¹⁰⁰ Warren-Jones, ‘Vital Parameters for Patent Morality’, note 65, 833.

¹⁰¹ Ibid 833. Warren Jones notes that the provisions in an application “must be guided by reasonable foreseeability in determining the intangible scope of the inventive concept and the probable uses to which the specific technology would be put.”

¹⁰² E Bonadio, ‘Stem Cell Industry and Beyond: What is the Aftermath of Brüstle?’ (2012) 1 EJRR 93.

¹⁰³ For a discussion of the practical difficulties this may cause, see Bonadio, Ibid.

¹⁰⁴ See, Warren Jones, ‘Taming Scary Monsters with morality’ note 26, chapter 5, which lists a number of sources of commentary, including: E Armitage and I Davies, *Patents and Morality in Perspective* (Common Law Institute of Intellectual Property 1994); Beyleveld and Brownsword, *Mice, Morality and Patents*, note 75; R Moufang, ‘Patenting of Human Genes, Cells and Parts of the Body? – The Ethical Dimensions of Patent Law’ (1995) 25(4) IIC 487; J Straus, ‘Patenting Human Genes in Europe – Past Developments and Prospect for the Future’ (1995) 26(6) IIC 920, 929; J Straus, ‘Patenting Human Genes and Living Organisms- The Legal Situation in Europe’ in F Vogel and R Grunwald (eds) *Patenting Human Genes and Living Organisms* (Springer: Germany: 1994); U Schatz, ‘Patents and Morality’ in S Sterckx (ed.) *Biotechnology, Patents and Morality* (Ashgate Publishing Ltd. 1997) 161.

¹⁰⁵ Convention on the Unification of Certain Points of Substantive Law on Patents for Invention 1963

peace or a breakdown of morals.”¹⁰⁶ The morality provision was relatively uncontroversial in relation to traditional inventions and its adoption from the Strasbourg Convention to the EPC gave rise to relatively little discussion.¹⁰⁷ However, as noted, the advent of biotechnology changed this.

Amanda Warren-Jones surveyed the literature on the interpretation of morality/ordre public and noted the following interpretations: Beyleveld and Brownsword, claim that ‘ordre public’ represents the fundamental rules of society contained in law,¹⁰⁸ viewing it as a “high road” definition of public policy, which they equate as meaning principles which accord with “the common good, “the Commonwealth...” or “the general will...”¹⁰⁹ Similarly, Moufang interpreted ‘ordre public’ as akin to the ‘legal order’ and morality separately as the social order.¹¹⁰ Whilst, Straus viewed ‘ordre public’ as something equating to public order which would be determined on a national level by individual MSs, the EPO would then decipher a commonality between all States which would be applicable at a supranational level.¹¹¹ Finally, Schatz suggested that ‘ordre public’ could be identified in a three step process; first it only included ethical principles which are expressly provided for in legislation; second it refers to considerations which are representative of the basic values of society and third, there must be a breach of the moral element of the legislation, not the legal element for ‘ordre public’ to be contravened.¹¹² Warren-Jones (referring to the overall context of the morality provision) argues that the “[d]efinition of the legislative terms may be a redundant exercise in so far as the provision can clearly be understood to regulate all of public morality”.¹¹³

¹⁰⁶ Armitage and Davies, *Patents and Morality in Perspective*, note 104, 17.

¹⁰⁷ Ibid.

¹⁰⁸ Warren Jones, *Human and Animal Biotechnology*, note 98, 133 citing Beyleveld and Brownsword, *Mice, Morality and Patents*, note 75, 54-63.

¹⁰⁹ Beyleveld and Brownsword, *Mice, Morality and Patents*, note 75, 62, as cited in Warren Jones, *Human and Animal Biotechnology*, note 98, 120.

¹¹⁰ R Moufang, ‘Patenting of Human Genes’, note 104, 503, cited in Warren Jones, *Human and Animal Biotechnology*, note 98, 120.

¹¹¹ J Straus, ‘Challenge for the Law’ in “EPOsium 1992: Genetic Engineering- The New Challenge” (1992) EPOscript vol. 1: European Patent Office, at 80 as cited in Warren Jones, *Human and Animal Biotechnology*, note 98, 120.

¹¹² U Schatz, ‘Patents and Morality’, note 104, 161, as cited in Warren Jones, *Human and Animal Biotechnology*, note 98, 134-135.

¹¹³ Warren-Jones, ‘Vital Parameters for Patent Morality’ note 65, 834.

Oliver Mills has more recently discussed the term arguing that under national law ‘ordre public’ is a body of positive law which he claims includes “...criminal law, constitutional law or other special laws protecting human life and dignity, as well as other basic values in society”.¹¹⁴ Mills argued that the conception of ‘ordre public’/morality under the Biotech Directive is wider than originally intended under the Strasbourg Convention and the EPC.¹¹⁵ Arguably, this point is affirmed by the recent *Brüstle*¹¹⁶ decision albeit in the context of the specific exclusions contained in Art. 6(2) of the Directive, a point which is developed further in chapter four.

From this overview, it is evident that there is no uniform agreement on the interpretation of: the term ‘ordre public’, the relationship that it enjoys with morality, or the precise scope which either concept should take. This thesis does not seek to contribute to the normative discussion of what morality or ‘ordre public’ should be in this context. Instead its contribution is in relation to an understanding of how these terms are moulded within differing institutional frameworks. In this vein, chapters three and four examine how the EPOrg and EU respectively have interpreted these provisions looking at the legislative provisions, guidance and case law in relation to the interpretation of the morality provisions. This analysis demonstrates the significance of institutional design and choice as factors which influence the interpretation of open-textured provisions in this and other contexts.

iii. Prohibited by law or regulation

Thirdly, the final proviso of contention is the phrase “shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States”. Beyleveld and Brownsword have interpreted this as meaning that patentability cannot be denied on the basis of the morality provisions, merely because the commercial exploitation of the invention is prohibited by law in one or all of the Contracting States: such prohibition is neither a necessary or sufficient condition.¹¹⁷ It suggests that an independent reason explaining why it is against morality/‘ordre public’

¹¹⁴ Mills, *Biotechnological Inventions*, note 26, 138.

¹¹⁵ *Ibid*, 138.

¹¹⁶ *Brüstle*, note 58.

¹¹⁷ Beyleveld and Brownsword, *Mice, Morality and Patents*, note 75, 80.

must be offered to exclude patentability under this ground and not merely that the exploitation is legally prohibited. Warren-Jones claims that the patent examiner must judge the overall morality of an invention interpreting its meaning not just in terms of legislation but inclusive of broader social values¹¹⁸ before it can be adjudicated as contrary to this provision. As in other contexts, the analysis seeks to reveal insights into how the institutional context may influence the interpretation of this proviso.

c) Definitional Questions in relation to Mandatory Prohibitions: Application of morality provisions to patentability of human embryonic stem cell technology

The third strand of the literature focuses on the application of the four listed categories of exclusions from patentability under Art. 6(2) of the Directive. To date, Art. 6(2)(c) which prohibits patents on “uses of embryos for industrial and commercial” purposes and its application to the patentability of hESC technology, has been the main focus, as this provision is the only of Art. 6(2) yet to be litigated. The meaning of this provision has come before the decision-making bodies of the EU¹¹⁹ and EPOrg¹²⁰ in a number of recent cases which have centred primarily on the definition of key scientific terms within the provision such as ‘embryo’.

The literature on this aspect has again focused primarily on normative questions surrounding whether patents on hESC technology should be excluded, which has considered the following aspects: the absence of consensus on hESC technology and how this should filter into decisions on patentability, and relatedly, whether divergence amongst Contracting States should be accommodated, which in turn links to issues of national sovereignty;¹²¹ the effect such restrictions may have on research relating to and

¹¹⁸ Warren Jones, *Human and Animal Biotechnology*, note 98, 136.

¹¹⁹ *Brüstle*, note 58; Case C-364/13 *International Stem Cell Corporation v Comptroller General for Patents*, 18th December, 2014.

¹²⁰ See: Case T1079/03 *Edinburgh University* (Unreported) [2003] OD EP 94913174.2; Case T522/ 04 *California Institute of Technology (CIT)* (Unreported) [2003] ED EP 93921175.1); *WARF*, note 54; *TECHNION/Culturing stem cells* [2014] EPOR 23; *ASTERIAS/Embryonic stem cells* [2015] EPOR 9.

¹²¹ See, Chapters 2,5 and 8 in Plomer and Torremans, *Embryonic Stem Cell Patents*, note 78; Plomer, ‘After Brüstle’ note 74; G Laurie, “Patenting stem cells of human origin” (2004) 26(2) EIPR 59.

using hESCs;¹²² and how the interpretations given and decisions made in patent law in this context may conflict with interpretations outside patent law.¹²³

Importantly, the thesis uses these specific exclusions, as a central avenue to explore how institutions differ in their interpretative roles, and also the inter-institutional influences which may arise across and between the EU/EPOrg. As will be discussed in chapter three, it is the decision-making bodies of the EPOrg along with national intellectual property offices which have had the greatest interaction with and arguably, also the greatest role in shaping the morality provisions. This is primarily, because they encounter these provisions most often in the examination process. However, the influence of the EU in the development of the morality provisions comes to the fore in the context of the four listed exclusions. This is because it was through the EU's Directive that these exclusions were initially incorporated into the patent system, and whilst the EU has generally advocated for a wide margin of manoeuvre to be given on the application of the general morality provision,¹²⁴ this margin does not apply to the four listed exclusions.¹²⁵ Thus, decisions concerning these provide an interesting site for the assessment of inter-institutional influences, and the relationship between the EPOrg and EU in the application of the morality provisions.

1.4.3 Distinguishing Existing Literature on Institutions and the Patent System

As noted, there is relatively little in the existing literature¹²⁶ that offers an institutional perspective on the morality provisions in the 'European' patent system. This type of

¹²² For overview, see, S Harmon and G Laurie, 'Dignity, plurality and patentability: the unfinished story of *Brüstle v Greenpeace*' (2013) 38(1) ELR 92-106; The authors cite the following sources: A Abbott, "European Court of Justice Rejects Stem-Cell Patents", *Nature News*, March 10, 2011; A Smith, "'No' to Ban on Stem Cell Patents" (2011) 472 *Nature* 418; A Plomer's response to E Callaway, 'European Ban on Stem-Cell Patents has a Silver Lining' (2011) 478 *Nature* 441; A Abbott, 'Stem Cells: The Cell Division' (2012) 480 *Nature* 310.

¹²³ A Plomer, 'Towards Systemic Legal Conflict: Article 6(2)(c) of the EU Directive on Biotechnological Inventions' in A Plomer and P Torremans, *Embryonic Stem Cell Patent: European Law and Ethics* (OUP 2008).

¹²⁴ Case C-377/98 *Netherlands v European Parliament and Council*, para. 37-39.

¹²⁵ Case C- 456/03 *Commission v Italy* [2005] ECR I-5335, para. 78-79.

¹²⁶ The significance and difficulties posed by the separate frameworks within the EPO and EU is discussed in the context of stem cell patents by Bakardjieva Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting', note 8, 227. More generally, see: Jaeger, 'All back to square one?' note 80; Luginbuehl, *European Patent Law: Towards a Uniform Interpretation*, note 80; Ottolia, "Moral limits to biotech patents in Europe", note 80, 309; S Thambisetty, 'The Institutional Nature of the Patent System: Implications for

research has started to develop more in recent years,¹²⁷ but there is still limited research looking specifically at the ‘European’ patent system and less on the morality provisions. Nonetheless, there are two authors whose work has particular resonance with this thesis, namely: Antonia Bakardijieva Engelbrekt and Sivaramjani Thambisetty. This section gives an overview of the main contours of their work in this context. In doing so, it highlights how the research conducted in this project differs from their work, reinforcing the need for and the original contribution of this work.

a) Bakardijieva Engelbrekt

Bakardijieva Engelbrekt’s main contribution in this context is a chapter entitled “Institutional and Jurisdictional Aspects of Stem Cell Patenting in Europe (EC and EPO): Tensions and Prospects”.¹²⁸ This chapter delves into the institutional structure in the ‘European’ patent system as it pertains to the application of the morality provisions in relation to hESC patents. The author examines the bifurcated institutional landscape existing within the ‘European’ patent system, highlighting some of the main distinctions between the EU and EPOrg’s institutional structures from a jurisdictional and competency perspective. In doing so, the work dovetails with themes running through this thesis. However, Bakardijieva Engelbrekt’s chapter focuses specifically on the jurisdictional and competency aspects¹²⁹ of the institutions and how these operate as *legally* constraining features. Although these issues feature as aspects of this current project, these are not the sole focus. Instead, this research looks more broadly at embedded influences created by various institutional characteristics, which may influence decision-makers operating within such institutions. As noted, the thesis draws on institutional theories to examine such influences arguing that they act not merely as binding constraints on decision-makers but that these characteristics may also lead to *institutionally* predisposed patterns of behaviour in decision-makers.

Bioethical Decision-Making’ in C Lenk, N Hoppe, R Andorno, *Ethics and Law of Intellectual Property: Contemporary Problems in Politics, Science and Technology* (Ashgate 2007).

¹²⁷ See: C Long ‘The PTO and the Market for Influence’ (2009) 157 *University of Pennsylvania Law Review* 1965, 1991; L Davies, ‘Technical Cooperation and the International Coordination of Patentability of Biotechnological Inventions’ (2002) 29(1) *Journal of Law and Society* 137; P Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (CUP 2010), Drahos, ‘Biotechnology Patents, markets and morality’, note 85.

¹²⁸ Bakardijieva Engelbrekt, ‘Institutional and Jurisdictional Aspects of Stem Cell Patenting’, note 8.

¹²⁹ *Ibid* 228.

In short, Bakardijeva Engelbrekt's chapter can be clearly distinguished from this thesis as her chapter examines just one sub-set of the aspects which this thesis explores. Her work focuses on the legal constraints which arise, whereas this work also examines behavioural patterns and influences of decision-making actors. Other differences include the fact that Bakardijeva Engelbrekt's chapter focuses primarily on the context of hESC patents, and was written in 2009 so it does not, or could not have accounted for developments in the law since then including: the *Brüstle* decision¹³⁰ and the developing unitary patent scheme. Having said this, Bakardijeva Engelbrekt's work was a useful initial starting point for thinking about the institutional system and its implications for patent law in this context, and it will be referred to in the analysis which follows.

b) Thambisetty

Thambisetty's recent work which was conducted and published parallel to this project,¹³¹ responded to similar concerns and hence resonates with the research themes explored here. Thambisetty also offers an institutional perspective on decision-making in the patent system, taking as her focus emerging technologies and specifically synthetic biology. However, she looks at the macro-level operation of institutional change within the patent system. In doing so, she analyses the institutional environment as characterised by its opacity, stickiness and messiness.¹³² Opacity according to Thambisetty has come about due to the existence of uncertainty in the quality of patents, in the property boundaries of individual patents, and uncertainty in the technical and commercial outlook of unprecedented technologies.¹³³ According to Thambisetty, this opacity leads to the development of epistemic communities within patent law and a hands-off approach from external policy makers who are reluctant to intervene in this realm.¹³⁴ Added to this, she notes that patent law is defined by its 'stickiness' which is described as the pattern of relying

¹³⁰ *Brüstle*, note 58.

¹³¹ S Thambisetty, 'The Analytical Significance of Emergence in the Patent System' (Nuffield Council for Bioethics 2012) <http://nuffieldbioethics.org/wp-content/uploads/2014/07/Emerging_biotechnologies_review_patent.pdf> accessed 16 July 2015;

Thambisetty, 'The learning needs of the patent system' note 81; Thambisetty, 'The Institutional Nature of the Patent System', note 126. She has also looked more generally at institutional aspects of the patent system comparing the UK and US systems, see S Thambisetty, 'Increasing Returns in the Patent System: Institutional Sources and Consequences for law' LSE Law, Society and Economy Working Papers 7/2009 <http://www.lse.ac.uk/collections/law/wps/wps2009-07_thambisetty.pdf> accessed 16 July 2015.

¹³² Set out in Thambisetty, 'The learning needs of the patent system' note 81; and in earlier forms in other works, including: Thambisetty, 'The Analytical Significance of Emergence in the Patent System', note 131.

¹³³ Thambisetty, 'The learning needs of the patent system', note 81, 17.

¹³⁴ Thambisetty, 'The Analytical Significance of Emergence in the Patent System', note 131, 8.

on early solutions within the patent system that foreclose the possibility of developing a later solution, and may lead to inefficiencies.¹³⁵ Essentially ‘stickiness’ is the staying power of legal doctrine within the system. She argues that this ‘stickiness’ is caused by “the density of institutional cluster and incomplete information”.¹³⁶ Finally, the messiness aspect which she refers to in more recent work describes the fragmented approach to patenting in the European system, or the “disaggregation of decision-making bodies and the fragmented results this can give rise to”¹³⁷ whereby she claims that “decisions in the patent system are made through and influenced by a complicated feedback loop between courts, patent offices and users”.¹³⁸

Thambisetty assesses how these macro-level features may impact and constrain decision-making in relation to the learning needs of the patent system, for instance in their application of terms such as “person skilled in the art” or determinations of inventive step or prior art.¹³⁹ She is particularly concerned with the way in which decision-making actors process complex information, looking at how actors operating in complex and opaque contexts become heavily biased in the way they “filter information into existing ‘mental maps’”.¹⁴⁰ In this context she cites Pierson who states that “confirming information tends to be incorporated and disconfirming information filtered out”.¹⁴¹ She argues that the learning needs such as ‘person skilled in the art’ or other mechanistic processes within the patent system drive legal change within patent law and that “in the absence of consensus on normative touchstones we can expect institutional features of the patent system to craft other, different, and for the large part unexpected, forms of legitimation”.¹⁴² In essence, her core message is that an understanding of institutional mechanics is vital in terms of substantive reform of the patent system, particularly in dispelling the assertion that the patent system will, if left to its own devices, find the most optimal standards for patentability or legal precepts for assessing patent eligibility.¹⁴³ Instead, she argues that

¹³⁵ Ibid 9.

¹³⁶ Ibid 9.

¹³⁷ Ibid 11.

¹³⁸ Ibid 12.

¹³⁹ Thambisetty, ‘The Analytical Significance of Emergence in the Patent System’, note 131, 13; See also, Thambisetty, ‘The learning needs of the patent system’, note 81.

¹⁴⁰ Thambisetty, ‘The Analytical Significance of Emergence in the Patent System’, note 131, 13.

¹⁴¹ Ibid, at 13, citing P Pierson, “Increasing Returns, Path Dependence and the Study of Politics” (2000) 94(2) American Political Science Review 251, 259.

¹⁴² Thambisetty, ‘The learning needs of the patent system’, note 81, 13.

¹⁴³ Ibid 39.

what is more likely is that decisions “made in response to learning needs expressed in opaque, sticky and institutionally complex patent systems lead to decisional outcomes that sacrifice substantive goals for short-term gains in certainty and homogeneity”.¹⁴⁴

This work and its institutional focus resonates with this thesis, however it can also be clearly distinguished from this research for three main reasons: Firstly, Thambisetty draws on differing theoretical aspects of institutional theories focusing particularly on epistemic communities and mental maps, whereas this thesis draws on political and sociological institutionalism and the work of MacCormick for insights into legal institutional theory, as will be highlighted in chapter two. Secondly, Thambisetty’s work does not focus specifically on the institutional structures within the EPOrg and EU, or intricacies involved in this multi-institutional framework. Instead, she looks broadly at the general operation of the patent system. She also frames her considerations in a differing manner using opacity, messiness and stickiness to examine how institutional frameworks affect decision-makers in devising patentability standards and mechanisms within the broader patent system. In contrast, this thesis develops a template which can be used to examine institutional influences on decision-makers operating specifically within the EU and the EPOrg, looking not at the macro-level patent system but at the actions of these specific decision-makers. Thirdly and most importantly, her work does not focus specifically on institutional influences on the application of the *morality* provisions. Instead, Thambisetty’s work focuses generally on decision-making in the patent system with particular reference to emerging technologies. Morality provisions are considered briefly as part of this discussion¹⁴⁵ in the context of bioethical policies in the patent system, but therein she again frames the considerations using her three-fold standard, which differs from the research conducted here.

Moreover, Thambisetty in fact confirms the gap which the thesis seeks to fill as she argues that “there is urgent need to evaluate bioethical decision-making infrastructure in the patent

¹⁴⁴ Ibid 39

¹⁴⁵ Thambisetty, ‘The Analytical Significance of Emergence in the Patent System’, note 131, 24-26, see discussion of “Bioethical policy and Learning Constraints” in the context of the patent system; Similarly, Thambisetty, ‘The learning needs of the patent system’, note 81.

Thambisetty’s earlier work examined the application of morality provisions in the patent system, however, this did not conduct an examination of the institutional influences in this context, see: S Thambisetty, ‘Understanding Morality as a Ground for Exclusion from Patentability under European Law’ (2002) 12 Eubious Journal of Asian and International Bioethics 48.

system”,¹⁴⁶ noting that “influential bodies like the European Parliament and national appellate courts could, given the right context, fulfil anticipated learning needs in the patent system in the context of ethically problematic inventions”.¹⁴⁷ These statements support the need for the research conducted in this thesis which focuses on the application of the morality provisions as these provisions arguably offer the most significant inlet for bioethical decision-making¹⁴⁸ within the patent system. In doing so, this thesis specifically seeks to address the institutional influences and indeed limitations which may arise in this context.

1.5 Conclusion: Original Contribution of the Research

It is hoped that the foregoing has demonstrated the scope, parameters and need for this research. Finally, it should be noted that the investigation which follows aims to make the following original contributions:

1. To use an institutionally framed analysis as a means to explain how the morality provisions are being applied by the decision-making bodies of the EPOrg and EU in the patent system.
2. To contribute to a deeper understanding of the institutional landscape and relationship between the EPOrg, EU and ECtHR, and the future UPCT, in the application of the morality provisions.
3. To highlight that another reason why the morality provisions have met with difficulty in their application, is because of the complex institutional influences on the decision-making bodies charged with their interpretation.
4. To highlight the potential difficulties which will arise in relation to the morality provisions when the unitary patent comes into force. The research also aims to suggest ways in which these institutional changes need not lead to more confusion and complexity as regards the application of the morality provisions.

¹⁴⁶ Thambisetty, ‘The Analytical Significance of Emergence in the Patent System’, note 131, 29.

¹⁴⁷ Ibid, 29.

¹⁴⁸ Thambisetty’s earlier work briefly looks bioethical decision-making but again applies her macro-level structure and can be distinguished from this work, see Thambisetty, ‘The Institutional Nature of the Patent System’, note 126.

5. To offer a useable template for the analysis of institutional influences on legal decision-making which is applied to the morality provisions in this context, but is transplantable to other areas of law.

Chapter Two: Theoretical Foundation: Institutional theories and Institutional influences on decision-making

2.1 Introduction

This chapter builds a theoretical framework for the examination of the institutional influences on the judicial/quasi-judicial decision-making bodies of the EPOrg/EU in their interpretation of the morality provisions. In doing so, it draws on relevant institutional theories looking for lessons that can be gleaned in relation to what factors affect decision-making. Institutional theories examine the way in which policies and decisions are structurally determined by institutions. ‘Institutions’ traditionally included state institutions e.g. legislature, executive, etc.,¹⁴⁹ but can also refer to embedded systems of rules, branches of law etc. The definition of ‘institution’ is expanded upon in section 2.2.1 below. Institutional theories broadly suggest that institutions - and to this I would add the specific institutional frameworks within which decision-making actors operate - constrain and influence decision-makers in deciding upon policy. These ideas resonate with the central hypothesis of this research and therefore offer a useful theoretical framework. Importantly, two types of influences will be identified in this context, namely: (1) prescriptive and constraining influences which act to *legally constrain* the scope of an adjudicative body’s actions in a particular context e.g., the legal competences of an adjudicative body; and (2) political/social influences on an adjudicative body in a particular institutional context - such influences, although not legally constraining, can be used to *predict* and explain the way which adjudicative bodies may act, particularly in relation to controversial issues.

Institutional theories often employ empirical methods to highlight the relevance of specific institutional factors in a particular context. However, this thesis does not seek to point to the causative effect of a particular institutional influence in the decision-making process. Therefore, rather than employ empirical methods to try to pinpoint how a particular influence may affect decision-making, it seeks to build a general picture of what is happening within the EU/EPOrg and the main strands of influence which will affect the CJEU and decision-making bodies in the EPO in interpreting the morality provisions. Thus,

¹⁴⁹ K Morrison, ‘Penal Transformation in Post-Devolution Scotland: Change and Resistance’ PhD Thesis Edinburgh (2012) 45.

this chapter sets out the relevant aspects of a number of institutional theories in order to piece together a picture of how institutional factors have been shown to influence decision-making generally. Drawing on these theories, it then builds a template of factors that can be used to examine decision-making influences in the legal context.

In terms of the structure of this chapter, Part one of the analysis commences by highlighting some caveats to the application of institutional theories and definitional factors which must be borne in mind. It also addresses some of the potential counter arguments to the hypothesis proposed, in particular, it concedes that other influences beyond those coming from within the EPORG/EU may be applicable. However, the contribution proposed is not to dismiss other influences or to track all influences on decision-making in this context. Rather, it seeks to highlight the main influences which arise due to the institutional frameworks in any decision-making framework and to highlight the significance of these in the 'European' patent system given the very distinct and overlapping frameworks offered in the EPORG and EU.

Part two then offers an overview of the institutional theories relevant to this research, and the inferences which can be drawn from these in relation to the characteristics of institutions which influence decision-making actors. Part three supplements these arguments by examining the work of Neil MacCormick in relation to legal institutions and the work of Clayton and May¹⁵⁰ in relation to judicial decision-making. Whilst, MacCormick's work indicates the main constraining and prescriptive influences on judicial/quasi-judicial actors; Clayton and May's work, on the other hand, offers significant insights into the likely social/political influences on adjudicative bodies. Therefore, understandings gleaned from these works complement each other, and provide important insights about the legal framework which can be incorporated into the template proposed. These theories also reinforce the claim that the nature of 'morality' renders decision-makers more susceptible to institutional influence.

Finally, part four - reflecting and building upon the theories outlined - sets out a template for mapping institutional influence. This template is then systematically applied to both the EPORG/EU in chapters three and four, respectively, to investigate the institutional pulls and

¹⁵⁰ Clayton and May, 'A Political Regimes Approach to the Analysis of Legal Decision', note 66.

predispositions of their respective judicial/quasi-judicial actors in the application of the morality provisions. This application highlights the differences in the institutional frameworks operating in the EPOrg/EU and in particular, the differing applicable constraining/prescriptive influences as per MacCormick's theory, but also the relevant social/political factors which may pull on the adjudicative bodies in each respective framework in a differing manner.

Importantly, the thesis goes beyond the claim that institutional frameworks influence the application of morality provisions. Instead it argues that such influences give rise to engrained institutional predispositions and that these cannot be changed through training of judicial/quasi-judicial actors, or by issuing guidance. Moreover, it argues that the prescriptive influences identified by MacCormick's theory - for example, the purpose of the underlying legal treaties – differ substantially in the EPOrg/EU contexts and this in turn provides distinct legal constraints on adjudicative actors operating within these respective institutional frameworks. Guidance or training may help to move these decision-makers in a particular way on a particular case, but there is no guarantee that this guidance/training will be assimilated within the institutional framework to be used in other contexts. Furthermore, in some contexts given the differing prescriptive legal constraints which may operate, the adjudicative actors may be legally unable to act in the same way. Instead, if the argument is borne out, institutional change may be difficult to achieve and will require fundamental changes to the institutional frameworks which would need to take place over an extended period of time. Thus, any change envisaged should take into account the differing institutional constraints/influences that operate. This point has significance for all normative proposals in relation to the application of the morality provisions, as it highlights that one must be mindful of both the change suggested and also how this may be interpreted within and across the institutional frameworks of the EPOrg/EU by the decision-making bodies in the EPO/CJEU, and indeed within the Unitary Patent Court ('UPCt') when this is established and operational. These points will be developed throughout the chapter and are revisited in chapters three and four in the context of the EPOrg and EU, respectively, and in chapter six in relation to the UPCt.

2.2 Caveats to applying an Institutional Approach

Prior to delving into the literature on institutional theories, and as noted, a number of caveats must be drawn.

2.2.1 Definition of 'institution'

Firstly, defining precisely what is meant by the term 'institution' in any given theory is often a complex task¹⁵¹ because a number of 'institutions' may be identified in any process depending on the level of decision-making and influences one wishes to investigate. Moreover, Weinberger argues that as institutions are so varied it is "...impossible to set down a unified class of attributes to define all of them..."¹⁵² and that "[T]here is... no commonly accepted view of what kinds of institutions exist, or what a typology of institutions ought to look like."¹⁵³ Despite this diversity, there has been discussion of the main shared characteristics of institutions. Ruiter claims there appears a "general agreement on a broad conception of institutions as systems of rules that provide frameworks for social action within larger rule-governed settings".¹⁵⁴ In the context of political and historical institutionalism, Amenta and Ramsey note that:

"Political and historical institutionalists see institutions as formal or informal procedures, routines, norms, and conventions in the organizational structure of the polity or the political economy, whereas sociological institutionalists add cognitive scripts, moral templates and symbol systems¹⁵⁵ that may reside at suprapstate or supraorganizational levels. These scholars break down the distinction between the institutional and cultural."¹⁵⁶

Defined in this way, institutions appear as formal procedures or norms in an organisational structure, and also as informal aspects such as aspects of culture *etc.* which may exist within

¹⁵¹J Bengoetxea, 'Institutions, Legal Theory and EC law' (1991) 67 *Archiv fur Rechts-und Sozaphilosophie* 195.

¹⁵²O Weinberger, *Law, Institution and Legal Politics. Fundamental Problems of Legal Theory and Social Philosophy*. (Kluwer Academic Publishers 1991) 155.

¹⁵³*Ibid* 158.

¹⁵⁴D Ruiter, 'A Basic Classification of Legal Institutions' (1997) 10(4) *Ratio Juris* 357, referring to E Ostrom, 'An Agenda for the Study of Institutions' (1986) 48 *Public Choice* 3-25 and D Ruiter, 'Economic and Legal Institutionalism: What Can They Learn from Each Other?' (1994) 1 *Constitutional Political Economy* 99-115.

¹⁵⁵P Hall and R Taylor, 'Political Science and the Three Institutionalisms.' (1996) 44 *Political Studies* 936, 938 and 947.

¹⁵⁶E Amenta and K Ramsey, 'Institutional Theory' in T. Leicht and J. Jenkins (eds.), *The Handbook of Politics: State and Civil Society in Global Perspective* (Springer 2010) 17.

broader society or even within formal organisations. This suggests a distinction between organisations and institutions. Indeed it should be acknowledged that there has been disagreement in some branches of institutional theory as to whether or not organisations which include universities, firms, political parties, or indeed international organisations - such as EU and EPOrg - are institutions *per se*. However, as this section demonstrates the distinction drawn in some theories is arguably not crucial for the purposes of this project. This is because even if we cannot describe the EU/EPOrg as ‘institutions’ under all theories examined, we can still say that the frameworks within the EU/EPOrg and so within which the CJEU/EPO operate, are comprised of differing ‘institutions’ providing a differing overall institutional framework in the CJEU and EPO within which the judicial/quasi-judicial actors operate. Therefore, this literature is still of relevance to the thesis and supports the hypothesis proposed. Reflecting on some of the literature relating to this distinction supports this approach.

In this vein, Douglas North is often attributed as arguing that institutions are not organisations.¹⁵⁷ He defines institutions as:

“Institutions are the rules of the game in society or, more formally, are the humanly devised constraints that shape human interaction. In consequence they structure incentives in human exchange, whether political, social, or economic... Conceptually, what must be clearly differentiated are the rules from the players. The purpose of the rules is to define the way the game is played. But the objective of the team within that set of rules is to win the game...”¹⁵⁸

His distinction between rules and players is often attributed as making a distinction between institutions as rules and organisations as players. However, Hodgson argues that North never actually states that organisations are not institutions *per se*. Instead, he suggests that North in his particular field defined organisations as players,¹⁵⁹ but that this characterisation of organisations was dependent on the particular context of North’s work and does not preclude organisations from being defined differently in other contexts should their

¹⁵⁷ G.M. Hodgson, ‘What are Institutions?’ (2006) 40(1) Journal of Institutional Economics 1, 8-9.

¹⁵⁸ D North, *Institutions, institutional change and economic performance* (CUP 1990) 3-5 as cited in Hodgson, ‘What are Institutions?’ note 157, 9.

¹⁵⁹ Hodgson, *Ibid* 9.

purposes and contours be different. Moreover, reflecting on North's definition of institutions, Hodgson argues that:

“Organizations involve structures or networks, and these cannot function without rules of communication, membership, or sovereignty. The unavoidable existence of rules within organizations means that, even by North's own definition, organizations must be regarded as a type of institution. Indeed, North has essentially accepted that organizations themselves have internal players and systems of rules, and hence by implication organizations are a special type of institution (letter to the author October 7, 2002).”¹⁶⁰

Hodgson proceeds to define ‘institutions’ as “socially embedded systems of rules” arguing that:

“Organizations are special institutions that involve (a) criteria to establish their boundaries and to distinguish their members from non-members, (b) principles of sovereignty concerning who is in charge, and (c) chains of command delineating responsibilities within the organization.”¹⁶¹

Similarly, Linarelli argues that organisations matter as they are institutions.¹⁶² He also minimises the significance of the distinction drawn in some branches of institutional theory between institutions and organisations arguing that: “Theory construction might be more a matter of emphasis than on strict demarcation based on logical differences in concepts like ‘organization’ and institution”.¹⁶³

This thesis adopts a similar approach and as noted, it argues that even though a formal organisation *per se* may not be perceived as a specific institution under a given theory, the general crux of these theories are still applicable. This is because, if an institution other than a formal organisation is the main site of investigation within a given theory, it is arguably merely taking a different level of analysis or emphasis as its starting point. In this context, the EPOrg or EU can be seen as the overarching amalgamations of different

¹⁶⁰ Ibid 9.

¹⁶¹ Ibid 8.

¹⁶² J Linarelli, ‘Organisations matter: they are institutions, afterall’ (2010) 6(1) Journal of Institutional Economics 83, 89.

¹⁶³ Ibid 89.

institutions (of the type described) which taken together form the overarching framework for decision-making. Under such a conception the primary argument remains the same, i.e., that the EPOrg or EU provide differing institutional frameworks for the decision-making actors situated within them, which offer embedded influences on the application of the morality provisions. In order to ensure clarity, the chapter will note differing conceptions of “institution” within the theoretical frameworks discussed where they arise.

2.2.2 Relevant ‘institutions’ in the patent system

Nonetheless, for the purposes of the ‘European’ patent system and the examination in this thesis, it is useful to reflect specifically on which ‘institutions’ within the patent system will be examined in subsequent chapters. In this context, the EPOrg and the EU are envisaged as the overarching institutions (or entities providing differing institutional frameworks, depending on the theoretical approach under investigation) for the application of the morality provisions. These two entities are seen as containing peculiar characteristics which affect and constrain the action, and importantly which influence the decisions of judicial/quasi-judicial actors within them charged with the application of the morality provisions. This classification of the EPOrg and EU as overarching institutions will be supported in this chapter by reference to other uses of the term ‘institution’ in the theories which are mapped below (particularly in MacCormick’s institutional theory of law).

Having said this, the idea that differing types of institutions can be defined depending on the level of influence one is examining, may be useful when examining institutional influences in the EPOrg and EU in chapters three and four, as will be seen, it allows the subdivision of this overarching framework into specific levels of influence to build a clearer picture of the institutional framework within which decision-making actors operate. For instance, looking from a top-down level at the overarching framework within the EPOrg and EU and how this may influence the judicial/quasi-judicial actors within the CJEU/EPO on the application of the morality provisions, is useful to assess the relevance of differing macro-level institutional factors, such as: the relationship between the EPOrg/EU and other international bodies, the differing goals/aims of these institutions, and the competences of such institutions in the area of morality more generally. In tracking lower level influences, it is useful to conceive of the CJEU/EPO as institutions of their own accord which would

allow one to look at factors such as; how the composition and expertise of agents sitting on such decision-making branches and the interpretative community they form, may influence the application of the morality provisions. Moreover, looking at the problem at a more general level, we can conceive of law itself as an institution, and map the potential influence of differing legislative texts within the EPO/CJEU framework on these decision-makers in their application of the morality provisions. These factors and this classification is supported by the examination of institutional theories conducted below.

In short, the existence of the various different types of institutions makes the task of examining the institutional literature on a theoretical level sometimes a complex one. However, it is useful on a practical level for the purposes of this research in order to capture and envisage differing levels of influences on decision-makers of the EPOrg and EU. Furthermore, for the purposes of this research, it is argued that it is not necessary to define precisely all possible meanings of the term ‘institution’ in law or within the patent system. The contribution claimed is not a contribution to legal theory nor is it one which seeks to add to the institutional theory of law *per se*. Instead, this research seeks to use institutional theories as a means to support the argument that the EPOrg and EU possessing differing competences, compositions, and characteristics, provide distinctive institutional frameworks for judicial/quasi-judicial decision-makers acting within these bodies. This in turn constrains and generates engrained preferences of decision-makers in favour of particular applications of the morality criteria in this context.

2.2.3 *Judicial independence*

A counterargument which could be levelled at this approach is that the decision-making bodies which this thesis focuses upon - being judicial or quasi-judicial entities - will not be affected by the institutional contexts given the independence associated with, and enshrined within, judicial/quasi-judicial entities. However, as will be discussed in chapter three, there are questions over the independence of the decision-making bodies in the EPO. More importantly, in the context of both frameworks the open-textured nature of the exclusionary provisions and the nature of morality itself, which requires some internal referential point to be decided upon poses challenges to this general principle. MacCormick’s institutional theory of law and also Clayton and May’s theories of judicial decision-making will be invoked in the sections that follow to support the proposition that institutional contexts may

affect judicial or quasi-judicial decision-makers especially when such open-textured provisions are in issue.

2.2.4 Accounting for other influences on decision-making

Finally, as noted, this research does not seek to offer a complete description of all of the influences on decision-making which may influence the application of the morality provisions. The influences in any system of decision-making are varied and complex. Rather, what this thesis seeks to do is to show that the position of decision-makers within the differing institutions of the EU/EPORG is one of the influences (and one which I argue plays a significant role) on the application of the morality provisions with the result that it is questionable whether a defensible approach to the application of these provisions is evident.

2.3 Overview of Institutional Theories

A number of differing branches of institutional analysis exist. Three of the main categories¹⁶⁴ are: sociological institutionalism, historical institutionalism and political institutional analysis.¹⁶⁵ However, even within these categories it should be noted that differences abound. This section aims to give a summary of the most relevant aspects of these theories in order to build a picture of institutional influences relevant for the examination proposed. This does not purport to be a comprehensive survey of all institutional theories, which is beyond the scope of the examination proposed.

2.3.1 Sociological, historical and political institutionalism

According to Amenta and Ramsey, the main principle in common with sociological, political and historical institutionalism is that “something identified at a higher level is used

¹⁶⁴ Amenta and Ramsey, ‘Institutional Theory’, note 156.

¹⁶⁵ Another branch is comparative institutional analysis, but due to its significant empirical component and differences between this branch and other branches of institutional theory this will not be examined in this work. See: R Coase, ‘The Problem of Social Cost’ (1960) 3 *Journal of Law and Economics* 1. For its use in the legal context, see: A Bakardjieva Engelbrekt, ‘The WTO Dispute Settlement System and the Evolution of International IP Law: An Institutional Perspective’ (November 30, 2009) <http://ssrn.com/abstract=1617885> accessed 16 July 2015; A Bakardjieva Engelbrekt, ‘Copyright from an Institutional Perspective: Actors, Interests, Stakes and the logic of Participation’ (2007) 4(2) *Review of Economic Research on Copyright Issues* 65; A Bakardjieva Engelbrekt, ‘Toward an Institutional Approach in Comparative Economic Law?’ in A Bakardjieva Engelbrekt and J Nergelius, *New Directions in Comparative Law* (Elgar, 2009).

to explain processes and outcomes at a lower level of analysis”.¹⁶⁶ In essence, overarching features or structures are used to suggest and explain the end outcomes of decision-making actors situated at lower levels. Overlaps occur amongst these three branches of institutional theory and they should not be viewed as mutually exclusive. Nonetheless, generally the main difference amongst these branches is the focus of the higher order determinants of each theory, and how much such determinants matter causally to the outcome of the decision.¹⁶⁷ In sociological institutionalism the focus tends to be on cultural and ideational causes which can influence at a supranational, state, or organisational level. In historical institutionalism the determinants focused on are those at a state or macro political level, and such approaches generally involve a historical analysis of policy/decision-making, looking at how the past has shaped current practice. Finally, in political institutionalism, the claims examined are again at a state or macro political level, whilst such theorists tend to argue that the “process of formation of states, political systems, and political party systems strongly influence political processes and outcomes”.¹⁶⁸ In short, each of the theories has a different origin, focus and function but they all look at how actions and decisions may be influenced by institutional factors and contexts. At this juncture, it is useful to examine each of these theories separately.

At the outset, it should be noted that these institutional theories generally offer indicators which are *predictive* of the influences that particular institutional contexts (or features of these) will have on decision-makers. These predictive factors contrast to the legally constraining influences which can be gleaned from McCormick’s work – such as the competences of an adjudicative body, or the purpose of relevant Conventions/Directives. As noted, these predictive factors are relevant as these must be considered alongside prescriptive factors to glean a clearer view of the likely behaviour of adjudicative actors in a given institutional framework. Moreover, any instances of prescriptive influences identified by the theories discussed will be highlighted where relevant.

¹⁶⁶ Amenta and Ramsey, ‘Institutional Theory’, note 156, who cite E Clemens, and J Cook, ‘Politics and Institutionalism: Explaining Durability and Change’ (1999) 25 Annual Review of Sociology 441-445; E Amenta, N Caren and SJ Olasky, ‘Age for Leisure? Political Mediation and the Impact of the Pension Movement on U.S. Old-Age Policy’ (2005) 70 American Sociological Review 516-538.

¹⁶⁷ Amenta and Ramsey, ‘Institutional Theory’, note 156, 2.

¹⁶⁸ Ibid.

a) Sociological institutionalism

Proponents of sociological institutionalism when studying policy adoption/implementation tend to examine attempts at the legitimation of political organisations by examining instances of policy diffusion and imitation by other organisations, and noting convergences in institutions and policies¹⁶⁹ across and between organisations. Sociological institutional theorists use the term ‘institution’ differently from other branches of institutional theory, emphasising “the social and cognitive features of institutions rather than structural and constraining features”.¹⁷⁰ Therefore, such theorists differ from the others examined, as the cultural norms are perceived of as institutions whilst organisations are seen as actors. According to Strang and Chang, their use of the term ‘institution’ makes “institutionalism” a misnomer as “the institutions of concern are the codified cultural constructions, not the organizations that mirror them”.¹⁷¹ Nonetheless, applying the caveats noted above in terms of definitional questions surrounding the term ‘institution’, this work is of relevance for the purposes of this thesis, as it highlights how bodies such as the EU/EPORG, which are understood as ‘organisations’ in this branch of theory can influence each other’s actions.

Amenta and Ramsey comment that a typical research product in sociological institutional theory would be “a cross-national time series or event history analysis of policy diffusion or convergence”¹⁷² amongst organisations. Thus, the main source of interest in this branch, is how/why different organisations come to imitate or emulate policies or structures of other organisations over time. Sociological institutionalism suggests that this is due to the presence of cultural institutions common to political actors.¹⁷³

This branch of institutionalism originated in the 1970s in Stanford, where a number of academics explored the relationship between organisational structures and culture.¹⁷⁴ These theorists began to challenge the orthodox position that organisations being formal, rational

¹⁶⁹ Ibid.

¹⁷⁰ M Finnermore, ‘Norms, culture, and world politics: insights from sociology’s institutionalism’ (1996) 50(2) *International Organization* 325, 326.

¹⁷¹ D Strang. and P Chang, ‘The International Labor Organization and the Welfare State: Institutional Effects on National Welfare Spending, 1960–1980.’ (1993) 47 *International Organization* 235, 237 cited in Amenta and Ramsey, ‘Institutional Theory’, note 156, 18.

¹⁷² Amenta and Ramsey, ‘Institutional Theory’, note 156, 4.

¹⁷³ Hall and Taylor., ‘Political Science and the Three Institutionalisms’ note 155, cited in Amenta and Ramsey, ‘Institutional Theory’, note 156, 18

¹⁷⁴ Finnermore, ‘Norms, culture, and world politics’ note 170, 328 citing W Powell, and P DiMaggio, *The new institutionalism in organisational analysis* (University of Chicago Press 1991).

structures were not influenced by culture.¹⁷⁵ For instance, Meyer working with others conducted a series of cross-national studies investigating political and economic change which highlighted that the world was becoming bureaucratised faster than it was developing economically.¹⁷⁶ This work highlighted that organisations in the developing world were coming to resemble organisations in the developed world. However, it was argued that organisations spread not necessarily because they were functionally the most efficient structures to achieve the aims sought, but rather they were driven by the fact that organisations are externally legitimated,¹⁷⁷ and the values that legitimated them were cultural ones. This in turn legitimated some structures, and indeed some organisational forms¹⁷⁸ leading to their proliferation.

Sociological institutionalism has developed over time but a central focus has remained in relation to how culture operates as an external legitimising factor in the convergence of policies/decisions. In examining this, the focus of theorists has been at a macro-level often looking at State interactions. For instance, Boli examines national constitutions in a number of different countries arguing that they reflect the central ideologies of other constitutions rather than the local conditions in specific States.¹⁷⁹ Thus, again they are not necessarily driven by functional efficiency or the needs of a particular nation.

A particularly relevant work within sociological institutionalism for the purposes of this thesis is Powell and DiMaggio's "The Iron Cage Revisited"¹⁸⁰ where the authors look at homogeneity across organisations and seek to explain this.¹⁸¹ They argue that initially organisations are diverse, but as a field develops there is a push towards homogenisation.¹⁸² They highlight examples of this: such as Coser, Kadushin and Powell who examined the American book publishing industry for college text books, where initially there was much

¹⁷⁵ Finnermore, Ibid 329.

¹⁷⁶ Ibid, 329 citing J Meyer, and T Hannan, *National development and the world system: Educational, economic and political change 1950-1970* (Chicago University Press 1979)

¹⁷⁷ Ibid 329, citing J Meyer and B Rowan, 'Institutionalised Organisations: Formal structure as myth and ceremony' (1977) 83 *American Journal of Sociology* 340-363.

¹⁷⁸ Ibid 329

¹⁷⁹ John Boli, 'Human rights or state expansion? Cross-national definitions of constitutional rights' in Thomas et al (eds.) *Institutional structure: Constituting state, society and the individual* (Sage Publications 1987) 1870-1970 as cited in Finnermore, Ibid, 335.

¹⁸⁰ P DiMaggio and W Powell, 'The Iron Cage Revisited :Institutional Isomorphism and Collective Rationality in Organizational Fields' (1983) 48(2) *American Sociological Review* 147-160

¹⁸¹ Ibid 148.

¹⁸² Ibid 148.

diversity, but eventually this funnelled down to two main approaches.¹⁸³ However, the authors contend this will only happen if organisations are structured within the same field. This structuring occurs by way of four processes:

“...an increase in the extent of interaction among organisations in the field; the emergence of sharply defined inter-organisational structures of domination and patterns of collation; an increase in information load which organisations in the field must contend with; and the development of mutual awareness among participants in a set of organisations that they are involved in a common enterprise.”¹⁸⁴

The EPOrg and EU arguably fit within this definition in their roles as decision-making actors in the application of the morality provisions. In this context, there has been increasing interaction between the EPOrg and EU since the adoption of the Biotech Directive. There are a number of inter-organisational (or inter-institutional depending on the focus one is taking) links, as discussed in chapter one, and in light of these links between these bodies as we have seen, there appears to be awareness of their common enterprise albeit in this specific context. Applying this to the morality provisions, they may be predicted to have mutual awareness of their overlapping functions and seek to mirror each other’s application of these provisions where possible, despite the lack of formal legal constraints on them to do so – indeed this is demonstrated by the fact that even though the EU is not party to the EPC, and similarly the EPC States have not all signed the Biotechnology Directive, however, this Directive has been adopted as supplementary interpretation to the EPC.

Powell and DiMaggio discuss institutional isomorphism which reflects the homogenisation that can occur across and between organisations, and which is relevant in this context. The authors draw on Hawley’s description of isomorphism which they describe as “a constraining process which forces one unit in a population to resemble other units that face the same set of environmental constraints”.¹⁸⁵ They argue that organisations are competing

¹⁸³ Ibid 148 citing L Coser, C Kadushin, and W Powell, *Books: The Culture and Commerce of Publishing* (Basic Books 1982).

¹⁸⁴ DiMaggio and Powell, Ibid 148 citing P DiMaggio, ‘The Structure organizational: an analytical approach and policy implications’ Paper prepared for SUNY-Albany Conference on Organizational Theory and Public Policy, April 1 and 2 (1982).

¹⁸⁵ Ibid 149.

not just for “resources and customers but for political power and institutional legitimacy, for social as well as economic fitness”.¹⁸⁶The authors argue that three types of isomorphism may occur, namely:

“(1) coercive isomorphism that stems from political influence and the problem of legitimacy; (2) mimetic isomorphism resulting from standard responses to uncertainty; (3) normative isomorphism associated with professionalization”.¹⁸⁷

Coercive isomorphism results from pressure exerted on an organisation from other external organisations in which the organisation in question depends. It can also be attributed to the cultural expectations of the organisation within broader society.¹⁸⁸ Powell and DiMaggio give examples such as: companies adopting pollution control technologies in the manufacture process in order to comply with government directions.¹⁸⁹ This aspect is interesting as arguably, due to the EPO’s role as patent granting body for all EPORG States in relation to ‘European’ patents, including EU countries, it will be coerced into adopting EU policies in the application of the morality provisions at the legislative level, as to do otherwise, would jeopardise its role in this context. This is supported by Powell and DiMaggio’s discussion of mimetic isomorphism which they argue arises from uncertainty whereby “when the goals are ambiguous or when the environment creates symbolic uncertainty, organizations may model themselves on other organizations”.¹⁹⁰ This feature is particularly acute in the context of the morality provisions, where the development of emerging biotechnologies and their reception by the public is an uncertain one. This supports the idea that, at least at a legislative level, the EPORG may try to mirror the EU’s action in the field of biotech patents, especially in relation to the application of the four specific exclusions from patentability brought into the patent system by the EU, and around which definitional questions abound.

¹⁸⁶ Ibid 150.

¹⁸⁷ Ibid 150.

¹⁸⁸ Ibid 150.

¹⁸⁹ Ibid 151, referring to Milofsky’s work on neighbourhood organisations; C Milofsky, ‘Structure and Process in community self-help organizations’ (1981) New Haven: Yale Program on Non Profit Organizations, Working Paper 17.

¹⁹⁰ Ibid 151.

Finally, normative isomorphism according to the author stems from professionalisation of an area whereby organisations within a field become composed of groups of professionals which:

“...create a pool of almost interchangeable individuals who occupy similar positions across a range of organisations and possess a similarity of orientation and disposition that may override variations in tradition and control that may otherwise shape organizations”.¹⁹¹

This is a telling point, as whilst the EU and EPOrg may relate to each other in the context of the application of the morality provisions at a legislative level, a broader look at their functions highlights that given their differing general functions, the decision-making bodies in the EPO and CJEU, are composed of a very different set of professionals, with different legally constraining features in each adjudicative body, e.g. differing competences, guiding interpretative principles etc. The EPO functions are solely in relation to patenting, and it is composed exclusively of patent professionals, who as will be argued and as these theories support may have a pre-disposition toward the grant as opposed to the refusal of a patent. In short, this thesis will argue that the EPO is both *legally constrained* by factors such as its lack of legal competences to deal with issues outside of patent law; and can also be *predicted* in light of the peculiar composition of its adjudicative bodies and the political/social influences acting on this body to favour a light touch application of exclusionary provisions such as the morality provisions. On the other hand, the CJEU is a vastly different entity, which deals with a variety of EU law disputes and is composed of generalist legal judges. Therefore a tension may arise as the CJEU and EPO will have differing institutional dispositions, including differing legal constraints acting upon them, in their application of the morality provisions. Moreover, this could not be rectified by changing personnel at the decision-making level in order to achieve convergence. This is because given the open-textured nature of the morality provisions, as noted, other engrained institutional factors will influence decision-makers in their application of these provisions. Thus, whilst isomorphism arguably operates at the legislative level in this context between the EPOrg and EU, it may not penetrate the internal operations of the decision-making institutions in all contexts.

¹⁹¹ C Perrow, ‘Is business really changing?’ (1974) *Organizational Dynamics* 31-44 as cited in DiMaggio and Powell, *Ibid* 152.

In short, sociological institutionalism is relevant in the thesis, when applied to explain convergence at a legislative level and inter-institutional influences between the EPOrg and EU on the application of the morality provisions. It is also relevant in looking to the inter-institutional influence of the ECtHR on these institutions in this context, which is examined in chapter five. This branch of theory highlights that it is not just internal forces within the EU and EPOrg which determine the application of the morality provisions, but that institutional forces exerted across these institutions may also cause convergence of the type we have seen. Notwithstanding this, as alluded to above, this thesis argues that the decision-making entities within the sub-institutions of the EPO and CJEU are constrained heavily in their actual interpretation/application of the morality provisions by their differing engrained internal institutional characteristics, including prescriptive influences such as their differing competences, jurisdictions, path dependencies etc. and also the differing social/political influences upon on these bodies which although not legally constraining may nonetheless, predict that they may adopt differing behaviours. As a result, although convergence may be desired and aimed for, internally the decision-makers may remain bound to their micro-institutional frameworks. This means that, even if directions are given at a macro-level in the EU/EPOrg context given the institutional make up and framework provided within the sub-institutions of the CJEU/EPO, differing influences may be exerted from within these contexts which will be likely to have a more immediate effect in binding the judicial/quasi-judicial actors charged with the interpretation of the morality provisions.

This may change in instances where there is a public outcry or controversy or where there is uncertainty in the approach the EU may take. In such cases, in order to maintain harmony, mimetic isomorphism highlighted above may arise as institutions seek to ensure “legitimation” of their action i.e. that these actions will be accepted by the community which they serve – this point is examined further below in the discussion of Clayton and May’s work in this area. In the context of the morality provisions, the EPO may strive to interpret the provisions as it feels the EU would in light of the fact that it is granting body for EU countries under the classical EP and for participating countries under the planned unitary patent scheme. However, in doing so in light of its differing institutional goals and experiences, it may fail to appreciate the subtle nuances of analysis necessary - or may simply be unable to give credence to these factors given the differing constraints on it in

comparison to the CJEU- for instance, in the consideration of human rights which have been suggested to fall part of the morality considerations in recent case law by the EU.¹⁹²

In such cases, a superficial “legitimation”¹⁹³ of the kind Powell and DiMaggio describe may be achieved, as the ‘right’ decision is generated or at least the decision which the EPO feels the CJEU would give is generated. However, it is argued that the internal coherence of the EPO’s decision-making processes in this context may come under question, as arguably the EPO is not equipped to apply the morality provisions in the same manner as the CJEU would apply these, particularly if considerations beyond the general scope of EPO’s action such as human rights are required, this point is discussed in chapters three and four.

b) Historical institutionalism

Historical institutionalism is a very diverse field, and authors within this field share less in common with each other¹⁹⁴ than for instance those within sociological or political institutionalism. Nonetheless, a number of general points of commonality can be gleaned. Institutions within historical institutionalism are generally conceived of as formal rules or organisations,¹⁹⁵ although they may also be informal rules and norms, and these are assessed to see how they influence behaviour or adoption of policy etc.¹⁹⁶ Moreover, the structure of political institutions is seen as particularly relevant. Generally, such theories may call for “historical research to trace the processes behind the creation and persistence of institutions and policies.”¹⁹⁷

Some types of historical institutionalism employ a clear distinction between institutions and organisations, whereby institutions are seen as rules of the game, such as legislation etc. One of the main authors within the field of historical institutionalism is Douglas North

¹⁹² Brüstle, note 58.

¹⁹³ At the initial stages of the thesis, it was discussed whether the focus of enquiry in the thesis would be centred around ‘legitimacy’. However, given the specific understanding of legitimacy within EU law, it was decided against focusing on this as this research seeks to investigate institutional influences in a much broader sense.

¹⁹⁴ Amenta and Ramsey, ‘Institutional Theory’, note 156, 16.

¹⁹⁵ W Streeck and K Thelen, (eds.) *Beyond Continuity: Institutional Change in Advanced Political Economies* (OUP 2005).

¹⁹⁶ S Steinmo, ‘What is Historical Institutionalism?’ in D Della Porta and M Keating (eds) *Approaches in the Social Sciences*, (CUP 2008) 159 < <http://spot.colorado.edu/~steinmo/HI.pdf> > accessed 16 July 2015.

¹⁹⁷ Amenta and Ramsey, ‘Institutional Theory’, note 156, 16.

referred to above, who, as noted, is sometimes suggested as holding a distinction between institutions and organisations. As discussed, this is a point which has been contested. Interestingly, North argues that:

“The organizations that come into existence will reflect the opportunities provided by the institutional matrix. That is, if the institutional framework rewards piracy then piratical organisations will come into existence, and if the institutional framework rewards productive activities then organisation – firms – will come into existence and engage in productive activities.”¹⁹⁸

He also claims that:

“The specific institutional constraints dictate the margins at which organisations operate and hence make intelligible the interplay between the rules of the game and the behaviour of actors. If organizations – firms, trade unions, farm groups, political parties, and congressional committees to name a few – devote their efforts to unproductive activity the institutional constraints have provided the structure for such activity.”¹⁹⁹

Historical institutional theory often inspires empirical studies which try to assess whether *institutions matter* within particular contexts.²⁰⁰ It aims to explain “how the past influences the present and the future, the way incremental institutional change affects the choice set at a moment of time and the nature of path dependence”.²⁰¹ For the purposes of illustration, it is useful to consider some examples of studies employing historical institutionalism, for instance: Immergut²⁰² used this approach to assess why some countries develop comprehensive national health care systems while others have decentralized and fragmented insurance programs. She analysed the political histories of several European countries and noted that each country’s political institutions differed in that they offered different interest groups veto points which had to be negotiated. She also observed that

¹⁹⁸ D North, ‘Economic Performance Through Time’ (1994) 84 *The American Economic Review* 359, 361 as cited by Bakardjieva Engelbrekt, ‘Copyright from an Institutional Perspective’, note 165, 70-71.

¹⁹⁹ D North, *Institutions, Institutional Change and Economic Performance* (CUP 1990) 110.

²⁰⁰ M Prado and M Trebilcock, ‘Path Dependence, Development and the Dynamics of Institutional Reform’ (2009) 59 *University of Toronto Law Journal* 341.

²⁰¹ Bakardjieva Engelbrekt, ‘Copyright from an Institutional Perspective’, note 165, 70.

²⁰² E Immergut, *Health Politics Interests and Institutions in Western Europe* (CUP 1992).

different institutions structured the menu of choices available. According to Steinmo, Immergut found that:

“...she could not explain the variation in policy outcomes without explaining the ways in which national political institutions structured both who participated in health insurance policies and the ‘rules of the game’ in which they participated”.²⁰³

Another example is Steinmo’s²⁰⁴ investigation of why particular countries have larger welfare states than others. Using detailed historical analysis of the welfare state in each country and also the development of national revenue systems, he concluded that “...the very different political institutions through which public and elite preferences were translated into policy had enormous effects on the structure of actual tax policy outcomes”.²⁰⁵ Interestingly, writing elsewhere, in the political context, Thelen and Steinmo stress “the way institutions shape the goals political actors pursue and the way institutions structure the power relations among them, privileging some and putting others at a disadvantage”²⁰⁶ which dovetails with the arguments proposed in this thesis.

Although, historical institutional approaches often employ a detailed empirical component²⁰⁷ as stated above, this is not feasible or necessary for the purposes of this thesis. Instead, the general theoretical basis of this theory, that the structural composition of institutions and the historical development of institutions or of decisions taken by such institutions in influencing behaviours and outcomes is relevant. This highlights the role of past actions or path dependencies of the EPOrg and EU, and their sub-institutions in applying the morality provisions within the ‘European’ patent system and will be incorporated in the template outlined at 2.6 below.

²⁰³ Steinmo, ‘What is Historical Institutionalism?’ note 196, 160.

²⁰⁴ S Steinmo, *Taxation and Democracy: Swedish, British and American Approaches to Financing the Modern State* (Yale University Press 1993).

²⁰⁵ Steinmo, ‘What is Historical Institutionalism?’ note 196, 161-162.

²⁰⁶ K Thelen, and S Steinmo, ‘Institutionalism in comparative politics’, in K Thelen, S Steinmo and F Longstreth, (eds), *Structuring Politics – Historical institutionalism in comparative analysis* (CUP 1992) 2.

²⁰⁷ An interesting analysis which does not seem to employ an empirical element is A Stack, *International Patent Law: Cooperation, Harmonisation an Institutional Analysis of the WIPO and the WTO* (Edward Elgar 2011).

c) Political Institutionalism

Political institutionalism, broadly speaking, focuses on long standing institutional differences amongst countries and generally posits that “national level political institutions mediate the influence of domestic organised political actors and global processes”.²⁰⁸ Within such theory, ‘old institutionalism’ has a narrower focus looking specifically at how state structures influence political decisions. On the other hand, ‘new institutionalism’ displays a broader understanding of institutions tending to argue that not only do formal apparatuses of government and structures within these shape behaviour but also that norms and conventions of behaviour, values and ideologies similarly shape and constrain action.²⁰⁹ A number of types of political institutionalism can be identified;²¹⁰ an overview of each type is beyond the scope of this work. Instead, this section focuses on the work of March and Olsen, as this raises points of relevance for the research conducted.

i. New Institutionalism: March and Olsen

March and Olsen argue that institutions provide the basic logic of action for political behaviour²¹¹ and claim that it is only by decoding this logic that one can understand how political dynamics shape policies. March and Olsen’s conception of new institutionalism is particularly relevant as within it they argue that institutions – by this they mean and focus on traditional political institutions such as the legislature, the legal system, the state and other economic institutions such as the firm²¹² - are actors in their own right rather than being merely a shell to influence behaviour.²¹³

They argue that this focus on ‘institutions’ as actors stems from the reality that the major actors in contemporary modern society are formal organisations and institutions of law and bureaucracy which occupy a “dominant role in contemporary life”.²¹⁴ March and Olsen

²⁰⁸ Amenta and Ramsey, ‘Institutional Theory’, note 156, 16.

²⁰⁹ Morrison, ‘Penal Transformation’, note 149, 41-42

²¹⁰ G Peters, *Institutional Theory in Political Science. The New Institutionalism* (2nd Edition) (Continuum 2005) 19-20.

²¹¹ J March and J Olsen, ‘Elaborating the ‘New Institutionalism’’, in R Rhodes, S Binder, and B Rockman, (eds), *The Oxford Handbook of Political Institutions* (OUP 2006) 7.

²¹² J March and J Olsen, ‘The New Institutionalism: Organizational Factors in Political Life’ (1984) 78(3) *The American Political Science Review* 734, 734.

²¹³ Morrison, ‘Penal Transformation’, note 149, 46 commenting on March and Olsen’s work.

²¹⁴ March and Olsen, ‘The New Institutionalism: Organizational Factors in Political Life’, note 212, 734.

argue that new institutionalism seeks to emphasise a more autonomous role for political actors but in doing so does not deny the importance of the social context of politics or the motives of individual actors. Interestingly for the purposes of this research, they note that:

“Political democracy depends not only on economic and social conditions but also on the design of political institutions. The bureaucratic agency, the legislative committee, and the appellate court *are arenas for contending social forces, but they are also collections of standard operating procedures and structures that define and defend interests.* They are political actors in their own right.”²¹⁵[Emphasis added]

In this vein, March and Olsen have argued that while such political actors are influential agents in shaping legislation, the behaviour of political actors is often directed by the contours of their institutional surroundings as institutions “are constitutive rules and practices prescribing appropriate behaviour for specific actors in specific situations”.²¹⁶ Thus, internal rules of operation or structural elements within decision-making bodies may impact upon the outcomes of decision-making.

Similar arguments can be made in relation to decision-makers situated in the CJEU or Boards of the EPO, as these organisations/institutions may be seen as offering a particular structure and parameters of action within which decision-making in the “European” patent system operates. This may be particularly influential in cases where issues for consideration fall outside prescribed circumstances of legislation and which decision-makers are vested with discretion, of which the morality provisions are a prime example. In such instances, the legislation or rules surrounding a particular legal provision offers little guidance and arguably decision-makers will seek to ensure their decisions comply with any constraints on their behaviour by looking to the characteristics of the institution which are known to them, such as the purpose, aims or previous actions of the institution.

This situation is further compounded in the context of the morality provisions because therein decision-makers are left entirely to their own devices in assessing the nature of

²¹⁵ Ibid 738.

²¹⁶ March and Olsen, ‘Elaborating the ‘New Institutionalism’, note 211, 3-8.

morality as no overarching principles or ethical framework currently exists. As will be discussed in chapters three and four, the human rights framework which underlies the Biotech Directive, arguably provides such background guidance in the EU context. However, the extent to which the same can be said of the EPO is questionable. Furthermore, as highlighted in chapter one morality is a difficult determinant. Individuals faced with a moral question may need to self-reflect and internalise a situation in order to make a decision. However, decision-makers rather than reflecting upon individual preferences or beliefs, instead will arguably consider the question by reflecting upon the institutional context they are situated in to ensure that they conform to legal constraints and other institutional influences on behaviour, in order to deliver what they perceive as a 'legitimate' decision. This in turn will result in a decision which is constrained by the individual characteristics of the institution in which the decision-maker is situated i.e. constrained by the overarching institutional framework of the EPOrg or the EU.

March and Olsen's comments resonate with MacCormick's institutional theory of law, discussed below, which posits that understanding the function of an institution is integral to understanding its influence on decision-making. In the patent system the very different functions of the EPOrg and the EU suggest different influences for decision-makers situated within these bodies. As will be argued in chapter three given the EPOrg's specialised function in the patenting field, and the common perception within this field that more patenting leads to greater innovation or market success,²¹⁷ then arguably the EPOrg may become blinkered to other considerations. Indeed, in many cases it will not have the legal competence to consider issues external to patenting. Moreover, if decisions on the morality of patenting are made in an environment where patents are perceived generally as 'good' such as in the EPO context a light-touch application of these provisions can be predicted. On the other hand, as the EU operates within the broader framework of European law, its goal can be seen as promoting the internal market and not solely patents. It also has broader legal competences than the EPOrg has, and has developed legal principles/tools to allow it to fulfil such competences in a way which is aimed at carefully balancing Member State sovereignty. Therefore, the EU offers a much broader legal framework and vantage

²¹⁷ This may be inferred if one looks to the reasons behind the adoption of the Biotechnology Directive. One of the primary reasons for its adoption was the belief that the uncertain patentability standards in Europe for biotechnological inventions could lead to biotechnological industry lagging behind that of Japan and US. See, Porter, 'The Drafting History of the European Biotechnology Directive', note 14, 6-10.

point for decision-makers to consider the moral implications of patents on biotechnological inventions than exists in the EPOrg framework.

Furthermore, as alluded to above, it is arguable that with the development of the Lisbon Treaty, the incorporation of the Fundamental Charter and the planned accession of the EU to the European Convention on Human Rights, the EU could be said to be broadening its functions to incorporate broader human rights concerns. These concerns are evident in the CJEU's more recent decisions on the morality provisions. These arguments are explored in further detail in chapters four and five.

Nonetheless, at this juncture, it can be noted that this potentially accounts for the reasoning in *Brüstle*²¹⁸ which placed particular emphasis on human dignity as a rationale for denying patentability to inventions involving hESCs and derivative products. Dignity is referred to twice²¹⁹ in the Biotechnology Directive, where no references are made to it in the EPC, the main governing legislation for the EPOrg. Furthermore, prior to this decision in *Brüstle*, 'dignity' had not been used by the Boards of the EPO in any cases relating to the general morality provision to deny a patent on the grounds of the morality provisions.²²⁰ This is despite the fact that the EPOrg voluntarily decided to adopt the Biotech Directive as supplementary interpretation for its provisions in this context.

Interestingly, in the earlier EPO decision in *WARF*²²¹ which like *Brüstle* related to the specific exclusion of 'uses of embryos for industrial and commercial purposes', the Board noted that the protection of human dignity was a rationale behind the Biotech Directive, but aside from this reference, there was little by way of a discussion of dignity or what this meant in the EPO context. Moreover, nowhere in the decision did the EPO independently cite the need to protect human dignity or refer to this as being a crucial element of the

²¹⁸ *Brüstle*, note 58.

²¹⁹ Recital 16 of the Preamble states that 'Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person...'; Recital 38 states 'Whereas the operative part of this Directive should also include an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to ordre public and morality; whereas this list obviously cannot presume to be exhaustive; whereas processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability...'.
²²⁰ Dignity was briefly alluded to in *Howard Florey/Relaxin* [1995] EPOR 541, but in that case the argument was dismissed and the patent was upheld.

²²¹ *WARF*, note 54.

morality provisions. Instead, it refers to this being a foundational aspect of the EU's Biotech Directive. In the recent decision of the EPO in Case T0149/11 of 24.11.2013, the EPO referred to the fact that 'ordre public' is underpinned by fundamental rights and freedoms as codified in the ECHR.²²² This is at least suggestive of inter-institutional influence and also institutional isomorphism between the decision-making bodies seeking to mimic action. However, the reasoning in this EPO decision can be questioned, and although this is only one decision, it suggests a lack of interpretative tools within the EPO context to grapple with human rights issues. This point and these cases are examined further in chapter three.

d) Interim Reflection on Institutional Theories and the Morality Provisions

In an apt statement for the purposes of this work, Immergut noted that:

“...institutions – be they the formal rules of political arenas, channels of communications, language codes, or the logic of strategic situations – act as filters that selectively favour particular interpretations either of the goals toward which political actors strive or of the best means to achieve these ends”.²²³

This statement and the idea of institutions as filters, reinforces the relevance of institutional theories for this thesis. It lends credence to the argument that if we take the judicial/quasi-judicial bodies of the EPOrg/EU as the focus of research, and view them as composed of differing amalgamations of institutional structures/characteristics - examined in chapters three and four respectively - this will arguably give rise to differing institutional pulls on decision-makers which in turn explain and allow us to predict how the morality provisions will be shaped in these contexts.

2.4 Institutional Theory of Law

Alongside the institutional theories outlined above, also of relevance to support the hypothesis claimed is the institutional theory of law espoused by writers such as Neil

²²² Case T0149/11 of 24 January 2013: Method and device for processing a slaughtered animal or part thereof in a slaughterhouse < <http://www.epo.org/law-practice/case-law-appeals/pdf/t110149eu1.pdf> > accessed 16 July 2015, para 2.5.

²²³ E Immergut, 'The Theoretical Core of new Institutionalism' (1998) 26(1) Politics and Society 5, 20.

MacCormick.²²⁴ The section gives an overview of MacCormick’s theory, highlighting how aspects of this work support the hypothesis proposed and inform the examination of the decision-making process for the application of the morality provisions.

2.4.1 Neil MacCormick’s Institutional theory of law

MacCormick’s institutional theory of law emanates from his 1973 inaugural lecture “Law as Institutional Fact,”²²⁵ the most recent expression of which is contained in his work entitled “Institutions of Law: An Essay in Legal Theory”.²²⁶ In essence, MacCormick perceived the human world as being composed of physical facts and also institutional facts. Institutional facts, he defines as “facts that depend on the interpretation of things, events, and pieces of behaviour by reference to some normative framework.”²²⁷ To illustrate this he gives three examples, namely: of a coloured plastic with curious marks which one can hold in one’s hand being a credit card, a disc attached to a clear strap behind which there are visible marks evenly distributed around the perimeter of a white surface which is a watch, and finally, discs in one’s pocket with an effigy of a human face on one side which are different in size, colour and marking they bear, but which are coins.²²⁸ In each case, the exact meaning of the object cannot be gleaned by mere physical facts, instead attached to each object is a body of legal or other rules without which the physical object would lose its current meaning. These details are the institutional facts which MacCormick describes as “omnipresent and inherent elements of social reality.”²²⁹

The idea of institutional facts, according to MacCormick links with the view that important elements of law in the contemporary state, are formed by ‘institutions’ such as contract, property, marriage, trust, foundation and the like. Interestingly, for the purpose of this research, MacCormick notes that the idea of institutional facts also connects with the notion “that law is institutional in the sense of being administered through ‘institutions’ such as courts, legislatures, public prosecution agencies, police forces and the like.”²³⁰ Thus,

²²⁴ See, MacCormick, *Institutions of Law*, note 99; N MacCormick and O Weinberger, ‘An Institutional Theory of Law. New Approaches to Legal Positivism’ (D. Reidel Publishing Company 1986); O Weinberger, *Law, Institution and Legal Politics. Fundamental Problems of Legal Theory and Social Philosophy* (Kluwer Academic Publishers 1991).

²²⁵ MacCormick, *Institutions of Law*, note 99, Preface.

²²⁶ Ibid.

²²⁷ Ibid 11.

²²⁸ Ibid 11.

²²⁹ Ibid 12.

²³⁰ Ibid 12.

institutions could be described as vehicles through which institutional facts or in the context of law the underlying legal rules and practices are considered and applied. This reinforces claims from the institutional theories examined above which highlights the role of institutions as filters for decision-making.

This understanding is supported by MacCormick's expansion in his recent work on the different conceptions of 'institutions' adopted by lawyers which highlights his pluralistic understanding²³¹ of the term. He noted that, firstly, the term 'institution' is used to refer to legislatures, courts, cabinets and government departments, police forces or other enforcement agencies which MacCormick calls institution agencies whose function it is to act in a specific way. Secondly, it may also be used to refer to companies or corporations who enjoy a "juristic personality by virtue of being incorporated under appropriate statute law"²³² these should also be referred to as institutional agencies.²³³ The third category of institutions according to him are contracts, trusts, property etc., which are not in and of themselves agencies but rather are arrangements that result from acts of persons and/or agencies,²³⁴ which MacCormick chooses to refer to as institution-arrangements. Fourthly, the final category which he discusses are institution-things: various incorporeal things whose existence is dependent on legal provisions giving them status, for instance stocks, shares in companies and various forms of intellectual property.²³⁵ MacCormick's approach looks holistically at the entire legal framework and multiple institutions which can exist within this.²³⁶ MacCormick's institutional typology is adopted in 2.6 below to classify the relevant institutions considered within the EPOrg and EU which is then used in chapter three and four to examine the potential institutional influences and likely effect of these on the application of the morality provisions.

²³¹M La Torre, 'Institutional Theories and Institutions of Law: On Neil MacCormick's Savoury Blend of Legal Institutionalism' in M Del Mar and Z Bankowski (eds.) *Law as Institutional Normative Order* (Ashgate 2009) 76.

²³² MacCormick, *Institutions of Law*, note 99, 35.

²³³ Ibid 35.

²³⁴ Ibid 35.

²³⁵ Ibid 36.

²³⁶ This can be distinguished from his earlier writing which focused on the particular instance of law as an institutional fact, and which distinguished between other institutions which may exist in a legal framework. See: N MacCormick, 'Law as Institutional Fact' in N MacCormick and O Weinberger, 'An Institutional Theory of Law. New Approaches to Legal Positivism' (D Reidel Publishing Company 1986) 49-76. MacCormick discussed such characteristics in more recent works but they are expanded to apply to other forms of institutions, as will be discussed in the sections that follow.

a) Relevance of the function of the institution

Nonetheless, the relevance of MacCormick's work in this context goes beyond providing a guide to the classification of institutions involved. His work also has significance in defining relevant characteristics which help to inform the template for assessing institutional influences set out in 2.6. These aspects are listed in this and the sections which follow. Firstly, and importantly as noted above, MacCormick referred to the importance of having a grasp of the function or main point of an institution when one is analysing it. He claimed that "an explanation of any institution requires an account of the relevant rules set out in light of its point".²³⁷ This idea of things having a point is one which resonates with the Aristotelian idea of entities of many kinds being accounted for in terms of their final cause²³⁸ or telos. According to MacCormick this does not mean that such institutions cannot be used for a variety of human purposes to which arrangements of such kinds can be adapted. However, if they are used for other purposes then "it is the institution that normally functions towards a given broadly-stated end – its 'final cause' – that is so adapted."²³⁹ Indeed, in the legal context, adjudicative bodies are legally constrained to operate in pursuit of their main objectives and in light of their functions set out in legislation. Moreover, acting beyond such functions would be *ultra vires* their role. This is relevant in the context of this research, as the central point or function of the overarching institution differs between the EPORG and EU, and equally the function/competences of their respective decision-making bodies which are the sub-institution involved differs. Thus, as will be seen, adjudicative bodies in the EPORG and EU are operating under different legal constraints in their interpretation of the morality provisions.

b) Role of Decision-Makers

Secondly, MacCormick's work on the classification of legal rules and relevance of discretion for decision-makers, is instructive for supporting the claim that institutional influences may be particularly cogent in the context of the morality provisions. In order to highlight this it is useful to reflect on his conception of institutional order and function of

²³⁷ MacCormick, *Institutions of Law*, note 99, 36.

²³⁸ Aristotle, *A Treatise on Government* (trans W Ellis) (J M Dent, 1912) 1252b – 1252a: 'For what every being is in its most perfect state, that certainly is the nature of that being, whether it be a man, a horse, or a house: besides, whatsoever produces the final cause and the end which we desire, must be best; but a government complete in itself is that final cause and what is best.' cited in MacCormick, *Institutions of Law*, note 99, 36.

²³⁹ MacCormick, *Institutions of Law*, note 99, 37. For further discussion, see, MacCormick, 'Norms, Institutions and Institutional Facts' (1998) 17(3) *Law and Philosophy* 301-345.

legal rules within this. In introducing the topic of institutional order, MacCormick gives the example of a managed queue i.e. a queue which is not just informal but which is managed by someone in a position of authority.²⁴⁰ In such cases the norms to which people line up in the queue are not merely conventional or reliant on mutual beliefs and expectations; rather they are norms which are explicitly laid down by the person in authority who is providing the service. In the case of managed lines when a difficulty or question arises e.g., whether priority should be maintained if someone does not come forward when their number in the queue is called out but comes forward later when it is someone else's turn, the resolution of such difficulties according to MacCormick is not a matter of "negotiating different interpretations of vague conventions but it is a matter for decision."²⁴¹ MacCormick notes that when there is a decision-making authority there is a possibility of making an explicit decision about priority in a queue in such cases, and in the event that problems are recurrent and consistent he states that "decisions can be taken explicitly or implicitly in such a way as to lay down general rules aimed at dealing with such recurrent problems."²⁴² Such explicitly made rules have an expressly promulgated text and in such cases the:

"...interpretation of norms in the form of explicit rules necessarily involves attending to the very words used by the rule-maker, and reflecting on the underlying point of the words only where the words seem unclear or where what seems their obvious meaning leads to what seem weird results in practice."²⁴³

In relation to the characteristics of explicit norms, they can occur as three types of rules: rules of absolute application, rules of strict application and rules of discretionary application.²⁴⁴ This classification is useful for considering the norms within legislative provisions, such as the morality provisions. Rules of absolute application are those whereby each occasion of particular operative facts must be attended unfailingly by a normative consequence or thing which has to be done. Examples of this type of situation are for instance rules of mathematical or closed ended games like chess. Rules of strict application then are those "where circumstances bearing on the values secured by it may occasionally

²⁴⁰ MacCormick, *Institutions of Law*, note 99, 21.

²⁴¹ Ibid 22.

²⁴² Ibid 23.

²⁴³ Ibid 23.

²⁴⁴ Ibid 27.

arise such that there is considerable derogation from those values.”²⁴⁵ The person applying such rule is given some degree of guided discretion to make exception or override it in special cases.²⁴⁶ Finally, rules of discretionary application are where the:

“decision maker is expected to consider every case in the light of all factors that appear relevant given the values and goals of the relevant activity or enterprise, and to decide in accordance with the clear balance of factors, but when all things are equal, or when the balance of factors is rather fine and difficult to judge, the decision maker is expected to use the rule as a fall back way of deciding the case.”²⁴⁷

The category to which rules should belong is not dependant on the content of the rules, but rather on the second tier norms which lay down the terms of authorisation or empowerment of the decision-maker. If rules are of absolute or strict application, then according to Raz they will belong to a category called “exclusionary reasons”.²⁴⁸ According to MacCormick the authorisation of the decision-maker entrenches a rule and the strict or absolute character demanded by the terms of authorisation is what renders it exclusionary.²⁴⁹ In the event of a rule being absolute in character, the only issue for the decision maker to ascertain is whether the operative facts obtain or not, i.e. the rule itself cannot be questioned.

The general morality provision attempts to exclude inventions whose commercial exploitation would be against *ordre public* or morality and so is an explicit rule which is of strict application. This is because the decision-maker cannot question the provision itself, and must apply the provision should the normative facts arise. However, some discretion arises given the broad nature of the general morality provision which does not specify specific inventions to be excluded. Accordingly, a difficulty arises, as even though the rule appears to be strict in nature ascertaining whether the operative facts exist, is not a simple task and one which requires a value judgment of some sort. In the case of the EPOrg and EU therefore, although the relevant rules in question mirror each other as the legislative guidance on the morality provisions for both is virtually identical. However, it is in the decision maker’s interpretation and application of such rules where potential divergence

²⁴⁵ Ibid 27.

²⁴⁶ Ibid 27.

²⁴⁷ Ibid 27.

²⁴⁸ Ibid 27.

²⁴⁹ Ibid 28.

may arise, given that the rules themselves cannot be applied without some normative/value-laden considerations being taken into account by the decision-makers. Arguably, it is at this point of interpretation that the institutional mark is placed on the development of the provisions as the decision-maker will apply the morality provisions in a manner which will reflect their competences, aims, relationships with Contracting States and other characteristics of the institutions, such as the external social/political factors which may also differently influence the adjudicative bodies in the EPOrg/EU.

Similarly, the four listed exclusions in Art. 6(2) can be seen as rules of absolute application, as once an invention falls within these categories it is automatically excluded from patentability. However, as will be seen the main terms within these provisions, are often uncertain. For instance, if one looks to the exclusion in relation to “uses of embryos for industrial or commercial purposes’ and the application of this to hESC technology. In this context, the meaning of ‘embryo’ was unclear in light of developing science, and when one compares, decisions given by the CJEU and Boards of the EPO in this context,²⁵⁰ one can see institutional influences come to the fore. In this context, as will be discussed, there is deeper reliance by the CJEU on principles such as dignity, and human rights, whereas the EPO gave a more superficial treatment to such concepts, and offered a narrower interpretation of the term than the CJEU subsequently adopted. These issues are discussed in chapter three and four.

As noted above, the likelihood of institutionally influenced decisions arising in this context is compounded by the fact that currently there are no express provisions/principles which guide decision-makers in ascertaining whether the commercial exploitation of an invention is against *ordre public* or morality, other than the four explicit exclusions, and even these categories have required further interpretation. Furthermore, no ethical framework exists nor have decision-makers of the EU or EPOrg attempted to explicitly set out such a framework in their judgments on the morality provisions. This arguably increases the likelihood of institutional factors playing a role as decision-makers are making difficult decisions on the morality provisions without any real concrete guidance or approach which

²⁵⁰ The EPO was required to consider this provision in *WARF*, note 54, discussed in chapter three. Whilst, the EU was required to consider it in *Brüstle*, note 58, and in Case C-364/13 *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks*, Judgment of the Court, Grand Chamber, 18 December, 2014 which is discussed in chapter four.

will aid them in formulating their decision. Arguably in such circumstances, they will be likely to look toward institutional factors and the institutional environment they are situated within in an attempt to make decisions which they feel will be ‘legitimate’ or acceptable in a given context, a point supported by Clayton and May’s theories discussed in 2.5 of this chapter. Moreover, specific examples of this occurring in the context of the EPO/CJEU are discussed in chapters three and four.

c) Moral versus legal decision-making

The claim that institutional influences may affect the way in which the EPOrg and EU apply the morality provisions, is predicated on the assumption that decisions on morality can be influenced and that such decisions do not lend themselves to self-evident, universal truths. MacCormick spends some time discussing the nature of moral decisions in the legal context. In an important paragraph for this purpose, he states that:

“Legal reasoning clearly must proceed in a highly institutionalized setting. Moral reasoning, though it often has to have close regard to the institutional context of a moral decision, has as its goal to form the autonomous will of the moral agent, in a context in which the value of any institutional obligation is also open to question. Judges enjoy autonomy of a kind under the doctrine of the independence of the judiciary, yet they are indeed bound by the provisions of constitutions and statutes and they must have regard to—in some cases indeed they are bound by—precedents. All these are certainly relevant in an appropriate setting to a well-founded moral judgment, but the element of the ‘binding’ is absent in this case.”²⁵¹

Thus, as judges are bound by legislation, precedent and other institutional aspects in making decisions, they cannot merely pass judgment on the basis of personal preference. Instead, they are legally constrained by the past actions of the institution. In other words, path dependencies – as also identified within historical institutionalism – play a significant *constraining* role in the context of legal adjudication. Support for this point is evident in MacCormick’s analysis of two decisions, namely the *Conjoined twins*²⁵² case and *Donoghue v Stevenson*.²⁵³ He analyses each case using both legal and moral reasoning,

²⁵¹ MacCormick, *Practical reason in Law and Morality*, note 67, 172.

²⁵² *A (Children), Re* [2000] EWCA Civ 254 (22 September 2000).

²⁵³ *Donoghue v Stevenson* [1932] UKHL 100.

and then compares the outcomes. In doing so, he finds that the conclusions based on legal reasoning would not necessarily mirror those reached by him if moral reasoning was used. MacCormick argues that:

“Autonomy in moral judgment means that each person is responsible for her/his view of what is good and bad, right and wrong and can never be overruled on that issue. This is distinct from the issue of what a public agency or authority may be required by law to do in a given dilemma, an issue which certainly has both moral as well as legal relevance—but not moral conclusiveness.”²⁵⁴

He concludes that:

“As for this, we have seen that both where the moral conclusion diverges from the legal conclusion and where it converges with it, there are differences in the appropriate reasoning, and these *are intimately bound up with the relative institutionalization of the context for legal reasoning.*”²⁵⁵ [Emphasis added]

The tenor of his reasoning is that decision-makers in a legal setting make moral decisions not as individuals, but rather in cognisance of the fact that they are representatives of the legal system. This in turn influences the conclusions generated. In applying the morality provisions, decision-makers are called upon to interpret what is meant by ‘morality’ in the context of the patentability of an invention. On first sight, this appears a curious hybrid of the reasoning described by MacCormick. However, even in this context, it is not a purely moral decision which is needed, because decision-makers are acting as representatives of the legal institution. In doing so, decision-makers are constrained in their decisions by legal precedents operating, by the legal competences of the adjudicative bodies and the scope of the underlying legislation applicable. Moreover, adjudicative bodies may also be predicted to be influenced by the social/political factors evident in an institutional context, as such factors may pull these decision-makers to act on the basis of what they feel will be acceptable to the community to whom the adjudicative body serves, a point supported by reference to Clayton and May’s work discussed below. Thus, these theories support the

²⁵⁴ MacCormick, *Practical reason in Law and Morality*, note 67, 182.

²⁵⁵ *Ibid* 192.

argument that decision-makers will decide on the morality provisions by taking into account the specific institutional framework within which they act.

d) Value judgements and bounded decision-making

Also of relevance is MacCormick's conception of bounded decision-making which reinforces the relevance of *deciding who decides*. MacCormick looks at instances where standards exist within rules; situations where the decision maker when applying the rule and assessing the presence of operative facts must also evaluate the scenario, which is similar to what occurs with the morality provisions. He offers the example of the Uniform Commercial Code in the USA and the section which states that:

“(2) where the buyer rejects a non-conforming tender which the seller has reasonable grounds to believe would be acceptable with or without money allowance the seller may if he *seasonably* notifies the buyer have a further *reasonable* time to substitute a conforming tender” [Emphasis added].

In this case, the words *seasonably* and *reasonably* require the decision maker to make value judgments but are according to MacCormick judgments of a “bounded kind”²⁵⁶ as “what is in issue is only the *seasonable* or the *reasonable* in a quite specific context of a sale of goods by description or by sample, where there are probably known usages of trade in a given market.”²⁵⁷ Similarly, the application of the general morality provisions will depend to a large extent on the decision-makers interpretation of the scope of the provisos within this provision, as outlined in 1.3(b) i.e. the meaning of ‘commercial exploitation’, ‘ordre public or morality’, and ‘prohibited by law or regulation’. Thus, these form the bounded criteria.

For instance, in order to demonstrate this, if we consider ‘commercial exploitation’, in applying this, decision-makers are being asked to ascertain not what inventions are immoral *per se* but rather the commercial exploitation of which inventions would be immoral. However, commercial exploitation is not defined in the context of either the Biotech Directive or the EPC, so this is left to the discretion of decision-makers. Moreover, emphasising this bounded nature determined by the interpretation of ‘commercial

²⁵⁶ Ibid 30.

²⁵⁷ Ibid 30.

exploitation' resonates with the utility/futility theme discussed in chapter one. Some would argue that if to deny a patent on the basis of morality where the objection is directed at the science itself would be futile, then it is questionable whether decision-makers in such contexts should invoke the morality provisions, arguing that such an interpretation goes beyond the scope of the provision which is directed at the 'commercial exploitation' not science per se. Similarly, applying the provision to consider whether any steps in its development are immoral which would taint the patent on the invention, as occurred in the EU decision in *Brüstle*, could be argued to be going beyond the bounded nature of the provisions if this occurred in the context of the general morality provision. However, it must be conceded that the decision in *Brüstle* was in the context of the specific morality provisions and as will be discussed in chapter three and four, a stricter definitional test applies in such contexts. Nonetheless, if the morality provisions are directed to science and to the development of the invention rather than to commercial exploitation, this could arguably give rise to increasing uncertainty for inventors potentially undermining the incentivising basis of the patent system. For these reasons, it is submitted that the idea of the bounded nature of legal provisions is a relevant aspect which should be borne in mind.

2.5 Clayton and May: Institutional Analysis of Decision-Making by Courts

Whilst MacCormick's work is relevant as a basis for the examination of convergences between the EPOrg/EU on legislative texts and the legal constraints on adjudicative bodies, Clayton and May's institutional analysis is of relevance in relation to explaining and predicting the likely influence of external factors such as political influences on decision-making bodies of the EU and EPOrg in the application of the morality criteria. Clayton and May examine the US Supreme Court decision-making functions within the broader context of the political and legal system. In doing so, they argue that "judicial attitudes and strategies in decision making are both constituted and constrained by the broader context within which the Court operates"²⁵⁸ arguing that "judges tend to make decisions on the basis of what they believe to be the most authentic understanding of "the law" and the appropriate mission or the role of the Court, not on the basis of their personal policy preferences alone."²⁵⁹ They contend that the meaning of the "law" is "contingent upon the views and relative relationship of institutionalised actors who make up the political system

²⁵⁸ Clayton and. May, 'A Political Regimes Approach to the Analysis of Legal Decision' note 66, 1.

²⁵⁹ Ibid 1.

or political regime at any given time”.²⁶⁰ If applied to the context of the ‘European’ patent system, it supports the argument that the decision-makers in the EU and EPOrg make decisions in cognisance of the role of the institutions in which they are situated and broader influences on the institution at any given time. Arguably, this may also be why we have seen a more restrained and narrow application of the morality provisions by the EPOrg to date in comparison to the EU’s application of these provisions (as the EU has broader competences and powers).

As an aside, it should be noted that influences within the institution may also arise from the composition of internal actors in a decision-making body. In this respect, Drahos has argued that the patent community, which he defines as the patent attorneys and lawyers, patent administrators and other parties who play a part in the patent system, serves as an “interpretative community” for the morality provisions. He claims that “it is the patent community working with a shared set of assumptions, understandings, conventions and values that settles issues and problems of interpretation within the patent system”.²⁶¹ He argues that in doing so “the patent community probably exercises more influence on the direction and content of patent policy than legislatures, which in any case rely on committees of specialists to advise them on matters of patent policy”.²⁶² This idea of the patent community as an “interpretative community” originates in jurisprudential debates in 1980s which sought to explain how the open-textured nature of language comes to have meaning attached to it.²⁶³ This is apt in relation to the morality provisions as given their open-textured nature they can only ever have effect when defined by an interpretative community. Institutional theory similarly implies the need to examine the interpretative community described as such, but adds to this, by also highlighting the significance of inter-institutional influences in given contexts, and other institutional constraints documented further in the template outlined at 2.6.

2.5.1 Clayton and May’s approach

Clayton and May propose a new institutionalism and political regimes approach to analysing judicial decision-making, an approach which according to them builds upon

²⁶⁰ Ibid 1.

²⁶¹ Drahos, ‘Biotechnology Patents, markets and morality’, note 85, 441-442.

²⁶² Ibid 442.

²⁶³ Ibid 449 at footnote 4 citing S Fish, *Doing What Comes Naturally: Change, Rhetoric and the Practice of Theory in Literary and Legal Studies* (Duke University Press 1989).

Rogers Smith's interpretative institutionalism²⁶⁴ and on the work of those engaged in political systems analysis or political jurisprudence.²⁶⁵ The authors claim there has been a new "appreciation for constitutive and normative conceptions of politics and the role that political institutions play in shaping individual attitudes and values."²⁶⁶ Moreover, they claim that Roger Smith has argued that "public law scholars in particular should recognize the centrality of legal institutions as independent forces in the decision making process of judges".²⁶⁷ However, this is arguably equally relevant in the context of private law especially in relation to patents which involves balancing between public and private interests. The authors claim that:

"...scholars in this mould largely retained the behaviouralist assumptions about the attitudinal motivations of judge, but explained the array of attitudes on the Court at any given time, and hence the pattern of Supreme Court decisions, in reference to its relative power relationship within the broader political regime."²⁶⁸

These theorists rely on the idea that "within certain institutionalised constraints judicial decisions reflected the instrumental politics of self-interest or preference maximisation."²⁶⁹ Interestingly, Clayton and May state that under this view "judges moderate their individual policy preferences when deciding cases not out of an authentic commitment to law and legal principles but because they are consciously or unconsciously influenced by restraints on their power."²⁷⁰ This point has resonance in the context of the patent system, where it can be observed that the decision-makers in the EPOrg and EU have very different constraints on their powers given the differing competences and functions etc of the institutions within which they are situated, a point expanded upon in chapters three and four.

²⁶⁴ See, Clayton and. May, 'A Political Regimes Approach to the Analysis of Legal Decision' note 66, 7 referring to R Smith, 'Ideas, Institutions and Strategic Choices' (1995) 28(1) Polity 135.

²⁶⁵ Clayton and. May, 'A Political Regimes Approach to the Analysis of Legal Decision' note 66, 7

²⁶⁶ Ibid, 4, citing J. March and Olsen, 'The new institutionalism: organisational factors in Political Life', (1984) 78 American political science review 734-49.

²⁶⁷ Clayton and. May, 'A Political Regimes Approach to the Analysis of Legal Decision' note 66, 4.

²⁶⁸ Ibid 7.

²⁶⁹ Ibid 7.

²⁷⁰ Ibid 8. A similar point is made by Cassillas, Enns, and Wohlfarth in relation to public constraints on decision making, they note that "With little formal institutional capability to enforce the Court's decisions and to compel the elected branches or the public to respect its judgments, justices must often act strategically in their opinion writing, adjusting to shifts in the public mood in order to ensure the efficacy of their decisions" in Cassillas, C., Enns, P., and Wohlfarth, P. 'How Public Opinion Constrains the U.S. Supreme Court' (2011) 55(1) American Journal of Political Science 74, 75.

Clayton and May note that the work of political jurisprudence scholars has been criticised for seeing the “role of courts as bounded entirely by their relationship to other political and social institutions and the groups that control their power.”²⁷¹ Moreover, they concede that this theory is deserving of this criticism but do not dismiss it. Instead they claim that there is an alternative way to conceptualise the interaction of the courts and legal framework with the political system which is worthy of exploration.²⁷² To explain this, the authors use the example of a judge’s commitment to the underlying purpose of separation of powers; in such cases a judge must be sensitive to the “positions and values of groups dominating Congress and the presidency.”²⁷³ Nonetheless, the authors claim that such sensitivity might not just be a strategic calculation about “achieving one’s own policy preferences, a fear of override by the political branches, or even an unself-conscious acceptance of the policy views of the dominant political coalition.”²⁷⁴ Instead, they claim that it may be “a belief that the law itself is dependent on *relative institutional relationships* within the political system”²⁷⁵ or to express this in another way that “a justice may believe that individual legal institutions are themselves embedded within, and draw meaning from, the larger political regime.”²⁷⁶ This has broader application if one looks outside the context of separation of powers. Indeed, the authors argue that “in most areas...law is similarly relative or sensitive to historically contingent political relationships.”²⁷⁷

A number of examples are given by the authors, some of which have relevance for the purposes of this thesis and the patent law context. For instance, the authors note that in decisions involving individual rights, the Court has often relied upon conceptions of law that require judicial sensitivity to “contemporary community standards” (*Miller v California*,²⁷⁸ the “habits and manners of civility” (*Bethel School District v. Fraser*²⁷⁹), “society’s evolving standards of decency” (*Trop v Dulles*²⁸⁰), or even the values found in

²⁷¹ Clayton and. May, ‘A Political Regimes Approach to the Analysis of Legal Decision’ note 66, 7.

²⁷² Ibid 8.

²⁷³ Ibid 8.

²⁷⁴ Ibid 8.

²⁷⁵ Ibid 8.

²⁷⁶ Ibid 8.

²⁷⁷ Ibid 8.

²⁷⁸ 413 US 13 (1973).

²⁷⁹ 478 U.S. 675 (1986).

²⁸⁰ *Tropp v Dulles* 356 US 33 (1915).

the “conscience and traditions of our people” (*Palko v Connecticut*²⁸¹).²⁸² The authors argue that the fact that a decision is decided in line with the dominant governing coalition does not mean that judges are merely deciding cases in line with personal policy preferences or strategic calculations concerning their power in comparison to power of other branches.²⁸³ Instead they argue that:

“...legal doctrines and standards such as those described above, recognise the political contingency of law and require any authentic commitment to law to be responsive to the views held by important political actors such as Congress, the president, states and interest groups.”²⁸⁴

Hence, they claim that a judge could be committed to law but also be sensitive to the dominant political ideologies. It is questionable whether this could be applied in the European context, as much of the stronger political influence arguably comes from the fact that judiciaries are elected in the US but not in Europe and this difference must be borne in mind. Nonetheless, it is not so much the political influence that is relevant in relation to this research but the general idea that an institution can shape/influence ideas in a court setting that is of note.

a) Controversial issues and decision-making

Interestingly, Clayton and May comment that on close analysis judicial attitudes about abstract principles such as *stare decisis* “...reveal themselves to be contingent on prevailing social and political values”.²⁸⁵ The example given by the authors to suggest this is *Planned Parenthood v Casey*.²⁸⁶ They claim that a majority of judges arguably held policy preferences at the time which would result in them abandoning the decision in *Roe v Wade*²⁸⁷ and the abortion right, but in spite of this, the abortion right was upheld. This leads the authors to conclude that there was more at work than the individual policy preferences of the judges concerned. The authors discuss Justice O’Connor’s decision in this case, particularly her discussion of what it means to give a legally principled decision and also

²⁸¹ *Palko v Connecticut* 302 US 3129 (1937).

²⁸² Clayton and. May, ‘A Political Regimes Approach to the Analysis of Legal Decision’ note 66, 8.

²⁸³ *Ibid* 9.

²⁸⁴ *Ibid* 9.

²⁸⁵ *Ibid* 9.

²⁸⁶ 503 U.S 833 (1992).

²⁸⁷ *Roe v Wade* 410 US 113 (1973).

the role of political values in the decision-making process.²⁸⁸ She argued that any judge/court in its decision should avoid pressure of deciding a case on the basis of the individual preferences which they or others may have. Instead, there should be an adherence to *stare decisis* unless the facts had changed from those which had been used to justify earlier decisions. The Court in its decision should also be sensitive to political values held in society which are reflected by the dominant coalition.²⁸⁹ This resonates with much of what MacCormick argued in relation to the differences between moral and legal reasoning and legal constraints on decision-making. However, it also reinforces that judges may be sensitive to the characteristics of and pressures upon the institution in which they are situated in making decisions.

In the context of the patent system, arguably, these external influences will come to the fore in cases of controversy, in such cases a strong preference within the majority in society may be discernible. In contrast, as will be argued in chapter three, the majority of patent applications which do not involve publicly controversial issues, tend to fall below the radar and go unnoticed by the broader public, thereby leaving it to the institution (the EPOrg or EU) void of such external public views to apply the provisions should a case arise. As will be argued, in such contexts, institutional influences will be significant in shaping the provisions. Nonetheless, this idea of external pressures affecting decision-makers in controversial areas is demonstrated by looking to the *Edinburgh Patent* (EP 0695351) case which concerned the patentability of animal transgenic stem cells. This case is interesting in this respect as the patent was initially granted by the EPO which did not specify the type of animals in the application. However, following international reaction in which fourteen countries lodged oppositions to the patent, it was reconsidered and limited in scope. The EPOrg limited the patent to inventions not involving hESCs. It is at least arguable in this case, that the political and other external pressures exerted by the Contracting States objections provided the impetus to limit the decision.

Moreover, Clayton and May cite a paragraph from Justice O'Connor's decision which has particular traction for this argument. Justice O'Connor stated that the court's authority and ability to exercise its role is dependent upon:

²⁸⁸ Clayton and May, 'A Political Regimes Approach to the Analysis of Legal Decision' note 66, 9.

²⁸⁹ Ibid 9.

“...its legitimacy, a product of substance and perception that shows itself in the people’s acceptance...a decision without principled justification would be no judicial act at all. But even when justification is furnished by apposite legal principle, something more is required. Because not every conscientious claim of principled justification will be accepted as such, the justification claimed must be beyond dispute. The Court must take care to speak and act in ways that allow people to accept its decision on the terms the Court claims for them ... *Thus, the Court’s legitimacy depends on making legally principled decisions under circumstances in which their principled character is sufficiently plausible to be accepted by the Nation.*”²⁹⁰

Clayton and May claim that this highlights a recognition by O’Connor that:

“abstract legal principles must draw meaning from their relationship to particular social and political facts, but that “facts” are historically contingent on broadly held social and political values. A principled jurisprudence will thus be responsive to broadly held social values which themselves will be represented in major political and social institutions.”²⁹¹

The idea of judicial decision-making or being responsive to dominant values held in society as articulated and expressed by key political institutions²⁹² is central to Clayton and May’s proposed application of institutionalism in the context of gleaning an understanding judicial decision-making. If we broaden Clayton and May’s approach outlined above, and consider this alongside the other aspects of institutional theory outlined above, together they support an argument that in the context of the EPOrg and EU, their inherent functions, capabilities and limitations (including the legal constraints on these institutions) *coupled* with the broader external framework within which they operate are fundamental to understanding how their decision-making bodies apply the morality provisions. Arguably reinforcing the claim that they will apply such provisions in a different manner given the differing

²⁹⁰*Planned Parenthood v Casey* 503 U.S 833 (1992) cited in Clayton and. May, ‘A Political Regimes Approach to the Analysis of Legal Decision’ note 66, 9.

²⁹¹ Clayton and. May, ‘A Political Regimes Approach to the Analysis of Legal Decision’ note 66, 10.

²⁹² *Ibid* 10.

institutional contexts in which they find themselves. A point which will be investigated in detail in chapters 3 and 4.

In concluding, Clayton and May claim that “whether there is agreement with our label of “political regime analysis matters less than their recognition that understanding the political meaning and significance of judicial decisions requires placing them in the appropriate contexts.”²⁹³ This supports the claim that the differing institutional contexts of the EPOrg/EU may significantly influence their application of the morality provisions, as such decision-makers are arguably *institutionally* predisposed to favour particular interpretations in this context.

2.6 Reflection: Assessing Institutional Influences on Judicial/Quasi-Judicial Bodies in the Application of the Morality Provisions.

Against the background of this extensive account of various approaches to institutional theory, this section will set out a template for assessing institutional influence, which will form the theoretical basis for the analysis that follows, and will be used to examine the application of the morality provisions within the EPOrg and EU in chapters three and four respectively. Again, the caveat that this research does not seek to account for all influences on decision-making in this context must be noted. Instead, the main contribution is building a deeper understanding of the significance of institutional frameworks in decision-making; the main claim being that in light of the differences between the EPOrg and EU, it is impossible to fully integrate the interpretative practices of the CJEU and EPO in the interpretation/application of the morality provisions, without fundamentally reconfiguring the institutional frameworks within which they are located

In terms of the institutions examined, MacCormick’s typology outlined above is applied. Accordingly, the main institutional frameworks examined for the purposes of the thesis are: First, the overarching institutions of the EPOrg and EU, institutional agencies, which provide peculiar frameworks for the application of morality by decision-making bodies situated within them. Secondly, the institutional framework provided by the decision-

²⁹³ Ibid 15.

making entities in the CJEU and the EPO. These entities can be seen as lower-level institutional agencies. In chapter five, the ECtHR will also be examined in order to ascertain its relationship with the EPOrg/EU; how it may influence these entities in their application of the morality provisions which is particularly important given the planned accession of the EU to the ECHR.

For the purposes of clarity, a simplified diagram of the main components of this template and factors which will be examined in this context, is provided in the table below. This will be explained further in the analysis which follows.

Categories of influence	Factors examined to ascertain influence	Relevant Institutional Theories
Central Objectives	<ul style="list-style-type: none"> • What are the main objectives of each overarching institution? • What are the objectives of the sub-institution i.e. the CJEU/EPO? 	<ul style="list-style-type: none"> • MacCormick's Institutional theory
Institutional Structure, role and composition of judicial/quasi-judicial organs	<ul style="list-style-type: none"> • What is the judicial/quasi-judicial structure? • What is the composition/eligibility requirements/training of decision-makers? • What mechanisms of introducing public engagement, or external opinions into the judicial/quasi-judicial process exist, if any? 	<ul style="list-style-type: none"> • Political/Sociological Institutional theory • Clayton and May's Institutional Theory • Stanley Fish, and Peter Drahos's work on 'interpretative communities'

	<ul style="list-style-type: none"> To what extent is the independence of judicial/quasi-judicial actors enshrined? Relatedly, are there any financial or other vested interests evident? 	
Path Dependency	<ul style="list-style-type: none"> Over-arching institution: legislative capacities and past experience of decision-making in relation to morality/ethics Judicial/Quasi-Judicial Body: How the morality provisions developed in case law and how moral issues are generally dealt with, if at all, by the adjudicative body. 	<ul style="list-style-type: none"> Historical Institutional Theory (Path Dependencies) MacCormick's Institutional theory
Inter-institutional relationship	<ul style="list-style-type: none"> Main inter-institutional influences on decision makers? 	<ul style="list-style-type: none"> Sociological Institutional theory

Fig. 1: Template for assessing institutional influences on judicial/quasi-judicial bodies.

2.6.1 Template of factors for the analysis of institutional influence

Four main categories of institutional influence can be gleaned from the analysis above, namely:

- the central objectives of the over-arching institution, and judicial/quasi-judicial institutions;
- the institutional structure, role and composition of the judicial/quasi-judicial institutions charged with the application of the morality provisions;

- the path dependency or historical influences on the over-arching and judicial/quasi-judicial institutions; and
- the inter-institutional relationships/agreements of the over-arching institutions with external institutions.

A brief overview of the main components which will be considered in each of these strands, is necessary at this juncture.

Firstly, a central factor of influence is the main objective of the overarching institution. MacCormick's work²⁹⁴ highlights that an explanation of any institution must take this into account. In examining the main 'point' of each institution, the thesis looks towards the mission statements, self-descriptions and preambles of their founding treaties which set out the objectives of each over-arching institution under investigation and also the function of each sub-institution, the CJEU/Boards of the EPO, under discussion. It argues that the actions of decision-makers will be applied in furtherance of these central objectives. Indeed, this operates as a legally constraining feature as adjudicative bodies must act within the confines of their legal roles/functions and objectives - actions outside of this would be considered *ultra vires* that body.

Secondly, the research looks at the institutional structure, role and composition of judicial/quasi-judicial actors involved in the application of the morality provisions. This factor is used to predict the likely effect that social/political influences may have on adjudicative bodies in each respective institution. It builds on the work of political and sociological institutionalism above, particularly March and Olsen's work on the influences that institutional surroundings may provide for decision-makers. The institutional framework is significant as it structures decision-making and facilitates access to and participation in the decision-making process. This in turn influences the level of external opinion in the decision-making process and the types of actors involved, thereby shaping the contours of cases. In this respect the thesis seeks to ascertain: a) what is the judicial/quasi-judicial decision-making structure within each institution, and b) whether any specific mechanisms exist to facilitate public/external participation in the process?

²⁹⁴ MacCormick, *Institutions of Law*, note 99; MacCormick, *Practical reason in Law and Morality*, note 67; MacCormick, 'Norms, Institutions and Institutional Facts' (1998) 17(3) *Law and Philosophy* 301.

Furthermore, the role and composition of the judicial/quasi-judicial actors may also prove influential. This is supported by drawing on the idea of an ‘interpretative community’ outlined by Stanley Fish.²⁹⁵ As noted, this was previously employed in the context of patent law by Peter Drahos. Whilst many criticisms have been levelled at Fish’s usage of the term,²⁹⁶ Drahos arguably employed it for more modest means. His use of it related specifically to patentability of hESCs, and the patent community. As noted, he claimed that “...it is the patent community working with a shared set of assumptions, understandings, conventions and values that settles issues and problems of interpretation within the patent system.”²⁹⁷ Relatedly, Clayton and May argue that judicial decision-makers seek to ensure decisions are seen to be appropriate or “legitimate” by the people/community which they serve.²⁹⁸ Mapping the role and composition of the decision-making bodies of the EPOrg and EU is a first step to assessing the type of interpretative community evident.

The inclusion of these factors is further supported through an extension of the concept of path dependence described below, which draws on historical institutionalism. Individual decision-makers are seen as influenced not just by past actions of the institution within which they are situated but also by their own past actions and experiences. Arguably, if decision makers are unaccustomed to making moral decisions they may be more reluctant to exercise discretion in such areas. In order to assess the influences which the role and composition of decision-makers may have, the thesis seeks to ascertain the following with respect to each institution: a) what is the composition and training of the decision-making actors situated within these institutions and particularly what experience have these actors of analysing moral/ethical issues in other cases and contexts?; and b) are there any financial or other vested interests evident in this decision-making process which may be of influence?

Thirdly, a picture of the interpretative community cannot be gained by merely looking at the role/characteristics of the decision-making actors; a significant factor is the path

²⁹⁵ S Fish, *Doing What Comes Naturally*, note 263.

²⁹⁶ Such critics include: R.B. Gill, ‘The Moral Implications of Interpretive Communities.’(1983) 33 *Christianity & Literature* 49; R Scholes, ‘Who Cares about the Text?’ (1984) 17 *A Forum on Fiction* 171; W.A. Davis, ‘The Fisher King: Wille zur Macht in Baltimore.’ (1984) 10 *Critical Inquiry* 668. One of the main critiques is that interpretative communities are not adequately defined in this literature which in turn leads to difficulties in the interpretation of the theory and inconsistencies in its application.

²⁹⁷ Drahos, ‘Biotechnology Patents, markets and morality’, note 85, 441-442.

²⁹⁸ Clayton and May, ‘A Political Regimes Approach to the Analysis of Legal Decision’, note 66.

dependency, broadly construed, of each institution. This term is generally understood as meaning how historical actions influence present acts²⁹⁹ and its relevance in this context is supported by historical institutionalism highlighted above. At the most basic level, it implies that “what happened at an earlier point in time will affect the possible outcomes of a sequence of events occurring at a later point in time.”³⁰⁰ Applying this theory to the over-arching institution, it implies that the way in which moral issues have generally been dealt with in the legal context by the institution will be influential. Thus, the thesis assesses: the legislative capacity/activities of the over-arching institution in the moral arena and how similar legislation (if any) on such matters has previously been enacted.

In the judicial context, path dependency is encapsulated by the principle of *stare decisis* which “creates a seamless web connecting the past to the present and future”³⁰¹ whereby “reliance upon binding precedents leads courts to begin every case with an examination of the past.”³⁰² Thus, the examination of this in the judicial/quasi-judicial context requires an investigation of how the case law on the morality provisions has developed and whether any pattern can be discerned. This is another *legally constraining* factor as adjudicative bodies are generally bound by past decisions on points of legal principle of superior or equivalent adjudicative-bodies. The thesis will also look at other morality-related case law of each decision-making body, if applicable, to ascertain how moral issues are generally dealt with by the judicial/quasi-judicial body. Furthermore, this section examines the values/principles which have been offered as guidance to decision-makers in the application of the morality provisions.

Finally, the thesis looks to the inter-institutional influences and relationships/agreements between the over-arching institutions and external institutions which may influence the application of the morality provisions thereby helping to predict/explain actions of decision-making bodies. Sociological institutionalism notes the influence of institutions on each other, viewing it as akin to a form of institutional peer pressure. Thus, in considering the potential institutional influences on the application of the morality provisions, the thesis

²⁹⁹ See O Hathaway, ‘Path Dependence in the Law: The Course and Pattern of Legal Change in a Common Law System’ (2001) 86 Iowa Law Review 101.

³⁰⁰ W. H. Sewell, Jr., ‘Three Temporalities: Toward an Eventful Sociology’ in T McDonald, (ed) *The Historic Turn in the Human Sciences* (University of Michigan Press 1996) 245, 262-263.

³⁰¹ Hathaway, ‘Path Dependence in the Law’, note 299, 101.

³⁰² Ibid.

will explore the pressures/relationships between overarching institutions and external institutions such as the ECtHR and how this may influence judicial/quasi-judicial decision-makers in their application of morality.

2.7 Conclusion

The foregoing has demonstrated the relevance of institutional theory to the research proposed and the main strands of institutional influence which have been relied on to develop the template for assessing institutional influences. This template will now be applied in chapters three and four in order to chart the institutional influences exerted on decision-makers within the EPORG and EU in their application of the morality provisions.

Chapter three: An examination of institutional influences on the adjudicative bodies of the EPOrg in the application of the morality provisions.

3.1 Introduction

This chapter applies the template set out in chapter two to examine the institutional influences on the adjudicative branch of the EPOrg – the EPO - in the application of the morality provisions. It argues that the adjudicative bodies within the EPO are *institutionally* configured and indeed pre-disposed to favour a narrow interpretation of the morality provisions. This narrow interpretation aligns with the distinctive characteristics of the EPOrg and the adjudicative bodies in the EPO, including: the EPOrg’s highly specialised remit; its limited (legislative) competences in relation to general moral issues; the EPO’s composition of largely technical decision-makers who have little broader exposure to ethical or moral issues; the dearth of guidance on the interpretative principles or values to be used by the EPO in applying the morality provisions; and, the limited independence of the EPO which consequently may be more susceptible to industry, client and stakeholder influences. This chapter argues that these characteristics combine to foster an *institutional* disposition within the EPO which favours patent grant - with a few notable exceptions - and generates a light touch and narrow application of the morality provisions.

This argument is supported by reference to decisions of the EPO. Moreover, although recent decisions of the EPO suggest a somewhat broader approach to the application of the morality provisions, it will be argued in part three, that this does not represent a change in the tide. Instead, this chapter argues that the EPO’s institutional predisposition in favour of a narrow interpretation of the morality provisions remains, and - drawing on sociological institutionalism and the work of Clayton and May³⁰³ - it will be argued that the EPO will only adopt a broad interpretation of these provisions in exceptional cases. Arguably, this will only arise in cases involving controversial issues which attract public interest, wherein the EPO tailors its approach in order to ensure public legitimation/acceptance of its decisions. Relatedly, the EPO may do this in order to demonstrate convergence with its perceived view of the EU approach in controversial areas particularly those involving the

³⁰³ Clayton and. May, ‘A Political Regimes Approach to the Analysis of Legal Decision’, note 66.

four specific categories excluded from patentability under Art. 6(2) of the Biotech Directive and as transposed into the EPC.

However, arguably this will only happen in rare cases and in such cases, the EPO to date has offered a superficial level of reasoning. It will be suggested that a factor leading to this superficial application is that therein the EPO is not acting out of a commitment to embedded institutional goals within its framework, as unlike the CJEU principles such as human dignity etc. are notably absent from its guiding legislative document, the EPC. Instead, it will be suggested that in such circumstances that decision-making bodies within the EPO are prompted to alter their interpretation, in order to address external pressures. Moreover, as these principles are not engrained within the EPO's institutional framework and as it lacks the interpretative tools to grapple with such issues in a way which we may expect the CJEU/ECtHR to do so, it is unsurprising that the reasoning is superficial as it will be argued that the EPO is simply not *institutionally* configured to deliver on a broader interpretation of such principles.

This chapter is structured around the four strands of influence identified in the institutional template set out in chapter two: namely: (1) *central objectives* of the EPOrg/EPO; (2) the *institutional structure, role and composition of quasi-judicial organs* in the EPOrg - the EPO; (3) *Path Dependencies*, looking at (a) legislative path dependencies and (b) past decisions of the EPO on the morality provisions which may influence/constrain their current actions; and (4) *inter-institutional influences*. In terms of this fourth category of inter-institutional influences as the ECtHR may influence both the EPO/CJEU in their application of the morality provisions, this is considered separately in chapter five which examines whether the ECtHR could form a bridge between the EPO/CJEU in this context. Moreover, in terms of the EU's influence on the EPO, as this permeates the EPO's application of the morality provisions and *vice versa*, this will be considered throughout the chapter as and when relevant within the discussion of the other strands. Equally, the influence of the EPOrg on the CJEU's interpretation of the morality provisions is considered throughout chapter four.

In terms of the other strands of influence, the first part of the analysis in this chapter draws on MacCormick's work on how institutions are constrained to act in accordance

with their central functions³⁰⁴ and examines the central objectives of the EPOrg and then the central objectives of the EPO in order to ascertain potential influences of these on the EPO's application of the morality provisions. The second part then starts to build a picture of the interpretative community within the EPO, by which the thesis refers to the community of actors and participants involved in the patent litigation, examination and application process within the EPO. This interpretation draws on Peter Drahos's use of the term outlined in chapter two.³⁰⁵ The analysis commences by examining the institutional framework and processes for decision-making within the EPO, as these form the channels through which decisions are taken. It pays particular attention to the characteristics of the adjudicative actors within this framework, including their role, composition, and eligibility criteria for appointment. It also looks at external pressures which may be exerted on decision-makers. Part three supplements this analysis, by examining the path dependencies which may arise in relation to the morality provisions. It commences by examining the legislative provisions and competences of the EPOrg in relation to moral issues generally which constrains the EPO's action in this context. It then turns to assessing the decisions of the EPO in relation to the morality provisions. This section argues that the past actions of the EPOrg/EPO in this context reinforce institutional predispositions and further constrain the adjudicative bodies in their application of the morality provisions.

The chapter concludes by reflecting on the analysis and highlighting an entrenched institutional predisposition towards a narrow application of the morality provisions within the EPO. It argues that even if directions are given at a legislative level to apply the morality provisions in a particular manner, these will not necessarily filter through to the adjudicative level given the institutional dispositions and normative values which permeate the EPO framework. Therefore, if a reform of the morality provisions is intended then a change is required not just at a legislative or policy level, but also to the values which exist within the EPO adjudicative bodies; this would require an incremental process of change over time. This argument suggests the need for further consideration of institutional choice when one is deciding who should decide on the application of the morality provisions.

³⁰⁴ MacCormick, *Institutions of Law*, note 99, 37. For further discussion, see, MacCormick, 'Norms, Institutions and Institutional Facts' (1998) 17(3) *Law and Philosophy* 301.

³⁰⁵ Drahos, 'Biotechnology Patents, markets and morality', note 85. See also discussion in Schneider, 'Governing the patent system in Europe', note 25, 621.

The significance of this is reinforced in chapter four which examines institutional influences on the CJEU in the application of the morality provisions, arguing that these provisions are perceived differently within the EU framework. These chapters taken together demonstrate that the CJEU and EPO are not institutionally configured in a manner which can speak to each other, and that despite attempts at a legislative level by the EU and EPOrg to converge on the application of morality provisions, given the fundamental differences in the underlying institutional foundations for both, at an adjudicative level, they are, perhaps - albeit unintentionally - often speaking past each other, and pulling the morality provisions in differing directions.

3.2 Central Objectives of the EPOrg and EPO

As discussed in chapter two, MacCormick highlighted that a decisive factor in understanding the behaviour/activities of an institution is gleaned by looking at its central objectives or core point. Thus, it is useful to commence by examining the central objectives and functions of both the EPOrg and the EPO by reference to relevant legislative provisions and self-describing statements of these goals.

3.2.1 Objectives of EPOrg

Turning first to the objectives of the EPOrg, Article 4 of the EPC states that “the task of the Organisation shall be to grant European patents.” The preamble to the EPC expands on this, setting out three aims of the Contracting States in adopting the EPC - the foundational treaty establishing the EPOrg - namely: the desire to “strengthen co-operation between the States of Europe in respect of the protection of inventions”; the desire “that such protection may be obtained in those States by a single procedure for the grant of patents and by the establishment of certain standard rules governing patents so granted”, and finally; “desiring for this purpose, to conclude a Convention which establishes a European Patent Organisation...”.³⁰⁶ This suggests that the main functions of the EPOrg are centred on the grant of patents and strengthening of co-operation amongst Contracting States in this area.

³⁰⁶ Preamble to the European Patent Convention, <<http://www.epo.org/law-practice/legal-texts/html/epc/2013/e/apre.html>> accessed 16th July 2015.

This specialised function³⁰⁷ arguably gives rise to a blinkering from external considerations. This is relevant for the morality provisions, as it may lead to an institutional stance which: a) fails to consider the broader moral issues as they are seen as being beyond the scope of its central objectives; b) even if it does consider these issues, on reflection of its role may deem such matters outside its scope of activity and/or it may also fear that the patent community and its fee paying patent applicants, may not accept broad moral pronouncements against the grant of patents. Arguably, this in turn will lead to a narrow application of the morality provisions.³⁰⁸ This specialised function of the EPOrg, contrasts with the broader scope of activity and objectives of the EU - examined in chapter four - whose functions manifestly extend far beyond the patenting sphere. The EU's mandate includes not only the furtherance of economic goals but it also has a role in the protection of human rights within the scope provided for in its treaties. In contrast, the relationship of the EPOrg with the ECHR is somewhat uncertain³⁰⁹ and no express mention is made to human rights in any of its stated objectives or in the EPC. This relationship between the EPOrg and EU with the ECtHR is examined in chapter five.

3.2.2 Objectives of EPO

In terms of the objectives of the EPO,³¹⁰ a number of statements on its website are instructive. Firstly, the EPO's mission statement states that:

“As the Patent Office for Europe, we support innovation, competitiveness and economic growth across Europe through a commitment to high quality and efficient services delivered under the European Patent Convention.”³¹¹

This self-identification as ‘the Patent Office’ and the suggested links between patents - the sole scope of activity of the office - and innovation/economic growth is revealing.

³⁰⁷ See Bakardjieva Engelbrekt, ‘Institutional and Jurisdictional Aspects of Stem Cell Patenting’, note 8, 248.

³⁰⁸ See H Ulrich, ‘Patent Protection in Europe: Integrating Europe into the Community or the Community into Europe?’ (2002) 8 EL Rev 433.

³⁰⁹ For a discussion see Plomer, ‘After Brüstle’ note 74.

³¹⁰ The composition of this body discussed in further detail in 3.3 below.

³¹¹ <<http://www.epo.org/about-us/office/mission.html>> accessed 16 July 2015.

This resonates with the belief in many Western policy circles that a strong intellectual property system is vital to increase investment activity.³¹² If patents are viewed in this light by the EPO and technological innovation is seen as a necessary pre-requisite to economic growth, this reinforces a positive view of patents. This suggests that the EPO would be reluctant to make decisions which would disrupt such investment activity,³¹³ such as denying patents on the basis of the morality provisions. Hence, the EPO will arguably favour patent grant rather than denial which forms an institutional value preference within the EPO or feature of its collective ‘frame of mind’.

Secondly, the EPO website states that “the main task of the European Patent Office is to grant European patents.”³¹⁴ The use of the term “to grant” rather than for instance “to assess” is suggestive of a leaning towards the patent grant rather than denial, resonating with a presumption in favour of patentability.³¹⁵ Similarly, in the EPO’s statement of its vision,³¹⁶ it asserts that the office will “contribute to innovation across Europe” reaffirming the equation of patents with innovation - given that patenting is its sole scope of activity. It is conceded that although these arguments are somewhat speculative, they are supported by looking at the other characteristics, particularly the financial interests of the EPO in the patenting process, considered below.

From the above, the EPOrg and EPO is charged with the specialised function of patent grant and the furtherance of innovation through this. There are no express references to ethics in the core objectives of the EPOrg/EPO or broader social/moral concerns. Instead, the EPOrg/EPO portray themselves as carrying out a technical economic endeavour in this patenting role. Moreover, the decision-making bodies of the EPO are constrained to act in furtherance of its stated objectives and role which from the above, suggests a focus on commercial aspects of patenting, and a preference in favour of a narrow application for the morality provisions.

³¹² Drahos, *The Global Governance of Knowledge*, note 127, 445.

³¹³ Ibid 446.

³¹⁴ <<http://www.epo.org/about-us/office/activities.html>> accessed 16 July 2015.

³¹⁵ For a discussion which argues that there is a presumption in favour of patentability in the US patent system see, Bagley ‘Patent first, ask questions later’, note 82.

³¹⁶ <<http://www.epo.org/about-us/office/mission.html>> accessed 16 July 2015.

3.3 Institutional Structure, Composition and Characteristics of the Decision-Making Bodies in the EPO.

It can be recalled that the functions of the decision-making bodies in the EPO are overseen by the Administrative Council³¹⁷ whose role was considered in chapter one and hence will not be revisited here. Instead, this section focuses on the institutional structure, function and characteristics of decision-making bodies within the EPO - and how these may influence the application of the morality provisions by the EPO.³¹⁸ This analysis is complemented by part three of this chapter which examines the path dependencies within the EPOrg and the EPO. Read together, part two and three offer a more holistic picture of the interpretative community within the EPO; the values that permeate this and which are relevant to the application of the morality provisions.

This section commences by looking at the decision-making structure and composition of decision-makers within the EPO. This gives an insight into the pathways through which decisions on the morality provisions are taken. It highlights that decision-makers are drawn largely from areas of technical rather than legal expertise, particularly in the lower divisions, and it will be suggested that the patent examination process may be seen - and is often described in the literature³¹⁹ - as a merely administrative process. This categorisation of the EPO's function as administrative rather than adjudicatory is a recurring theme in the decisions of the EPO³²⁰ where a pattern of downplaying the role of the patent system in terms of moral or ethical concerns can be discerned. This view of patenting as an administrative undertaking has consequent effects for decision-makers' perception of their role in the interpretation of the morality provisions which will be discussed. Following this, the section considers the independence of the decision-making bodies of the EPO, including an examination of the financial incentives in the patent grant process and the external influences which may be exerted on the EPO. Finally, this

³¹⁷ Art 4 of the EPC (1973) 15th edition as amended. The role of the Administrative Council has been considered in chapter one and will also be examined briefly in part three of this chapter.

³¹⁸ For a discussion which makes a claim as to a presumption in favour of patentability existing in the US patent system see, Bagley 'Patent first, ask questions later', note 82.

³¹⁹ Schneider, 'Governing the patent system in Europe', note 25, 622

³²⁰ This issue will be discussed in the examination of case law under 3.4 which addresses path dependencies.

section looks at the role of the Economic and Scientific Advisory Board and how this may influence the application of the morality provisions.

3.3.1 An overview of the decision-making structure in the EPO

Prior to examining the structure and composition of the decision-making bodies within the EPO, for the purposes of clarity, the diagram below offers a simplistic overview of this decision-making structure.

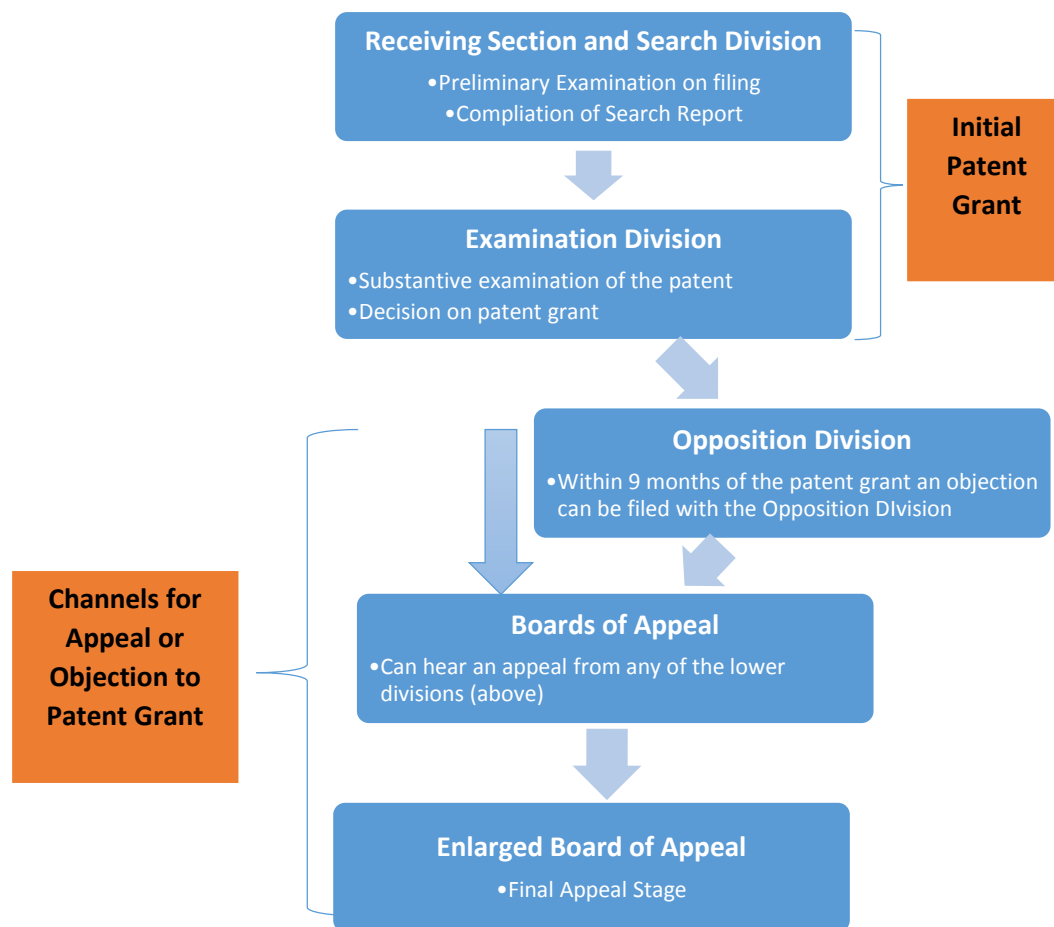


Fig. 2: Overview of the Decision-Making Structure within the EPO.

The EPO has seven main departments, namely: the Receiving Section; Search Divisions; Examining Divisions; Opposition Divisions; Legal Division; Board of Appeal (BoA); and an Enlarged BoA.³²¹ An applicant can apply to the EPO for a patent

³²¹Art. 15, EPC.

in any of the Contracting EPC signatory states. The initial patent application process comprises of two main stages. The first stage involves “an examination on filing, formalities examination, preparation of the European search report and a preliminary opinion on patentability, and publication of the application and the search report.”³²² This stage is carried out by the Receiving Section and Search Divisions of the EPO. The Receiving Section carries out the initial pre-examination which ensures that the patent meets the formal requirements for patent grant.³²³ Once this is conducted the applicant receives a preliminary examination report to which they may respond,³²⁴ and following this the application goes to the Search Division which is responsible for drawing up European search reports which identify the prior art in the area.

a) Examining Division

The second stage is carried out by the Examining Division.³²⁵ This stage is relevant for the purpose of this research as it is at this stage that the substantive examination is carried out,³²⁶ and therefore the assessment of whether an invention complies with patentability criteria, which includes an assessment of whether the application is excluded on the basis of the morality provisions. The Examining Division acts as a granting body for all classical ‘European’ patents, and as will be seen in chapter six, it will be the granting body for unitary patents once this system comes into effect. In doing so, it plays a significant role in shaping the contours of the morality provisions. Moreover, as discussed in chapter one, it is only when its decisions on patent grant are appealed or challenged, that the Boards of Appeal of the EPO, or the CJEU - depending on which forum the decision is challenged in - have the opportunity to intervene and influence the application of these provisions. In short of the supranational bodies involved in the application of the morality provisions, the Examining Division has the most interaction with the morality provisions.

³²² See, EPO, ‘How to get a European Patent: Guide for Applicants Part 1’ 15th Edition (May 2015) <http://www.epo.org/applying/european/Guide-for-applicants/html/e/ga_d_i.html> accessed 16 July 2015, para 130.

³²³ Art. 16, EPC.

³²⁴ For a discussion of this process see, T Alpin and J Davis, *Intellectual Property Law: Texts, Cases and Material* (2nd edn, OUP 2013) 564.

³²⁵ Art 18, EPC.

³²⁶ See EPO, ‘How to get a European Patent: Guide for Applicants Part 1’, note 322, para. 131.

This Division differs substantially from the Boards of Appeal of the EPO and particularly, from the CJEU. In terms of its composition, the Examining Division is composed of three technically qualified examiners. The Division can add a legally qualified examiner should it consider that the “nature of the decision” requires this.³²⁷ However, even when added, the legal examiner often deals with technical procedural points.³²⁸ Arguably, a similar mechanism could be used to add someone with ethical expertise into the process. However, the fact that it is up to the Examining Division to decide whether the presence of a legal expert is required somewhat undermines this provision as it is questionable whether the division being devoid of legal (or ethical) expertise would have sufficient knowledge to identify cases where additional expertise is needed. This could give rise to further difficulties should this be used as a mechanism to introduce ethics experts within the system, given the diffuse nature of ethics and as there is no precise formula for assessing whether ethical issues are implicated.³²⁹

Despite the significance of the Examining Division’s role, there is little evidence of its members being selected on the basis of having an awareness of the ethical issues posed by new technologies. The eligibility requirements for technical members of the Examining Division, are as follows: citizenship of any country which is a Contracting State to the EPC; a university degree in physics, chemistry, engineering or natural sciences which should be relevant to the technical field in which an examiner wishes to work; knowledge of one official language (English, French and German) and the ability to understand the other two.³³⁰ There is no reference to the need for awareness of the potential ethical issues raised by new technologies. This is understandable as this may be seen by some as a relatively minor part of the role of a patent examiner which is particularly implicated in biotechnology but not as much in other areas. Nonetheless, it is curious given the responsibility entrusted to examiners in this regard, that no mention of an awareness of ethical issues is made.

³²⁷ Art 18(2), EPC.

³²⁸ A Plomer, ‘Human Dignity and Patents’ in C Geiger (ed.) *Research Handbook of Human Rights and IP Rights* (Edward Elgar 2015) 489.

³²⁹ For a discussion of the difficulties posed by having external ethics committees in the patent system, see, E Petit, ‘An Ethics Committee for Patent Offices?’ in A Plomer and P Torremans (eds.) *Embryonic Stem Cell Patents, European Law and Ethics* (OUP 2009).

³³⁰ <<http://www.epo.org/about-us/jobs/examiners/profile.html>> accessed 16 July 2015.

On this point, it is conceded, that examiners have to undertake a two year training course which could incorporate guidance on ethical issues. However, there is no reference to an ethics component on the training programme on the EPO website or training documentation made publicly available.³³¹ This lack of transparency and likely lack of expertise of examiners on ethical issues suggests that their awareness of such issues will be limited. Moreover, this again suggests a lack of emphasis on ethical issues within the EPO's system, and reinforces the marginal role which the EPO plays or perceives itself as playing in this area.

This likely marginalisation of ethics within patent law, is arguably compounded by the fact that examiners are drawn from within the patent community and as noted, given the favourable view of patents within this community – where patents are viewed as instrumental elements of economic success - examiners may, even if not deliberately, be predisposed to decide in favour of the grant rather than denial of patents. All of these factors suggest that the Examining Division is institutionally predisposed and moreover, institutionally *configured* to apply a light touch narrow application of the morality provisions.

b) Opposition Proceedings

Following patent grant, there are a number of channels to challenge or appeal the grant/denial of a patent within the EPO, discussed in this section and the sections which follow. One such route is through Opposition Proceedings³³² which must be filed within nine months³³³ of the grant of a patent and allows an individual/group to object to the grant of a patent on a number of specified grounds. The main grounds are that: (a) the subject matter of the patent is not patentable within the terms of the EPC, and/or (b) the patent does not disclose an invention in a manner sufficiently clear and complete for it to be carried by a person skilled in the art, and/or (c) the subject matter of the patent extends beyond the content of the relevant application, or, if the patent was granted on a divisional application

³³¹ <<http://www.epo.org/about-us/jobs/examiners/training.html>> accessed 16 July 2015. See also, A Bailas, 'Examiner Training at the EPO', *Tokugikon*, No. 247, 14th November, 2007 <<http://www.tokugikon.jp/gikonshi/247tokusyu6.pdf>> accessed 16 July 2015, which similarly makes no mention of morality or ethics.

³³² Part V, EPC.

³³³ Art 99, EPC.

or on a new application filed under Article 61, that it is beyond the content of the earlier application as filed.³³⁴ Under the first of these conditions (a) an opposition can be raised on the grounds that the invention is against *ordre public* or morality and so should be deemed unpatentable. Opposition proceedings have been invoked on a number of occasions seeking to deny patents on the basis of *ordre public/morality*.³³⁵

The procedure creates an important avenue for outside influence to be filtered into the patent system.³³⁶ Any person can instigate Opposition Proceedings and there is no need to show a particular interest or *locus standi*.³³⁷ Furthermore, alongside the original opponent, observations can be adduced to the Division from other interested third parties. This in turn allows for a greater pool of external opinions to be introduced and upon which the Division may base its decision.³³⁸ Indeed, these proceedings have been commended for increasing public engagement within the patent system.³³⁹

Whilst it is conceded that Opposition Proceedings offer an avenue for facilitating external engagement within the EPO decision-making process, it is questionable whether such procedures generate sufficient external engagement to alter the institutional disposition of decision-making actors within the EPO. Instead, it is argued that, whilst change may be perceived in a particular case in which Opposition Proceedings are invoked, this particular change will not have the effect of generating broader institutional change in the collective disposition of the EPO which favours patent grant. One of the primary limitations in this vein is that Opposition Proceedings are dependent upon someone raising an opposition to a patent.³⁴⁰ This means that individuals/groups would have to externally monitor decisions and would also need scientific knowledge to identify ethical issues which may arise in relation to patents on technology. For logistical reasons, in light of the number of patent

³³⁴ Art 100, EPC.

³³⁵ See section 3.5 below.

³³⁶ S Harmon, 'The rules re-engagement: the use of patent proceedings to influence the regulation of science ('What the salmon does when it comes back downstream')' (2006) 4 *IPQ* 378.

³³⁷ EPO, Guidelines for Examination, (November 2014) Part D, Chapter 1 < http://www.epo.org/law-practice/legal-texts/html/guidelines/e/d_i_4.htm> accessed 16 July 2015, para. 4.

³³⁸ S Harmon, 'The rules re-engagement: the use of patent proceedings to influence the regulation of science ('What the salmon does when it comes back downstream')' (2006) 4 *IPQ* 378, 390.

³³⁹ *Ibid.*

³⁴⁰ Other shortcomings of the process are outlined by Bakardjieva Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting', note 8, 252.

applications and the broad fields involved, it would not be possible to use the Opposition Proceedings as a check on patent grant in the majority of cases.

Reference to the figures on patent applications provided annually by the EPO reinforces this point. In 2014, there were 151,981 patent applications,³⁴¹ of which 5,905 were defined as in the biotechnology technical field.³⁴² Other potentially relevant applications, included: 11,124 applications for medical technology.³⁴³ In 2014, 115,595³⁴⁴ examinations were carried out by the EPO and 64,601 patents were granted³⁴⁵ (some of the applications examined may not have been completed in the year so this does not represent a figure out of those applied for or examinations carried out). In terms of Opposition Proceedings, there were 2,143 opposition decisions which represents an opposition rate – defined by the EPO as the number of oppositions in 2014 divided by the number of granted patents for which the time limit for filing an opposition expires in 2014 – of 4.7%. Of these Opposition Proceedings, 31% were rejected, the patent was upheld in amended form in 38% of cases, and in 31% of cases the patent was revoked.³⁴⁶

These figures demonstrate the sheer number of applications that would need to be monitored if the Opposition Proceedings were to be used as a check on the Examining Division's application of the morality provisions. Furthermore, this also assumes that external organisations have the personnel power, expertise and interest to monitor such decisions. In reality as can be seen, the overall percentage of Opposition Proceedings – a breakdown of figures for opposition directed at each technology is not available - is relatively low at 4.7% in comparison to the number of total granted patents. The number of oppositions based on the morality provisions - although not available from the statistics - is likely only to be a small proportion of this figure, given that the 4.7% indicates all oppositions for all technologies on all grounds. Moreover, whilst the argument has been made above that the limited ethical expertise of technical examiners may make it difficult

³⁴¹ <<http://www.epo.org/about-us/annual-reports-statistics/annual-report/2014/statistics/patent-applications.html?tab=1>> accessed 16 July 2015.

³⁴² Ibid.

³⁴³ Ibid.

³⁴⁴ <<http://www.epo.org/about-us/annual-reports-statistics/annual-report/2014/statistics/searches.html>> accessed 16 July 2015.

³⁴⁵ <<http://www.epo.org/about-us/annual-reports-statistics/annual-report/2014/statistics/granted-patents.html>> accessed 16 July 2015.

³⁴⁶ <<http://www.epo.org/about-us/annual-reports-statistics/annual-report/2014/statistics/searches.html>> accessed 16 July 2015.

for them to identify ethical issues, the corollary is equally true and the limited technical expertise of external parties may make it difficult to understand scientific inventions sufficiently to identify ethical implications of patenting these which is crucial to objecting on the basis of the morality provisions. It must also be borne in mind that even if technologies are denied patentability in Opposition Proceedings the ruling may only apply to the specific features of the application and hence will not have an impact on similar inventions in future applications.³⁴⁷

Finally, although more diverse external opinions may be gleaned in Opposition Proceedings, the decision-makers sitting on the Opposition Division who decide on such objections are generally all technically qualified experts. The Opposition Division is composed of three technically qualified experts, two of whom cannot have taken part in the proceedings which granted the application.³⁴⁸ There is a provision to have cases heard by four members, by including a legally qualified examiner if the Opposition Division deems this is necessary.³⁴⁹ This process for the addition of a legal expert is similar to the Examining Division's procedure which depends on technical experts identifying circumstances which require the inclusion of a legally qualified person with the same shortcomings outlined above. There is no provision for inclusion of an ethics expert/advisor in this procedure.³⁵⁰ The absence of a legal expert in the majority of cases means that technically qualified members who do not need to have any experience of analysing or engaging with ethical issues or the reasoning required in such evaluations will have to evaluate complex questions of whether the morality provisions apply. This is not to propose that legal (or ethical) experts are always the best placed to make such complex decisions. In many cases, they may not be. However, they do have expertise in legal reasoning, in evaluating legal arguments and in balancing complex rights and questions, skills which would be necessary if a broad interpretation of the morality provisions were to be applied. This suggests that the Opposition Division was established with the view to having to consider the morality provisions in rare occasions, and is institutionally configured to apply these provisions in a narrow light-touch manner.

³⁴⁷ EPO, 'Interview Dr Ingrid Schneider', note 42, 595.

³⁴⁸ Art. 19(2), EPC.

³⁴⁹ Art. 19, EPC.

³⁵⁰ The thesis does not argue in favour of setting up ethics committee in the patent system, this was tried by the Swedish Patent Office which encountered many difficulties leading to widespread criticism. See, Petit, 'An Ethics Committee for Patent Offices?', note 329.

Furthermore, and more importantly, even if technical examiners had training in legal reasoning, given that they are drawn from within the patent community institutional predispositions are still likely to arise. This is supported by reference to DiMaggio and Powell's work in relation to normative pressures giving rise to isomorphism within organisational fields. In this context, the authors define the organisational field as "those organisations that in the aggregate, constitute a recognized area of institutional life: key suppliers, resource and product consumers, regulatory agencies and other organizations that produce similar services or products."³⁵¹ The EPO, together with the patent applicants it serves, arguably represent such a field, as it forms a key element to the functioning of patent law within the 'European' patent system. As noted, DiMaggio and Powell argue that within modern organisational fields, the increased professionalisation of areas, such as is evident within the patent system, leads to isomorphism or mimicking of behaviour within an institutional/organisational field, as discussed in chapter two. The sources of this according to the authors are "the resting of formal education and of legitimation in a cognitive base produced by university specialists" and "the growth and elaboration of professional networks that span organizations and across which new models diffuse rapidly".³⁵² The authors argue that universities are one forum for the development of organisational norms amongst professional staff, and professional and trade associations are another vehicle for this. The result is to:

"...create a pool of almost interchangeable individuals who occupy similar positions across a range of organizations and possess similar orientation and disposition that may override variations in tradition and control that might otherwise shape organizational behaviour."³⁵³

In the context of the morality provisions, the relevant adjudicative bodies in the EPO are composed of examiners and judges that are drawn from a pool of patent professionals. This reinforces the idea of a community or culture which will have similar collective views surrounding patent grant.³⁵⁴ In fact it would be difficult to avoid this scenario given that

³⁵¹ DiMaggio and Powell, 'The Iron Cage Revisited', note 180, 148.

³⁵² Ibid 152.

³⁵³ Ibid.

³⁵⁴ Similar arguments have been made in the literature surround epistemic communities referring to the broader diffusion of policy within expert groups. Epistemic communities have been defined as 'a network of

individuals need to have patent experience in order to assess patent grant, thus a change of personnel would arguably not resolve such issues. Nonetheless, given the EPO's institutional configuration, it is questionable whether it can deliver on an interpretation of the morality provisions which may fit the EU's interpretation of these provisions - examined in chapter four. Furthermore, whilst Opposition Proceedings allow for some outside influence in the system, it is arguably unlikely that this will alter or shift engrained institutional perspectives on morality within the EPO in the majority of cases.

c) Boards of Appeal and Enlarged Board of Appeal

Appeals from decisions issued by the Receiving Section, the Examining Divisions, Opposition Divisions, and the Legal Division can be taken to the Boards of Appeal of the EPO. There are currently twenty seven Technical Boards of Appeal and one Legal Board of Appeal, the Enlarged Board of Appeal and the Disciplinary Boards of Appeal.³⁵⁵ The status of members of the BoA is described on the EPOrg website as “comparable to a judge of a second instance national court.”³⁵⁶ The Legal BoA is composed of three legal members and the Technical BoA are generally composed of two technical experts and one legal expert. The type of Board which hears the appeal depends on where the appeal originated from. Appeals from the Receiving section and Legal Division will go to the Legal BoA.³⁵⁷ For appeals of decisions taken by an Examining Division which was comprised of less than four members, the BoA will be composed of two technically qualified members and one legally qualified member.³⁵⁸ If the decision was taken by an Examining Division consisting of four members, the appeal will be heard by a Board comprising of three technically and two legally qualified members; it will also be similarly composed in instances where the Board thinks the case requires this composition. Finally for appeals from the Opposition Division, if the division who made the decision was composed of three members then the BoA will be composed of two technically qualified members and one legally qualified

professionals with recognised expertise and competence in a particular domain and an authoritative claim to policy relevant knowledge within that domain of issue area” in P Hass, ‘Introduction: Epistemic Communities and International Policy Coordination’ (1992) 46(1) International Organization 1, 3 as cited by Thambisetty, ‘The Analytical Significance of Emergence in the Patent System’, note 131, 8.

³⁵⁵ The Disciplinary Board of Appeal is outside the scope of this research. It “hears appeals against decisions of the EPO Disciplinary Committee and the EPO Disciplinary Board on infringement of the rules of conduct for professional representatives before the EPO. The Disciplinary Board also deals with appeals against decisions of the EQE Examination Board and Secretariat.” < <http://www.epo.org/about-us/boards-of-appeal.html>. > accessed 16 July 2015.

³⁵⁶ <<http://www.epo.org/about-us/boards-of-appeal/faq-boards-of-appeal.html>. > accessed 16 July 2015.

³⁵⁷ Art. 21(2), EPC.

³⁵⁸ Art 21(3)(b), EPC.

member.³⁵⁹ If the Opposition Division was composed of four members, then the Board will be composed of three technically qualified and two legally qualified members.³⁶⁰

Furthermore, in order to ensure the uniform application of laws or in the event of a significant point of law arising, a case can be referred to the Enlarged BoA. A referral can be made by the BoA or by the President of the EPO.³⁶¹ There is just one Enlarged BoA which has three functions: (1) It decides on points of law which have been referred to it by the BoA under Art. 112; (2) It gives opinions on points of law referred to it by the President of the EPO under Art. 112. In these cases it will be composed of five legally and two technically qualified members;³⁶²(3) It decides on petitions for the review of decisions of the BoA under Art. 112a.³⁶³ In such cases, the Enlarged Board shall be composed of either three or five members as set out in the Implementing Regulations.³⁶⁴ Furthermore, in all proceedings the Chairman of the Board shall be a legally qualified member.³⁶⁵

Therefore, these Boards - aside from the Enlarged BoA - are mostly composed of technical and not legally trained members. Members are appointed to the BoA on a five-year basis appointed by the Administrative Council following a proposal from the President of the EPOrg.³⁶⁶ There is a facility for reappointment provided the President of the Administrative Council is consulted. In terms of eligibility, the criteria of the technical members is the same as the criteria for such members on the Examining Division, discussed above. For legal experts on the BoA, the eligibility criteria were set out in a recent vacancy notice on the EPO website, which listed the following criteria:

- a university diploma in legal studies, although in exceptional cases “equivalent knowledge acquired over many years of qualified work, as well as many years of professional experience”³⁶⁷ will be sufficient;
- “...special aptitude for judicial work...Candidates should have worked as judges, preferably in the field of patent law, and/or have practical experience in patent

³⁵⁹ Art 21(4)(a), EPC.

³⁶⁰ Art 21(4)(b), EPC.

³⁶¹ <<http://www.epo.org/about-us/boards-of-appeal.html>> accessed 16 July 2015.

³⁶² Art 22(2), EPC.

³⁶³ Art 22, EPC.

³⁶⁴ Art 22(2), EPC.

³⁶⁵ Art 22(2), EPC.

³⁶⁶ Art 11(3), EPC.

³⁶⁷ <<http://internet-i.epo.org/about-us/jobs/vacancies/other/int-ext-5259.html>> accessed 10 October 2014.

opposition, appeal, nullity, infringement proceedings as lawyers in private practice, or as legal advisers in public administration or industry. They should preferably be between 45 and 55 years of age”³⁶⁸

- excellent knowledge of one of the EPO languages along with the ability to understand the other two languages.³⁶⁹

From this, it is evident that all decision-making experts are drawn from within the patent community with experience of patent law being essential for appointment. This is entirely sensible given that they will be adjudicating on patent issues. Nonetheless, institutional theories discussed above highlight the likelihood of diffusion in common thinking or normative positions amongst individuals in an organisational field like this, which suggests that individuals within a field will resemble each other in terms of training and normative values and hence further perpetuate normative positions. This taken alongside the recurring lack of reference to the need for an awareness of broader ethical issues surrounding new technologies, reinforces an engrained institutional position which side-lines morality, giving it a marginal role in the patent system.

3.3.2 Independence of the Decision-Making Actors in the EPO

It might be argued that the independence of the BoA would minimise institutional influences which may arise. The independence of members of the BoA and the Enlarged BoA of the EPO is enshrined in Article 23 of the EPC. This provides that: the members of these bodies are appointed for a period of five years; they may only be removed in exceptional circumstances; and in their decisions they are bound only by the EPC. However, for a number of reasons this independence has been called into question. In this context the institutional differences between the decision-making bodies of the EPO and national/international judicial entities becomes increasingly stark.

The primary criticism relates to the lack of a separation of powers, as the BoA are situated within the EPO which is also responsible for patent grant.³⁷⁰ Consequently, in 2004 a draft proposal for the revision of the EPC³⁷¹ was tabled which aimed to separate the BoA from

³⁶⁸ Ibid.

³⁶⁹ Ibid.

³⁷⁰ Schneider, ‘Governing the patent system in Europe’, note 25, 622-623.

³⁷¹ President of the EPO, Draft basic proposal for a revision of the EPC implementing the organisational autonomy of the BoA of the European Patent Office within the European Patent Organisation (28 May 2004) CA/46/04

the EPO in order to strengthen the independence of these Boards. However, these proposals have not progressed in the interim, and now appear “dead in the water”.³⁷²

The independence of the BoA of the EPO was reignited by a number of controversies in the last twelve months. For instance, the issue was raised before the CJEU in Case C-146/13³⁷³ which related to Spain’s challenge of the legality of the regulation bringing into effect the enhanced co-operation scheme. The challenge was dismissed by the CJEU in May 2015. Nonetheless, one of the grounds raised was that the regulation was contrary to the rule of law under Art. 2 TEU as it delegated administrative responsibility for patent grant for the unitary patent to the EPO in circumstances where: (1) the BoA and the Enlarged Board of the EPO are established within the EPO and therefore not independent from it; and (2) their decisions were not subject to judicial review³⁷⁴ which is necessary to ensure a uniform application of EU law and guarantee of fundamental rights.³⁷⁵ The CJEU dismissed this argument in a rather technical manner, stating that the regulation did not delimit conditions for the grant of European patents which is governed by the EPC, and not EU law; nor did it incorporate procedures for the grant of European patents into EU law.³⁷⁶ Instead, the CJEU held that the regulation retained the existing structure for patent grant but merely established conditions for patents to be recognised as having unitary effect. Thus, the CJEU represented the EPO’s intervention as an “‘accessory’ administrative act”³⁷⁷ of registering this unitary effect. As a result of this reasoning, the court did not discuss the issue of the independence of these Boards of the EPO, thereby evading this critical point.³⁷⁸ The CJEU’s lack of consideration of this point is all the more disappointing given that two recent incidents within the EPO have reinforced concerns surrounding the independence of these Boards.

[http://documents.epo.org/projects/babylon/eponet.nsf/0/7A1361053D710985C12572410029C28D/\\$File/C_A_46_04_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/7A1361053D710985C12572410029C28D/$File/C_A_46_04_en.pdf) accessed 16 July 2015.

³⁷² ‘The independence of the Boards of Appeal: Merpel roars again’, *The IPKat*, 18 December 2014 <<http://ipkitten.blogspot.co.uk/2014/12/the-independence-of-boards-of-appeal.html>> accessed 16 July 2015.

³⁷³ Case 146/13 *Spain v European Parliament and Council*, 5 May 2015.

³⁷⁴ *Ibid* para 24.

³⁷⁵ A Plomer, ‘Spain v Parliament & Council (C-146/13) – a giant step towards (dis)integration of the European patent system’ *Eutopia Law*, 11 May, 2015 < <http://eutopialaw.com/2015/05/11/spain-v-parliament-council-c-14613-a-giant-step-towards-disintegration-of-the-european-patent-system/>> accessed 16 July 2015.

³⁷⁶ Case 146/13, *Spain v European Parliament and Council*, 5 May 2015, para 30.

³⁷⁷ Plomer, ‘Spain v Parliament & Council’, note 375.

³⁷⁸ *Ibid*.

The first incident was an interlocutory decision of the Enlarged BoA in R19/12³⁷⁹ which related to a petition for review involving a challenge to the proposed composition of the Enlarged BoA. The case involved a challenge to the partiality of a Chairman of the BoA involved in the decision and this was upheld by the Enlarged Board which ordered that he be replaced in the proceedings.³⁸⁰ The challenge related to the fact that the Chairman was also serving as a Vice President (VP) of the Directorate General 3 (DG3) which involves sitting on a management committee within the EPO and assisting the President of the EPO³⁸¹ on general patent issues. It was held that this compromised his judicial independence, as there was a lack of separation between the executive and judicial functions of the EPO.³⁸² Importantly there is nothing within the EPC to suggest that a Board member cannot hold such a position.³⁸³ This exacerbates the issue as it highlights that such structural deficiencies within the Boards could be pervasive. This in turn gives rise to broader questions surrounding the independence of actors sitting on the BoA.

Moreover, in December 2014 further questions were raised following a ‘house ban’ being imposed on an EPO Board member by the President of the EPO for the alleged distribution of defamatory material against an individual within the EPO management.³⁸⁴ This suspension was confirmed by the Administrative Council on 11 December 2014.³⁸⁵ However, as noted, under the EPC, an EPO Board member can only be removed from office in rare cases and this should be done following a proposal from the Enlarged BoA for removal and a decision of the Administrative Council on this.³⁸⁶ The house ban imposed by the President, and subsequent suspension of the Board member based on the President’s

³⁷⁹ R19/12 Enlarged Board of Appeal, 25 April 2014.

³⁸⁰ See R Teschemacher, ‘EPO – Vice-president DG3 as Chairman of the Enlarged Board of Appeal – Conflict of interests between the tasks as member of the management and as a presiding judge in review cases’ *EPLaw Patent Blog*, 5 May, 2014 <<http://www.eplawpatentblog.com/eplaw/2014/05/epo-vice-president-dg3-as-chairman-of-the-enlarged-board-of-appeal-conflict-of-interests-between-the.html>> accessed 16 July 2015.

³⁸¹ Art 10, EPC.

³⁸² Ingve Björn Stjerna, “‘Unitary patent’ and court system – Advocate General’s Statements of Position: Superseded by reality”, 5 March 2015, 3. <http://www.stjerna.de/index_en.htm_files/Unitarypatent_OpinionC-146_13.pdf> accessed 16 July 2015.

³⁸³ See D Smyth, ‘Suspicion of Partiality in Enlarged Board of Appeal found justified’, *IP Kat* (15 May 2014) <<http://ipkitten.blogspot.co.uk/2014/05/suspicion-of-partiality-in-enlarged.html>> accessed 16 July 2015; Teschemacher, ‘EPO – Vice-president DG3 as Chairman’ note 380.

³⁸⁴ Ingve Björn Stjerna, “‘Unitary patent’ and court system – Advocate General’s Statement”, note 382, 4; J Phillips, ‘Judicial independence: Europe’s IP judges raise EPO concerns’, *IPKat*, 5 January 2015 <<http://ipkitten.blogspot.co.uk/2015/01/judicial-independence-europes-ip-judges.html>> accessed 16 July 2015.

³⁸⁵ Ingve Björn Stjerna, “‘Unitary patent’ and court system – Advocate General’s Statement”, note 382, 4.

³⁸⁶ Art 23(3) EPC, for discussion see Ingve Björn Stjerna, “‘Unitary patent’ and court system- Advocate General’s Statement”, note 382.

proposal reinforces questions surrounding the separation of the management and judicial/quasi-judicial branches of the EPO. The President is a member of the EPO's executive branch, and therefore his suspension of the Board member, albeit later approved by the Administrative Council, is arguably, a temporary interference with the EPO's quasi-judicial branch.³⁸⁷ As a result of this incident, the EPO suggested a number of proposals for the reform of the BoA³⁸⁸ in March 2015. These proposals differ substantially from the EPO's 2004 proposals and instead of separating the BoA from the EPO, they propose that the BoA should remain within the EPO but should be given more independence within this, with no revision of the EPC.³⁸⁹ A consultation process on these proposals just concluded at the time of writing,³⁹⁰ and we await the outcome.³⁹¹

The foregoing highlights that the positioning of the BoA and the Enlarged Board within the EPO raises serious questions as to the independence of these bodies. These difficulties are exacerbated in light of some of the characteristics of the EPO considered below which arguably renders decision-making bodies situated within it highly susceptible to influence by external factors and stakeholder interests. It must also be remembered that there are no legislative provisions guaranteeing the independence of lower level decision-making bodies of the EPO such as the Examination Division, who have relevant functions in terms of assessing the applicability of the morality provisions on patent grant; thus the influences highlighted below will arguably have even greater impact on such bodies.

a) Financial interests in the decision-making process

Of particular importance in terms of external influences on judicial/quasi-judicial actors within the EPO, are the financial implications surrounding patent grant and renewal.

³⁸⁷ Ingve Björn Stjerna, "Unitary patent" and court system- Advocate General's Statement', note 382, 4

³⁸⁸ EPO, Proposal for a structural reform of the EPO Boards of Appeal (BOA) CA16/15 (6 March 2015) <http://www.epo.org/modules/epoweb/acdocument/epoweb2/164/en/CA-16-15_en.pdf> accessed 16 July 2015.

³⁸⁹ These proposals have been criticised by some, see European Patent Lawyers Association, 'Letter to Benoit Battistelli - Reform of the BoA -User Consultation' (5 June 2015) <<http://www.eplawpatentblog.com/2015/June/20150604%20Letter%20to%20Mr.%20Battistelli.pdf>> accessed 16 July 2015; Council of Bars and Law Societies of Europe (CCBE), 'Letter to Mr. Jesper Kongstad, President of the Administrative Council EPO - Independence of the Boards of Appeal of the EPO' (15 May 2015) <<http://www.eplawpatentblog.com/eplaw/2015/06/epo-letter-from-president-eplaw-to-president-epo.html>> accessed 16 July 2015.

³⁹⁰ The consultation closed on 30 June 2015.

³⁹¹ This is correct at the time of writing 16 July 2015.

Intellectual property offices such as the EPO are generally self-funded, therefore it is in their financial interests to grant more and not fewer patents. According to Drahos, offices try to keep the cost of patenting low to encourage applicants to apply for patent protection instead of other forms of protection.³⁹² Moreover, such offices rely on the renewal stream to recover costs. For example, in the EPO, the costs of initial search and examination represents 30% of the EPO's real cost,³⁹³ suggesting a shortfall of 70%. The EPO relies on the grant and renewal of patents to recover this cost.³⁹⁴ Therefore, it is not in its interest to deny patents on the basis of exclusionary provisions such as the morality provisions as this reduces its income stream because even if only a small number of patents are denied on this basis this could engender uncertainty within the system which may jeopardise the use of patents in the biotech sector. This could be perceived as risky by the EPO, and decision-makers within it. Similar direct financial constraints are not evident in the CJEU when it is charged with the interpretation of the morality provisions.³⁹⁵

b) Global Market influences and Industry Capture

Relatedly, because of the perception of the interconnectedness between intellectual property and economic productivity, Drahos highlights that none of the three lead patent offices can afford to be seen as weakening the patent system; “[t]o do so would be to imperil investment flows in the territory for which the patent office has responsibility for.”³⁹⁶ This is exacerbated in the EPO context, as the other lead jurisdictions, the US and Japan, do not have express moral exclusions within their patent systems. It also does not matter whether the causal connections between investment and patents are true; it is sufficient that the patent administrators and policy makers think that they are true.³⁹⁷ This resonates with arguments within institutional analysis discussed above, which highlight the significance of institutional perception within a decision-making context. This belief in turn may increase the reluctance of decision-making bodies within the EPO to deny patents on the basis of the morality provisions as this would drive work away from the EPO.

³⁹²Drahos, *The Global Governance of Knowledge*, note 127, 19.

³⁹³Ibid 19.

³⁹⁴For a discussion of the influence of market forces on the US patenting culture see, C Long, ‘The PTO and the Market for influence in patent law’ (2009) 157 *University of Pennsylvania Law Review* 1965.

³⁹⁵It is conceded that the Member States within the EU and national intellectual property offices could lose out financially if the denial of patents were to discourage research/commercial activity in the EU territory.

³⁹⁶Drahos, *The Global Governance of Knowledge*, note 127, 446.

³⁹⁷Ibid.

Potential for industry capture is also high within the patent system as it has become deeply absorbed and intertwined by a private governance network³⁹⁸ composed of three main influential groups, namely; big business owners of patents, the patent profession and the lead states in patenting.³⁹⁹ Intellectual property offices including the EPO are not purely public in nature; as unlike other purely administrative organs, they not only enforce the law but are charged with granting legal entitlements.⁴⁰⁰ Patent applicants have a significant financial interest in the patent system. Furthermore, a small number of multinational companies own a substantial proportion of patents worldwide.⁴⁰¹ According to Drahos, these actors have colluded “in the development of patent claim drafting techniques to overcome publicly mandated restrictions on patentability”⁴⁰² the morality exclusions being one such provision. Similarly, Schneider has argued that there is a “tacit-policy making process [of (re)interpretation by patent offices] which is masked as a mere administrative execution of law.”⁴⁰³ Consequently, patent applicants and private corporations play a significant role in shaping patent law, and arguably in influencing a narrower interpretation of these exclusions.

Indeed, intellectual property offices, such as the EPO, and private industry could be described as having a symbiotic relationship: the offices depend on private industry for income streams from patent applications/renewals, and equally the private industry depends on such offices to grant patents. This again contrasts with the EU, the overarching institution within which the CJEU is based, as the EU, does not gain commercially from the grant of patents. Additionally, these private interests within the EPO are often not offset by a sufficiently vocal public interest. Opposition proceedings provide mechanisms for including broader public interest in the system. However, the shortcomings of these proceedings have been highlighted.

All of the above raises doubts as to the independence of the decision-making bodies of the EPO and highlights their susceptibility to influence both internally as their adjudicative actors are drawn from the patent community and also external influences on the EPO. From

³⁹⁸Ibid 290.

³⁹⁹Ibid 287.

⁴⁰⁰ Schneider, ‘Governing the patent system in Europe’, note 25, 620.

⁴⁰¹ J Bessen and M.J. Meurer, *Patent Failure*, note 93, 109.

⁴⁰² P. Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients*, (CUP 2010) 288.

⁴⁰³ Schneider, ‘Governing the patent system in Europe’, note 25, 622

an institutional perspective, this again gives rise to questions in relation to institutional choice and whether - given the structure of the EPO and its differences with the CJEU – if the EPO and EPOrg can fulfil expectations which the EU may have in terms of the role the morality provisions should play. As noted, this is developed further in chapter four which looks at the EU’s framework for the interpretation of the morality provisions and influences on the CJEU in this context.

3.3.3 *Economic and Scientific Advisory Board to EPO*

Having said this, scope for introducing broader public interest concerns is provided by the recently established Economic and Scientific Advisory Board (ESAB) to the EPO. This Advisory Board was set up in January 2012⁴⁰⁴ to “address important economic and social issues relating to patents in a more dedicated and selective way than hitherto possible”.⁴⁰⁵ It is composed of 10-12 members⁴⁰⁶ - currently it has 11 members⁴⁰⁷ – and each member is appointed for a term of three years. The members are selected as “well renowned” experts and the EPO states that they will be “economists and social scientists with a focus on the patent system.” Others will be practitioners with significant experience of the European patent system.⁴⁰⁸

In terms of its objectives, to paraphrase the EPO, it states that the ESAB will:

- contribute to a comprehensive analysis of the patent system in the economic and social context;
- address issues related to the patent system which are also of interest to the European economy and society at large, and identify scientifically grounded, independent assessment of these issues;
- advise the EPO on the scope of relevant economic and social studies, providing guidance on related research projects and evaluating their impact;
- be responsible for providing early warning signals on sensitive developments and issues;

⁴⁰⁴ <<http://www.epo.org/about-us/office/esab.html> > accessed 16 July 2015.

⁴⁰⁵ EPO, *Economic and Scientific Advisory Board* (Munich, March, 2011), available at [http://documents.epo.org/projects/babylon/eponot.nsf/0/4EFA1E32DC0A6DCDC1257A6E0027B579/\\$File/esab_mandate_en.pdf](http://documents.epo.org/projects/babylon/eponot.nsf/0/4EFA1E32DC0A6DCDC1257A6E0027B579/$File/esab_mandate_en.pdf) > 1.

⁴⁰⁶ Ibid 2.

⁴⁰⁷ For further information on its composition, see <http://www.epo.org/about-us/office/esab/composition.html>

⁴⁰⁸ EPO, *Economic and Scientific Advisory Board*, note 405, 2.

- present policy recommendations for dissemination to relevant media and stakeholders.⁴⁰⁹

ESAB members will have the opportunity to take part in seminars run by the European Patent Academy where research results will be presented to the public. These results will also be published by the EPO in a dedicated selection of papers in which members can participate.⁴¹⁰ In terms of the scope of its work, the ESAB looks at matters relating to:

“...the role of patents (applications) in the early stage of the innovation process and during application procedures at the EPO, as well as the governance of the patent system and economic and social issues relating to the impact of patents after grant.”⁴¹¹

Interestingly, the ESAB will also look at “...issues related to ethical questions linked to certain technology developments, competition matters, interests of developing countries, etc.”⁴¹² The EPO stresses that the Board will be independent in its mandate and scope and will have the ability and freedom to choose issues for analysis at its own initiative.⁴¹³ However, there is no suggestion that the EPO decision-makers may refer a case or a question to the ESAB for an opinion.

The establishment of the ESAB undoubtedly offers potential to consider external public interest concerns, thereby, broadening the discussions within the EPOrg on patent issues. Nonetheless, a number of caveats must be made. First, the body considers issues externally from the decision-makers and there is no reference to its advice being binding on the EPOrg or EPO, indeed, its name clearly suggests it is merely advisory in nature. The difficulties associated with having external advisory boards in the patent system - particularly in the context of ethics bodies - have been highlighted in the literature, and similar arguments could be raised in this context.⁴¹⁴ Secondly, it is currently composed of primarily legal and

⁴⁰⁹ Ibid.

⁴¹⁰ Ibid.

⁴¹¹ Ibid.

⁴¹² Ibid.

⁴¹³ Ibid

⁴¹⁴ Petit, ‘An Ethics Committee for Patent Offices?’, note 329.

economic experts⁴¹⁵ and whilst this membership is not static, so there is scope to appoint individuals with expertise in relation to ethical issues in future; however, the absence of ethical expertise or reference to this is again suggestive of a marginal role for ethics in the work load of the ESAB. Thirdly, and related to point one, even if the Board provides an analysis or recommendations in relation to the morality provisions, it is not clear how such advice will be applied by the adjudicative bodies charged with the application of the morality provisions. It is conceded that reports issued by the ESAB could engender a shift in thinking surrounding patent policy which could be passed on to the decision-makers in the EPO. However, in light of the institutional framework and predispositions toward patent grant within the EPO, this would likely take significant time to produce results so it is questionable how much impact the ESAB would have in this context.

Finally, the focus of the body thus far appears to have been on economic aspects of the patent system.⁴¹⁶ At the time of writing, none of its reports has dealt specifically with ethical issues. It is not clear whether or to what extent it will examine ethical issues in the future. Thus, whilst it could be used as a tool to encourage further debate on the ethics of patents on new technologies, to date, as in other areas of the patent system, ethical issues appear marginalised. Fundamentally, the Advisory Board - regardless of its merits - is external to the EPORG system, and whilst it may seek to exert an influence on the EPO it is entirely unclear how this may play out in practice. Indeed, it is questionable whether: (a) it will seek to delve into moral issues; (b) if it does whether it would simply share the normative preference in favour of a marginal role for morality provisions; and finally, (c) if it does suggest change, it is unclear to what extent, if at all, this may be adopted and assimilated within the institutional framework in the EPORG, to the adjudicative bodies of the EPO.

⁴¹⁵This is correct at the time of writing 16 July 2015. For a list of members, see < <http://www.epo.org/about-us/office/esab/composition.html> > accessed 16 July 2015. A number of the current members who are drawn from a legal background have written on the ethical aspects of the patent system, in particular, Geertrui Van Overwalle who has challenged the place for the morality provisions in the patent system, see, G Van Overwalle and E Van Zimmeren, 'Functions and Limits of Patent Law' in E Claes, W Devroe and B Keirsbilck (eds), *Facing the Limits of the Law* (Springer, 2009), 415-442; G Van Overwalle, 'Bio-Patents, Law and Ethics. Critical Analysis of the EU Biotechnology Directive' *Revista de Derecho y Genoma Humano* – *Law and the Human Genome Review*, 19, (July-December 2003), 187-203; G Van Overwalle, 'Biotechnology Patents in Europe. From Law to Ethics' in *Biotechnology, Patents and Morality*, (2nd edition, Ashgate 2000) 197-206.

⁴¹⁶ It has written reports to date on the following topics: Patent Quality; Fees; Patent thickets; Recommendations for improving the Patent system – this did not discuss the morality provisions; the Unitary Patent Package; the Unitary Patent and the Unified Patent Court; Patent Aggregation and its impact on competition and innovation policy; and the economic impact of introducing a grace period in Europe. <<http://www.epo.org/about-us/office/esab/workshops.html> > accessed 16 July, 2015.

3.3.4 Reflections on the decision-making structure provided by the EPO

The decision-making bodies of the EPO differ substantially from the adjudicative bodies within national jurisdictions or the CJEU. They are composed of largely technical, not legal experts, and whilst the Boards of Appeal have a guarantee of independence enshrined within the EPC, as noted this has been called into question. Furthermore, these decision-making bodies within the EPO appear more susceptible to financial, client and industry influences than bodies such as the CJEU. These characteristics considered together reinforce the view that the decision-making bodies are institutionally predisposed and indeed configured to favour patent grant, and hence to adopt a narrow interpretation of the morality provisions which may be accepted more readily by the community to which its decisions are directed at.

Moreover, it will be argued in the next section, that if the EPO decision-making bodies were to apply the morality provisions in a manner so as to take into account broader human rights and ethical concerns or to suggest that it would do so, given the limited interpretative tools which they have this may give rise to further questions of appropriateness of the institution to fulfil such a purpose. This analysis is not arguing that the decision-making bodies within the EPO should not be applying morality provisions. Instead, it is arguing that if they start to apply such provisions with a view to adopting broader position in line with the EU trajectory in recent cases in this area, they will arguably be institutionally 'out of its depth' and without fundamental institutional change within the EPO, as will be seen below, this could be deeply problematic.

3.4 Path Dependencies

This section explores the past legislative actions of the EPOrg and also decisions of the Boards of the EPO on the morality provisions. The analysis is divided into two parts: The first part examines the competences of the EPOrg on moral issues generally which acts as a legal *constraint* on the scope of the EPO's application of the morality provisions and consideration of 'moral' issues in this context. This section also considers the EPO guidance on the interpretative principles to be used by decision-making bodies of the EPO in the application of the morality provisions. The second part focuses on the decisions of EPO, both in terms of references to moral issues generally, and also its specific decisions

in relation to the morality provisions. This analysis supports the argument that the morality provisions are generally applied in a narrow manner by the quasi-judicial bodies of the EPO, with some notable exceptions which are also examined.

3.4.1 Legislative Path Dependence and Influences on the EPO

The EPOrg is an intergovernmental organisation which was established by the EPC in 1973 and started work on the 1st June 1978 when the EPC came into force.⁴¹⁷ As noted in chapter one, there are currently thirty eight States which are signatories to the EPC. These include the twenty eight EU Member States and Switzerland, Norway, Iceland, Turkey and many of the Balkan States. Furthermore, Bosnia Herzegovina and Montenegro are extension States to the EPC which recognise European patents on request.⁴¹⁸ Thus, the Contracting and extension States to the EPC are drawn from a range of countries, and unlike the EU there is no general overarching legal community to bind these countries together; rather these countries entered into the EPC system with the sole function of having harmonised patent law in the territory covered. Furthermore, unlike the EU, the EPOrg does not create a separate legal order, nor does it have any broader constitutional principles from which the EPO decision-making bodies may refer to in their interpretation of the morality provisions. Instead, the EPO is charged with the specific task of patent grant and as will be discussed, its main guidance on this is the EPC and examiner guidelines. Furthermore, despite the EPO's role in patent grant for EU States, as noted in chapter one, the EU is not party to the EPC, nor is EU law binding on the EPOrg/EPO or *vice versa*.⁴¹⁹ In short, the EPOrg system was established for a specific purpose of patent grant and accordingly has limited powers in other respects.

Turning to the legislative competences of the EPOrg, as noted, the Administrative Council is often seen as its legislative branch,⁴²⁰ although technically it does not have formal

⁴¹⁷ Waelde, et al, *Contemporary Intellectual Property*, note 27, 10.23.

⁴¹⁸ <<http://www.epo.org/about-us/organisation/member-states/extension-states.html>> accessed 16 July 2015.

⁴¹⁹ This was confirmed in *WARF*, note 54, 15 which stated that : “While Article 23(3) EPC is in its present form, the Enlarged Board concludes that neither it, nor any Board of Appeal of the EPO, has the power to bind itself to follow a ruling of the ECJ on the interpretation of Article 6(2)(c) of the Directive and apply this to Rule 28(c) (formerly 23(c)) EPC”.

⁴²⁰ Schneider, ‘Governing the patent system in Europe’, note 25, 622.

legislative powers as recognised in the EPC.⁴²¹ Nonetheless, it is the primary forum through which changes to patent policy under the EPC can be achieved. The broader role of the Administrative Council has been considered in chapter one, and so will not be considered here again. Instead this section is concerned primarily with the EPOrg's legislative competences and activity in the field of the morality provisions, and the EPO guidance to aid decision-makers in the interpretation of these provisions.

a) Competence of the EPOrg on moral issues

Given its specialised functions, the EPC contains no legislative provisions which touch on moral issues *per se*. The EPOrg also has no express legislative remit on such issues and must remain conscious of Contracting States sovereignty. This is important given that morality involves sensitive issues affecting States constitutional, historical and cultural traditions,⁴²² and States are generally given a wide margin of discretion on such issues by international courts such as the ECtHR. Indeed, some of the EPO decisions on the morality provisions note the difficulties in obtaining a consensus on moral issues⁴²³ particularly those relating to emerging technologies. In such cases, the EPO has suggested that it would be presumptuous of it to intervene.⁴²⁴ The difficulties in ascertaining a consensus are exacerbated in the EPOrg context given the multiple States which the EPC operates in and the lack of any general common goals outside of patent law amongst these countries, this may be another reason why the EPO has been reluctant to intervene in the moral realm.

Moreover, unlike the EU whose Biotech Directive highlights guiding principles such as human dignity to be maintained when biotechnological patents are granted, the EPC does not contain such express principles which should inform its interpretation of the morality provisions. Furthermore, were the EPOrg to propose legislation providing for further interpretative principles in this context, this would need to be justified on the basis of being linked to the harmonisation of patent policy: the primary function of the EPO; otherwise it would arguably be *ultra vires* its functions.

⁴²¹ Bakardjieva Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting', note 8, 249.

⁴²² See A Plomer, 'Human Dignity, Human Rights and Article 6(1) of the EU Directive on Biotechnological Inventions' in A Plomer and P Torremans (eds.), *Embryonic Stem Cell Patents: European Law and Ethics*, (OUP 2010).

⁴²³ Decision of the Board of Appeal of the European Patent Office, *Greenpeace Ltd. v. Plant Genetic Systems*, decision of 21 February 1995, T 356/93, 16, Reasons for the decision, point 6.

⁴²⁴ See Opposition Division, *Leland Stanford*, 16 August 2001, (2002) EPOR 2, para 44.

The absence of any legislative provisions on morality in other contexts in the EPOrg may further compound the restrictive view of the morality provisions as decision-makers do not have a general familiarity of examining moral questions. In the face of such unfamiliarity, decision-makers may perceive the safer option to ensure issues are accepted by the community to which they serve would be to apply such provisions only in limited cases. This reinforces points made previously which confirms the picture of reluctance to intervene in such contexts. Moreover, given its lack of legal competences outside the patenting realm, and the fact that the EPOrg's relationship with its Contracting States relates solely to patenting, arguably it would be going beyond its legal competences were it to interpret the morality provisions in a very broad manner and deny patents on this basis more frequently.

Alongside the above, as noted the patent system is often seen as having functions which are merely technical in nature; sealed off from broader ethical considerations.⁴²⁵ The thesis does not support this view and instead argues that patent criteria require further interpretation in their application as arguably each act of patent grant requires considerable value-based decisions to be made.⁴²⁶ Nonetheless, it is how the institution views itself which is crucial in this context. If the EPOrg and EPO view themselves as being sealed off from ethics/morality and decision-makers within the EPO are unfamiliar with adjudicating on moral questions in other contexts, this arguably reinforces an institutional reluctance to apply the morality provisions to deny patents. In the absence of guiding principles or values to apply in the interpretation of these provisions (aside from the examiners guidelines which as will be discussed below these leave much discretion to the Boards) decision-makers within the EPO will look inward upon the institution itself; refracting the morality provisions through its internal institutional lens. The interpretation of the morality provisions by the judicial/quasi-judicial branch of the EPO will, in turn, reflect the limited purpose which it sees itself playing in the area and which its legal competences and interpretative tools provide for. As has been stressed above, there is nothing indefensible about this approach, what is arguably indefensible is that the EPO operates as a patent

⁴²⁵ For a discussion of this view see Bently and Sherman, 'The Ethics of Patenting: Towards a Transgenic Patent System', note 83.

⁴²⁶ See G Laurie, 'Should There Be an Obligation of Disclosure of Origin of Genetic Resources in Patent Applications? – Learning Lessons from Developing Countries' (2005) 2(2) SCRIPTed 265, 269.

granting body for EU countries and as will be argued in chapter five, the CJEU is arguably institutionally predisposed to apply such provisions in a different manner.

b) Development of the morality provisions in the EPC

Further insights can be gleaned by examining the trajectory of the legislative development of the morality provisions in the EPOrg.

i. Early legislative developments: Strasbourg Convention and EPC

The morality provisions contained in Art. 53(a) EPC developed from Art. 2(a) of the Strasbourg Convention 1963 which stated that:

“The Contracting States shall not be bound to provide for the grant of patents in respect of: (a) Inventions the publication or exploitation of which would be contrary ‘ordre public’ or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.”

Armitage and Davies who were involved in the drafting of the EPC state that the morality provision was not a feature of early drafts of the EPC. They claim that it was only added at later stages in order to permit “the continuation of powers existing in national law to refuse patents where the granting of them would be unacceptable on moral or public order grounds”.⁴²⁷ The authors raise two important points which are relevant to understanding the historical development of these provisions. Firstly, they note that the provision was not introduced as an essential feature of the substantive law that was meant to rank alongside the other requirements for patentability e.g. novelty. Rather, they argue that its introduction aimed to “do no more than permit countries to go on with what they were already doing”.⁴²⁸ This reinforces the passive role which the morality provisions were perceived as having within the EPC. Secondly, the authors recall that there was no dramatic discussion on the morality provisions and rather their inclusion was to satisfy two concerns: 1) that the government should not publish a patent specification which is obscene, blasphemous etc.; and 2) that the government would not be bound to publish instructions to the reader of a

⁴²⁷ Armitage and Davies, *Patents and Morality in Perspective*, note 104, 16.

⁴²⁸ *Ibid* 17.

patent on how to perform acts which would lead to a breach of the peace or breakdown of morals.⁴²⁹

Accordingly, they argued that “the morality check has to be seen as merely an optional, conventional, feature on the margins of the system”⁴³⁰ in the Strasbourg Convention. Moreover, they claim that when the EPC was drafted, the morality provision was adopted without controversy because it was seen as an “unremarkable but necessary marginal safeguard”.⁴³¹ Armitage and Davies conclude that a light-touch regulatory regime is consistent with the historical background and interpretation of the morality provisions. They concede that this does not necessarily mean that this is the type of regime which should operate henceforth but argue that “it seems plain to us, however, that to move from the traditional light regime to a regime of interventionist moral judgment would be a severe change in direction for the patent system.”⁴³² From this, it appears that in the Strasbourg Convention, and at the adoption of the EPC in 1973, the morality provisions were perceived as relatively marginal provisions in patent system.

ii. Advancement of Biotechnology and Entry of the EU into the Patent Arena

Nonetheless, Armitage and Davies conceded that a change in the way in which the morality provisions were applied could be justified if three conditions were met: 1) there was some event compelling a re-think and consequent change; 2) there would be significant benefits for society; and 3) such a change would not cause an impairment to the patent system in serving its primary purpose.⁴³³ Arguably, precisely such a change came about with the advancement of biotechnology and advent of biotechnological patents which could have justified a broader approach, or at least raised questions on the approach which should be taken. As a result of the advances in biotechnology, the ethical concerns in the patenting sphere were heightened and the question of what types of inventions should be patentable became increasingly uncertain. The ensuing uncertainty led the EU to adopt the Biotechnology Directive as it feared that such uncertainty would

⁴²⁹ Ibid 17.

⁴³⁰ Ibid 20. This analysis was based on their reflections on the drafting of the Strasbourg Convention which they were involved in and on reports of the committee meetings which they inspected.

⁴³¹ Ibid 24.

⁴³² Ibid 43.

⁴³³ Ibid 44-45.

lead to the biotechnological industry in the EU falling behind that of competitor jurisdictions.

As noted, the adoption of the Directive was the start of the EU's direct involvement in this area, and gave rise to the fundamental institutional overlaps explored. Following the adoption of the Directive, it should be recalled that the EPOrg voluntarily adopted the non-exhaustive list of four expressly prohibited moral exclusions contained in the Directive and also adopted Regulation 26(1) of the Implementing Regulations, which states that the Directive should be used as a supplementary means of interpretation in the context of biotechnological patents.⁴³⁴ Although EU guidance was not binding on the EPO as confirmed in *WARF*,⁴³⁵ which is discussed below, the EPOrg appeared committed to looking to the EU for guidance on its interpretation of the morality provisions. Indeed, this pattern of events is a prime example of the inter-institutional influence between the EU and EPOrg. The morality provisions started out as being contained within the EPC, but the EU then adopted its own legislative instrument in this area. The wording of the general morality provisions the EU adopted in Art. 6(1) of the Directive replicated the general morality provision contained in the EPC. Similarly, the four specific exclusions inserted by the EU were then transplanted to the EPO framework, all concrete instances of institutional influence. Nonetheless, aside from changes the EPO put in place to replicate the EU provisions, it did not adopt any other provisions of its own accord in relation to the morality provisions in response to the advent of biotechnology.

c) EPO Guidance and interpretative principles used in the application of the morality provisions

Moreover, from a decision-making perspective no further guidance was given to the EPO decision-makers on how they should go about applying the four specific exclusions from patentability. Equally there was no published guidance from the EPOrg on how the EU Directive should be used as guidance, or which principles within this should be given

⁴³⁴ As confirmed in *WARF*, note 54, 15.

⁴³⁵ *Ibid* para 7.

priority. There was also no suggestion that the interpretation of the morality provisions by the EPO would be changed dramatically in light of the EU's involvement in this area, which can be inferred by the lack of debate surrounding the adoption of these provisions in the EPO, discussed in chapter one. To further exacerbate matters, although the identical text of these four exclusions was transplanted into the EPC framework from the EU, these provisions leave much to the decision-makers discretion. For instance, key terms within these categories such as 'embryo' within Art. 6(2)(c) remained undefined leaving it to the decision-makers to give effect to these principles, which will be discussed further below.

A look at the guidance on the interpretative tools which the EPO has for applying the morality provisions reinforces the gaps that exist. As noted, unlike the EU's Biotechnology Directive, the EPC makes no reference to specific values such as human dignity or human rights which should be used in the interpretation of the morality provisions, and instead the focus of the EPC is entirely economic in nature. The preamble to the EPC notes that the Contracting States agreed to the adoption of the EPC, in light of the desire "to strengthen co-operation between the States of Europe in respect of the protection of inventions". There is no mention of overarching interpretative principles or values or any nod to ethical or moral issues which may arise. This is in stark contrast to the preamble to the Biotechnology Directive which makes a number of references to ethical implications and values such as human dignity and fundamental rights which should be upheld.⁴³⁶

The economic focus of the preamble to the EPC might be expected, given that the EPC was adopted in order to harmonise patent policy and strengthen economic performance. Furthermore, the EPC was adopted long before the advances in biotechnology would have been envisaged or the consequent ethical issues perceived. However, even after these ethical issues came to light, as noted, the EPOrg did not issue further instructions on the ethical frameworks to be adopted by decision-makers in applying the morality provisions. This suggests that the EPOrg did not envisage that decision-makers would take on a more

⁴³⁶ 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.

active role in these areas, even in light of the advances in biotechnology. To this, it is conceded that the Directive is supplementary interpretation for the EPO in applying these provisions, so one could argue that this was the transplantation of these principles. However, this appears to ignore how principles develop and need to be engrained within and supported by an institutional framework to become interpretative tools for a decision-making body.

The only express instructions for decision-makers on the morality provisions are contained within the EPO's guidelines for examination.⁴³⁷ These guidelines state that the purpose of the exclusion is to deny "protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour". It gives anti-personnel mines as an "obvious example" and states that the provisions are likely to be invoked only in "rare and exceptional cases".⁴³⁸ Notwithstanding this, the guidelines are void of any instructions on the values or interpretative principles to be used when applying the provisions, merely noting that a "fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable."⁴³⁹ In this context, these assertions that the test is 'fair', that anti-personnel mines are an 'obvious example' and that the provisions are to be invoked in 'rare and exceptional' cases are offered with no justification, instead they are presented as fact. Indeed, within the guidelines one can observe a pattern of presenting complex normative stances as truths with little or no justifications offered. This pattern is replicated in other contexts within the EPOrg, particularly in the decisions of the EPO. This suggests that over time these so-called 'truths' have become engrained within the institution which in turn supports the argument of there being an institutional predisposition existing in favour of a narrow interpretation of the morality provisions.

These references highlight an insular view of ethics and ethical questions existing within the EPO. For instance, the assertion that a test is fair in any legal context requires an explanation of why this is the case. Legal reasoning demands us to justify such normative positions. However, the EPOrg and decision-making bodies of the EPO, as will be seen, often do not offer such explanations, and when justifications are given they are often

⁴³⁷ See http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_1.htm.

⁴³⁸ Ibid.

⁴³⁹ Ibid.

superficial; failing to engage with or balance competing arguments/claims. This is arguably a result of the fact that the decision-making bodies within the EPO differ from judicial entities such as national courts or the CJEU, and perhaps an underlying fallacy in all of this is the idea that we should be expecting the same types of (legal) reasoning from such bodies.

3.4.2 EPO: Decisions on the application of the morality provisions

Turning to the decisions of the EPO on the morality provisions, the early decisions demonstrate an acute reluctance on the part of the EPO to intervene in questions of morality, whereas two recent cases⁴⁴⁰ suggest a move away from this narrow interpretation. In these recent cases, the EPO applied the morality provisions in a broader fashion incorporating the protection of fundamental human rights within the purview of these provisions. Arguably, this is a result of the inter-institutional influence of the EU, and is suggestive of mimetic or coercive isomorphism set out within sociological institutionalism, discussed in chapter two. However, this isomorphism or convergence is problematic because despite pressure coming at a legislative level for the EPO to converge with the EU's approach to the morality provisions, the institutional framework within the adjudicative bodies of the EPO remains unchanged. This means that: (a) institutional predispositions within the EPO towards a narrow interpretation of the morality provisions will prevail in the majority of cases. Arguably convergence is likely only to occur in limited cases, involving controversial issues because as noted decisions on patentability are relatively insulated from public interest, with the exception of controversial areas such as hESC patents which are widely publicised. In these contexts, arguably decision-makers within the EPO are prompted to alter the application of the morality provisions in order to ensure the legitimisation of its decisions by the public and to ensure it mirrors its perceived view of the EU approach to such areas; (b) the adjudicative bodies of the EPO are not institutionally configured to offer a comprehensive examination of principles such as human rights which the CJEU might engage with. In fact, as noted, the EPO's attempts in this context demonstrate limited reasoning, suggestive of a superficial approach to the interpretation of morality provisions. It will be argued that part of the reason for this is that the EPO is

⁴⁴⁰ These decisions are: *WARF*, note 54 and Case T0149/11 of 24 January 2013: Method and device for processing a slaughtered animal or part thereof in a slaughterhouse < <http://www.epo.org/law-practice/case-law-appeals/pdf/t110149eu1.pdf> > accessed 16 July 2015.

merely seeking to satisfy what it perceives as broader public sentiment or to mimic the EU's approach but it is not institutionally configured to deliver on a broader interpretation of these provisions.

a) *Early Decisions of the EPO on Art 53(a) EPC*

An analysis of the early decisions on the morality provisions supports the claims made above in relation to the reluctance of the decision-making bodies of the EPO to involve themselves with ethical questions. Some of the main decisions which illustrate this are as follows.⁴⁴¹ Firstly, the decision in *Leland Stanford*⁴⁴² which involved a patent sought over a modified mouse implanted with human tissue. This was intended for use in the study of treatments for HIV and also had potential as a source of cells and organs for transplant in humans.⁴⁴³ The patent was granted, but challenged in Opposition proceedings on the basis of the morality provisions for a number of reasons, including the following: that it was unethical to grant patents on life, which the modified mouse constituted; that granting such a patent would also increase costs of medicines and for experimental animals; and that the invention involved the use of human foetal cells. The Opposition Division held that the role of the EPO was not to act as a moral censor.⁴⁴⁴ Whilst acknowledging the technology was controversial, it stated that there was no consensus on the desirability of the technology in Europe, and therefore it would be presumptuous of it to intervene. Instead, it stated that the purpose of Article 53(a) was to deny patents on technology relating to extreme subject matter such as letter bombs and anti-personnel mines which “would be regarded by the public as so abhorrent that the grant of a patent would be inconceivable.”⁴⁴⁵ As this was not the case with the technology in question, the Opposition Division dismissed the challenge.

⁴⁴¹Other EPO decisions on the application of Art 53(a) EPC include: *Harvard/Onco-Mouse* [1989] OJ EPO 451; [1990] OJ EPO 476; [1992] OJ EPO 588; [2003] OJ EPO 473; [2005] OJ EPO 246; *Howard Florey/Relaxin* [1995] EPOR 541; *Lubrizol/hybrid plants* [1990] EPOR 173; *Plant Genetic Systems/Glutamine Synthetase Inhibitors (Opposition by Greenpeace)* [1995] EPOR 357; *University of Utah Research Foundation T0666/05*, Technical Board of Appeal, 13 November 2008.

For decisions of the EPO involving hESCs, see: Case T1079/03 *Edinburgh University* (Unreported) [2003] OD EP 94913174.2; Case T522/ 04 *California Institute of Technology (CIT)* (Unreported) [2003] ED EP 93921175.1); *WARF*, note 54; *TECHNION/Culturing stem cells* [2014] EPOR 23; *ASTERIAS/Embryonic stem cells* [2015] EPOR 9.

⁴⁴² *Leland Stanford* [2002] EPOR 2.

⁴⁴³ *Ibid* 22.

⁴⁴⁴ *Ibid* 23.

⁴⁴⁵ *Ibid* 23

However, no justification is provided for why the abhorrence standard was adopted or why the provisions only apply in rare cases. Equally, there is little elaboration on why a patent on a modified mouse would be acceptable but letter bombs would not be or the criteria which justified such choices. These are presented as self-evident truths in a similar fashion to the ethical stances taken in the Examination Guidelines. This reinforces the idea of engrained perceptions of the morality provisions existing within the EPO which arguably lends credence to the notion that ethics/morality are institutionally refracted in this context.

This restrictive approach to the morality criteria and use of the standard of public abhorrence is also evident in *Plant Genetic Systems N.V. et al*⁴⁴⁶ which involved an application for a patent on a way to produce genetically modified plants and seeds resistant to particular types of herbicides, namely glutamine synthetase inhibitors. It was argued that it would be immoral to grant such a patent, as plants were part of the genetic heritage of mankind and so even if modified should not be patentable. It was also argued that a modified plant would pose a risk to the environment and was dangerous to the public. However, the Technical BoA stated that the exceptions to patentability should be narrowly construed in relation to plant and animal varieties. It stated that from the historical documentation surrounding the EPC, it was evident that the European patent system was envisaged as being as wide as possible.⁴⁴⁷ A similarly narrow approach was adopted in *Novartis*⁴⁴⁸ where the Enlarged BoA acknowledged that the technology in question was controversial, as it involved genetically modified plants, but as there was no consensus in the Contracting States which condemned genetic engineering, the patent should not be denied on morality grounds. Again little by way of justification or reasoning was offered for these stances.

The EPO was particularly emphatic on the need for a narrow construction of the morality provisions in T 0866/01 *Euthanasia Composition/Michigan State University*.⁴⁴⁹ This concerned a patent granted in relation to compositions to provide euthanasia on lower mammals. The patent was challenged on the basis of the morality provisions on a number

⁴⁴⁶ [1995] EPOR 357. For an analysis, see Bently and Sherman, 'The Ethics of Patenting: Towards a Transgenic Patent System', note 83, 280.

⁴⁴⁷ [1995] EPOR 357, 367.

⁴⁴⁸ [2000] EPOR 303.

⁴⁴⁹ Case T 0866/01 Decision of the Technical Board of Appeal 3.3.02 of 11 May 2005 <<http://www.epo.org/law-practice/case-law-appeals/recent/t010866eu1.html#q=>> accessed 16 July 2015.

of grounds, including that it could have an application in humans. The Technical Board stated that it is generally accepted that:

“Article 53(a) is to be construed narrowly and that such a restrictive interpretation is, while having regard to the particular circumstances of each individual case not only correct but also justified”.⁴⁵⁰

Furthermore, it noted that the exploitation of an invention only infringes morality if “...it is regarded as reprehensible by society in general or at least by the trade concerned.”⁴⁵¹ Similarly, these statements were unaccompanied by justifications or reasoning in support of these arguments, instead they were again presented in a self-evident manner.

b) Recent Decisions

Notwithstanding the narrow application of the morality provisions in these earlier decisions; as noted two recent cases have adopted a broader interpretation of the provisions..

i. Wisconsin Alumni Research Foundation (WARF)

The first decision is *Wisconsin Alumni Research Foundation (WARF)* where a patent was sought over hESC cultures which could proliferate *in vitro*.⁴⁵² The patent was initially denied by the Examining Division as it claimed subject matter which was said to be excluded under rule 28(c) of the EPC. This states that patents will be denied for inventions which concern “uses of human embryos for industrial or commercial purposes”. *WARF*, the patent applicant, challenged this to the Technical Board, which referred four questions to the Enlarged BoA concerning the application of rule 28(c). In particular, the Board had to consider whether this exclusion would include inventions where embryos were used as a base material for the invention in question, but would not be used in the technical teaching and application of the invention. In its decision, the Board stated that the EU and EPC had

⁴⁵⁰ Ibid para. 5.4.

⁴⁵¹ Ibid para. 6.12 referring to Singer/Stauder/Schatz, Art. 53, 16-18.

⁴⁵² For a discussion of this, see S Harmon, “The rules re-engagement: the use of patent proceedings to influence the regulation of science "What the salmon does when it comes back downstream” (2006) IPQ 378, 389.

chosen to leave the term ‘embryo’ undefined in the Directive, and the Implementing Regulations.

However, it stated that:

“Given the purpose to protect human dignity and prevent the commercialization of embryos, the Enlarged Board can only presume that “embryo” was not to be given any restrictive meaning in Rule 28 (formerly 23d) EPC, as to do so would undermine the intention of the legislator.”⁴⁵³

The Board did not engage in any discussion of the meaning of dignity, the uncertainty surrounding this concept, or the potential for other dignities to be positively affected by hESC technologies. One might argue that this was because the Board was called on to decide upon one of the specific moral exclusions which offers no discretion to Contracting States. However, the legislative provision did not make it clear whether downstream technology which uses embryos as a base material would be covered and thus at least some discussion or acknowledgement of the contentious nature of the relationship between dignity, hESC research, and the rights and interests which may be implicated in the patentability of technologies involving hESC might have been expected.

Nonetheless, despite the lack of engagement with this term, the Board proceeded to use ‘dignity; as a rationale for offering a wide interpretation of ‘uses of embryos for industrial and commercial purposes’. It held firstly that ‘uses’ would include the destruction of an embryo in the preparation of the process/invention, as the technical teaching of an invention included the preparation of an invention/process. It stated at para 22 that to find otherwise would “have the undesirable consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such claim.” Moreover, the Board gave a wide interpretation to ‘industrial and commercial purposes’ stating that a product has to be made before it can be used and therefore, if the destruction of the embryo is involved in the preparation this would be seen as use for industrial and commercial purposes. Thus, the proviso had no limiting effect in this case, which contrasts with earlier decisions of the EPO

⁴⁵³ WARE, note 54, para. 20.

which offered much narrower interpretations of the morality provisions. The Board concluded that Rule 28(c) EPC:

“...forbids the patenting of claims directed to products which - as described in the application - at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, even if the said method is not part of the claims.”⁴⁵⁴

However, the inclusion of the reference to the filing date within this is interesting as it does not refer to claims which could be produced by a means other than the destruction of embryos at or before the date of filing. This meant that after the decision in WARF there was a possibility for patents on pluripotent stem cells for inventions using hESC if they were derived from publicly available stem cell lines.⁴⁵⁵ Grund and Farmer note that: “pre-existing hES cells could be obtained from a publicly available or otherwise deposited hESC cell line from a recognised public stem cell bank or other depository institution after a certain date.”⁴⁵⁶ This contention is supported⁴⁵⁷ by the fact that the UK IPO’s *Practice Note on inventions involving human embryonic stem cells following Case G02/06* issued in response to the decision in WARF referred to pluripotent stem cells which ‘can be grown in culture and the cell lines stored in cell banks’ and stated that:

“the Office will continue to grant patents for inventions involving such cells provided they satisfy the normal requirements for patentability and provided that, at the filing or priority date, the invention could be obtained by means other than the destruction of the embryo”.⁴⁵⁸

This highlights the potential for divergence at national level depending on how decisions such as this are interpreted by national intellectual property offices. Moreover, this decision

⁴⁵⁴ Ibid, Order point 2.

⁴⁵⁵ See, Grund & Farmer, ‘Brüstle v Greenpeace: the end of the road for embryonic stem cell patent’ (2012) 12(2) Bioscience Law Review 4, 43.

⁴⁵⁶ Ibid.

⁴⁵⁷ See Penny Gilbert and Geoff Lees, ‘Stemming the Tide: No more patents for human embryonic stem cells?’ (2012) 12(2) Bioscience Law Review 63, 64.

⁴⁵⁸ See UK IPO’s *Practice Note on inventions involving human embryonic stem cells following Case G02/06* (3rd February, 2009) <<http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20090203.htm>> accessed 16 July 2015.

in *WARF* contrasts with the subsequent CJEU decision in *Brustle*⁴⁵⁹ which pertained to similar subject matter, but where the court excluded from patentability any inventions which involved the destruction of the embryo even if such destruction occurred “long before the implementation of the invention.”⁴⁶⁰ So even though the decision in *WARF* arguably represented a broader interpretation of the morality provisions than previously seen in the EPO context, it did not go as far as the CJEU did – the decision in *Brustle* is discussed in chapter four. One might argue that this was a mere oversight, but nonetheless, there appears to be a sense that the EPO is constantly seeking to keep up with the EU/CJEU position in this area. Moreover, the EPO’s latest decision Case T0149/11⁴⁶¹ highlights that it is institutionally ill-equipped to do so.

ii. Case T0149/11

Case T0149/11 delivered on the 24th January, 2013 involved a patent application by Stork PMT B.V. for a process for the slaughtering of animals. Part of the patent application included the provision for an observer(s) who would be situated along the slaughter line in order to observe the process.⁴⁶² The patent was challenged via opposition proceedings by Meyn Food Processing and when this was rejected, the decision was appealed to the Technical BoA. A number of grounds were raised in appeal, including that the inclusion of this observer in the patent application was contrary to Art. 53(a) EPC as it could lead to a limitation of the liberty of a human being or slavery in breach of Art. 4 ECHR. The Board agreed with this argument and upheld the objection. It ordered the case be remitted to the first instance, where the patent could be maintained in amended form if the claims were adapted to address such issues. In its decision, the Board made a number of relevant comments in relation to the morality provisions which suggest a greater move toward the

⁴⁵⁹ *Brüstle*, note 58. Some of the literature on this case, includes: S Harmon, G Laurie, A Courtney, ‘Dignity, plurality and patentability: the unfinished story of *Brüstle v Greenpeace*’ (2013) 38(1) *European Law Review* 92-106; Plomer, ‘After *Brüstle*’ note 74; Gilbert and Lees, ‘Stemming the Tide: No more patents for human embryonic stem cells?’, note 457; E. Bonadio, ‘Stem Cells Industry and Beyond: What is the Aftermath of *Brüstle*?’ (2012) *European Journal of Risk Regulation* 93; Grund and Farmer, ‘*Brüstle v Greenpeace*: the end of the road for embryonic stem cell patent’ (2012) 12(2) *Bioscience Law Review* 4, 43.

⁴⁶⁰ *Ibid* para. 49.

⁴⁶¹ Case T0149/11 of 24 January 2013 *Method and device for processing a slaughtered animal or part thereof in a slaughterhouse* < <http://www.epo.org/law-practice/case-law-appeals/pdf/t110149eu1.pdf> > accessed 16 July 2015.

⁴⁶² *Ibid*, at 4

consideration of human rights principles by the EPO. This contrasts with earlier decisions, which firmly side-stepped ethical considerations of the subject matter under patent.

Moreover, a few statements within the decision are of note. For instance, the Board stated that:

“‘ordre public’ must be seen in particular as defined by norms that safeguard fundamental values and rights such as the inviolability of human dignity and the right of life and physical integrity. See also Singer/Stauder, *Europäisches Patentübereinkommen*, 6th ed. 2013, Art. 53 note 7, opining that human and civil rights, such as those guaranteed by international treaties and national constitutions, are to be regarded as the principal foundations of the legal order of the contracting states and as such also the foundations of ‘ordre public’”⁴⁶³

Furthermore, the Board referred explicitly to the ECHR and the Fundamental Charter of Human Rights and for the first time in decisions on the morality provisions, stated that these were incorporated within the consideration of ‘ordre public’:

“Fundamental rights and freedoms that underpin “ordre public” are codified in Articles 4 and 5 of the European Convention on Human Rights (Convention for the Protection of Human Rights and Fundamental Freedoms, Rome 1950), according to which no one should be held in slavery, and everyone has the right to liberty and shall be deprived thereof only under certain circumstances. This corresponds to the human right of integrity, the prohibition of slavery and the right to liberty under the Charter of Fundamental Rights of the European Union (Official Journal of the European Communities C 361/1 of 18 December 2000), Article 3 to 6. Since patents are instruments of private property and as such freely transferable, a patent for an invention that includes one or more human beings among its features gives rise to serious concerns as to these fundamental freedoms of the particular human beings that would be the subject of such a patent when commercialised, however, far-fetched such an interpretation may seem.”⁴⁶⁴

⁴⁶³ Case T0149/11 of 24 January 2013: Method and device for processing a slaughtered animal or part thereof in a slaughterhouse < <http://www.epo.org/law-practice/case-law-appeals/pdf/t110149eu1.pdf> > accessed 16 July 2015, para 2.5.

⁴⁶⁴ Ibid para 2.5.

Accordingly, the Board held that the claim which included having an observer should be excluded even if it was highly unlikely that the human rights of the claimed observer would be infringed. The reasoning given for this was that:

“...public trust would erode if the broader public outside of the patent profession would perceive that a morally unacceptable condition – here the ownership of a human being – somehow acquires official approval through the seal of the granted patent.”⁴⁶⁵

This reference to the public directly supports the arguments raised above in relation to the EPO actions being tailored in some cases, not because of a change in the institutional disposition towards the application of the morality provisions, but rather because it is concerned about the public perception of specific decisions. It has been argued that this will only arise in rare cases where the decision-making bodies in the EPO feels the object under patent is likely to generate controversy: to date this approach has only been taken in relation to cases where patents involved human life or hESCs. Arguably, in other less controversial applications of the morality provisions, the EPO will continue to apply the morality provisions in a narrow manner reflecting its institutional goals.

However, worryingly, when one assesses how the Board applied the morality provisions in this case, the superficial nature of its engagement with the morality provisions and interests at stake can be perceived. Similarly to *WARF*, the reasoning in this case is virtually non-existent. No real discussion is offered by the Board of the core rights implicated in this context, such as slavery, how these should be balanced or the jurisprudence of the ECtHR on these rights. Commenting on this aspect of the decision in T0149/11, Plomer notes that:

“...needless to say there is no reference in the TBA’s decision to the jurisprudence of the ECtHR on the prohibition on torture and slavery or to national or supranational regulatory frameworks on animal slaughter. Such dearth of legal

⁴⁶⁵ Ibid para 2.6.

argument would simply be inconceivable had an alleged breach of Articles 3 and 4 been subject of adjudication at the European Court of Human Rights.”⁴⁶⁶

This is only one case and definitive conclusions cannot be drawn. Nonetheless, the lack of discussion surrounding the contentious aspects involved in adjudicating on human rights such as slavery is symptomatic or at least suggestive, of an institutional configuration within the EPO which is ill-equipped to incorporate human rights values within its framework. This argument has been made above by reference to the composition of the Boards which involve individuals with limited legal expertise in adjudicating on human rights issues, with an “alarming lack of constitutional and legal anchors guiding the reasoning of the member of these [EPO higher level tribunals] boards”.⁴⁶⁷ In this decision as in *WARF*, it appears as if the EPO is merely showing lip service to a perception of how it believes it should apply the morality provisions in order to comply with the CJEU approach, and/or be accepted by the broader public. However, when one delves into the decisions there is a lack of justification or depth as to the conclusions reached. Having said this, instead of questioning the competences of the Boards in this respect, arguably we should be questioning whether the morality provisions within the current institutional framework of EPOrg as interpreted by the decision-making bodies of the EPO, can truly fulfil the same role as in the EU/CJEU context.

3.4.3 Reflections on the Path Dependencies within the EPO

From the above, it can be observed, that the EPO has no general legislative competence on moral issues, aside from the morality provisions, nor are its decision-making bodies accustomed to adjudicating upon such issues in other contexts. Furthermore, when it engages with the morality provisions it has traditionally done so in a cautious, restrictive manner. Although, recent cases suggest that the EPO may be adopting a broader approach, to date this has only happened in controversial cases. Nonetheless, it is submitted that this does not represent a change in the tide within the EPO, but rather represents a reaction to perceived extrinsic influences which may challenge the EPO’s position in terms of patent grant.

⁴⁶⁶ A Plomer, ‘Human Dignity and Patents’, note 328, 493.

⁴⁶⁷ Ibid.

The EPO's recent decision *WARF* highlights the EPO's attempt to converge with the EU position or at least what it perceives as being the EU position. In *WARF*, the EPO specifically mentioned human dignity referencing principles within the EU Directive, however, as has been argued, it offered limited reasoning in the case, and its application of the provision was more limited than the EU's position outlined in the subsequent decision of *Brustle*.⁴⁶⁸ It is conceded, that after the EU's decision in *Brustle*, the EPOrg adopted the EU's position⁴⁶⁹ by changing its Examination Guidelines (June 2012). The EPO also specifically references aspects of the Biotech Directive in its guidelines on Rule 28 and 29 of the Implementing Regulations,⁴⁷⁰ again reaffirming the role of the Directive as supplementary guidance of these provisions. Nonetheless, arguably, these instances represent not institutional change within the EPO but rather an attempt in specific instances to ensure its approach follows what it perceives as the EU approach, where it feels such an approach is needed. It is submitted that this will influence the decision-making bodies in the EPO particularly in cases involving the interpretation of the four specific exclusions brought in by the EU in Art. 6(2) of the Biotech Directive. However, as noted above, its actual application of the morality provisions and reasoning applied in such decisions is superficial at best, as the decision-making bodies of the EPO are simply not institutionally configured to deliver an interpretation of morality which aligns with the EU's approach. It remains to be seen how such guidance will be interpreted in future cases by the decision-making bodies of the EPO.

Finally, it should be noted that the most recent case of the EPO, in Case T0149/11 coincides with a time when the EU has recently adopted the fundamental charter on human rights and has made way for the planned accession to the ECHR, which could place the EPO under greater pressure to be seen to converge with these developments. Both the ECHR and the Fundamental Charter on Human Rights were referred to in Case T0149/11, having never previously been alluded to by the EPO in its decisions on the morality provisions. This could be coincidental and as this is just one case therefore firm conclusions cannot yet be drawn on this. Nonetheless, its timing is interesting and is discussed in further in chapter

⁴⁶⁸ *Brüstle*, note 58.

⁴⁶⁹ For a discussion see, 'EPO hustle to follow *Brüstle*', *IPKat*, 21 June 2012) <<http://ipkitten.blogspot.co.uk/2012/06/epo-hustle-to-follow-Brüstle.html>> accessed 16 July 2015.

⁴⁷⁰ Guidelines for Examination, Part G, (September, 2013) para 5.3 <http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_3.htm> accessed 16 July 2015.

five. Of equal interest is that this case was delivered during the final negotiations and implementation phase of the EU's unitary patent, which as noted will make the EPO the granting office for all unitary patent applications. This is a significant role for the EPO and is perhaps another impetus for it to seek to ensure that its provisions on the morality provisions are seen to align with the EU. However, it is unclear how such attempts will trickle down to the examining divisions of the EPO, and whether and to what extent this approach may influence future decisions of the Boards of the EPO in relation to the morality provisions. It is submitted that in the majority of cases, the EPO's predisposition towards a narrow interpretation of the morality provisions will remain.

3.5 Conclusion

This chapter has argued that the decision-making bodies of the EPOrg are institutionally pre-disposed to offer a narrow interpretation of the morality provisions. As has been seen, the legal constraints on the EPO including its limited legal competences in relation to moral issues, the path dependencies evident in this context and core objectives which relate primarily to patenting reinforce this view. Furthermore, the likely external influences on the EPO which have been identified predict that it will adopt a narrow interpretation of such exclusionary provisions.

Moreover, in cases where the EPO adopts a broader approach to these provisions, this may give rise to difficulties in light of: the relatively limited relationship which the EPOrg has with its Contracting States in comparison to the EU's relationship with its MSs; its lack of broader competences in the moral arena; its lack of constitutional anchoring in this context, and its limited interpretative tools to grapple with human rights questions. This is evidenced by its decisions to date, which as has been seen, are often sparse on legal reasoning or justifications in relation to the application of the morality provisions. In short, the EPO is arguably not *institutionally* configured to incorporate broader human rights concerns within the morality provisions. This is relevant in the context of the research problem explored, as it has been argued that the decision-making bodies of EU and EPO operate within vastly distinct institutional frameworks and therefore, from an institutional perspective, the decision-making bodies in the EPO should arguably not be expected to perform the same interpretative role as the CJEU in this context. This thesis suggests that because of the

institutional differences, there will always be a chasm across and between which these institutions' interpretations of morality provisions fall. This argument is strengthened by examining the institutional framework of the CJEU for the morality provisions, considered overleaf in chapter four.

Chapter four: An examination of institutional influences on the adjudicative bodies of the EU in the application of the morality provisions.

4.1 Introduction

This chapter applies the institutional template outlined in chapter two to examine the framework in the EU for the application of the morality provisions. The analysis is tailored around identifying whether, and to what extent, the institutional characteristics of the EU will influence the judicial decision-makers in the CJEU in their application of Art. 6 of the Biotechnology Directive. Therefore, it follows the same structure to chapter three. However, prior to applying the template outlined in chapter two, given the complex and broad-ranging nature of the EU as an overarching institution, 4.2 of this chapter will first provides an outline of its main contours. This includes an outline of the sub-institutions within the EU and legal principles created by the EU legal order of relevance for the application of the morality provisions. This overview is necessary background for the analysis which proceeds, as it provides context for the discussion of the institutional influences on the CJEU.

Following this overview, from 4.3 onwards the chapter moves to applying the template for assessing institutional influence as outlined in chapter two. The strands to this template can be recalled as follows: (1) The *central objectives* of the overarching institution – the EU which is considered in 4.3. This section will look at the expanding role of human rights within the EU framework, and how this and the relatively broad EU objectives may influence the CJEU in its application of the morality provisions. (2) *Institutional structure, role and composition of judicial branch* of the EU, the CJEU, and the influences which may arise in this context which are considered at 4.4. (3) Part 4.5 then considers the *path dependencies* evident within the EU which will influence the application of the morality provisions. This section will be divided into an examination of: (a) path dependencies at a legislative level which will look at the competences of the EU on moral issues generally and will then consider the development of the morality provisions within the EU's legislative framework; and (b) judicial path dependencies which considers the

jurisprudence of the CJEU relating to moral issues generally, and then focuses specifically on CJEU cases on the application of the morality provisions. A fourth strand of influence is the *inter-institutional influences* on the application of the morality provisions. However, as noted in chapter three on the EPOrg, the influences of the EU and EPOrg on each other permeate this area as the morality provisions in these frameworks were developed in parallel and with reference to the other framework, therefore such influences are considered throughout each chapter as they arise. Moreover, as noted previously the influences of the ECTHR on the EU/EPOrg will be considered separately in chapter five.

The analysis in this chapter, like in chapter three, aims to demonstrate how the institutional idiosyncrasies of the EU influence judicial decision-makers situated therein when interpreting the morality provisions. In doing so, it highlights both *legally constraining* factors such as competences/objective of underlying legislation; and also *predictive aspects* such as how the composition of the CJEU may influence how decision-makers within this body apply the morality provisions. The analysis conducted reinforces the significant differences in the scope, form, and function of the EU in comparison to the EPOrg. Moreover, it again argues that these distinctions give rise to fundamental differences in how cases on the morality provisions may be interpreted by the adjudicative bodies within the EU and EPOrg. This reinforces questions over the appropriateness of the ‘European’ patent system, as the decision-making bodies of the EPO decide upon patent applications for EU States under the classical EP process, and the EPO will also be the main granting body for the unitary patent when this comes into force.

As a caveat, this chapter does not seek to provide a comprehensive overview of the institutional framework within the EU, which is beyond the scope of this work. Instead, this chapter provides a tailored examination of each sub-heading of the institutional template outlined in chapter two with a view to ascertaining how these characteristics may influence the CJEU and judicial decision-makers within this, in their application of the morality provisions.

4.2 Nature of the EU and Guiding Legal Principles

The precise nature of the EU's legal order has been discussed since the 1960s.⁴⁷¹ Recently Niamh Nic Shuibhne examined this issue and noted that: “what the European Union is, what it is for, and ultimately who it is for, are questions that we have preferred to avoid resolving too definitively.”⁴⁷² She claims that the ambiguity surrounding the EU may be for a good reason; because this has enabled the EU as an organic polity to evolve considerably from its early beginnings, and were its purposes, form and objectives tied rigidly to a specific end(s), this development may have been precluded. She argues that:

“... the fact that the European Union is, simultaneously, many things to many people is partly *why* it can persist and develop in the face of sometimes critical political and economic challenges. Somehow, the European Union must—and manages to—balance itself on the precarious line between those who consider that it already is (or seek its constitution as) *a federal state, and those who consider that it is and should remain, essentially, an international and/or intergovernmental organisation.*”⁴⁷³[Emphasis added]

This suggests that the EU's fluid nature has allowed it to adapt over time to suit the needs of its MSs and the extent of this development has been significant. The EU's origins can be traced to the European Coal and Steel Community (ECSC) which was composed of six countries⁴⁷⁴ and regarded by many as the earliest steps towards European integration.⁴⁷⁵ The ECSC was a very different entity to the EU which exists today; the latter institution is composed at the time of writing of twenty eight MSs and is committed to objectives which extend far beyond the realm of coal and steel; these objectives are discussed in part two below.

⁴⁷¹ B De Witte, ‘Direct Effect, Primacy, and the Nature of the Legal Order’ in P Craig and G De Búrca (eds), *The Evolution of EU Law* (2nd ed, OUP 2011) 323, 324.

⁴⁷² N NicShuibhne, ‘What is “Europe” for and who is it for?’ (2012) 37(6) EL Rev 673.

⁴⁷³ *Ibid* 673.

⁴⁷⁴ France, Germany, Italy, Belgium, the Netherlands and Luxembourg were the MSs who formed the ECSC by signing of the Treaty of Paris in 1951.

⁴⁷⁵ P Craig and G De Búrca (eds), *The Evolution of EU Law* (2nd ed, OUP 2011) 5.

The EU as currently constituted, has been described as a separate legal order comprising of a ‘hybrid’ of federalist and intergovernmental features.⁴⁷⁶ Two main views on EU integration exist: Some see the EU as being state centric,⁴⁷⁷ meaning that EU integration does not challenge the autonomy of nation states,⁴⁷⁸ whereas, others propose a multi-level governance model⁴⁷⁹ which views authority as shared across a number of levels of national, supranational and subnational levels.⁴⁸⁰ A key element of this discussion centres on MS sovereignty; particularly how the EU interacts with national constitutional laws⁴⁸¹ examined in 4.2.2 below. This debate is on-going, although constitutional pluralism is gaining ground as a more palatable alternative to State or EU-centred monism.⁴⁸² Moreover, others such as Craig argue that the EU is a constitutional legal order.⁴⁸³ These specific discussions are beyond the scope of this work, but what can be taken from these for the purposes of this thesis is a sense of the complex nature of the EU.

⁴⁷⁶ A Bakardjieva Engelbrekt, ‘Institutional and Jurisdictional Aspects of Stem Cell Patenting’, note 8, 231 citing Case C-26/62 *Van Gend en Loos* [1963] ECR 1, 12; T Hartley, *The Foundations of European Community Law. An Introduction to the Constitutional and Administrative Law of the European Community* (OUP 2003) 9.

⁴⁷⁷ For an outline of these theories see: G Marks, L Hooghe, K Blank, ‘European Integration from the 1980s: State-Centric v Multi-level Governance’ (1996) 34(3) *JCMS* 341; Craig and De Búrca, *The Evolution of EU Law*, note 475, 22; G Marks, FW Scharpf, PC Schmitter, and W Streeck, *Governance in the European Union* (Sage 1996); J Caporaso, ‘The European Union and Forms of State: Westphalian, Regulatory or Post Modern’ (1996) 34 *JCMS* 29.

⁴⁷⁸ Marks, Hooghe and Blank, ‘European Integration from the 1980s’, note 477, 342.

⁴⁷⁹ *Ibid*, which cites S Liebfried and P Pierson (eds), *European Social Policy. Between Fragmentation and Integration* (Brookings Institution 1995); G Marks, ‘Structural Policy in the European Community’ in A.B. Sbragia, (ed) *Euro-Politics, Institutions and Policymaking in the ‘New’ European Community* (Brooking Institution 1992); G Marks, ‘Structural Policy After Maastricht’ in A Cafruny and G Rosenthal, (eds) *The State of the European Community* (Lynne Rienner 1993); Paul Pierson, ‘The Path to European Integration: A Historical Institutional Analysis’ (1996) 29 *CPS* 123.

⁴⁸⁰ Marks, Hooghe and Blank, ‘European Integration from the 1980s’, note 477, 342.

⁴⁸¹ P Craig, ‘Britain in the European Union’ in J Jowell, and D Oliver (eds), *The Changing Constitution* (7th ed, OUP, 2007); M Claes, ‘Constitutionalising Europe at its Source: The “European Clauses” in the National Constitutions: Evolutions and Typology’ (2005) 24 *YEL* 81; C Grabenwarter, ‘National Constitutional Law Relating to the European Union’ in A von Bogdandy, and J Bast, (eds), *Principles of European Constitutional Law* (2nd ed., Hart 2010).

⁴⁸² P Craig and de Búrca, *EU Law: Texts, Cases and Materials* (OUP, 2011), 297 citing: N McCormick, *Questioning Sovereignty* (OUP 1999); C Schmid, ‘From Pont d’Avignon to Ponte Vecchio: The Resolution of Constitutional Conflicts between the EU and the Member States through Principles of Public International Law’ (1998) 18 *YEL* 415; M Kumm, ‘Who is the Final Arbiter of Constitutionality in Europe?: Three Conceptions of the Relationship between the German Federal Constitutional Court and the European Court of Justice!’ (1999) 36 *CMLRev* 351; N Walker, ‘The Idea of Constitutional Pluralism’ (2002) 65 *MLR* 317; N Walker, ‘Late Sovereignty in the European Union’ in N Walker, (ed) *Sovereignty in Transition* (Hart, 2003); M Maduro, ‘Contrapunctual Law: European’s Constitutional Pluralism in Action’ in N Walker, (ed) *Sovereignty in Transition* (Hart, 2003); A von Bogdandy, ‘Pluralism, Direct Effect and the Ultimate Say: On the Relationship between International and Domestic Constitutional law’ (2008) 6 *I.Con* 367.

⁴⁸³ P Craig, ‘Constitutions, Constitutionalism and the European Union’ (2001) 7(2) *ELJ* 125. Also argued by J Weiler, ‘The Transformation of Europe’ (1991) 100 *Yale LJ* 2403, A Stone-Sweet, *Governing with Judges, Constitutional Politics in Europe* (OUP 2000); JC Piris, ‘Does the European Union have a Constitution? Does it Need one?’ (1999) 24 *ELR* 557, 559-565.

Whilst this thesis is not seeking to make a contribution to the nature of the EU or to the literature on its institutional landscape, as noted, some discussion of the institutional structure is necessary in order to frame the analysis which proceeds. The sections which follow offer an exposition of the differing sub-institutions contained within the EU, pointing to the specific sub-institutions which have influenced the legislative development of the morality provisions, and which may impact upon the CJEU in its application of the morality provisions.

4.2.1 Main Institutions within the EU

The EU is a complex overarching institution composed of multi-levels of overlapping and interwoven sub-institutions. There are seven main sub-institutions within the EU set out in Art 13 TEU,⁴⁸⁴ namely: the European Parliament, the European Council, the Council of Ministers, the European Commission, the CJEU, the European Central Bank and the Court of Auditors.⁴⁸⁵ Many functions are shared between these sub-institutions, so it is impossible to describe any one body as the sole legislator or sole executive⁴⁸⁶ rather inter-institutional co-operation is vital. This section examines the roles of the sub-institutions which have the most potential to influence the morality provisions at a legislative and policy level, namely, the: European Parliament, European Commission, European Council and Council of Ministers. Particular attention is given to the Commission and Parliament which have the most relevant functions in this context. The CJEU, the judicial branch of the EU, is considered separately in section 4.4 below. The two remaining institutions: the Court of Auditors whose duty is to audit the revenue and expenditure of the EU⁴⁸⁷ and the European Central Bank which is responsible for defining and implementing the monetary policy of the EU's single currency scheme,⁴⁸⁸ will not be examined as they are not relevant to the development of the morality provisions.

⁴⁸⁴ Craig and De Búrca, *EU Law*, note 482, 31.

⁴⁸⁵ <<http://europa.eu/about-eu/institutions-bodies/>> accessed 16 July 2015.

⁴⁸⁶ Craig and De Búrca, *EU Law*, note 482, 31.

⁴⁸⁷ See D Chalmers, G Davies and G Monti, *European Union Law* (2nd ed, CUP 2010), 89.

⁴⁸⁸ For a discussion of its functions, *Ibid*, 727-737.

a) The Commission

The functions of the Commission are set out in Art 17 TEU, most notably for the purposes of this thesis, are that it is responsible for: promoting the general interests of the EU; ensuring the application of the Treaties; and overseeing the application of EU law under the CJEU. Moreover, EU legislative acts may only be adopted on the basis of Commission proposals except in circumstances where the Treaty provides otherwise. The Commission may bring MSs before the European Court of Justice (CJ) a branch of the CJEU, if it believes they are in breach of EU law.⁴⁸⁹ Following the adoption of the Biotechnology Directive, the Commission referred eight MSs to the European Court of Justice for failing to implement the Directive by the July 2000 deadline.⁴⁹⁰ The Commission also monitors MS's abidance with CJEU judgments and may bring MSs before the court if it feels they have not complied with a judgment of the CJEU.⁴⁹¹

The Commission's role in initiating legislation is also relevant to the current analysis. In this vein, it enjoys the role of gate keeper as other EU bodies come to it with legislative suggestions.⁴⁹² This means the Commission can be a highly politicised arena, as bodies seek to influence it.⁴⁹³ The Commission can also exercise its veto power to influence actors, as in many cases legislative proposals cannot go ahead without it deciding to initiate them and even after it has initiated them, it can withdraw them, hence parties may be influenced into taking account its views.⁴⁹⁴ Thus, the Commission has a pivotal function in the introduction of new legislation. Indeed, the Commission introduced the first draft of the Directive on 17th October, 1988.⁴⁹⁵ However, as discussed in chapter one, this initial proposal soon ran into difficulties and was eventually rejected. The drafting process is reflected upon in further detail in 4.5.1 (b) below.

Another important feature of the Commission in the context of the morality provisions, is the role of the European Group on Ethics and New Technologies (EGE) which is an

⁴⁸⁹ Art. 258, TFEU.

⁴⁹⁰ The countries referred were Austria, Belgium, France, Germany, Italy, Luxembourg, the Netherlands and Sweden. Porter, 'The Drafting History of the European Biotechnology Directive', note 14, 17.

⁴⁹¹ Art 260(2) TFEU.

⁴⁹² Ibid 61.

⁴⁹³ G Peters, 'Agenda Setting in the European Community' (1994) 1 JEPP 9 as cited in Chalmers, Davies and Monti, *European Union Law*, note 487, 61.

⁴⁹⁴ Ibid 61.

⁴⁹⁵ Porter, 'The Drafting History of the European Biotechnology Directive', note 14, 7.

external advisory body to it. The EGE is discussed at this juncture in order to provide a more complete picture of how influences acting upon the Commission may also influence the morality provisions, and as will be seen the EGE's role was integral to the development of the morality provisions in the Biotechnology Directive.

i. European Group on Ethics in Science and New Technologies (EGE)

The origins of the EGE lie in the Group of Advisors to the European Commission on the Ethical Implications of Biotechnology (GAEIB) which operated from 1991-1997.⁴⁹⁶ When the GAEIB's mandate expired it was succeeded by the EGE in 1998.⁴⁹⁷ The EGE's aim is to "advise the Commission on ethical questions relating to sciences and new technologies, either at the request of the Commission or on its own initiative".⁴⁹⁸ Questions may also be brought to the attention of the EGE by Parliament or the Council if they consider these to be of major ethical importance.⁴⁹⁹ In order to fulfil its functions, the EGE meets at least six times every twelve months. In preparing its opinions it may invite experts having specific competences to guide work of the EGE.⁵⁰⁰ It may also initiate studies in order to garner technical/scientific data deemed necessary, or set up working groups to consider a particular area.⁵⁰¹

Composition of the EGE

The EGE is composed of a maximum of fifteen members⁵⁰² who are appointed for a period of five years and can be reappointed for a further two terms.⁵⁰³ The list of members is published in the Official Journal of the European Union. At the time of writing, it is

⁴⁹⁶ E Griessler, 'Citizen Participation in Controversial EU Research Policies? The Debate on Human Embryonic Stem Cell Research Within the 6th Framework Programme' "in P Robins, F Huzair, (eds) *Exploring Central and Eastern Europe's Biotechnology Landscape* (Springer 2012) 46. An overview of the history of this body is provide by Plomer (Co-ordinator), *Stem Cell Patent Report*, note 47, 119-122.

⁴⁹⁷ A Plomer, 'The European Group on Ethics: Law, Politics and the Limits of Moral Integration in Europe' (2008) 14(6) ELJ 839, 841.

⁴⁹⁸ Art 2 Commission Decision 2010/1/EU of 23 December 2009 on the renewal of the mandate of the European Group on Ethics in Science and New Technologies [2010] OJ L1/8. (Decision 2010/1/EU)

⁴⁹⁹ Ibid Art. 2.

⁵⁰⁰ Ibid Art. 4.

⁵⁰¹ Ibid.

⁵⁰² Ibid.

⁵⁰³ Ibid.

composed of fifteen members;⁵⁰⁴ including eight members who have been reappointed⁵⁰⁵ and seven new members.⁵⁰⁶ Individuals are selected on the basis of an open call for interest,⁵⁰⁷ but must be appointed by the President of the Commission. They are appointed *ad personam*; in other words they are expected to be independent and represent their own views.⁵⁰⁸ They must advise the Commission free from outside influence, and the EGE shall be “independent, pluralist and multidisciplinary”.⁵⁰⁹

Influence of the EGE in the patentability of biotechnological inventions

The EGE has published a number of opinions relating to the patentability of biotechnology which have been influential to the morality provisions. Of particular relevance are: Opinion No. 3 of 1993 on the Commission proposal for a Directive on biotechnological inventions (Opinion No. 3 of 1993);⁵¹⁰ Opinion No. 8 of 1996 on Ethical Aspects of Patenting inventions involving elements of human origin⁵¹¹ (Opinion No. 8 of 1996); and Opinion No. 16 of 2002 on Ethical Aspects of Patenting involving Stem Cells of Human Origin⁵¹²(Opinion No. 16).

Busby et al argue that the EGE had substantial influence over the final text of the Biotechnology Directive⁵¹³ and that its role “was no less than to validate EU legislation”.⁵¹⁴ They claim that the establishment of the GAEIB in 1991 was at least partly to address the ethical debate surrounding the development of the Biotech Directive.⁵¹⁵ They also point to

⁵⁰⁴ This is correct at the time of writing 16 July 2015.

⁵⁰⁵ These are: Emmanuel Agius, Inez de Beaufort, Hille Haker, Julian Kinderlerer, Linda Nielsen, Paula Martinho da Silva, Pere Puigdoménech Rosell, Günter Virt. See, Decision of the President of the European Commission 2011/C12/04 of 10 January, 2011 on the appointment of the members of the European Group on Ethics in Science and New Technologies for its fourth mandate [2011] OJ C12/9.

⁵⁰⁶ Ibid, these are: Peter Dabrock, Andrzej Górski, Ritva Tuulikki Halila, Herman Nys, Siobhán Marie O'Sullivan, Laura Palazzani, Marie-Jo Thiel.

⁵⁰⁷ Art. 3(2) of Decision 2010/1/EU.

⁵⁰⁸ A Mohr, H Busby, T Hervey, R Dingwall, ‘Mapping the role of official bioethics advice in the governance of biotechnologies in the EU: The European Group on Ethics’ Opinion on commercial cord blood banking’ (2012) 39 Science and Public Policy 105, 108.

⁵⁰⁹ Art 3, Decision 2010/1/EU.

⁵¹⁰ GAEIB, *Opinion No 3 on ethical questions arising from the Commission proposal for a Council directive for legal protection of biotechnological inventions*, 30 September 1993.

⁵¹¹ GAEIB, *Opinion No. 8 on ethical aspects of patenting inventions involving elements of human origin*, 25 September, 1996.

⁵¹² EGE, *Opinion No. 16: Ethical Aspects of Patenting Inventions Involving Human Stem Cells*, 7 May 2002.

⁵¹³ H Busby, T Hervey and A Mohr, ‘Ethical EU law? The influence of the European Group on Ethics in Science and New Technologies’ (2008) 33 ELR 803, 834.

⁵¹⁴ Ibid 834

⁵¹⁵ Ibid 811.

the significant influence of Opinion No. 3 of 1993; and Opinion No. 8 of 1996⁵¹⁶ on the early development of the Directive. Opinion No. 3 of 1993 offered a statement in support of the adoption of the Directive⁵¹⁷ and fed into the initial draft of the Directive. However, as noted this first draft was rejected by Parliament. Nonetheless, in 1996 the Commission sought the GAEIB's opinion again on the amended Directive⁵¹⁸ and this advice came in the form of Opinion No. 8 of 1996.

There are a number of examples of how the final text of the Directive was heavily influenced by GAEIB and the EGE's opinions. For instance, the four categories specifically excluded from patentability, now contained in Art. 6(2) of the Directive, derive from the GAEIB's Opinions in this area.⁵¹⁹ Moreover, Busby et al⁵²⁰ note that the ethical considerations in the recitals to the Directive reflect guidance in Opinion No. 3 of 1996 and Opinion No. 8 of 1996, particularly Recital 16 which is discussed at 4.5.1 (c) below. Furthermore, in Opinion No. 3 of 1996, the EGE requested further guidance on the scope of the Directive⁵²¹ which was addressed by the adoption of chapter two of the Directive entitled "Scope of Protection". The EGE is also expressly referred to in the Directive in Art 7 which states that "The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology" and again in recital 44. Interestingly, Busby et al claim that without the ethical stamp of approval from the GAEIB/EGE, it is unlikely that the Directive would have been adopted;⁵²² as the Directive represented "all of the public's worries about biotechnology, eugenics and dignity"⁵²³ and the GAEIB helped to address these and the intense public debate surrounding the issues which smoothed the legislative path.⁵²⁴

From an institutional perspective this is interesting, as rather than resolve issues through existing organs, the EU established the GAEIB (later becoming the EGE) to filter these. In

⁵¹⁶ Ibid 811.

⁵¹⁷ Opinion No. 3 of 1994, 9.

⁵¹⁸ Busby, Hervey and Mohr, 'Ethical EU law?' note 513, 812.

⁵¹⁹ Ibid 813.

⁵²⁰ Ibid 813.

⁵²¹ The GAEIB stated that "since these issues have never previously arisen in the field of patent law, some clarifications are urgently needed on certain concepts and on the scope of certain provisions in the Directive." Opinion, No. 3 of 1993, 9. See, Busby, Hervey and Mohr, 'Ethical EU law?' note 513, 813.

⁵²² Busby, Hervey and Mohr, 'Ethical EU law?', note 513, 834.

⁵²³ R Gold and A Gallochat, 'The European Biotech Directive: Past as Prologue' (2001) 7(3) ELJ 331, 339, as cited in Busby et al, Ibid 814.

⁵²⁴ Ibid 814.

doing so, ethical issues in relation to biotechnologies were centralised in a body which has questionable status within the EU constitutional order. Both the GAEIB and the EGE are composed of unelected representatives and therefore, the fact that their guidance played a significant role in the drafting of the Directive is questionable in terms of democratic accountability. These points are returned to in considering the criticisms of the EGE below. Nonetheless, despite the EGE's influence at a legislative level in the Directive's development, this does not mean that the EGE guidance will be followed by the CJEU in cases involving the application of the morality provisions.

The EGE's role is merely advisory and its advice is not legally binding on national or supranational courts.⁵²⁵ Moreover, Plomer et al highlight that it can only issue guidance in respect to the application of basic ethical principles in relation to biotechnologies and an "evaluation of individual patent applications lies outside"⁵²⁶ its competence. Indeed, in the *Edinburgh* case,⁵²⁷ which was the first EPO decision relating to the patentability of isolated pluripotent hESCs, the EPO rejected the application. In doing so it departed from the majority guidance of the EGE which had recommended that there was no obstacles to patents on hESC technology or inventions "in so far as they fulfil the requirements of patentability (novelty, inventive step and industrial application)".⁵²⁸ The Opposition Division in *Edinburgh* instead held that such cells were unpatentable on the grounds that the specific exclusion for 'uses of embryos for industrial or commercial purposes' was aimed to exclude patentability for any cells obtained from the human embryo, in a manner that necessitated the destruction of the embryo.⁵²⁹ Whilst, the EPO is outside the EU framework, one may have thought the EGE guidance would have been persuasive to this body given that the Biotech Directive is supplementary interpretation for the EPO in the relation to the morality provisions. More surprisingly, the CJEU decision in *Brüstle*⁵³⁰ which was the first case before the CJEU to deal with such issues and is discussed below, also departed from this EGE guidance and held that inventions involving hESCs would be

⁵²⁵Plomer (Co-ordinator), *Stem Cell Patent Report*, note 47, 118.

⁵²⁶Ibid 118.

⁵²⁷European patent No. EP0695351 (University of Edinburgh), Decision of the Opposition Division of 21st July 2003 (Unreported) < <https://register.epo.org/application?number=EP94913174>> accessed 16 July 2015.

⁵²⁸ EGE, Ethical aspects of Patenting Inventions involving Human Stem Cells, 7th May, 2002, 15. For discussion, E Toumi, 'EC Patents' note 98, 15.

⁵²⁹ Plomer et al claim its decision related to the reasoning in the dissenting opinion of one EGE member, Prof. Günter Virt's in EGE, Opinion No. 16 of 2002, 14. Plomer (Co-ordinator), *Stem Cell Patent Report*, note 47,12

⁵³⁰ *Brüstle*, note 58.

unpatentable. In short, whilst the EGE helped pave the way for the adoption of the Directive, its guidance can and has been departed from by the CJEU, so despite its influence in the drafting process, its influence on the CJEU is arguably likely to be minimal.

Criticisms of the EGE

The criticisms of the EGE centre on the lack of transparency of the EGE's functioning, the questionable independence of this body, and its lack of democratic accountability. Mohr et al have criticised the ambiguous role the EGE plays within the EU framework for the governance of biotechnologies,⁵³¹ arguing that it lacks a clear constitutional basis, and has a somewhat unclear relationship with the European Commission.⁵³² The difficulties surrounding professional ethical committees in other contexts have also been highlighted by Petit.⁵³³ Similarly, Busby et al also note that ethics bodies have been criticised for drawing on a narrow and limited field of expertise⁵³⁴ which can reinforce a reductionist view of "ignorant incompetent publics".⁵³⁵ They argue that the EGE's elite membership and narrow repertoire of ethical arguments excludes and masks alternative views".⁵³⁶ Furthermore, given the unelected nature of members of the EGE, questions as to the democratic deficit of this body persist.⁵³⁷ Issues have also been raised by Plomer et al in relation to the methodology of the EGE: given that members are drawn from different disciplines each with different methodologies, they highlight that early opinions of the EGE were criticised as lacking in clarity as to the conclusions reached.⁵³⁸ Questions also arise as to quality of their guidance;⁵³⁹ and the independence of the members of the EGE; in particular the extent to which the group is or should be representative of various

⁵³¹ Mohr, Busby, Hervey and Dingwall, 'Mapping the role of official bioethics advice', note 508, 105.

⁵³² Ibid 106.

⁵³³ Petit, 'An Ethics Committee for Patent Offices', note 329.

⁵³⁴ Mohr, Busby, Hervey and Dingwall, 'Mapping the role of official bioethics advice', note 508, 114 citing JL Scully, T Shakespeare and S Banks, 'Gift not commodity? Lay people deliberating social sex selection' (2006) 28 *Sociology of Health & Illness* 749; HT Engelhardt, 'Confronting moral pluralism in post-traditional Western societies: Bioethics critically reassessed' (2011) 36 *Journal of Medicine and Philosophy* 243.

⁵³⁵ Mohr, Busby, Hervey and Dingwall, 'Mapping the role of official bioethics advice', note 508, 114.

⁵³⁶ Ibid 114.

⁵³⁷ Ibid 114.

⁵³⁸ Plomer (Co-ordinator), *Stem Cell Patent Report*, note 47, 123.

⁵³⁹ Ibid 122-125.

perspectives.⁵⁴⁰ Moreover, like other national and supranational bioethics committees, it is arguably prone to political capture.⁵⁴¹

It is curious that despite these shortcomings the EGE plays an important role in the web of bioethical governance that exists within the EU⁵⁴² and has been a central influence to the legislative drafting of the Directive. Nonetheless, from an institutional perspective, although the role this body plays as an internal ethical eye within the EU framework in the context of biotechnologies is evident, however, as has been demonstrated its guidance can and has in the past been departed from by the CJEU in the interpretation of the morality provisions. This again highlights the potential for disconnect in terms of what is being advised or happening at a legislative level, and how this is translated or not, as the case be may, to the adjudicative level in the application of the morality provisions. Arguably, due to the EGE's curious positioning it is seen by the CJEU as external to the EU institutional framework, and so despite its influence in the drafting of the Directive, it is not embedded sufficiently within the EU to be persuasive to the CJEU in its judicial interpretation of the morality provisions. Moreover, the EGE's most recent guidance in this context was written over ten years ago, and since then science has developed, so the questions now posed differ from those considered at the time, this is evident in looking at recent cases of the CJEU in this context, discussed at 4.5.2(b) below.

b) The European Parliament

The European Parliament has a number of powers within the legislative process which are of relevance. It may act in an agenda setting capacity by requesting the Commission to submit a legislative proposal.⁵⁴³ It may also use an 'own initiative report', whereby the relevant parliamentary committee draws up a report. Parliament then votes on this in plenary session where it can adopt a resolution that requires the Commission to act.⁵⁴⁴ However, the Parliament's role in the legislative procedure differs depending on whether

⁵⁴⁰ Ibid 126.

⁵⁴¹ Ibid 126 citing K Braun, 'Deliberation, democracy, and bioethics: How to democratise the politics of biomedicine?' Paper presented at the European Consortium for Political Research, Joint Session of Workshops, Turin, March 22-27, 2002.

⁵⁴² Mohr, Busby, Hervey and Dingwall, 'Mapping the role of official bioethics advice', note 508, 114.

⁵⁴³ Chalmers, Davies and Monti, *European Union Law*, note 487, 86.

⁵⁴⁴ Ibid 86.

it is the consultation or ordinary legislative procedures⁵⁴⁵ - the latter was previously the co-decision procedure. Under the consultation procedure the Parliament will be consulted about a proposal and may then propose amendments, whereas under the ordinary legislative procedure it can also veto the proposal.⁵⁴⁶ Parliament also has extensive powers over other institutions, for instance, it has the power to dismiss the Commission,⁵⁴⁷ to approve the President of the Commission nominated by Heads of Government⁵⁴⁸ and to question any incoming Commissioner before approval is given for their appointment.⁵⁴⁹ These functions highlight the clear inter-institutional co-operation and checks between various sub-institutions of the EU in the legislative process. As evident from the discussion in chapter three, these checks are notably absent in the EPOrg framework, again reinforcing the differences between the institutional frameworks within the EPOrg and EU.

c) Council of Ministers and the Council of the European Union

These institutional overlaps are also evident in the functions of the Council of Ministers and the Council of the European Union (the Council), which represent national MSs in the EU. Art 16(1) TEU states that the Council of Ministers “shall, jointly with the European Parliament, exercise legislative and budgetary functions.” The Council also acts as a forum for MSs to consult each other in order to harmonise behaviour in areas which the EU has competence in.⁵⁵⁰ Furthermore, it can bring other EU institutions to court for failing to comply with EU law⁵⁵¹ or to act when required to do so by the EU;⁵⁵² and it has the final decision on whether legislation will be adopted in most areas of EU law.⁵⁵³ According to Chalmers et al, this last function means that it is perceived as “the most important institution in the law making process” which is interesting as the Council is composed of a minister from each MS.⁵⁵⁴ This prominent role of the Council, and the fact that it is composed of elected representatives from EU MSs highlights the democratisation of the process and the

⁵⁴⁵Ibid 86.

⁵⁴⁶Ibid 86.

⁵⁴⁷ Art. 17(8) TEU, Art 234 TEU.

⁵⁴⁸ Art. 17(7) TEU.

⁵⁴⁹Chalmers, Davies and Monti, *European Union Law*, note 487, 87.

⁵⁵⁰ Art. 121 TFEU.

⁵⁵¹ Art. 225 TFEU.

⁵⁵² Art. 265 TFEU.

⁵⁵³ For further description of these functions see Chalmers, Davies and Monti, *European Union Law*, note 487, 68.

⁵⁵⁴ Art. 16(2) TEU.

link with MSs voting publicly to EU policy. This contrasts with the Administrative Council of the EPOrg, often seen as the ‘legislative’ body of the EPOrg. As discussed, the Administrative Council is composed of a national representative of each State, however, there is no requirement that such representatives be elected officials and instead are generally the heads of intellectual property offices in the various countries.⁵⁵⁵ This highlights the absence of a similar link within the Administrative Council between voting publicly and the legislative process in the EPOrg.

d) European Council

An extra safeguard in terms of giving MSs a say on EU policy is provided through the European Council which is made up of the heads of government of all EU MSs, a President and the President of the Commission.⁵⁵⁶ The European Council was formally recognised as an institution in the Lisbon Treaty. Under Art 15(1) TEU it is endowed with the role of providing “the Union with the necessary impetus for its development and shall define the general political directions and priorities thereof.” Art 15(1) also provides that it will not have a legislative role. Nonetheless, Chalmers suggests that its role will instead be to “steer, direct and prompt the general course of the Union far more actively than previously.”⁵⁵⁷ It has a number of powers to shape the membership, dictate criteria for new membership of the EU and importantly, may instigate treaty reform.⁵⁵⁸ It also has powers in relation to setting the composition of the Parliament and Commission⁵⁵⁹ and finally, it appoints various members of other institutions including the President of the Commission. These functions, are akin to an overseeing role, and given that the Council is composed of heads of the governments of MSs this reaffirms the link between the governance of the EU, as an institution, and MSs voting publicly.

⁵⁵⁵ For a list of the representatives <<http://www.epo.org/about-us/organisation/administrative-council/representatives.html#gb>> accessed 16 July 2015.

⁵⁵⁶ Art 15(2) TEU. For further information: Chalmers, Davies and Monti, *European Union Law*, note 487, 74.

⁵⁵⁷ Ibid 76.

⁵⁵⁸ Ibid 76.

⁵⁵⁹ Art. 14(2) and 17(5) TEU.

e) Interim reflections on the nature and institutional structure of the EU

From the above, it is evident that the EU comprises a complex amalgamation of sub-institutions who work together to deliver legislative and policy change and exercise a number of checks on each other in this context. At times, it acts as a highly politicised forum given the powers which institutions may hold over each other, which may result in bargaining or negotiating within the institutions and between the institutions and MSs. As has been seen, these checks are notably absent in the EPOrg context.

At this juncture, in order to build a more complete picture of the EU, the authority of EU law vis-à-vis MSs must also be considered as this is a key feature which sets the EU apart from other international institutions such as the EPOrg.

4.2.2 EU law and Member States sovereignty

Two characteristics of EU law are particularly relevant in considering its relationship with MS sovereignty, namely: direct effect and the principle of supremacy. Direct effect is defined by De Witte as “the capacity of a norm of Union law to be applied in domestic court proceedings”⁵⁶⁰ whilst supremacy has been defined as “the capacity of that norm of Union law to overrule inconsistent norms of national law in domestic court proceedings.”⁵⁶¹ De Witte argues that whilst other international organisations are not precluded from introducing similar powers they generally have not.⁵⁶² It is useful to reflect on how both of these principles apply under EU law at this juncture.

a) Direct Effect

The direct effect of EU law was confirmed in the decision of *Van Gend en Loos* which held that the Treaties constituted a “new legal order of international law”⁵⁶³ in which citizens’ derived rights directly from the EEC Treaty, even if this was not usually the case in other

⁵⁶⁰ De Witte, ‘Direct Effect, Primacy’, note 471, 324.

⁵⁶¹ Ibid 323.

⁵⁶² Ibid 362.

⁵⁶³ Case 26/62 *Van Gend en Loos* [1963] ECR 1, para 2.

international treaties.⁵⁶⁴ This was reiterated in *Francovich and Bonifaci v Italy* which stated that:

“[the] EEC Treaty has created its own legal system which is an integral part of the legal systems of the Member States and which their courts are bound to apply; the subjects of that legal system are not only Member States but also their nationals.”⁵⁶⁵

Nationals can obtain enforceable rights from the EU,⁵⁶⁶ and EU law may be directly invoked within national courts. However, the choice of legal act is important, as whilst regulations are always directly applicable, directives such as the Biotechnology Directive, only bind States as to the result to be achieved but leave the means and form of implementation up to national States. Indeed, Bakardjieva Engelbrekt has argued that the choice of implementation of the Biotechnology Directive as a Directive rather than a Regulation or other legislative tool, suggests a lower harmonisation ambition of the EU.⁵⁶⁷ Moreover, the Biotechnology Directive leaves some concepts open to interpretation. For instance, it does not provide a definition of *ordre public* or morality which has been held to suggest that a wide margin of manoeuvre for MSs. This concept draws on the European Court of Human Rights (ECtHR) margin of appreciation doctrine which is discussed further below; whilst the cross fertilisation between the ECtHR and CJEU in this context is explored in chapter five.

b) Supremacy of EU law and relevant balancing tools

The related concept of the supremacy or primacy of EU law was confirmed in the decision in *Costa v ENEL*⁵⁶⁸ and has been the subject of extensive literature.⁵⁶⁹ Supremacy means

⁵⁶⁴Craig and De Búrca, *EU Law*, note 482, 185.

⁵⁶⁵ Cases C-6 and 9/90 *Francovich and Bonifaci v Italy* [1991] ECR I-5357, para 30.

⁵⁶⁶ P Pescatore, 'The Doctrine of 'Direct Effect': An Infant Disease of Community Law' (1982) 8 EL Rev 155, 158 as cited in Craig and De Búrca, *EU Law*, note 482, 186.

⁵⁶⁷Bakardjieva Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting', note 8, 235.

⁵⁶⁸ Case 6/64 *Costa v ENEL* [1964] ECR 585.

⁵⁶⁹See A Dyeve, 'European integration and national courts: defending sovereignty under institutional constraints?' (2013) 9(1) *ECL Rev* 139; S Hix, *The Political System of the European Union* (Palgrave 2005) 2; H H Weiler and U R Haltern, 'Constitutional or International? The Foundations of the Community Legal Order and the Question of Judicial Kompetenz-Kompetenz' in A M Slaughter et al. (eds.), *The European Courts and National Courts - Doctrine and Jurisprudence* (Hart Publishing 1998) 331-364; G van der Schyff, 'The constitutional relationship between the European Union and its Member States: the role of national identity in article 4(2) TEU' (2012) 37(5) *ELR* 563.

that in the event of conflict between MS and EU law, EU law will take precedence.⁵⁷⁰ However, EU powers are limited by the doctrine of conferral or conferred powers governed by Art 5(1) TEU which provides that the EU must act within the scope of its Treaties and cannot intervene in areas outside this scope.⁵⁷¹ Nonetheless, there are flexibilities to this, for instance, the doctrine of implied powers whereby powers can be implied from provisions.

Furthermore, a number of specific legislative provisions expand upon the competences of the EU, for instance Art 114 TFEU allows the EU to adopt measures of harmonisation with the objective of the “establishment and functioning of the internal market”. Also relevant is, Art 352(1) TFEU which replaces Art 308 EC, and grants legislative powers to the EU whenever these are necessary to realise EU objectives listed in Art 3(2), (3) and (5) TFEU.⁵⁷² This is curtailed by Declaration 42 which states that Art. 352 “cannot serve as a basis for widening the scope of Union powers beyond the general framework created by the provisions of the Treaties as a whole...”⁵⁷³ Moreover, whilst the EU has no conferred powers within the field of IP law, it has been argued by Bakardjieva Engelbrekt that the territorial nature of IP rights may be in conflict with the goals of the internal market,⁵⁷⁴ hence bringing it under scope of EU law. In this vein, the Biotechnology Directive was originally adopted under Art 100a of the EC Treaty which conferred powers for the purpose of ensuring the proper functioning of the internal market. Arguably in light of this legislative basis, the intention of the Directive was to act as a harmonising measure but not to “radically overhaul existing law”.⁵⁷⁵

These competences are also kept in check by the principles of subsidiarity and proportionality. Subsidiarity means that the EU must intervene in an area which falls outside its exclusive competence (in cases where it shares competences with MSs) only:

“...if and insofar as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at the central or at regional and local level,

⁵⁷⁰ As an aside, the guarantee of primacy was removed from the text of the Treaty by Lisbon, which instead adopted a declaration on primacy. For discussion, see De Witte, ‘Direct Effect, Primacy’, note 471, 345; Craig and De Búrca, *EU Law*, note 482, 266. M Dougan, ‘The Treaty of Lisbon 2007: Winning Minds not Hearts’ (2008) 45 CML Rev 617, 700.

⁵⁷¹ Chalmers, Davies and Monti, *European Union Law*, note 487, 212-213.

⁵⁷² *Ibid* 214.

⁵⁷³ Declaration 42 on Article 352 of the Treaty on the Functioning of the European Union.

⁵⁷⁴ Bakardjieva Engelbrekt, ‘Institutional and Jurisdictional Aspects of Stem Cell Patenting’, note 8, 232.

⁵⁷⁵ Porter, ‘The Drafting History of the European Biotechnology Directive’, note 14, 10.

but can rather, by reason of the scale of the effects of the proposed action, be better achieved at Union level”.⁵⁷⁶

The principle of proportionality means that the mechanisms the EU adopts should be proportionate to the aims sought to be achieved and set out in the Treaties.⁵⁷⁷ Another limitation on EU powers, relevant in the context of the morality provisions, is the protection which the EU provides for cultural and linguistic diversity of its MSs enshrined in Art. 3(3). Furthermore, Art. 4(2) TEU provides respect for MS’s national identities including constitutional provisions of States. These provisions are discussed in chapter five but highlight the need for the EU to act in a way which respects MS’s constitutional traditions and histories. Therefore, whilst the EU has a range of legislative powers in a variety of areas, MS sovereignty must be carefully considered and is safeguarded by the measures above.

4.2.3 Reflection on the institutional structure and nature of the EU

From the above it is evident that the EU is a powerful institution, which treads the line between being akin to a federal entity and an international organisation. Arguably, the best description of the EU is that it is a *sui generis* body with broad reaching powers over MSs and conferring rights to citizens within the EU. Furthermore, although the precise nature of the entity remains elusive, for the purposes of the thesis it can be argued that, it is without doubt very different to the EPOrg. In particular, the EPOrg as noted in chapter three was set up by the EPC to provide for a granting scheme for patents and its competences are geared specifically towards this function, this is in contrast to the far broader role and competences of the EU.

Moreover, the EU’s institutional framework is imbued with several institutional checks and structures to safeguard MS sovereignty. It is a wholly different enterprise to the EPOrg system, indeed this is to be expected given their differing functions. The difficulty that arises in the context of the thesis, is that if the decision-making bodies in the EPO as evident in recent cases, seek to mirror protection for human rights that the EU might give within

⁵⁷⁶ Art. 5(3) TEU. The principle of subsidiarity is discussed in Craig and De Búrca, *EU Law*, note 482, 94-100.

⁵⁷⁷ <http://europa.eu/legislation_summaries/institutional_affairs/treaties/lisbon_treaty/ai0017_en.htm> accessed 16 July 2015.

their decisions, on the morality provisions, it does so without this extensive backdrop of protections for national laws which the EU has built and developed over time and as will be seen in chapter five this is arguably deeply problematic. Further support for these differing institutional influences and the significance of this in the context of the morality provisions, is gleaned by applying the institutional template outlined in chapter two.

4.3 Central Objectives of the EU

This section commences applying the template outlined in chapter two by examining the objectives of the EU which as suggested by MacCormick is crucial for gaining an understanding of how an institution acts and behaves. The central objectives are a key *constraining* influence, as decision-making bodies must act in a way which is in line with its competences and in furtherance of their central aims as set out in statute. The evolution of the EU has been significant and according to the self-description on EUROPA, the official website of the EU, from “[w]hat began as a purely economic union has evolved into an organisation spanning policy areas, from development aid to environment.”⁵⁷⁸

4.3.1 Objectives of the EU

Guidance on the EU’s aims can be gleaned by looking to the Treaties; in particular Art 3 TEU, which sets out the following:

“1. The *Union's aim is to promote peace, its values and the well-being of its peoples.*

...

3. The Union shall establish an internal market. It shall work for the sustainable development of Europe based on balanced economic growth and price stability, a highly competitive social market economy, aiming at full employment and social progress, *and a high level of protection and improvement of the quality of the environment. It shall promote scientific and technological advance.*

⁵⁷⁸ <http://europa.eu/about-eu/index_en.htm> accessed 16 July 2015

It shall combat social exclusion and discrimination, and shall promote social justice and protection, equality between women and men, solidarity between generations and protection of the rights of the child.

It shall promote economic, social and territorial cohesion, and solidarity among Member States.

It shall respect its rich cultural and linguistic diversity, and shall ensure that Europe's cultural heritage is safeguarded and enhanced.” [Emphasis added]

This highlights the diverse aims of the EU, further reinforced by examining the values of the EU outlined in Art 2 TEU which states that:

“The Union is founded on the values of respect for *human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities*. These values are common to the Member States in a society in which pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men prevail.” [Emphasis added]

These aims are focused around the promotion of balanced and sustainable economic activities, economic and social progress; central to which is the development and establishment of a single internal market. However, as evident from these provisions, there is also an expressed desire to protect citizens’ welfare and interests. For instance, Art 3 TEU refers to the promotion of “well-being of its peoples”, whilst the values espoused by Art 2 TEU refer to respect for human dignity and human rights. In fact, the protection of human rights has long been promoted as one of the foundational aims of the EU,⁵⁷⁹ and the EU can impose restrictions on States who fail to adhere to human rights values on which the EU is founded.⁵⁸⁰ This role is strengthened in light of the EU’s planned accession to the ECHR, which is examined in chapter five.

⁵⁷⁹ Craig and De Búrca, *EU Law*, note 482, chapter 11; G De Búrca ‘The Evolution of EU Human Rights Law’ in P Craig and G De Búrca, *The Evolution of EU Law*, note 475; P Popelier, C van de Heyning, P van Nuffel, *Human Rights in the European Legal Order: The Interaction Between the European and the National Courts* (Intersentia, 2011); H J Blanke, ‘The Protection of Fundamental Rights in Europe’ in H J Blanke et al. (eds) *The European Union after Lisbon: Constitutional Basis, Economic Order and External Action* (Springer 2012) 159-232.

⁵⁸⁰ Craig and De Búrca, *EU Law*, note 482, 363.

At this juncture, an introductory outline of the development of human rights discourse within the EU framework is necessary to highlight these broader EU objectives, which is also relevant background for the discussion of recent EU cases on the morality provisions in 4.5.2(b) below. Thus, the main function of section 4.3.2 is to highlight the engrained role which the protection of human rights has within the EU framework, which is examined in further detail in chapter five.

4.3.2 Expansion of EU objectives: Role in human rights protection

References to fundamental rights in the Treaties can be traced to the Maastricht Treaty 1992.⁵⁸¹ According to Craig and de Búrca, the centrepiece of human rights protection in the EU framework is now contained in Art. 6 TEU which includes a statement that the Charter of Fundamental Rights of the European has the same legal value as the Treaties. Art. 6(2) TEU provides that the EU shall accede to the ECHR and Art. 6(3) provides that:

“Fundamental rights, as guaranteed by the European Convention for the Protection of Human Rights and Fundamental Freedoms and as they result from the constitutional traditions common to Member States, shall constitute general principles of Union’s law”.

However, despite these protections, Craig and de Búrca argue that the main focus of the EU is still an economic one, and hence the scope of the role for human rights remains a contested point.⁵⁸² In terms of the development of human rights within the EU legal framework, in a series of cases in the 1950s/1960s⁵⁸³ the CJEU, expressed a reluctance to incorporate human rights and other principles of national law such as legitimate expectations into the EU framework.⁵⁸⁴ This approach gradually subsided and the CJEU confirmed the recognition of fundamental rights principles in EU law in *Stauder*,⁵⁸⁵ which

⁵⁸¹ Art. 6(2) Maastricht Treaty.

⁵⁸² Craig and De Búrca, *EU Law*, note 482, 364.

⁵⁸³ Cases 1/58 *Stork v High Authority* [1959] ECR 17; Cases 36, 37, 38 and 40/59 *Geitling v High Authority* [1960] ECR 423; Cases 40/564 *Sgarlata and others v Commission* [1965] ECR 215.

⁵⁸⁴ Craig and De Búrca, *EU Law*, note 482, 364.

⁵⁸⁵ Case 29/69 *Stauder v City of Ulm* [1969] ECR 419.

was elaborated upon in *Internationale Handelsgesellschaft*.⁵⁸⁶ This pattern continued in *Nold*⁵⁸⁷ where the CJEU held that international human rights agreements and common national constitutional traditions were the primary source of inspiration for the EU general principles.⁵⁸⁸ Nonetheless, despite this case law, De Búrca claims that even in 1998, human rights did not feature extensively in EU law and there was no human rights policy under EU law at that time.⁵⁸⁹ De Búrca acknowledges that this has changed significantly in the preceding years and claims that there is an emergent constitutional regime in the EU for human rights protection,⁵⁹⁰ and the CJEU is now generally open to looking to the ECtHR for guidance on human rights protections.⁵⁹¹

Nonetheless, there are a number of limitations to the human rights protection within EU law. Firstly, the Charter can only be considered in areas where the EU already has competence, hence this development should not extend EU competences.⁵⁹² Secondly, Craig notes that the Charter does not affect the previously established fundamental rights jurisprudence of the CJEU which precedes it. Moreover, it would be inaccurate to attribute to the Lisbon Treaty the growing significance of human rights within EU law. Instead, these developed gradually in the EU as ECtHR jurisprudence developed more prominence within EU law as the Treaties progressed and as the CJEU began to cite case law of the ECtHR more frequently. Arguably, the Charter and the planned accession to the ECHR merely solidifies the place of fundamental rights within the EU system but cannot be seen as a departure as the EU particularly since the Maastricht Treaty placed a significant emphasis on human rights within its case law. Instead, a gradual process of norm diffusion and inter-institutional influences developed between the EU and ECtHR.

⁵⁸⁶Case 11/70 *Internationale Handelsgesellschaft v Einfuhr und Vorratstelle fur Getreide and Futtermittel* [1970] ECR 1125.

⁵⁸⁷ Case 4/73 *Nold v Commission* [1974] ECR 491.

⁵⁸⁸ Craig and De Búrca, *EU Law*, note 482, 366.

⁵⁸⁹ Grainne De Búrca ‘The Evolution of EU Human Rights Law’, note 580, 465 citing P Alston and JHH Weiler (eds) *The EU and Human Rights* (OUP, 1999); P Aston and JHH Weiler (eds) ‘An Ever Closer Union in Need of a Human Rights Policy’ (1998) 9 *EJIL* 658-723.

⁵⁹⁰ *Ibid.*

⁵⁹¹ Craig and De Búrca, *EU Law*, note 482, 367 citing Case C-400/10 *PPU J McB v LE*, 5 Oct. 2010, 53; Case C-279/09 *DEB v Bundesrepublik Deutschland*, 22 Dec 2010 333-52.

⁵⁹² Prior to its coming into effect the UK and Poland negotiated a Protocol seeking to limit the effect of the Charter, this Protocol confirms that the ECJ or national courts cannot find national laws contrary to the Charter see P Craig, ‘The Treaty of Lisbon, process, architecture and substance’ (2008) 33(2) *ELR* 137, 163.

Moreover, human rights are not merely external to the EU legal framework, instead over time they have become a fabric of its legal framework becoming embedded and assimilated within it. Evidence for this is Art. 52(3) of the Charter which states that the provisions of the Charter shall have the same meaning as corresponding rights laid out in the ECHR but “this provision shall not prevent Union law providing more protection”. This implies that the ECHR is not a ceiling of protection for rights within the EU, but rather it should be seen as a base level of protection, which the EU can go beyond if it deems necessary. This highlights an independent ownership for rights protections within the EU’s institutional framework. Given the relatively recent nature of the Charter, it is unclear how Art 52(3) will be utilised but nonetheless it highlights the engrained nature of rights within the EU – these points are expanded upon in chapter five.

Nonetheless, the CJEU’s engagement with the jurisprudence of the ECtHR, and growing ties between the EU and the ECHR, contrasts with the more limited functions of the EPOrg in this context. There is an absence of any clear role for human rights in the EPOrg’s institutional framework or at least uncertainty surrounding this and there is a dearth of references to the jurisprudence of the ECtHR in EPO decisions concerning the morality provisions. These points are developed in chapter five, but of note here is the contrast between the EPOrg and EU. Human rights play a concrete role within the EU both as an external influence on the CJEU- as it has proven open to relying upon the ECtHR jurisprudence in its own case law - and also internally within the EU framework as it develops its own standards of rights protections within the Treaties, Charter and CJEU’s case law. Unlike the EPOrg context, human rights are arguably embedded within the EU’s framework. Crucially, the EU has also developed tools such as subsidiarity etc. which allow it to interpret human rights issues without encroaching on MS sovereignty. These balancing principles and broader interpretative tools are notably absent in the EPOrg context.

4.4 Institutional Structure, Composition and Characteristics of the Decision-Making Bodies in the CJEU

Bearing in mind these central objectives of the EU, this section turns to examine the judicial arm of the EU which is known collectively as the Court of Justice of the European Union

(CJEU) in order to ascertain how its structure/composition and features will influence this body in its interpretation of the morality provisions. The CJEU comprises of three sub-institutions namely; the Court of Justice (CJ), the General Court and specialised courts.⁵⁹³ The specialised courts were originally established by the Nice Treaty and were then called judicial panels. These are now governed by Article 257 TFEU and are panels in specific areas of law, established in order to ease the workload of the CJ. There are no specific panels assigned to patenting issues and hence these courts will not be analysed in this section. This analysis will focus primarily on actors within the CJ, as this is the main body which deals with the application of the morality provisions, and to a lesser extent the General Court which may be involved in limited circumstances.

4.4.1 An Overview of the Decision making structure in the CJEU

Prior to delving into the specific compositions and eligibility criteria of the CJ and General Court, this section provides an overview of the decision-making structure and role of each body. This highlights how power is distributed within the CJ/General Court and also between these bodies and MSs. The composition/eligibility requirements of the CJ/GC are then considered together in 4.4.2, for the purpose of convenience given the similarities in the criteria for judges in both the CJ and General Court. This differs to the analysis of the composition/eligibility of members in the EPO where each branch of the EPO was considered individually because of the differences across the branches of the EPO. Nonetheless, the primary focus of both sections is the same: namely how the decision-making structure and composition of the branches of the EPO/CJEU may influence the application of the morality provisions by such adjudicative actors.

a) Court of Justice (CJ)

The CJ is a court of final jurisdiction within the EU. The CJ's role is set out in Art 19(3) TEU which states that it shall:

“(a) rule on actions brought by a Member State, an institution or a natural or legal person; (b) give preliminary rulings, at the request of courts or tribunals of the

⁵⁹³ Art. 19(1) TEU.

Member States, on the interpretation of Union law or the validity of acts adopted by the institutions; (c) rule in other cases provided for in the Treaties.”

Its jurisdiction is limited by rules as to *locus standi* dictating who can bring cases before the court. One of the main avenues which the morality provisions may come before the CJ, is through preliminary references whereby, national courts can refer a specific question on the meaning of EU law to the CJ.⁵⁹⁴ The ECJ’s judgment must then be applied by the national judge in the case before them. This procedure was used in the recent *Brüstle*⁵⁹⁵ decision which concerned the application of Art. 6(2) of the Biotechnology Directive; discussed in 4.5.2(b)(iii) below.

Also of relevance are enforcement actions, which are actions brought by the Commission or other MSs in cases where a declaration may be sought from the CJ stating that a MS is in breach of EU law.⁵⁹⁶ The Commission may also bring a MS before the CJ for failure to comply with a previous decision of the CJ.⁵⁹⁷ Furthermore, the CJ gives opinions on the conclusion of international agreements deciding on whether or not the EU has lawfully concluded a draft treaty with an international organisation. If the CJ rules that the agreement is illegal, it must be amended prior to coming into force.⁵⁹⁸ The CJ also deals with judicial review actions of EU institutions by other EU institutions or of the Council or Parliament by MSs⁵⁹⁹ and may consider appeals from the General Court on point of law under Art 256(1) TFEU. Finally, under Art 262 TFEU following consultation with the Parliament, the Council can adopt provisions to confer jurisdiction on the CJ with regard to disputes concerning intellectual property law.⁶⁰⁰ Thus, there are a number of avenues through which the CJ may be involved in the interpretation of the morality provisions.

National remedies must be exhausted before a question is referred to EU courts, hence questions in relation to the morality provisions would first be dealt with by the national courts and only if these go to the highest court within the national system can a question on

⁵⁹⁴ Art. 267 TFEU.

⁵⁹⁵ *Brüstle*, note 58.

⁵⁹⁶ Art. 258 and 259 TFEU.

⁵⁹⁷ Art. 260 TFEU.

⁵⁹⁸ Art. 218(11) TFEU.

⁵⁹⁹ Art. 263(2) and 265(1) TFEU.

⁶⁰⁰ The application of this provision in terms of the previously proposed unitary patent was considered in Opinion 1/09 [2011] ECR I-1137.

interpretation be referred to the CJ. This in turn means that the opportunity for the CJ to influence the interpretation of the morality provisions will be limited, particularly, when one compares this to the potential interaction decision-making bodies in the EPO may have with the morality provisions, at examination, grant, opposition and appeal division phases. In short, as noted in chapter three, the EPO has much greater opportunity to shape the contours of these provisions at a decision-making level than the EU has.

A point of internal procedure of note is that the CJ is assisted by eight Advocate Generals who have the same eligibility criteria and appointment process as judges in the CJ.⁶⁰¹ Art 252 TFEU states that it shall be the duty of the Advocate General “acting with complete impartiality and independence, to make, in open court, reasoned submissions on cases which, in accordance with the Statute of the Court of Justice of the European Union, require his involvement”. The Advocates do not represent either party in the proceedings but rather can be seen as representing the public interest.⁶⁰² Moreover, the Opinions of the Advocate Generals are not binding on the CJ but are issued in advance of the judgment in order to allow the court sufficient time to consider these opinions and are often cited in decisions of the CJ.⁶⁰³

b) General Court

The General Court is often seen as the main administrative court in the EU, and has jurisdiction to hear a number of different actions, two of which may be of relevance, albeit in a limited context to the morality provisions: first, it may hear judicial review applications of individuals for actions of the EU institutions or actions for non-contractual damages against EU institutions; and secondly, it may hear applications by MSs against the Commission,⁶⁰⁴ although there is an exception for challenges against Commission’s authorisation of enhanced co-operation which must be heard by the CJ. There is a right of appeal from the General Court to the CJ on points of law, provided by Art 256 (1) TFEU.⁶⁰⁵ Importantly, this right of appeal extends not just to the parties to the case but also to MSs

⁶⁰¹ Chalmers, Davies and Monti, *European Union Law*, note 487, 145.

⁶⁰² Ibid 145.

⁶⁰³ Ibid 145.

⁶⁰⁴ Art. 263 TFEU.

⁶⁰⁵ See Chalmers, Davies and Monti, *European Union Law*, note 487, 148.

and EU institutions provided the decision directly affects them.⁶⁰⁶ In the event of the CJ upholding an appeal, it can either decide to give judgment in the case itself or can refer the matter back to the General Court. If it decides to refer the matter back to the General Court, the judgment will be binding on the General Court on the point of law.⁶⁰⁷ Interestingly, the CJ will only uphold an appeal if the law was misapplied in the operative part of the judgment and hence it is possible for the General Court to misapply the law in other areas and the appeal to be dismissed.⁶⁰⁸ Even in such cases where the operative part of the law is found to be misapplied, this may be found justified if shown to be well-founded on legal reasons.⁶⁰⁹

c) Reflection on the role of the courts

The analysis highlights that the CJ is the primary EU judicial body involved in the application of the morality provisions. However, the opportunities it has to influence these provisions are limited given that all national avenues must first be exhausted. Moreover, if the provisions come before the court as a preliminary reference - which is the most likely source of challenge of current provisions - then the scope for the CJ to influence is highly dependent on the type of questions posed by the national State. Hence, the CJ and therefore the EU has a much more limited role in directly influencing the application of the morality provisions at an adjudicative level in comparison to the EPO.

4.4.2 Composition and eligibility requirements of judges

Turning to the composition and eligibility requirements for judges within the CJEU; the CJ has twenty eight judges, one from each MS,⁶¹⁰ and generally sits in Chambers of three or five judges. A MS or EU institution party to a case can also request that the CJ to sit as a thirteen bench court, the Grand Chamber.⁶¹¹ The CJ only sits as a full court in very limited

⁶⁰⁶ Art. 56, Protocol No. 3 on the Statute of the Court of Justice [2010] OJ C83/223.

⁶⁰⁷ Art. 61, Ibid.

⁶⁰⁸ Chalmers, Davies and Monti, *European Union Law*, note 487, 148.

⁶⁰⁹ Case C-30/91 *P Lestelle v Commission* [1992] ECR I-3755; Case-226/03 *P Jose Martii Peix v Commission* [2004] ECR I-11421. As cited in Chalmers, Davies and Monti, *European Union Law*, note 487, 148.

⁶¹⁰ Art. 19(1) TEU.

⁶¹¹ Art. 16, Protocol No. 3 on the Statute of the Court of Justice [2010] OJ C83/223.

circumstances,⁶¹² including where it decides that the case is of exceptional importance.⁶¹³ The General Court must be composed of at least one judge from each MS⁶¹⁴ and is currently composed of 28 judges. The General Court like the CJ, generally sits as a three or five chamber court, but may sit in full if it considers that the circumstances of the case require this.⁶¹⁵

In terms of the eligibility of judges to sit on the CJ, they must “...possess the qualifications required for appointment to the highest judicial offices in their respective countries or who are jurisconsults of recognised competence”.⁶¹⁶ They are appointed for a period of six years, and they may apply for reappointment.⁶¹⁷ A President is elected by the judges from among their number, who serves a three-year term.⁶¹⁸ The same eligibility requirements applies to judges on the General Court and the Advocate Generals. Thus, the CJEU is composed entirely of legal experts. This contrasts with the EPO as its Examining Divisions and Technical Boards are composed by a majority of technical experts. The difference in the composition of these bodies reflects the differing tasks which the EPO and CJEU perform; much of the work in the EPO involves the examination of technical and scientific matter, hence requiring scientifically trained personnel. The differing backgrounds of decision-makers, their differing roles, and indeed differing perceptions of their roles, will arguably impact upon how these decision-makers filter and apply the morality provisions; and would lead one to predict different outcomes in terms of their decision-making in light of these factors. This is not to suggest that legally qualified personnel in the CJEU are more qualified or appropriate to interpret the morality provisions in comparison to technical experts in the EPO, or *vice versa*. Instead the argument is that the differences amongst these decision-makers, together with differences in other characteristics of the EPO/CJEU, will give rise to differing institutional dispositions towards the morality provisions within these respective institutional frameworks and thus divergences in the interpretation.

⁶¹² Governed by Art 16 of Protocol 3, Ibid, which states that “...The Court shall sit as a full Court where cases are brought before it pursuant to Article 228(2), Article 245(2), Article 247 or Article 286(6) of the Treaty on the Functioning of the European Union. Moreover, where it considers that a case before it is of exceptional importance, the Court may decide, after hearing the Advocate-General, to refer the case to the full Court.

⁶¹³ Chalmers, Davies and Monti, *European Union Law*, note 487, 145.

⁶¹⁴ Art. 19(2) TEU.

⁶¹⁵ Rule of Procedure of the Court of First Instance, Art 14(1) cited by Chalmers, Davies and Monti, *European Union Law*, note 487, 147.

⁶¹⁶ Art. 253 TFEU.

⁶¹⁷ This ability for reappointment has given rise to fears that this may jeopardise the independence of the judges, see Chalmers, Davies and Monti, *European Union Law*, note 487, 145.

⁶¹⁸ Art. 253 TFEU.

4.4.3 Independence and susceptibility to external influence

The independence of the CJEU is guaranteed by Art 19(2) TEU which states that judges must be “persons whose independence is beyond doubt”. This is reinforced by Art 2 of the Statute of the Court of Justice of the European Union which states that prior to commencing his/her functions a judge shall “take an oath to perform his duties impartially and conscientiously and to preserve the secrecy of the deliberations of the Court”. Art 4 provides that judges may not “hold political or administrative office” and “may not engage in any occupation, whether gainful or not, unless exemption is exceptionally granted by the Council, acting by a simple majority”. Moreover, Art 4 extends this duty beyond judges’ term of office, by providing that:

“When taking up their duties, they shall give a solemn undertaking that, both during and after their term of office, they will respect the obligations arising therefrom, in particular the duty to behave with integrity and discretion as regards the acceptance, after they have ceased to hold office, of certain appointments or benefits.”

Furthermore, Art. 3 states that judges are immune from legal proceedings except in exceptional circumstances where this may be waived. Judges may be removed from office for failing to fulfil his/her obligations⁶¹⁹ which presumably could include failing to meet these criteria of independence. Moreover, the principle of collegiality strengthens the independence of the CJEU. This provides that only a single judgment is issued in each case and hence the opinion of a particular judge is not seen. This may mitigate against the possibility of influencing judges to decide a certain way in order to secure reappointment to the Court.⁶²⁰ Finally, the CJEU is not self-funded and there is no direct financial consideration tied to the outcome of a particular decision for the CJEU. This contrasts to the EPO, which as discussed in chapter three, is self-funded and derives its income stream from the grant of patents. Given these safeguards which highlight that the independence of the CJEU is enshrined within the EU Treaties and furthermore, that there are no direct monetary links between patents granted and the funding of the CJEU, for the purposes of

⁶¹⁹ Art. 6, Protocol No. 3 on the Statute of the Court of Justice [2010] OJ C83/223.

⁶²⁰ Chalmers, Davies and Monti, *European Union Law*, note 487, 145.

this section, unlike section 3.3 on the EPO, it is not necessary to examine further the financial interests in the CJEU or the potential for industrial capture of this court.

4.4.4 Interim reflections

Overall, the CJEU can be distinguished from the EPO, and its sub-institutions (the CJ, General Court), in a number of ways, including: in terms of its structure, the more limited avenues it has to shape the morality provisions, and the composition and eligibility of the judicial/quasi-judicial members of each institution. The CJEU appears less susceptible to external influence; although it is conceded that political jostling is evident within other institutions of the EU such as the Commission and Parliament. Importantly, should questions on the morality provisions come before the CJEU, what is certain is that the judges who deal with them will have very different competences, expertise and constraints to the actors within the EPO who examine similar questions. Arguably, such differences will impact considerably on the types of considerations and reasoning of these decision-makers. This is reinforced when one considers the path dependencies of the EU in this context.

4.5 Path Dependencies

The past actions of the EU in relation to the morality provisions may lead to path dependencies within the EU which are an indicator as to how it may deal with these provisions in future. Such actions can be divided into legislative actions, and actions by the judicial branch and each are considered separately below.

4.5.1 Legislative Path Dependencies

a) Competence of the EU on moral issues generally

The EU has no general competence in the area of morality⁶²¹ and MSs are generally offered a wide margin of discretion⁶²² in this context. Rothmar and Rowlandson in an article which

⁶²¹ Bakardjieva Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting', note 8, 233.

⁶²² See N Nic Shuibhne 'Margins of Appreciation: National Values, Fundamental Rights and EC Free Movement Law' (2009) 34(2) ELR 230.

tracks the role of ethics and morality in EU law with particular reference to the funding and patentability of hESC research, note that the primary aim of the EU is the harmonisation of the internal market and consequently, bioethical questions are treated differently within EU law in comparison to international human rights law.⁶²³ They also highlight the variable nature of morality and the difficulty with ascertaining a ‘European morality’ particularly in relation to biotechnology, stating that:

“...the concept of morality is relative to the prevailing views underlying a specific society. Even within the EU differences exist as to what is morally acceptable behaviour and what is not. This is most evident within the field of biotechnology, most recently, in regard to the research into hESCs and patenting hereof.”⁶²⁴

Moreover, as noted above, the EU enshrines protection for MSs’ identities and cultures in its law and hence must be cautious of intruding on MS authority in relation to moral issues. However, whilst it cannot pursue legislative measures directly related to moral issues, Bakardjieva-Engelbrekt notes that it may pursue non-market objectives in order to achieve harmonisation in limited circumstances.⁶²⁵ Nonetheless, even when such policies are pursued deference must be given to MSs in order to respect MSs’ constitutional traditions and identities. This aspect alongside the development of the margin of discretion within the CJEU’s jurisprudence which may be used to accommodate divergence on moral issues, is discussed further in chapter five.

b) Development of the morality provisions in the Biotechnology Directive

The patenting of biotechnology came within the realm of EU law with the adoption of the Biotechnological Directive. Art. 6 of this Directive, is the only EU legislative provision relating to morality and patents. Prior to the adoption of the Directive, the EU had little to no dealings in this context and without this express legislative provision it is questionable whether the EU would have competence to delve into this issue. Member States of the EU are separately party to the EPC, however, this arguably would not have brought the morality provisions in the EPC within the jurisdiction of the EU. Importantly, the EU provisions

⁶²³J Rothmar Hermann & M Rowlandson, *The Role of Ethics and Morality in EU law*, (2008) 6(5) JIBL 241-251, 241.

⁶²⁴ *Ibid*, 242.

⁶²⁵Bakardjieva Engelbrekt, ‘Institutional and Jurisdictional Aspects of Stem Cell Patenting’, note 8, 233.

pertain only to biotechnological inventions; this differs from Art. 53(a) of the EPC which is not limited as to the type of invention. Consequently, the EU appears to have little jurisdiction to question the morality of traditional inventions, having no express legislative provision in this area.

As alluded to in chapter one, the development of the morality provisions in the Directive was marred in controversy. Much of this controversy related to the position of ethics/morality within the Directive. Some of the difficulties with the adoption of the Directive have already been outlined, but it is useful to reflect further on these aspects as this is relevant to determining the likely institutional perception of the provisions which has emerged. The drafting process has been carefully examined by Porter⁶²⁶ which provides a useful overview. Importantly, this process was deeply divisive, involving over ten years of debate and negotiation.⁶²⁷ The Directive was originally proposed by the Commission⁶²⁸ and then considered by Parliament who proposed a number of amendments to the original draft.⁶²⁹ It was then reconsidered by Parliament which suggested further amendments⁶³⁰ in 1993. Many of these amendments were adopted by the Council.⁶³¹ However, some members of the European Parliament (MEPs) were still unsatisfied with the Directive, particularly with whether it fully addressed the ethical concerns raised by biotechnologies and as a result further amendments were suggested by the Parliament. Nonetheless, in spite of these amendments, it was again rejected by the Council in September 1994.⁶³² This led to conciliation proceedings between the Council and the Parliament and the production of a joint text in January 1995 which was subsequently rejected by the Parliament. Indeed, this was the first time the Parliament used its veto powers under the co-decision procedure to reject legislation.⁶³³ Subsequently, an amended proposal was put forward by the Commission in December 1996, and accepted by the Parliament in May 1998 after a number of amendments.⁶³⁴

⁶²⁶ Porter, 'The Drafting History of the European Biotechnology Directive', note 14, 3-28.

⁶²⁷ Ibid 16.

⁶²⁸ EC "Proposal for a Council Directive on the legal protection of biotechnological inventions" COM 88 496 final, 17 October 1988, C10/3, as cited by Porter, 'The Drafting History of the European Biotechnology Directive', note 14, 9.

⁶²⁹ (1992) OJ C125/112; (1992) OJ C305/160 as cited by Porter, Ibid, 10.

⁶³⁰ (1993) OJ C342/2 as cited by Porter, Ibid, 13.

⁶³¹ Common Position of the Parliament (1994) OJ C101/65 cited by Porter, Ibid, 13.

⁶³² Porter, Ibid, 13.

⁶³³ Ibid 13.

⁶³⁴ Ibid 14.

Nonetheless, the legality of the Directive was subsequently challenged by the Netherlands, joined by Italy and Norway in October 1998.⁶³⁵ However, this challenge was rejected and the Directive has been in force with no amendments since its adoption. Nonetheless, the sheer number of amendments to the Directive and subsequent challenges highlight the level of controversy surrounding it, and the morality provisions and ethical concerns were the source of much of these difficulties. From an institutional perspective, given the controversy which shrouded its adoption, arguably the EU would be wary of introducing further legislative provisions in this area, and also cognisant of the need to show deference to MSs on the general morality provision.

Interestingly, as noted, following the Directive's adoption, the EPOrg voluntarily incorporated the Directive's additional morality provision in Art. 6(2) within the EPC and this attracted little controversy within the EPOrg. This move symbolised convergence at a legislative level between the EPOrg and the EU, but as suggested this is not necessarily reflected at the adjudicative level. This argument is supported, when one delves further into the underlying principles evident in Directive to guide the CJEU in its interpretation of these provisions.

c) EU Guidance and interpretative principles within EU law on the application of the morality provisions

In order to understand the jurisprudence of the EU, Craig and de Búrca highlight that one must look to the CJEU's purposive approach to interpretation. This does not relate to understanding the purpose of the original drafters as the *travaux préparatoires* to the original treaties were never published. Rather, the interpretation is purposive in the sense that the CJEU examines the context of a provision, and then presents an opinion which will further what that provision was most likely trying to achieve.⁶³⁶ This suggests that one must look at the aims of the morality provisions in the context of the broader aims of the Biotechnology Directive and EU, in order to ascertain how the CJEU will interpret these provisions.

⁶³⁵ Ibid.

⁶³⁶ Craig and De Búrca, *EU Law*, note 482, 64.

A number of principles articulated in the Directive's recitals shed light on the aims of the Directive. Recitals are intended to provide instructions for those implementing a Directive into national law but are not legally binding.⁶³⁷ Nonetheless, they are instructive as to the drafter's aims, and have been referred to in the case law of the Court.⁶³⁸ Some of the most significant recitals in the context of the morality provisions, include recital 16 and 38. Recital 16 states that:

“Whereas patent law must be applied so as to respect the *fundamental principles safeguarding the dignity and integrity of the person*; whereas it is important to *assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented*; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented;”
[Emphasis added]

This highlights the aim to protect and safeguard human dignity, which underlies the Directive and the interpretation of the morality provisions. This focus on the protection of human dignity is reiterated in recital 38, the relevant part of which, states:-

“...whereas processes, *the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals, are obviously also excluded from patentability...*” [Emphasis added]

This coincides with the foundational aim of the EU to promote human rights in areas within its competences. This is supported by recital 14 which states that restrictions on patents may be imposed in view of the requirements of “public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards”. These recitals tie in with broader EU objectives outlined in 4.3 above, and demonstrate the drafters intentions to use the Directive and provisions therein including the morality provisions to further human well-being, fundamental rights etc. This confirms that the Directive is not merely focused on economic goals. These broader

⁶³⁷ M Kaeding, ‘Active Transposition of EU Legislation’ (2007/03) EPIA Scope 27-34, 29 <http://aei.pitt.edu/11064/1/20080313162050_MKA_SCOPE2007-3_Internet-4.pdf> accessed 16 July 2015.

⁶³⁸ The recitals were referred to extensively in *Brüstle* to adduce the aim of Art 6(2) and the Directive as a whole. See *Brüstle*, note 58, para 27, 32, 32, 42 and 44.

objectives are absent from the EPC framework which is a primarily economic instrument and speaks solely about patenting with little if any reference to external issues. This is unsurprising given the limited competences and specialised function of the EPOrg. As noted, the Directive is supplementary guidance for the EPC, but this does not mean that the decision-making bodies in the EPO are bound to take it into account. Moreover, given the differing institutional contexts within the EPO, its decision-makers will arguably interpret such provisions in a differing manner to align with its own institutional framework. At this juncture, it is appropriate to consider the development of the provisions at a judicial level, which reinforces the chasm in interpretation between the EU and EPOrg in this context.

4.5.2 Judicial Decisions in relation to morality and the morality provisions

This section commences by looking at the jurisprudence of the CJEU on general issues which touch on morality, and then considers its specific jurisprudence on the morality provisions.

a) General CJEU jurisprudence in relation to morality

The main area the CJEU has dealt with moral issues, outside the morality provisions is in relation to State derogations from fundamental freedoms on the basis of morality or public interest grounds. This jurisprudence highlights the Court's reluctance to involve itself in such matters, particularly when national values are at stake.⁶³⁹ Public morality is an express derogation from the prohibition of quantitative restrictions on imports and exports and measures having equivalent effects. However, it has also arisen in relation to other fundamental freedoms and in particular, freedom to provide services.⁶⁴⁰ It has been invoked as a justification in a limited number of cases⁶⁴¹ and when invoked it is generally done in relation to sexual and private morality.⁶⁴² This jurisprudence highlights the deference to MS's sovereignty within the EU legal framework, for instance in *Darby and Henn*⁶⁴³ the CJEU stated that: "in principle, it is for each Member State to determine in accordance with its own scale of values and in the form selected by it the requirements of public morality

⁶³⁹ Nic Shuibhne 'Margins of Appreciation', note 622.

⁶⁴⁰ As discussed in Plomer (Co-ordinator), *Stem Cell Patent Report*, note 47, 41.

⁶⁴¹ Bakardjieva Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting', note 8, 238.

⁶⁴² See, Case C-34/79 *Darby and Henn* [1979] ECR 3795, Case C-121/85 *Conegate* [1986] ECR 1007

⁶⁴³ Case C-34/79 *Darby and Henn* [1979] ECR 3795.

on its territory.”⁶⁴⁴ Indeed, a margin of discretion has been granted to MSs to allow restrictions on fundamental freedoms where moral issues were concerned in a number of contexts,⁶⁴⁵ including; in relation to abortion,⁶⁴⁶ narcotics⁶⁴⁷ and prostitution.⁶⁴⁸ In such contexts certain services have been allowed to be restricted in some States whilst legal in others, despite the fact that this is contrary to goals of harmonisation within the internal market. The Court has engaged most prominently with moral issues, in a series of cases concerning whether aspects of gambling can be prohibited in individual States. The kernel of the CJEU jurisprudence in this context is that the:

“...moral, religious or cultural factors, as well as the morally and financially harmful consequences for the individual and for society associated with betting and gaming, may serve to justify a margin of discretion for the national authorities, sufficient to enable them to determine what is required in order to ensure consumer protection and the preservation of public order.”⁶⁴⁹ [Emphasis added]

This highlights the CJEU’s emphasis on a margin of discretion approach and this will be examined further in chapter five in relation to how this mirrors ECtHR jurisprudence. Finally, *ordre public* or public policy, also provides a derogation for MSs. This ground is only used as a justification when all other grounds are exhausted, and in order for it to be justified, there must be evidence of a “genuine and sufficiently serious threat to the requirements of public policy affecting one of the fundamental interests in society”.⁶⁵⁰ Moreover, the CJEU has stated it must be exercised strictly and under control or supervision

⁶⁴⁴ Case C-34/79 [1979] ECR 3795. For discussion, see Aurora Plomer (Co-ordinator), *Stem Cell Patent Report*, note 47, 41.

⁶⁴⁵ See, P McCrea, *Religion and Public Order of the European Union*, (OUP, 2010)

⁶⁴⁶ See, Case C-159/90, *SPUC v Grogan*, Judgment of the Court, 4th October, 1991

⁶⁴⁷ Case C-137/09 *Marc Michel Josemans v Burgemeester van Maastricht*, Judgment of the Court (Second Chamber) of 16 December 2010.

⁶⁴⁸ Case C-268/99 *Jany and others v Staatssecretaris van Justitie* [2001] ECR I-8615.

⁶⁴⁹ Case 258/08 *Ladbrookes v. Ladbrokes Betting & Gaming Ltd, Ladbrokes International Ltd v Stichting de Nationale Sporttotalisator*, Judgment of the Court, Second Chamber, 3 June, 2010, See also Case C-67/98 *Zenatti* [1999] ECR I-7289; Case C-42/02 *Lindman* [2003] ECR I-13519; Case C-6/01 *Anomar* [2003] ECR I-8621; Case C 243/01 *Gambelli* [2003] ECR I-13031; Cases C-338, 359 and 360/04 *Placanica, Palazzese and Sorricchio* [2007] ECR I-1891; Cases C-447-448/08 *Otto Sjoberg and Anders Gerdin*, 8 July 2010; Case C-46/08 *Carmen Media Group v Land Schleswig-Holstein*, 8 Sept 2010; Case C-64/08 *Ernest Engelmann*, 9 Sept 2010.

⁶⁵⁰ Case C-30/77 *Bouchereau* [1977] ECR 1999 paras 33-5, confirmed in Joined Cases 115/81 and 116/81 *Adoui and Cornuaille* [1982] ECR 1665 para. 8; Case C 348/96 *Calfa* [1999] ECR I-11, para 21; Case C-268/99 *Jany and Others* [2001] I-8615 as cited in Bakardjieva Engelbrekt, ‘Institutional and Jurisdictional Aspects of Stem Cell Patenting’, note 8, 240.

of the EU.⁶⁵¹ Nonetheless, discretion for MSs is provided depending on the context of each case, as confirmed in Case C-41/74 *Yvonne Van Duyn v Home Office* where the Court stated:

“...the particular circumstances justifying recourse to the concept of public policy may vary from one country to another and from one period to another, and it is therefore necessary in this matter to allow the competent national authorities an area of discretion within the limits imposed by the Treaty.”⁶⁵² [Emphasis added]

This again highlights the discretion which EU MSs have in relation to the use of public policy restrictions, which was reaffirmed in Case 32/06 *Omega*.⁶⁵³ This involved a restriction on the use of laser game technology in Omega’s laserdrome in Germany. The game involve using laser guns to simulate killing other players, and the German Constitutional Court ruled that this offended against principles of dignity under Germany’s constitutional law. Omega challenged this arguing this was against EU freedom of services, as this game was provided under a franchise from a British company which was providing comparable services in the UK.⁶⁵⁴ However, the CJEU reiterated the statement quoted above from *Van Duyn*, highlighting that circumstances justifying recourse to public policy can vary amongst MSs and MSs must be allowed discretion in such circumstances. Hence, the national restriction was allowed. As an aside, this case also demonstrates the potential for differing concepts of dignity to operate within individual EU MSs, and the need to ensure MSs are respected in upholding these. This is returned to below in the discussion of *Brustle* at 4.5.2(b)(iii).

The foregoing demonstrates the complex amalgam of competing objectives which arise in the EU context, and which must be carefully balanced in any case. The EU is generally reluctant to involve itself in questions of public morality due to the link between morality and MS culture and the need to respect MSs’ constitutional and legal traditions. Having said this, freedom to provide services and goods, which the cases outlined above deal with, is a matter of negative integration⁶⁵⁵ which may require broader discretion to be left to

⁶⁵¹ Case 36/75 *Rutili* [1975] ECR 1219, para. 32.

⁶⁵² Case C-41/74 *Yvonne Van Duyn v Home Office*, para. 18.

⁶⁵³ Case C-36/02 *Omega Spielhallen- und Automatenaufstellungs-GmbH v Oberbürgermeisterin der Bundesstadt Bonn* [2005] 1 CMLR 5.

⁶⁵⁴ *Ibid* 117

⁶⁵⁵ This is where the EU imposes prohibitions on States for restrictive practices.

States. On the other hand, intellectual property matters concern issues of positive integration⁶⁵⁶ and arguably this may give rise to, or at least allow arguments in favour of, less discretion to ensure more coherent integration⁶⁵⁷ as this is the objective of the EU in such areas.

b) Jurisprudence of the EU on Art 6 of the Biotechnological Directive

Four CJEU decisions have considered the application of Art 6 of the Biotechnology Directive. Two decisions involved challenges posed by MSs on the legality of the Directive, whilst two recent cases pertained to preliminary references on the meaning of Art 6(2)(c). The small number of cases confirms the limited role which the Court plays in judicially shaping the morality provisions. Each case is considered below to shed light on the potential institutional influences which are evident.

i. Case C-377/98 Netherlands v European Parliament and Council

The first case, which considered the morality provisions was Case C-377/98 *Netherlands v European Parliament and Council*.⁶⁵⁸ This case involved an unsuccessful challenge to the legality of the Biotechnology Directive. A number of interesting points were made in the judgment in relation to the scope for manoeuvre offered to EU MSs under the Biotechnology Directive. One of the arguments made by the Netherlands was that Art 6 of the Directive created legal ambiguity given the discretion offered to MSs. The Court rejected this, specifically endorsing MS's discretion on the application of Article 6(1), stating that: "...it is common ground that this provision allows the administrative authorities and courts of the Member States a wide scope for manoeuvre."⁶⁵⁹ The rationale offered for this by the ECJ, as it was then (now the CJ, as its name changed following the entry into force of the Lisbon Treaty in 2009) was that the:

⁶⁵⁶ These are provisions aimed at harmonising the standards within the EU.

⁶⁵⁷ See generally, Bakardjieva Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting', note 8, 242.

⁶⁵⁸ [2001] ECR I-7079,

⁶⁵⁹ Ibid para. 37.

“...scope for manoeuvre is necessary to take account of *the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State*, a context which the national legislative, administrative and court authorities are better placed to understand than are the Community authorities.”⁶⁶⁰

[Emphasis added]

This rationale is almost identical to the ECtHR’s rationale for its margin of appreciation doctrine, namely, given the different traditions of MSs, they are in a better position to decide upon moral issues pertaining to individual MSs. Nonetheless, the ECJ placed some restrictions on the scope for manoeuvre stating that:

“the scope for manoeuvre left to Member States is not discretionary, since the Directive limits the concepts in question, both by stating that commercial exploitation is not to be deemed to be contrary to *ordre public* or morality merely because it is prohibited by law or regulation, and by giving *four examples of processes or uses* which are not patentable. Thus, the Community legislature gives guidelines for applying the concepts at issue which do not otherwise exist in the general law on patents.”⁶⁶¹ [Emphasis added]

This is a reference to the four exclusions listed in Art 6(2) which are deemed unpatentable. However, this refining suffers from the flaw that the scope of the four exclusions listed in Art 6(2) are in some cases ambiguous, and it is also questionable, in light of the development of technologies, whether there is still consensus on the immorality of patents in relation to these four mandatory exclusions, or related technologies. This point elaborated upon below in the discussion of these cases.

Nonetheless, the *Netherlands* case highlights that MSs have discretion in applying Art. 6(1) which provides some leeway to MSs if the commercial exploitation of certain inventions is perceived as contrary to particular national conceptions of morality which may differ across MSs. Art. 6(2) on the other hand must be interpreted in a unified way across the EU, and

⁶⁶⁰ Ibid para. 38.

⁶⁶¹ Ibid para. 39.

once an invention falls within any of the categories in Art 6(2) it is automatically excluded from patentability.

ii. Case C- 456/03 Commission v Italy

Article 6 of the Biotechnology Directive was considered again in Case C-456/03 *Commission v Italy*⁶⁶² where it was successfully argued that the Italian authorities had failed to implement or at least implement properly, parts of the Directive. In relation to the discretion offered to MSs in implementing Art 6, the Court reiterated that:-

“Unlike Article 6(1) of the Directive, which allows the administrative authorities and courts of the Member States *a wide discretion in applying the exclusion from patentability of inventions whose commercial exploitation would be contrary to ordre public* (public policy) and morality, Article 6(2) allows the Member States *no discretion* with regard to the patentability of the processes and uses which it sets out, since the very purpose of this provision is to give definition to the exclusion laid down in Article 6(1) (see, to this effect, *Netherlands v Parliament and Council*, paragraphs 37 to 39). It is apparent from the 40th recital in the preamble to the Directive that processes for cloning human beings must be excluded ‘unequivocally’ from patentability, since *there is a consensus* on this question within the Community.”⁶⁶³ [*Emphasis added*]

This statement emphasises the discretionary nature of the morality provisions contained in Article 6(1) and reaffirms that no discretion applies to Article 6(2). Furthermore, the reference to the ‘consensus’ and inference that this is why patentability is denied in the case of human cloning, is of note. If a consensus standard is informing the interpretation of such provisions, then it is at least curious that ‘uses of embryos for industrial and commercial purposes’ were originally included by drafters in the legislative list under Art 6(2)(c), as it has been accepted that there is no consensus generally on hESC research in Europe. It is even more curious that hESC patents are now denied in light of the decision in *Brustle* discussed below, which notably did not address the issue of consensus or absence of same in relation of hESC research. Instead, as will be seen, it side stepped many ethical issues and took as a starting point, that its role was merely to decide the definitional scope of the

⁶⁶² [2005] ECR I-5335.

⁶⁶³ Ibid para 78-79.

term ‘embryo’. To this, one might argue that the CJEU is bound to this interpretation given the wording of the Directive which cannot be changed, and that Art. 6(2) is a definitional test which does not provide discretion to MSs. However, arguably, the decision in *Brüstle* in its broad interpretation of Art 6(2)(c) went beyond what may have been the necessary definitional claim. At this juncture, it is appropriate to examine this landmark case.

iii. Case C-34/10 *Brüstle v Greenpeace*

In *Brüstle v Greenpeace*⁶⁶⁴ the CJ’s Grand Chamber was called upon to assess the meaning of Art. 6(2)(c) and whether this would include hESC technology, so a key question was what can be defined as ‘uses of embryo for industrial and commercial purposes’. As noted, it held that inventions which involved the destruction of the human embryo regardless of what stage this occurred, should be denied patentability. In course of the judgment, the CJ addressed the meaning of Article 6(2)(c) in detail, noting in relation to the definition of the term ‘embryo’ that: “The only possible interpretation of that concept is European and unified.”⁶⁶⁵ It is questionable why the only possible interpretation of ‘embryo’ must be a unified concept, given the reluctance of the EU and indeed to ECtHR to define the term in other aspects of law. To this, CJ argued that a single definition was needed as:

“It is apparent from the case-law of the Court that, unlike Article 6(1) of the Directive, which allows the administrative authorities and courts of the Member States a wide discretion in applying the exclusion from patentability of inventions whose commercial exploitation would be contrary to *ordre public* and morality, Article 6(2) allows the Member States no discretion with regard to the unpatentability of the processes and uses which it sets out, since the very purpose of this provision is to delimit the exclusion laid down in Article 6(1). It follows that, by expressly excluding from patentability the processes and uses to which it refers, Article 6(2) of the Directive seeks to grant specific rights in this regard (see *Commission v Italy*, paragraphs 78 and 79).”⁶⁶⁶

⁶⁶⁴ *Brüstle*, note 58.

⁶⁶⁵ *Ibid* para. 21

⁶⁶⁶ *Ibid* para. 29

It is true that in general, in order to be effective, expressly listed exclusionary provisions should have a clear unified meaning, and the Court was confined in its interpretation by the wording of the Directive, which had to be read in light of other provisions in the Directive. However, it is not necessarily true that, as will be seen the particularly restrictive unified meaning which the CJ adopted was the only meaning it could have adopted. Furthermore, given the level of controversy and lack of consensus surrounding the status of the embryo and embryo research more generally, a related question is why the Biotechnology Directive included such a provision, and whether the drafters envisaged it would include patents relating to hESC technology.

The Court acknowledged the absence of consensus on the ‘human embryo’, stating that:-

“ As regards the meaning to be given to the concept of ‘human embryo’ set out in Article 6(2)(c) of the Directive, it should be pointed out that, although, the definition of human embryo is a very sensitive social issue in many Member States, marked by their multiple traditions and value systems, the Court is not called upon, by the present order for reference, *to broach questions of a medical or ethical nature*, but must restrict itself to a legal interpretation of the relevant provisions of the Directive (see, to that effect, Case C-506/06 *Mayr* [2008] ECR I-1017, paragraph 38).”⁶⁶⁷[*Emphasis added*]

This statement that the court must decide upon the legal interpretation of the meaning of ‘embryo’ and not ethical questions is difficult to correlate with the reality that the Court in this instance is interpreting the meaning of a term ‘embryo’ for the specific purpose of a morality provision, therefore, can it truly be said that it is not in some way broaching questions of a moral or ethical nature? This argument might be stronger if it were adopting a narrow meaning of the term ‘embryo’ but it is adopting the most restrictive interpretation possible of uses of embryos. In this context, the CJ held that because the EU intended to “exclude any possibility of patentability where respect for human dignity could thereby be affected”,⁶⁶⁸ therefore the ‘human embryo’ within the meaning of Article 6(2)(c) should be “understood in a wide sense”.⁶⁶⁹ Accordingly, ‘embryo’ used in this context was held to include any human ovum once it was fertilised as fertilisation was “such as to commence

⁶⁶⁷ Ibid para. 30.

⁶⁶⁸ Ibid para 34.

⁶⁶⁹ Ibid para 34.

the process of development of a human being”,⁶⁷⁰ but would also apply to “a non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis”.⁶⁷¹ The rationale offered for this by the CJ was that such techniques resulted in the ovum being “capable of commencing the process of development of a human being just as an embryo created by fertilisation of an ovum can do so.”⁶⁷² Moreover, the Court stated that:

“...Article 6(2)(c) of the Directive excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.”⁶⁷³

At an institutional level, this argument could be seen as an attempt by the EU to avoid the controversies which have often surrounded the morality provisions by trying to mask this case as one which involved mere technical decision making relating to the interpretation of a term and not relating to a moral question. This allowed it to avoid questions relating to moral concerns and MS sovereignty which the EU is obliged to respect. However, the decision raised numerous questions, particular in relation to how it sits within other fields of EU law where there is generally a wide discretion given to States on the regulation of sensitive moral issues, including issues relating to hESCs.⁶⁷⁴

Another issue which arises from the decision is the boundaries and scope of the morality provisions. *Brüstle* suggests the patent should be denied given the court’s interpretation of ‘dignity’ as attaching to embryos. However, this could be contested given the absence of a settled position on the status of the embryo, or on the meaning of dignity within the EU – this latter point was indeed expressly confirmed in *Omega*, discussed above. This reference

⁶⁷⁰ Ibid para 35.

⁶⁷¹ Ibid para 36.

⁶⁷² Ibid para 36

⁶⁷³ Ibid para 52

⁶⁷⁴ See generally, A Plomer ‘After *Brüstle*’, note 74; See also, A Plomer, ‘Towards Systemic Legal Conflict’ note 123, this chapter was written prior to the decision in *Brüstle* but raises interesting points in relation to the differences between the broad application of the prohibition on patents for ‘uses of embryos for industrial or commercial purposes’ in the EPO’s decision in *WARF*, note 54 and the EU legislative framework for the use of human embryos more generally.

to dignity suggests an incorporation of human rights concerns within the morality provisions, which is to be expected and is supported by looking at the recitals to the Directive but as will be discussed in chapter five, if this is the case and if this is to be interpreted broadly, it is questionable whether the EPO is equipped to engage in similar analysis. Moreover, given that the court held that such patents would be immoral regardless of what stage destruction of an embryo took place this decision gives rise to questions such as how far back into the invention one should delve to ascertain if moral issues are implicated.

The decision in *Brustle*, although characterised by the Court as a technical/definitional exercise involving the interpretation of terms within the Directive, arguably goes much beyond this. Its reference to dignity, consideration of the development of the invention and adoption of a broad interpretation can be contrasted with the EPO's approach in WARF which although also referred to dignity, did not go as far as the CJEU in *Brustle* did in this context.

iv. Case C-364/13 *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trademarks*

The most recent CJEU decision on the morality provisions is the *International Stem Cell Corporation* case,⁶⁷⁵ which involved a referral from the UK Court on the following question:

“Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings, included in the term ‘human embryos’ in Article 6(2)(c) of Directive 98/44...?”⁶⁷⁶

Uncertainty arose because in *Brustle* the CJ stated that inventions/processes involving parthenotes –embryos generated through parthenogenesis, i.e. where an unfertilised egg is stimulated to develop into an embryo without fertilisation - if capable of commencing the

⁶⁷⁵ Case C-364/13 *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks*, Judgment of the Court, Grand Chamber, 18 December, 2014.

⁶⁷⁶ *Ibid* para 20.

process of development into a human being, could be excluded from patentability. The evidence presented in the *International Stem Cell Corporation* case was that whilst capable of commencing this process, parthenotes could only develop to blastocyst stage and could not complete the development process.⁶⁷⁷ The CJ held that in order to be defined as a ‘human embryo’ for the purposes of Art 6(2), the ovum “must have the inherent capacity of developing into a human being”⁶⁷⁸ and that “the mere fact that the organism commences a process of development is not sufficient for it to be regarded as a ‘human embryo’, within the meaning and for the purposes of the application of Directive 98/44”.⁶⁷⁹ It stated that it was for the referring court to decide whether parthenotes have such inherent capacity to develop into a human being, depending on relevant scientific evidence.

From an institutional perspective, the decision is of interest, as it is a relatively short judgment of a highly technical nature with no detailed discussion of dignity or other relevant provisions. Instead, the CJ seeks to apply a definitional examination of what the term embryo means in the context of the Directive. It states that: “...the purpose of Directive 98/44 is not to regulate the use of human embryos in the context of scientific research and that it is limited to the patentability of biotechnological inventions”⁶⁸⁰ and that the human embryo must be regarded as an autonomous term for the purposes of the Directive.⁶⁸¹ It is conceded that the CJ is bound and constrained by the Directive. The application of Art. 6(2) is also largely definitional, given that States are not given discretion on the application of this provision; once an invention falls within the provision it is excluded.

However, the extent to which this is a straightforward case of definition and application is questionable. The use of term ‘embryo’ in Art 6(2) is vague and science has clearly moved on from 1998 when the Directive was adopted, whilst the wording of the Directive remains unchanged. Thus, the Court is performing an important interpretative role in cases such as this but yet presents this as a technical test. It is unlikely parthenogenesis or the effect this could have on an unfertilised ovum was envisaged in 1998 when the Directive was drafted. Arguably, couching the case as a technical application of the provision, was in an attempt

⁶⁷⁷ Ibid para 17.

⁶⁷⁸ Ibid para 27.

⁶⁷⁹ Ibid para 29.

⁶⁸⁰ Ibid para 22.

⁶⁸¹ Ibid para 23.

to avoid controversy generated in previous cases involving hESC technologies but it is questionable whether given the lack of consensus amongst MSs if it is appropriate for the CJEU to intervene without further dialogue with MSs.

Moreover, whilst the decision in *International Stem Cell* appears to be a slight step back from the wide interpretation in *Brustle*, the very fact that the EU is deciding such issues in a technical manner, without reference to States discretion on such issues is problematic, as it is questionable if any of these techniques were truly envisaged by the drafters of the Directive, and if not then arguably these should fall to be considered under Art 6(1) which would grant discretion to States. On a literal interpretation ‘uses of embryos’ taken at face value does not equate to ‘uses of stem cells’ or ‘uses of parthenotes’ the CJ has used the principle of dignity to extend the Courts purview to looking at the development of the invention which in turn brings such issues before the CJ. However, this arguably conflicts with its reasoning in *Omega* which confirmed the divergences amongst MSs on the meaning of ‘dignity’ and following accession should such a case come before the ECtHR where the EU has adopted a broad interpretation of ‘dignity’ to exclude patents, arguably the ECtHR would be in favour of a broader margin of appreciation to be given to MSs, a point discussed in chapter five.

4.6 Conclusion

It is useful to recall Immergut’s argument that institutions may “...act as filters that selectively favour particular interpretations of the goals toward which political actors strive or of the best means to achieve these ends”.⁶⁸² It is hoped that this chapter together with chapter three on the EPOrg, has demonstrated the vast differences between the EPOrg and EU as institutions, particularly in terms of their characteristics, competences, and interaction with moral issues in other contexts. It has also highlighted the stark differences in composition, characteristics and structures of their judicial/quasi-judicial institutions. In light of these contrasting features, it has been argued that the judicial/quasi-judicial decision makers situated within these institutions will and have interpreted the morality provisions in a different manner through their respective institutional prisms, in order to give effect to

⁶⁸² E Immergut, ‘The Theoretical Core of New Institutionalism’, note 223, 10.

the goals/objectives of the institution within which they are situated. However, a final element which must be added to this picture, in order to build a more comprehensive view of the institutional complexity which arises, is the inter-institutional relationship of these institutions with the ECtHR, considered in chapter five.

Chapter five: The European Court of Human Rights and the Morality Provisions: A Unifying Bridge between the EU and EPOrg?

5.1 Introduction

The foregoing analysis has suggested that the EPO and CJEU are applying the morality provisions in a manner which is influenced significantly by, and indeed is dependent upon, the institutional frameworks within which these bodies sit. As a result, whilst there is convergence at a legislative level between the EU and EPOrg on the text of the morality provisions, it has been argued that this convergence is not automatically or indeed will ever necessarily be replicated at a decision-making level. In fact, it has been argued that the decision-making bodies of the EPO and CJEU are predisposed to apply the morality provisions in an *institutionally* refracted manner which results in the potential for divergence in the interpretation of these provisions. Having said this, there are some unifying strands between the two institutions, prominent amongst these is the ECHR to which all EU and EPOrg Contracting States are party. Beyleveld and Brownsword previously argued that the Convention rights and jurisprudence form part of the ‘ordre public’ which is uniform to both institutional frameworks.⁶⁸³

This chapter critically investigates whether human rights discourse and particularly the ECHR – which is a major cross-cutting theme and point of reference for both institutions in their recent decisions concerning the morality provisions – is, or could potentially in the future act as, a bridge between the EPOrg and EU in their application of the morality provisions. In other words, is the influence of the ECHR, which is a common feature underlying both institutional frameworks, acting as a bridging force in the institutional application of the morality provisions?

In examining this issue, part one commences by setting out some of the core institutional aspects of the ECHR system relevant to how it may influence the application of the morality provisions. Importantly, it has been decided against employing an institutional analysis of the ECtHR similar to that conducted in chapters 3 and 4 in relation to the EPO and CJEU.

⁶⁸³ Beyleveld and Brownsword, *Mice, Morality and Patents*, note 75, 69-70.

This is because the aim of this thesis is not to determine the institutional influences which exist within the ECHR system, even though it is acknowledged that these will also arise. Instead, the thesis is concerned primarily with the institutional framework within the EPO and CJEU for the application of the morality provisions and influences on these bodies in this context. Therefore, in the interests of brevity, the analysis in this chapter is tailored to this specific issue. It will only examine the institutional features of the ECtHR to the extent these are relevant to determining how ECtHR jurisprudence and the ECHR system generally may influence the EPO and CJEU in their application of the morality provisions. Accordingly, part one examines: (i) the development of the ECHR system; (ii) admissibility of complaints before the ECtHR; and (iii) the margin of appreciation doctrine which the ECtHR has employed when deciding upon moral issues.

Parts two and three examine the relationship of the EPOrg and EU, respectively, with the ECtHR. These sections provide an overview of the interactions of the EU/EPOrg with the ECHR system of rights, and the accountability of both bodies to the ECtHR; this includes a discussion of the indirect accountability of the Contracting States of the EU/EPOrg to the ECtHR for actions of the EU/EPOrg, or their adjudicative bodies.

Finally, part four reflects on the analysis in order to critically assess the role of human rights in the application of the morality provisions and particularly, whether the ECHR is or could potentially act as a bridge between the EPO and CJEU, in this context. It argues that human rights, in a similar manner to morality, are susceptible to institutional influence. Moreover, because of the need to recognise Contracting State sovereignty, the ECtHR will ensure a minimum standard of protection, but outside of this, higher levels of protection of human rights are provided for. As will be seen, the ECtHR's margin of appreciation approach is crucial in this context. There is also evidence of cross fertilisation between the EU and ECHR, as a developing margin of discretion approach is evident within EU case law which has similarities with the ECHR's approach. As yet there have been no references to such a margin existing within EPO cases. Indeed, given the EPOrg's fundamental objectives include providing uniformity of patent protection, such an approach would appear inconsistent with the aims of this institution, and difficult to operate in practice. Nonetheless, it will be argued that the EPO's narrow application of morality provisions, and the fact that post-grant issues are generally decided upon by Contracting States of the EPC, means that individual Contracting States objections may be accommodated at the

post-grant stage through national revocation proceedings, thereby preserving national moral traditions.⁶⁸⁴ This arguably indirectly achieves the same as a margin of discretion application of morality/human rights, albeit at post-grant stage.

In short, this classical EP system provides a means for States to exercise their own discretion in the application of the morality provisions, so at the post-grant level, a breathing space exists for Contracting States to depart from the EPO approach. Whilst not perfect, given the institutional constraints within the EPOrg, this system arguably provides a way in which to mediate the need for certainty at grant stage, with preserving a space for the protection of Contracting States' traditions. It is conceded that this leaves a number of questions as to the defensibility of the application of the morality provisions, and the role of the EPO as overseeing the grant of the morality provisions. This is because if the EU is incorporating, or could incorporate a higher level of protection for human rights through the morality provisions than the EPO, then it is questionable whether it is appropriate for the EPO to be assessing patent grant for EU countries.

This analysis is of contemporary relevance as the proposal to adopt a unitary patent will remove the scope for post-grant divergence amongst States party to the unitary patent scheme. The unitary patent as currently envisaged will be granted by the EPO and post-grant issues dealt with by a new supranational entity the unitary patent court (UPCt). The UPCt will bring its own institutional influences to play, influences which are more akin to the EPO than the CJEU. Hence, the discussion in this current chapter is significant in considering the defensibility of the morality provisions should the unitary patent scheme be adopted. The unitary patent proposal and its implications for the application of the morality provisions are examined in chapter six.

Prior to delving into the substantive issues, it must be noted that this thesis is not arguing that the morality provisions should be used to incorporate human rights concerns, rather it is pointing to the fact that if this is the intention, then we need to give serious thought to whether the institutional matrix which currently exists, can vindicate such rights within this application, particularly, in light of the unitary patent plans.

⁶⁸⁴ Plomer (Co-ordinator), *Stem Cell Patent Report*, note 47, 133

5.2 The European Court of Human Rights: An Overview of its Institutional Characteristics

The Council of Europe (CoE)⁶⁸⁵ was established on the 5th May, 1949 by the signing of the Treaty of London 1949,⁶⁸⁶ which was initially signed by ten States.⁶⁸⁷ On the 4th November 1950 its Contracting States signed the ECHR which entered into force on 3rd September, 1953, thereby creating the ECtHR, its judicial branch which is charged with overseeing and enforcing rights protection. The ECHR must be ratified by all States party to the CoE.⁶⁸⁸ Its membership, as will be discussed below, has since increased to 47 States. According to Steiner, Alston and Goodman, the impetus for the Convention system was multifaceted, in particular, it was: the first regional response to the atrocities of World War Two and was driven by a belief that governments which were united in respecting human rights would be less likely to engage in a war with their neighbours; following World War Two, there was also a belief that the best way to ensure that Germany would be a force for peace was by adopting regional integration and the institutionalisation of common values.⁶⁸⁹ Thus, the ECHR system was grounded in a desire for peace and stability within Europe. Importantly, a core feature of the debate surrounding its early development was the question of how to preserve Contracting States' sovereignty driven by the reluctance of States to be directly accountable to a supranational body.⁶⁹⁰

The ECHR system has developed to become one of the strongest regional bodies for the enforcement of human rights. It has changed in a number of ways since its establishment. Firstly, its membership has expanded significantly. Initially, as noted, the CoE had just ten members. This expanded to twenty three by 1990. The aftermath of the Cold War led to a

⁶⁸⁵ The main sub-institutions of the Council of Europe are: the Committee of Ministers; the Consultative or Parliamentary Assembly; the Congress of Local and Regional Authorities; the European Court of Human Rights, the Commissioner for Human Rights; and the Council of NGOs. See <<http://www.coe.int/en/web/about-us/structure>> accessed 16th July, 2015.

⁶⁸⁶ Also known as the Statute of the Council of Europe.

⁶⁸⁷ Belgium, Denmark, France, Ireland, Italy, Luxembourg, the Netherlands, Norway, Sweden and the United Kingdom.

⁶⁸⁸ Council of Europe, Resolution 1031 (1994) Honouring commitments entered into by member states when joining the Council of Europe.

⁶⁸⁹ H J Steiner, P Alston and R Goodman, *International Human Rights in Context*, (3rd edn, OUP 2008) 933.

⁶⁹⁰ Ibid, 934. The authors note that a number of States expressed a reluctance but the most detailed historical analysis of this has been conducted in relation to the United Kingdom, see, AW Brian Simpson, *Human Rights and the End of Empire: Britain and the Genesis of the European Convention* (OUP 2004); G Marston, 'The United Kingdom's Part in the Preparation of the European Convention on Human Rights 1950' (1993) ICLQ 796.

doubling of States by 2007⁶⁹¹ and it currently has forty seven members.⁶⁹² The twenty eight EU MSs are all members of the CoE, as are all of the EPC Contracting States. Thus, the ECHR system is a central external underlying framework to both the EPORG and the EU frameworks. Moreover, as discussed further below, the EU plans to accede to the ECHR which will strengthen its relationship with the ECHR system. As noted, despite the recent CJEU decision rejecting the draft accession agreement,⁶⁹³ this thesis proceeds under the assumption that an accession will go ahead in the future, even if delayed.

The second change in the CoE system concerns the enforcement of rights and accountability of States. There were three main reform stages⁶⁹⁴ brought about by the adoption of Protocol 9 which came into force in 1994⁶⁹⁵, Protocol 11 coming into force in 1998⁶⁹⁶ and Protocol 14⁶⁹⁷ which entered into force on 1st June 2010.⁶⁹⁸ These protocols have been examined elsewhere,⁶⁹⁹ and the changes brought about by each will not be reopened here. Nonetheless, it is important to ground the analysis by offering an overview of the framework for the enforcement of rights within the ECHR system which currently exists and the role of the ECtHR in this context.

⁶⁹¹ Steiner, Alston and Goodman, *International Human Rights in Context*, note 689, 936.

⁶⁹² See <<http://www.coe.int/en/web/about-us>> accessed 16th July, 2015.

⁶⁹³ Opinion 2/13 *Accession of the European Union to the European Convention for the Protection of Human Rights and Fundamental Freedoms* ECLI: EU: C: 2014:2454

⁶⁹⁴ See Steiner, Alston and Goodman, *International Human Rights in Context*, note 689, 940.

⁶⁹⁵ Protocol No. 9 to the Convention for the Protection of Human Rights and Fundamental Freedoms (6th November, 1990).

⁶⁹⁶ Protocol 11 to the European Convention for the Protection of Human Rights and Fundamental Freedoms, Restructuring the Control Machinery Established Thereby (11th May, 1994).

⁶⁹⁷ Protocol 14 to the European Convention for the Protection of Human Rights and Fundamental Freedoms Amending the Control System of the Convention (13th May, 2004).

⁶⁹⁸ For a discussion of the system now envisaged under Protocol 14 see, A Mowbray, *European Convention on Human Rights* (OUP 2012) 14-63.

⁶⁹⁹ For an overview of the changes see, Steiner, Alston and Goodman, *International Human Rights in Context*, note 689, 940. For literature on each, see the following: In relation to Protocol 9, see: J A Andrews, 'European Convention on Human Rights, Protocol No.9' (1991) 16(5) EL Rev 425; In relation to Protocol 11, see: V Schlette and N Rowe, 'The protection of human rights in Europe after the Eleventh Protocol to the ECHR' (1998) EL Rev 23 Supp HR 3; H G Schermers, 'Adaptation of the 11th Protocol to the European Convention on Human Rights' (1995) 20(6) EL Rev 559; A R Mowbray, 'A New European Court of Human Rights' [1994] PL 540; In relation to Protocol 14, see: M Beernaert, 'Protocol 14 and new Strasbourg procedures: towards greater efficiency? And at what price?' (2004) 5 EHRLR 544; S Greer, 'Protocol 14 and the future of the European Court of Human Rights' [2005] PL 83; S Greer, 'Reforming the European Convention on Human Rights: Towards Protocol 14' [2003] PL 663; A R Mowbray, 'Beyond Protocol 14' (2006) 6(3) HRLR 578.

5.2.1 Admissibility of complaints to the ECtHR

Briefly, in terms of the structure of the ECtHR, there are currently forty seven judges on the ECtHR, one judge from each Contracting State. The judges are elected by the Parliamentary Assembly of the CoE, which selects one candidate from a list of three candidates proposed by each Contracting State. Each judge is elected on the basis of a nine year non-renewable term.⁷⁰⁰ Depending on the significance of the case, the court can sit as: a Grand Chamber which consists of seventeen judges; a Chamber consisting of seven judges; a Commission of three judges; or a single judge formation.

The ECtHR deals with both interstate applications under Art 33 which are rare,⁷⁰¹ and individual petitions under Art 34. Individuals, non-governmental organisations and groups of individuals⁷⁰² can bring applications, as can legal persons.⁷⁰³ Under Art 34, individuals must demonstrate they were directly affected as a victim⁷⁰⁴ by the action/inaction of one State or groups of Contracting States which breached their Convention rights.⁷⁰⁵ A list of seven criteria which individual applicants must satisfy is set out in Art 35(2) and (3),⁷⁰⁶ however, a discussion of this is beyond the scope of this work.

The CoE places primary responsibility for compliance with the ECHR with Contracting States; domestic remedies must be exhausted by parties prior to bringing a claim before the ECtHR. An exception to this is that inter-State applicants do not need to exhaust domestic remedies if the applicant is alleging an “administrative practice” involving widespread and connected breaches of Conventions rights.⁷⁰⁷ In other cases, once domestic remedies are exhausted, individual⁷⁰⁸ or interstate petitions⁷⁰⁹ can be brought, but applicants must lodge applications within six months of when it was considered by the final domestic court. This

⁷⁰⁰ Council of Europe, ‘The ECHR in 50 Questions’ (February, 2014) <http://www.echr.coe.int/Documents/50Questions_ENG.pdf> accessed 10th July, 2015

⁷⁰¹ Mowbray, *European Convention on Human Rights*, note 698, 29.

⁷⁰² Ibid 29.

⁷⁰³ *Krone Verlag GmbH & Co KG v Austria* (No. 3), Application no. 39069/97 (ECtHR, 11 December 2003) 680.

⁷⁰⁴ As discussed in *Klass et al. v United Kingdom*, Application no. 5029/71 (ECtHR, 6 September 1978) Series A, no. 28.

⁷⁰⁵ Mowbray, *European Convention on Human Rights*, note 698, 30-31.

⁷⁰⁶ These are discussed in Mowbray, *Ibid*, 37-38.

⁷⁰⁷ See Mowbray, *ibid*, 35 citing *Manole and others v Moldova*, Application no 13936/02, (ECHR, 17 September 2009) 633.

⁷⁰⁸ Art. 34 ECHR.

⁷⁰⁹ Art. 33 ECHR. For a discussion see, Steiner, Alston and Goodman, *International Human Rights in Context*, note 689, 938.

timeline will be changed to four months by Protocol 15 of 2013, however, this will not come into force until it has been signed by all parties. At the time of writing, it has been signed by twenty one countries and ratified by only one of these countries.⁷¹⁰

Therefore, the ECHR system is predicated on ensuring a balance with national sovereignty, and its role only comes into play once domestic procedures are exhausted.⁷¹¹ This deference to Contracting States is reinforced by one of the hallmarks of the ECtHR jurisprudence: the margin of appreciation principle which is often employed by the ECtHR in relation to controversial issues or those upon which there is no consensus. Given that the application of the morality provisions fits within these circumstances it is useful at this juncture to briefly examine this doctrine.

5.2.2 Margin of Appreciation doctrine

The “margin of appreciation” doctrine refers to the discretion or scope for manoeuvre bestowed upon Contracting States of the ECHR in fulfilling their obligations under the Convention. It has been defined as:

“...the latitude or deference or error which the Strasbourg organs allow to national legislative, executive, administrative and judicial bodies before it is prepared to declare a national derogation from the Convention, or restriction or limitation upon a right guaranteed by the Convention, to constitute a violation of one of the Convention’s substantive guarantees.”⁷¹²

The roots of the doctrine have been traced by Yourow to classical martial law doctrine⁷¹³ and the jurisprudence of the French *Council d’etat* which used the term “*marge d’appréciation*.” It also used other equivalent national institutions as a tool to review the legitimacy of the activities and the discretionary powers of administrative authorities.⁷¹⁴ The doctrine was not mentioned in the ECHR until the recent Protocol 15, discussed below;

⁷¹⁰ Accurate as of 16th July 2014, <<http://www.conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=213&CM=8&DF=27/06/2013&CL=ENG>> accessed 16th July, 2015

⁷¹¹ Mowbray, *European Convention on Human Rights*, note 698, 35.

⁷¹² H Yourow, *The Margin of Appreciation Doctrine in the Dynamics of European Human Rights Jurisprudence* (Kluwer Academic Publishers 1996), 13.

⁷¹³ Ibid 14

⁷¹⁴ Ibid. See also, R Nigro, ‘The Margin of Appreciation Doctrine and the Case-Law of the European Court of Human Rights on the Islamic Veil’ (2010) 11 HR Rev 531.

nor was it referred to in the drafting history of the Treaty (the *Travaux Préparatoires*).⁷¹⁵ Instead, it originated and was developed through the jurisprudence of the ECtHR.⁷¹⁶ Its origins are commonly traced to *Handyside v United Kingdom*⁷¹⁷ delivered in 1976, however according to Yourow it can be traced to the earlier Commission report in *Greece v United Kingdom* (“*Cyprus*”)⁷¹⁸ delivered in 1958.

The scope of the margin of appreciation varies depending on the circumstances, subject matter and background to the case.⁷¹⁹ Furthermore, some Articles are absolute rights which cannot be limited, an example of which is Art 3 which prohibits torture or inhuman/degrading treatment, whilst, others are qualified rights, such as Art 8 (respect for private and family life). In the case of qualified rights, certain limitations contained in the text of the Article can be invoked to limit their protection.⁷²⁰ It is in these contexts that the margin of appreciation may apply. When applying the doctrine the ECtHR will consider whether any interference with Convention rights are ‘necessary’ and ‘proportionate’ in a democratic society. The proportionality aspect requires the ECtHR to consider the level of interference with a right and to balance the consequences of this interference on the individual affected versus the State’s interest in interfering with the right.⁷²¹ The notion of necessity was summarised in *Olsson v Sweden*⁷²² which held that it: “...implies that the interference corresponds to a pressing social need and, in particular, that it is proportionate to the legitimate aim pursued.”⁷²³

⁷¹⁵ Ibid 531.

⁷¹⁶ See Yourow, note 712, 15-16. Early case law of relevance includes: *Lawless v Ireland*, Judgment of 1 July 1961, European Court of Human Rights, (Series A, No 3); *Denmark v. Greece*; *Norway v Greece*; *Sweden v Greece*; *Netherlands v Greece*, 12 *Yearbook of the European Convention*, Special Edition, 1969; *Klass et al. v United Kingdom*, Judgment 6 September, 1978, European Court of Human Rights, Series A, no. 28; *Arrowsmith v. United Kingdom*, Comm. Rep. 1978, 19 DR 5; Significantly, it was expanded outside the application to Art. 15 ECHR in the decision in *Case relating to Certain Aspects of the Laws on the Use of Languages in Education in Belgium* (“Belgian Linguistic Case”) (No. 2) (Merits), Eur. Ct H.R., Series A, no. 6 (1968) and subsequently developed further in *Handyside v United Kingdom* (1979-80) 1 E.H.R.R. 737. and *The Sunday Times v. United Kingdom* (No. 1) (1979) 2 EHRR 245.

⁷¹⁷ (1979-80) 1 EHRR 737.

⁷¹⁸ 2 *Yearbook of the European Convention* 174-199, (1958-59) as cited by Yourow, note 712, 15-16.

⁷¹⁹ *Frette v France* (2004) 38 EHRR 21

⁷²⁰ See Art 8(2) ECHR which qualifies Art 8(1) ECHR.

⁷²¹ MW Janis, R S Kay and A K Bradley, *European Human Rights law, Texts and Materials*, (3rd edn, OUP 2008) 243.

⁷²² (1989) 11 EHRR 259.

⁷²³ Ibid 261.

When the margin of appreciation operates States are given discretion in their actions, provided any State interference with a right that is engaged is justified. A “staple”⁷²⁴ of the ECtHR approach in this context, is its use of consensus, whereby the recognition of consensus on an issue in other Contracting States may be used to limit the margin of appreciation allocated to States, and *vice versa*.⁷²⁵ Although, this approach can be ambiguous in practice because it is not clear entirely how many States are necessary to form a sufficient consensus, and as will be seen, in some cases even where consensus is evident, the ECtHR has still granted a margin of appreciation. Arguably, the approach offers a shaky foundation upon which to calibrate the margin of appreciation but it is necessary to minimise tensions and maintain the delicate balance with Contracting States’ sovereignty, vital to the ECHR’s operation.

This is supported when one looks to the rationale for the margin of appreciation approach as set out in *Handyside v United Kingdom*⁷²⁶ where the ECtHR stated that:

“By reason of their *direct and continuous* contact with the vital forces of their countries, State authorities are in principle *in a better position* than the international judge to give an opinion on the exact content of these requirements as well as on the “necessity” of a “restriction” or “penalty” intended to meet them.”⁷²⁷ [*Emphasis added*]

This highlights the deference given to national jurisdictions in the protection of rights. Janis et al claim that two assumptions underlie the doctrine, namely, that what is necessary to attain the stated aims of the Convention may vary from State to State, and that given the government’s position and proximity to vital forces in their respective jurisdictions they are in the best position to assess the necessity than an international court.⁷²⁸ Similarly, Hutchinson has argued that the ‘margin of appreciation’ doctrine was “designed to prevent the Strasbourg organs from intervening in a State’s affairs to too great an extent.”⁷²⁹ Moreover, given the number of States subject to the ECHR and the various cultures and traditions within these States it would be difficult if not impossible in some cases, to adopt

⁷²⁴ Janis, Kay and Bradley, *European Human Rights law*, note 721, 24.

⁷²⁵ *Ibid*, 243.

⁷²⁶ (1979-80) 1 EHRR 737

⁷²⁷ *Ibid* 753.

⁷²⁸ Janis, Kay and Bradley, *European Human Rights law*, note 721, 242.

⁷²⁹ M R Hutchinson, ‘The Margin of Appreciation in the European Court of Human Rights’ (1999) 48(3) ICLQ 638, 647.

a uniform standard for all States without conflict arising. The margin of appreciation allows leeway to the Court to protect human rights whilst also minimising tensions with States. This is particularly relevant in cases which concerning controversial issues, such as those to which the morality provisions in the patent system may give rise to. The issues which may arise in the context of the morality provisions resonate in particular with issues considered in ECtHR jurisprudence relating to questions surrounding the beginning of life which is thus useful to examine at this juncture.

a) Application of the margin of appreciation doctrine by the ECtHR to moral questions relating to the beginning of life

Three areas of overlapping jurisprudence can be identified in relation to start of life issues, namely, cases relating to: (1) the status of the embryo; (2) assisted reproduction; and (3) access to abortion services. The approach of the ECtHR in relation to each area is briefly mapped in the discussion that follows.

i. The status of the human embryo

The ECtHR has considered the status of the embryo in a number of relevant cases. In *Vo v. France*,⁷³⁰ the applicant attended Lyons General Hospital when she was six months pregnant for a check-up. As a result of a misidentification, a doctor carried out an incorrect procedure, piercing the amniotic sac causing a loss of fluid, as a result of which the pregnancy had to be terminated for therapeutic reasons. The applicant and her partner lodged a criminal complaint claiming unintentional injury to the applicant and unintentional manslaughter of her child. Under French law, an unborn foetus is not a person and thus the claim failed. The applicant subsequently complained to the ECtHR that the absence of a provision in French law to prevent and punish the act of taking the life of an unborn foetus was in breach of Art 2 of the ECHR which provides that “everyone’s right to life shall be protected by law.” The ECtHR focused on the level of consensus on the issue within the Contracting States, concluding that as there is no European consensus on

⁷³⁰ *Vo v France* (2005) 40 EHRR 12.

the “scientific and legal definition of the beginning of life”; this question comes within the margin of appreciation of each Contracting State.⁷³¹

A similar approach was adopted in *Evans v United Kingdom*⁷³² where the applicant brought proceedings to the ECtHR seeking custody of stored embryos which had been created using her eggs and her former partner’s sperm. Following the breakdown of the relationship, he refused to give consent for her to use the embryos in IVF treatment. The applicant asserted that her human rights had been violated as a result of the applicable UK law, namely, Schedule 3 of the Human Fertilisation and Embryology Act 1990, which provides that a party who provided gametes may withdraw consent up to the point of implantation. The English court previously held that as consent was the governing criterion in the Act the applicant was not entitled to implant the frozen embryos once consent was withdrawn.⁷³³ This was accepted by the ECtHR which dismissed her claim and instead gave a wide margin of appreciation to the United Kingdom.

Interestingly, for the purposes of this research, one of the grounds raised was whether such embryos had a right to life under Art 2 EHCR. However, the ECtHR referring to *Vo v France* again confirmed that States had a wide margin of appreciation to decide given the absence of consensus in Europe on the issue.⁷³⁴ The applicant also argued that her Art 8 rights were being interfered with, which she argued was exacerbated in the case as the embryos represented her only chance to have a biological child, as she had created these embryos prior to undergoing chemotherapy. However, the ECtHR emphasised that in situations where there is no consensus within Contracting States as to the importance of the interests at stake and the means to protect these, and in particular where the issues raise sensitive moral and ethical issues, a broad margin of appreciation would apply.⁷³⁵ In relation to IVF treatment, it stated that the margin of appreciation must be a wide one given that its use:

“...gives rise to sensitive moral and ethical issues against a background of fast-moving medical and scientific developments, and since the questions raised by the

⁷³¹ Ibid, para. 82.

⁷³² (2008) 46 EHRR 34.

⁷³³ See also, H Coveney, ‘Assisted Reproductive Technologies and the Status of the Embryo’ (2007) 12 (1) *Medical Law Journal of Ireland* 14, 16.

⁷³⁴ Ibid 747.

⁷³⁵ Ibid 748.

case touch on areas where there is no clear common ground amongst the Member States.”⁷³⁶

This again demonstrates reluctance of the Court to encroach upon areas where there is no consensus amongst Contracting States, and the application of the morality provisions is a prime example of such a case. This is because, one of the requirements for patentability is that a technology is novel. Hence, patent applications are generally subject to little if any discussion prior to their submission to the intellectual property office because this would destroy the novelty of an inventor’s application. Therefore, in the absence of improvements in technology foresighting it is unlikely that any consensus would be evident on the patentability of such emerging technologies. Thus, were the ECtHR to consider the application of the morality provisions, for instance in a case challenging a CJEU decision involving these provisions post-accession of the EU to the ECHR, it would be likely to offer a margin of appreciation to the EU and/or States involved.

ii. Margins Beyond Consensus: Assisted reproduction and Abortion Jurisprudence

Jurisprudence in relation to assisted human reproduction and access to abortion services are also instructive. In such cases, the ECtHR has allowed States discretion even where an emerging consensus contrary to the State’s position is evident. This highlights that it is more than just consensus that is at stake, suggesting that the ECtHR will also defer to State’s discretion on issues which are controversial or raise complex moral questions. For instance, in *S.H. and Ors. v Austria*,⁷³⁷ four applicants claimed that legislation in Austria which prevented them from using donor gametes for *in vitro* fertilisation violated their rights under Art 8 ECHR. Despite alluding to an emerging consensus in favour of providing such services,⁷³⁸ the ECtHR stated this was not based on settled principles and instead “reflects a stage of development within a particularly dynamic field of law and does not decisively narrow the margin of appreciation of the State.”⁷³⁹ It held that that the Austrian government did not exceed its margin of appreciation and was not in violation of Art 8, stating that:

⁷³⁶ Ibid 753.

⁷³⁷ *S, H and Ors. v Austria*, Application no. 57813/00, (ECHR 3rd November, 2011).

⁷³⁸ Ibid para 96-97.

⁷³⁹ Ibid para 96.

“Since the use of in vitro fertilisation treatment gave rise then and continues to give rise today to sensitive moral and ethical issues against a background of fast-moving medical and scientific developments, and since the questions raised by the present case touch on areas where there is not yet clear common ground among the member States, the Court considers that the margin of appreciation to be afforded to the respondent State must be a wide one”⁷⁴⁰

The ECtHR went further in the decision in *A, B and C v. Ireland*⁷⁴¹ where it left a margin of appreciation to Ireland in relation to restriction of abortion services, despite acknowledging a consensus in favour of the provision of such services by a majority of Contracting States. The case related to claims brought by three applicants who alleged that the restriction on abortion services in Ireland violated their Convention Rights. Each applicant had to travel to the UK to obtain a termination, and each suffered complications. The third applicant was successful in proving a violation of her Convention rights, as Irish law provides for an exception to the general restrictions on abortion in cases where a woman’s life is at risk. The third applicant alleged such a risk but it was unclear how she could prove her entitlement to access such services in Ireland and eventually had to travel abroad for a termination. This was held to be contrary to Convention rights, as the authorities:

“...failed to comply with their positive obligation to secure to the third applicant effective respect for her private life by reason of the absence of any implementing legislative or regulatory regime providing an accessible and effective procedure by which the third applicant could have established whether she qualified for a lawful abortion in Ireland in accordance with Article 40.3.3 of the Constitution.”⁷⁴²

However, the other two applicants, who did not claim to fall within this exception, and instead challenged the general prohibition on abortion in Ireland, were unsuccessful. Notably, in this context, the ECtHR stated that ascertaining if there was a consensus had long played a role in the development of Convention protections and had been invoked to justify a dynamic interpretation of the Convention.⁷⁴³ However, it stated that even though

⁷⁴⁰ Ibid para 97.

⁷⁴¹ *A, B and C v Ireland* [2010] ECHR 2032.

⁷⁴² Ibid para 267.

⁷⁴³ Ibid para. 234.

there was a consensus amongst a substantial majority of the Contracting States of the CoE to allow abortion on broader grounds than allowed in Irish law, this consensus did not decisively narrow the broad margin of appreciation of the State.⁷⁴⁴ Of central importance was the decision in *Vo* discussed above where the question of when life begins was held as coming within the States' margin of appreciation.⁷⁴⁵ Moreover, the ECtHR held that since the rights claimed on behalf of the foetus and those of the mother are inextricably linked, the margin of appreciation accorded to the State's protection for the unborn translates into the margin of appreciation for that State as to how it balances the conflicting rights of the mother.⁷⁴⁶ It emphasised that the margin of appreciation was not unlimited, and that the prohibition impugned must be compatible with the State's Convention obligations and whether it offered an appropriate and fair balance of rights.⁷⁴⁷

Having regard to the right of Irish women to travel to obtain abortion services⁷⁴⁸ and the information and counselling provided to them, it did not consider that the:

“...prohibition in Ireland of abortion for health and well-being reasons, based as it is on the profound moral views of the Irish people as to the nature of life and as to the consequent protection to be accorded to the right to life of the unborn, exceeds the margin of appreciation accorded in that respect to the Irish State”.⁷⁴⁹

The ECtHR held there was a fair balance in respect of their private lives and the rights invoked on behalf of the unborn,⁷⁵⁰ and there was no violation of Art 8 in this respect.

These cases suggest: (1) that in the absence of consensus, a margin of appreciation will generally apply; and (2) that cases which involve sensitive moral issues will also give rise to a margin of appreciation even if a consensus on such issues is evident or emerging. This makes it likely that the ECtHR would defer to Contracting States or to the EU post-accession on decisions involving the application of the morality provisions, should it be called upon to interpret such questions. However, the difficulty with this is that in the context of the patent system one is dealing with two other supranational actors along with

⁷⁴⁴ Ibid para. 235-236.

⁷⁴⁵ Ibid para. 237.

⁷⁴⁶ Ibid para. 237.

⁷⁴⁷ Ibid, para. 238.

⁷⁴⁸ The 13th and 14th Amendment in Ireland removed any legal impediment to Irish women travelling abroad to obtain an abortion.

⁷⁴⁹ *A, B and C v Ireland* [2010] ECHR 2032, para. 241.

⁷⁵⁰ Ibid para. 241.

States which could prove problematic in relation to how multiple margins of appreciation would apply.

In this context, Nic Shuibhne's work is instructive.⁷⁵¹ She has used the right to life as a lens through which to examine the operation of the ECHR/EU systems for protection of rights. In doing so, she argues that multiple margins of appreciation exist within the current system, and these allow for 'internal state value spaces' for Contracting States. Nic Shuibhne provides the example of the discretion given in the context of Irish abortion laws where the Irish State is free to restrict access to abortion services within Ireland on the grounds of (Art. 2) but this cannot be used to prevent individuals traveling abroad to gain access to such services nor can it be used to influence the provision of abortion services in other States where it is not seen as contrary to Art. 2. This allows for differing levels of protection within and outside a MS, creating an internal seal on rights protection within the MS.

This analysis resonates with issues that arise in the EPO/CJEU/ECtHR interaction in the patent system, and the potential for the morality provisions to be used to support the denial of a patent on the basis of human rights arguments. However, allowing for discretion is arguably more complex in this context as it involves three supranational actors, and as will be seen the institution which has the most significant role in the application of the morality provisions, the EPO, has no direct link with the ECtHR. Moreover, the EPO performs the function of patent grant in this context and it is not clear how it might employ a margin of discretion to distinguish between State preferences at the grant stage. It has never used the margin of discretion at opposition stage or in the decision of its Boards, to provide for differing results for patent applications in differing jurisdictions. Nonetheless, as discussed above, Contracting States are able to diverge from the EPO decisions at the post-grant stage as the EP classical route results in the grant of a bundle of national patents. This in turn alleviates the potential for tensions. Furthermore, given the EPO's institutional disposition towards a narrow interpretation of the morality provisions, it is likely to grant patents in the majority of cases and where it does not, if Contracting States wish to do so, they can deny patents at a post-grant stage if these are challenged.

⁷⁵¹Nic Shuibhne, 'Margins of Appreciation', note 622.

From the perspective of preserving Contracting State identity, it would be far more problematic if the EPO were to deny patents which Contracting States would be happy to uphold, as the denial of a patent by the EPO means a patent cannot be obtained under the EPC. Equally, denial by the EPO of a patent through Opposition Proceedings revokes this patent in all Contracting States and would be problematic in terms of Contracting State sovereignty. Thus, by applying the morality provisions in a narrow fashion, the EPO process allows for post-grant divergence by Contracting States or the EU, which could act akin to an indirect margin of discretion if needed should States wish to deny patents on the basis of the morality provisions post-grant within their jurisdiction. It is conceded that this is not without its issues. One particular criticism from the perspective of the defensibility of the morality provisions within the current system, is that patents will be granted initially and would need to be challenged post-grant if the EU or Contracting States envisaged the morality provisions as encompassing broader human rights issues in their jurisdiction. Thus, this is by no means a perfect system; however, it is questionable how else it would operate in practice if one wished to have one supranational granting body. This is discussed further in section 5.5 below.

Having said this, once the unitary patent is adopted, as will be seen in chapter six, the governing provisions mean that it must be applied in a uniform manner at the post-grant stage by the unitary patent court (UPCt) and participating States cannot limit patents with unitary effect, essentially, an all or nothing approach applies. The unitary patent system therefore does not appear to accommodate divergences amongst Contracting States. This is particularly in terms of States wishing to adopt a divergent approach based on the morality provisions for patents which have been granted and are operable in their jurisdiction. However, it will be particularly problematic should the UPCt apply the morality provisions to incorporate broad applications of ‘human dignity’ and human rights claims to deny patentability on the basis of these provisions, as has been seen in more recent CJEU decisions. This aspect and the future implications when the unitary patent comes into force is examined in chapter six.

5.3 The Relationship between the EU and the ECtHR

The relationship between the EU and the ECHR system has been discussed extensively in the literature.⁷⁵² The implications this has for the application of the morality provisions has also been examined,⁷⁵³ albeit to a much lesser extent. This section provides an overview of the contours of this relationship. As the purposes of the thesis is not to make a contribution in relation to the relationship between the EU and ECHR, this does not represent a comprehensive overview of all issues relating to the relationship between EU and the ECHR; rather it is a deliberately brief analysis, tailored to assessing the extent of the influence the ECtHR may have on the EU and particularly, on the CJEU in the interpretation of the morality provisions.

5.3.1 Co-operation between the EU and CoE in human rights protection

As discussed in chapter four, the EU has developed its role in protecting human rights significantly since its establishment. This role has been solidified by the commencement of the Lisbon Treaty on 1st December, 2009⁷⁵⁴ as it recognised the Charter of Fundamental Rights of the EU as having the same legal status as the Treaties. Moreover, Art. 6(2) TEU places the EU under a legal duty to accede to the ECHR.⁷⁵⁵ The accession of the EU is discussed at 5.3.3 below in relation to what this is likely to mean in terms of the EU's accountability to the ECtHR.

Within the current system, there is clear cooperation between the EU and CoE. The CJEU regularly refers to jurisprudence of the ECtHR in its decisions,⁷⁵⁶ and Lock argues the interpretation of human rights by the CJEU is generally parallel to interpretation of similar ECHR rights by the ECtHR.⁷⁵⁷ However, Lock also highlights the careful balance of

⁷⁵² See, T Lock, 'Beyond Bosphorus: the European Court of Human Rights' Case law on the Responsibility of Member States of International Organisations under the European Convention on Human Rights' (2010) 10(3) HRLR 529; T Lock, 'The ECJ and the ECtHR: The Future Relationship between the Two European Courts' (2009) *The Law and Practice of International Courts and Tribunals* 375; C Costello, 'The Bosphorus Ruling of the European Court of Human Rights: Fundamental Rights and Blurred Boundaries in Europe' (2006) 6 HRLR 87.

⁷⁵³ The main work discussing this is Plomer, 'After Brüstle' note 74.

⁷⁵⁴ *Ibid.*, 111.

⁷⁵⁵ See also, Protocol No. 14 to the European Convention on Human Rights.

⁷⁵⁶ See Lock, 'The ECJ and the ECtHR: The Future Relationship between the Two European Courts' note 752, see in particularly footnote 18.

⁷⁵⁷ Lock gives the following examples: Case C-7/98 *Kromback v Bamberski* [2000] ECR I 1935; Case C 112/00 *Schmidberger v Austria* [2003] ECR I-5659; Case C-60/00 *Carpenter v Secretary of State for the*

supranational powers evident; evidence for this can be seen in the Preamble to the EU's Fundamental Charter of Human Rights which provides that the jurisprudence of the ECtHR is but one of several aids to interpreting this Charter. Lock notes that one cannot assume that the Charter means that the EU will be directly bound by the case law of the ECtHR.⁷⁵⁸ Nonetheless, to date there has been significant inter-institutional convergence on human rights principles between the EU and CoE, and also between the CJEU and ECtHR.

An aspect of this convergence is the CJEU's use of a 'margin of appreciation' type approach which appears transplanted from the ECtHR jurisprudence. As discussed in chapter four, the CJEU indicated such a margin would be applied to the application of the morality provisions.⁷⁵⁹ It stated that States had "a wide scope for manoeuvre in applying"⁷⁶⁰ However, the scope of manoeuvre was limited by the Directive⁷⁶¹ which provides four examples of processes or uses which are not patentable in Art. 6(2), and which no margin of discretion applied to.⁷⁶² As noted, the CJEU's adoption of a margin of discretion approach and reasoning behind this mirrors the ECtHR's reasoning in cases involving moral questions and highlights the cross fertilisation of principles between the two institutions in relation to the adjudication of rights. Torremans confirms that:

"...in the absence of a consensus on the morality of a particular invention and where the jurisprudence of the European Court of Human Rights, as well as the European Court of Justice, point to the need for a margin of discretion to be granted to Member States to determine the scope of the moral exclusions to be implemented so as to reflect national cultures"⁷⁶³

More generally, Lock claims that the co-operation between the EU and the ECtHR does not arise from a legal duty, but instead from comity between the institutions such that cooperation can end at any point depending on the actions of either court.⁷⁶⁴ Nonetheless,

Home Department [2002] ECR I-6279. See Lock, "The ECJ and the ECtHR: The Future Relationship", note 752.

⁷⁵⁸ Lock, *Ibid*, 387

⁷⁵⁹ Case C-377/98, *The Kingdom of the Netherlands v European Parliament and Council* [2001] ECR I-07079.

⁷⁶⁰ *Ibid* para. 37.

⁷⁶¹ *Ibid* para 39.

⁷⁶² This was confirmed in Case 456/03 *Commission of the European Communities v The Italian Republic* [2005] ECR I-0533, para 78.

⁷⁶³ P Torremans, 'The Construction of the Directive's Moral Exclusions under the EPC' in A Plomer and P Torremans (eds) *Embryonic Stem Cell Patents* (OUP 2009) 159. See also, Plomer, 'Human Dignity, Human Rights, and Article 6(1)', note 422, 226.

⁷⁶⁴ Lock, 'The ECJ and the ECtHR: The Future Relationship', note 752, 381 which cites N Kirsch, 'The Open Architecture of European Human Rights Law' (2008) 71 MLR 183, 201.

it appears relatively secure, and is also two-sided as Craig and de Búrca note that the ECtHR has also cited CJEU decisions in its jurisprudence.⁷⁶⁵ However, this convergence does not mean that these institutions will foster the same interpretation of rights. In fact, the entire basis of the margin of appreciation doctrine supports the idea that differing levels of human rights protections can co-exist and indeed is to be expected. Moreover, as noted, the margin of appreciation will not apply in cases involving the application of Art 6(2) of the Biotech Directive which could give rise to tensions between the EU, Contracting States and the ECtHR should a case arise post-accession. Nonetheless, in such cases it is plausible that the ECtHR would show deference to the EU, as the categories specified in the legislation could be seen as an expression of consensus on an issue amongst MSs, a point returned to below. Moreover, in this context, much will also depend on the revised modalities of accession discussed further below.

5.3.2 Current accountability of the EU to the ECtHR

Turning to the accountability of the EU to the ECtHR and reviewability of EU laws by the ECtHR.⁷⁶⁶ The EU is not a party to the ECHR and therefore pre-accession it cannot be held directly accountable for any violations of the ECHR. However, indirect challenges against EU acts may be brought in some circumstances against one or all EU MSs because all EU MSs⁷⁶⁷ are individually party to the ECHR. In other words, applicants could challenge the compatibility of national law, implementing EU law, before the ECtHR. This would hold national States accountable but one cannot hold the EU directly accountable as it is not currently a party to the ECHR.

In *Matthews*⁷⁶⁸ the ECtHR held that a Contracting State may transfer powers to another international organisation which is not party to the ECHR, provided Convention rights are secured. However, Contracting States remain accountable under the ECHR after the transfer of powers.⁷⁶⁹ This was confirmed in *Bosphorus*⁷⁷⁰ which involved a case brought

⁷⁶⁵ For instance, see App Nos 65731/01 and 65900/01 *Stec v UK* judgment of the ECtHR 12 April 2006, para 58; App. No 57325/0 *DH and Others v Czech Republic* judgment of the Grand Chamber of 13 November 2007 at para 85-91 and para 187, as cited Craig and De Búrca, *EU Law*, note 482, 405.

⁷⁶⁶ See, Craig and De Búrca, *EU Law*, note 482, 400-404.

⁷⁶⁷ *Ibid* 400.

⁷⁶⁸ *Matthews v United Kingdom* ECHR 1999-I.

⁷⁶⁹ *Ibid* para 32

⁷⁷⁰ *Bosphorus v Ireland*, App No 45036/98, 30 June 2005, para 152-153

against Ireland for the impounding of an aircraft without compensation, in reliance on an EU Regulation and the interpretation of this regulation given by the CJEU following a reference from the Irish Supreme court.⁷⁷¹ The ECtHR confirmed that States party to the ECHR who have transferred powers are responsible:

“...for all acts and omissions of its organs regardless of whether the act or omission in question was a consequence of domestic law or of the necessity to comply with international legal obligations”.⁷⁷²

It stated that if States were excluded from responsibilities under the ECHR where they transferred powers to an international organisation, this would allow rights to be limited or excluded thereby undermining the ECHR.⁷⁷³ Nonetheless, the ECtHR held that actions of Contracting States pursuant to a strict obligation under another international agreement - in *Bosphorus* this related to an EU Regulation- would be justified provided that the relevant international organisation was considered to protect human rights in a manner which was “at least equivalent to that for which the Convention provides.”⁷⁷⁴ Equivalence was defined as “comparable”.⁷⁷⁵ It held that EC law -as it was at the time- could be presumed to offer ‘equivalent’ protections of fundamental rights as the ECHR⁷⁷⁶ and therefore no liability arose for Ireland in the case. However, this presumption of equivalence could be rebutted in a particular case, if the “protection of Convention rights was manifestly deficient.”⁷⁷⁷ In short, there is a presumed equivalence of EU law with the ECHR, and for EU Acts where there is no discretion for MSs, there is a presumption of equivalence, unless this can be rebutted and it can be proven that the protection of rights is ‘manifestly deficient’ in a particular case.

However, the presumption only applies in cases where no discretion is left by the EU to MSs, such as in the case of a regulation.⁷⁷⁸ If an EU MS has discretion on the

⁷⁷¹ Craig and De Búrca, *EU Law*, note 482, 401; See also, Lock ‘Beyond Bosphorus’, note 752.

⁷⁷² *Bosphorus*, note 770, para. 153.

⁷⁷³ *Ibid* para 154.

⁷⁷⁴ *Ibid* para 155.

⁷⁷⁵ *Ibid* para 155.

⁷⁷⁶ *Ibid* para 156-166. For a discussion of this case, see Lock “Beyond Bosphorus”, note 752.

⁷⁷⁷ *Ibid* para 156. For a discussion of this standard, see, Craig and De Búrca, *EU Law*, note 482, 403.

⁷⁷⁸ T Lock, ‘The future of EU accession to the ECHR after Opinion 2/13: is it still possible and is it still desirable?’ *University of Edinburgh School of Law Research Paper* 2015/18, Europa Working Paper No 2015/02, 30 citing *Michaud v France* ECHR 2012, para 113; See Craig and De Búrca, *EU Law*, note 482, 403.

implementation of EU law, for instance if it is an EU Directive which is at issue,⁷⁷⁹ such as the Biotechnology Directive, then this presumption does not apply. In such circumstances, challenges can be brought to the ECtHR against States on the basis of a lack of compatibility of implementing laws.⁷⁸⁰ As an aside it should be noted, that another gap in protection exists, confirmed in *Connolly v 34 Member States of the Council of Europe*⁷⁸¹ which involved complaints about deficits in CJEU proceedings relating to a labour dispute involving an employee of the European Commission against the European Community.⁷⁸² The applicant brought a challenge to the ECHR, against the then EU MSs, alleging a breach of Art. 6 of the ECHR. This was held inadmissible as the MSs were not directly involved in any stage of the proceedings, the actions were those of the CJEU alone.⁷⁸³ Thus, actions can only be attributed to MSs if action of authorities in the MS were involved in some way.⁷⁸⁴

Applying the above to the morality provisions, the foregoing highlights that as the EU is currently not party to the ECHR therefore it cannot be held responsible for violations of the ECHR through decisions of the CJEU or otherwise. This will remain the case until the EU accedes to the ECHR. However, EU MSs remain accountable to the ECtHR in cases of transferred powers in the situations described above. Given that all EU States are also party to the ECHR, this should encourage soft harmonisation between the EU and ECHR systems. Indeed, this is necessary for the EU to retain the presumption of equivalence of protections with the ECHR. The planned accession will also have significant implications for the EU's accountability to the ECHR and therefore should also be considered.

5.3.3 Implications of Accession of the EU to the ECHR for the morality provisions

As noted, Art. 6(2) TEU places the EU under a legal duty to accede to the ECHR. Accession would further align EU rights protections with the ECHR system, increasing the avenues possible to challenge decisions of the CJEU on the morality provisions.⁷⁸⁵ Despite recent

⁷⁷⁹ App No 30696/09 *Cantoni v France*, Judgment of the European Court of Human Rights, 15 November 1996.

⁷⁸⁰ Craig and De Búrca, *EU Law*, note 482, 403.

⁷⁸¹ Application No. 73274/01, Admissibility Decision of 9 September 2008.

⁷⁸² Lock 'Beyond Bosphorus', note 752, 533.

⁷⁸³ Lock, 'The future of EU accession to the ECHR after Opinion 2/13', note 778, 28.

⁷⁸⁴ *Ibid*, 28

⁷⁸⁵ Plomer, 'After Brüstle' note 74, 129.

developments that suggest potentially significant delays in accession in light of the CJEU's rejection of the draft accession agreement⁷⁸⁶ this section considers the future on the enduring assumption that accession will occur at some point.⁷⁸⁷

At the outset, in terms of a timeline for accession, the negotiations are still on-going. A draft accession agreement was finalised by representatives of the 47 Contracting States to the ECHR in on the 5th April 2013. However, as noted, this was rejected by the CJEU as incompatible with EU law in its judgment of 18th December, 2014.⁷⁸⁸ Hence, it is back to the drawing board in terms of redrafting a new agreement to take into account issues raised by the CJEU in this Opinion 2/2013,⁷⁸⁹ which are beyond the scope of this work. Nonetheless, Tobias Lock has also indicated the Treaties may also need to be amended to take into account some of the concerns raised by the CJEU.⁷⁹⁰ Once a revised agreement is drafted, this would need to be approved by the CJEU in terms of its compatibility with EU law. Following approval, it would then need to be unanimously approved by a decision of members of the Council of the EU authorising the signature of the Agreement. Procedures must also be followed within the CoE which needs to consult the Parliamentary Assembly and the Committee of Ministers prior to formally adopting the instrument; it is only after this that the Accession Agreement would be open for signature and ratification by all EU MSs and Contracting Parties of the ECHR.⁷⁹¹ It was previously estimated that the process for the now rejected draft agreement would take at least three years⁷⁹² and so accession of a revised agreement is not likely to happen for a number of years yet. However, proceeding on the assumption accession will take place, it is useful to examine its implications for the morality provisions.

⁷⁸⁶ Opinion 2/13 *Accession of the European Union to the European Convention for the Protection of Human Rights and Fundamental Freedoms* ECLI: EU: C: 2014:2454

⁷⁸⁷ It is conceded that others have suggested that accession may be jeopardised by Opinion 2/13, see discussion in Lock, 'The future of EU accession to the ECHR after Opinion 2/13', note 778, 34. He cites Fabrice Picod, 'La Cour de justice a dit non à l'adhésion de l'Union européenne à la Convention EDH' [2015] *La Semaine Juridique - Édition Générale* 230, 234, who argues accession may now be a dead letter.

⁷⁸⁸ Opinion 2/13 *Accession of the European Union to the European Convention for the Protection of Human Rights and Fundamental Freedoms* ECLI: EU: C: 2014:2454

⁷⁸⁹ See, Lock, 'The future of EU accession to the ECHR after Opinion 2/13', note 778; Editorial Comments, 'The EU's accession to the ECHR - a "NO" from the ECJ!' (2015) 52(1) *CML Rev* 1-15.

⁷⁹⁰ See, Lock, 'The future of EU accession to the ECHR after Opinion 2/13', note 778.

⁷⁹¹ See 'Council of European, *Accession by the European Union to the European Convention on Human Rights Answers to frequently asked questions* (30 April, 2013) <http://www.coe.int/t/dghl/standardsetting/hrpolicy/Accession/Accession_documents/EU_accession-QA_updated_2013_E.pdf> accessed 16th July, 2015.

⁷⁹² *Ibid.*

Accordingly, in the first instance, one might question why EU accession to the ECHR was deemed necessary in light of the general convergence between the two systems. Craig and de Búrca cite a number of reasons for this, namely: (1) Accession would reinforce the EU's credibility in terms of human rights protections and its intentions behind this. The EU has been accused of using human rights discourse to expand the remit and influence into areas which should instead be within the sole reserve of MSs;⁷⁹³ (2) The CJEU has been accused of advancing market rights rather than protecting fundamental rights *per se*, being primarily focused on promoting integration.⁷⁹⁴ Moreover, it has been argued that as the CJEU's main function is not the monitoring of rights, therefore it should not model itself on the ECtHR; particularly as the CJEU - unlike the ECtHR - does not have an express human rights jurisdiction, nor does it have the moral stature of the ECtHR;⁷⁹⁵ (3) Having two supranational bodies, the ECtHR and EU, responsible for fundamental rights and making national bodies answerable to both could lead to possible conflicting interpretations between the courts which would be problematic; (4) There was a desire to be able to challenge acts of the EU before the ECtHR, the EU would then no longer be the final arbiter of the lawfulness of its own action.⁷⁹⁶

These arguments resonate with the institutional discussion carried out in the thesis, particularly the analysis of the role of the EU in the interpretation of the morality provisions conducted in chapter four. For instance, considering the second concern listed above, that the EU would use human rights discourse to further its primary purpose of promoting internal market goals, this echoes what is predicted by an institutional analysis. Chapter two argued that institutions act in furtherance of their main objectives. Foundational to the EU framework is the maintenance of the internal market, and hence it is unsurprising that human rights have traditionally been filtered in the EU and within the CJEU cases through the lens of the internal market. The institutional framework lends itself to such a filtering. Judges striving to achieve their, and the overarching institution's primary purpose will interpret decisions in a manner which best fulfils the purpose of the institution. This

⁷⁹³ Craig and de Burca note the controversy over the decision in relation to the provision of information on abortion in Ireland citing Case C-159/90 *SPUC v Grogan* [1991] ECR I-4685; See also debate between J Coppel and A O'Neill, 'The European Court of Justice: Taking Rights Seriously?' (1992) 29 CML Rev 669 and JHH Weiler and N Lockhart, "Taking Rights Seriously" Seriously: The European Court and its Fundamental Rights Jurisprudence (1995) 32 CMLRev 51 and 579, as cited in Craig and De Búrca, *EU Law*, note 482, 399, footnote 227.

⁷⁹⁴ Craig and de Burca, *Ibid*, 399.

⁷⁹⁵ *Ibid* 399.

⁷⁹⁶ *Ibid* 400.

filtering is also arguably necessary to ensure the EU does not encroach upon MSs' sovereignty, as it only has competence to act in areas set out in the Treaties, and generally these areas relate to the internal market.

Similarly, the third concern in relation to the potential for conflicting interpretations highlights the malleability of human rights. This thesis has argued that abstract concepts such as morality, are open to interpretation and susceptible to being shaped by the institutional matrix within which they are decided. Human rights, as a concept, is similar to morality, in the sense that its contours need to be defined by adjudicative bodies and thus it is susceptible to influence by the institutional context within which the scope and contents of the rights are constructed. Drawing on the analysis in chapter two, conflicting interpretations of rights by the CJEU and ECtHR are possible, and indeed are likely, given the differing institutional contexts within which such concepts are decided upon. Moreover, divergence is plausible regardless of there being convergence at a legislative level, because this may not filter through to judicial actors whose interpretations of their role and the purpose of rights within the institution may be deeply engrained. In fact, the possibility of differing standards of protections and interpretations of rights is facilitated by the margin of appreciation doctrine. It is also recognised by Art. 52(3) of the Charter of Fundamental Rights which provides that the EU's Charter guarantees protections corresponding to that provided by the ECHR but that this does not prevent Union law from providing more extensive protections.

Turning to the consequences of accession of the EU to the ECHR, as noted, the most significant consequence is that the EU will be directly subject to the jurisdiction of the ECtHR, and accountable for any breaches of human rights. Applicants will be able to challenge the compatibility of EU actions under Art. 34 (for individual applicants) of the ECHR, which could result in a direct finding of non-compliance of the EU. Moreover, arguably MSs will be able to challenge the EU under Art 33 ECHR. An obstacle to this is Article 344 TFEU which provides that:

“Member States undertake not to submit a dispute concerning the interpretation or application of the Treaties to any method of settlement other than those provided for therein.”

However, others previously argued that, albeit likely to be rare, it would be possible for EU MSs to take a State action to the ECtHR against the EU.⁷⁹⁷ Nonetheless, this issue was one of the CJEU's objections to the draft accession agreement where it argued that this possibility for challenges by States would be contrary to Art 344⁷⁹⁸ which provides that the CJEU should be the final arbiter in cases involving the interpretation of EU law. It remains to be seen how this may be addressed in a revised accession agreement. Moreover, the general contours of the interaction between the EU and CoE in this context are also difficult to predict because at the time of writing it has not yet been indicated how the draft accession agreement is to be modified to address the CJEU's concerns which led to its rejection.

Nonetheless, it is likely that accession will lead to an increase in the number of legal avenues for MSs or individual applicants to challenge the EU directly before the ECtHR⁷⁹⁹ including EU actions in relation to the morality provisions. This is discussed by Aurora Plomer using the *Brustle*⁸⁰⁰ decision as a lens to examine how accession to the ECHR would impact on the application of the morality provisions by the CJEU, albeit in the context of the now rejected draft accession agreement. Should a challenge to the CJEU's decision in *Brustle* to the ECtHR arise, Plomer argued that the ECtHR would need to consider, amongst other aspects, whether or not the measure or in this case restriction (i.e. the denial of a patent) amounted to an interference with rights to property/possession under Art 1 of 2001 Protocol on Enforcement of certain Rights and Freedoms.⁸⁰¹ It would then need to ascertain whether any interference found was necessary and proportionate with the aims of the decision as identified by the CJEU.⁸⁰² The CJEU's aim of the ruling in *Brustle* was stated as the protection of human dignity, where the court felt it was implicated in the context of patents on hESCs.

⁷⁹⁷ M Kuijer, 'The accession of the Europeans Union to the ECHR: A Gift for the ECHR's 60th Anniversary or an unwelcome intruder at the party?' (2011) 3(4) Amsterdam Law Forum <<http://amsterdamlawforum.org/article/view/240/428>> accessed 16 July 2015.

⁷⁹⁸ Opinion 02/13, para 201-214.

⁷⁹⁹ Plomer, 'After Brüstle' note 74, 129.

⁸⁰⁰ Ibid 129.

⁸⁰¹ This states that "Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.

The preceding provisions shall not, however, in any way impair the right of a State to enforce such laws as it deems necessary to control the use of property in accordance with the general interest or to secure the payment of taxes or other contributions or penalties."

⁸⁰² Plomer, 'After Brüstle' note 74, 129.

However, Plomer highlights the wide nature of the interpretation of Art. 6(2)(c) in *Brustle*, alongside the differing conceptions of dignity amongst MSs and the general margin of appreciation given by the ECtHR and EU to States in relation to competing interpretations of dignity. She argues that the extension of dignity for the protection of hESC lines in *Brustle*:

“...arguably overreaches the narrow terms of the exclusion on the basis of an inputted moral consensus in Europe that respect for human dignity is violated by uses, including research uses, which are destructive of human embryos.”⁸⁰³

One might attempt to counter this by arguing that the question of consensus on the patentability of hESC research can be distinguished from the divergence seen in relation to hESC research. Evidence showing support for prohibiting hESC patents could be suggested by citing the adoption of Art. 6(2) of the Directive which all States in signing the Directive would have agreed upon. States have no discretion on any applications falling within Art. 6(2), as a definitional test and not a moral test applies.⁸⁰⁴ However, the Directive was adopted in 1998 before the techniques in question had been fully developed (it was not until later in 1998 that Thompson et al⁸⁰⁵ managed to culture hESC), so it cannot be said with certainty that the States in signing up to the Directive, or legislators drafting it, were expressing a desire to prohibit patents for downstream uses of embryos such as hESC lines as the decision suggests.⁸⁰⁶ If the invention did not fit definitional parameters of Art. 6(2), then arguably Art. 6(1) would have been the more appropriate measure to apply, which as we have seen above would result in a margin of appreciation for States.

As an aside, the case demonstrates the definitional difficulties under Art. 6(2) which may prove integral to questions concerning the balance between sovereignty and protection of rights which the ECtHR would have to achieve in such contexts. Moreover, definitional difficulties created by the advancement of science are not just confined to Art 6(2)(c). Another example which comes to mind is Art. 6(2)(b) which precludes patents on “(b) processes for modifying the germ line genetic identity of human beings”. It is questionable

⁸⁰³ Ibid 131

⁸⁰⁴ Ibid 123

⁸⁰⁵ Thompson et al, Embryonic stem cell lines derived from human blastocysts (1998) 282(5391) *Science* 1145-1147; See also discussion in, Plomer, ‘After Brüstle’ note 74, 120

⁸⁰⁶ For a discussion of this problem generally, see, A Scalia and B A Garner, *Reading Law: The interpretation of Legal Texts* (Thomson/West 2012), 349-358; K Liddell, ‘Purposive Interpretation and the march of genetic technology’ (2003) 62(3) CLJ 563-566.

whether this will apply to claims, should they arise, on the patentability of current techniques under development for the processing of mitochondrial DNA transfer or ‘three parent IVF’. This issue is particularly salient, as the UK has recently adopted regulations to allow the use of these techniques in specific circumstances.⁸⁰⁷ These techniques involve the modification of the embryo or egg by replacing mitochondrial matter within this.⁸⁰⁸ As it gives rise to a relatively minor change⁸⁰⁹ it is at least questionable whether: (1) this technology would be defined as modifying the germ line for the purposes of the Directive; and (2) if it were, if the techniques involved in this would be unpatentable under the morality provisions. It is conceded that this would be provided such processes would not be excluded under recital 35 which excludes patents on “processes for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body”. However, it is not entirely clear if recital 35 would apply, given that the method of ‘mitochondrial transfer’ is not used on a human body *per se* but on an egg or embryo.

The ECtHR, CJEU, EPO may also differ in how they define terms within the four specific exclusions, for instance in how they define ‘germ line’. This would raise further issues for the application of the morality provisions, and the evaluation of claims in relation to implicated human rights should this arise. Moreover, arguments could be raised, in the context of mitochondrial transfer or hESC technologies, that such technologies are an attempt to bolster human rights, giving individuals who do not have the opportunity of having a healthy biological child a chance to do so, thereby introducing countervailing arguments in favour of the dignity enhancing potential of such measures. Should such issues come before the ECtHR, all of these aspects would need to be considered.

As noted, given the ECtHR’s marked reluctance to intervene on areas where there is no consensus, it is likely that in the absence of certainty as to whether cases would fall within Art. 6(2) it would decide instead they fell within Art. 6(1) which would allow the ECtHR to apply a margin of appreciation and leave such questions to the EU or MSs. However, if an invention were held as falling directly under Art. 6(2), where no margin of appreciation applies, a difficulty may arise if a broad application of a provision by the CJEU was

⁸⁰⁷The Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015.

⁸⁰⁸See generally, Nuffield Council, *Novel Techniques for the prevention of mitochondrial DNA disorders: an ethical review* (2012).

⁸⁰⁹ See M Darnovsky, ‘A slippery slope to human germline modification’ (11 July 2013) 499 *Nature World View* 127.

challenged on human rights grounds by individual EU MSs, assuming this would be possible under the revised accession agreement. If this occurred, it would create a sticky situation for the ECtHR. It has been argued that the ECtHR would give a wide margin of appreciation to EU's actions post accession.⁸¹⁰ Indeed, some have argued that the 'margin of appreciation' for the EU may be higher than given to Contracting States in light of the fact, that EU Acts represent harmonisation and agreement amongst its twenty eight States.⁸¹¹ Nonetheless, in such a scenario, the ECtHR would also be dealing with a Contracting State which would generally benefit from a margin of appreciation from the ECtHR on sensitive moral issues. The difficulty is that the margins of appreciation are mutually exclusive as to uphold a margin of appreciation for the EU would be contrary to the breath generally give to States. Thus, a decision of the ECtHR in such context, would either encroach upon the EU or a Contracting State's margin of appreciation. This would undoubtedly place the ECtHR in a difficult position, but if an agreement were reached and such actions were possible under the revised modalities of accession, it would arguably address issues raised earlier in relation to the defensibility of the EU's action in the realm of human rights, as this mechanism places a check on EU actions and could be used to bridge conflicting interpretations where necessary.

In short, whilst generally in cases concerning the application of the morality provisions the ECtHR is arguably likely to show deference to decisions of States and the EU. It is unclear where it would draw the line between the margins of appreciation it affords to Contracting States and to the EU, should conflict arise. Arguably, such scenarios would be very rare, and may require a case-by-case analysis of the issues at stake and whether ECtHR interference with EU decisions is warranted. Given the nature of the EU's relationship with its MSs and the sovereignty of EU law over EU MSs, the ECtHR would only intervene in limited instances. Nonetheless, it could in this manner act as a check on the EU and its Contracting States actions, and could be used to bridge conflicting interpretations where necessary.

⁸¹⁰ A Rosas, 'The European Court of Justice in Context: Forms and Patterns of Judicial Dialogue' (2007) 1 EJLS 1, as cited in Craig and De Búrca, *EU Law*, note 482, 405.

⁸¹¹ L Garlicki, 'The Relationship between the European Court of Justice and the European Court of Human Rights: The Strasbourg Perspective' in J Iliopoulos-Strangas & H Bauer (eds) *La nouvelle Union européenne (SIPE 2006)* 127 as cited by Polakiewicz, J., 'EU law and the ECHR: Will EU accession to the European Convention on Human Rights square the circle?', *Fundamental Rights In Europe: A Matter For Two Courts*, Oxford Brookes University, 18 January 2013 <http://www.coe.int/t/dghl/standardsetting/hrpolicy/accesion/Accession_documents/Oxford_18_January_2013_versionWeb.pdf> accessed 16 July 2015.

5.4 The Relationship between the EPOrg and the ECtHR

There is no direct link between the EPOrg and the Council of Europe (CoE). The EPOrg is not a signatory to the ECHR, nor could it be without the amendment of the ECHR.⁸¹² There are also no plans in place or discussions around the possibility/need for the EPOrg to accede to the ECHR. In terms of potential mechanisms for interaction between the EPOrg and CoE, as noted in chapter one, observers may attend meetings of the Administrative Council of the EPOrg. Thus, representatives of the CoE could attend such meetings and have an input into patent policy at the legislative level.⁸¹³ The EPOrg's openness to interaction with the CoE is confirmed by documents citing the CoE as being allowed to participate in an EPOrg conference discussing negotiations on the revisions of the EPC, along with other observers such as WIPO.⁸¹⁴ The internal auditor of the CoE also sits on the Audit Committee of the EPOrg.⁸¹⁵ Nonetheless, as will be seen below, the links between the EPOrg and the CoE are relatively minimal, in comparison to the links between the CoE and the EU, and as noted, the level of scrutiny of the CoE or ECtHR over the EPOrg is tenuous, to say the least.

In examining the relationship between the ECtHR and the EPOrg, this section looks at: (1) EPOrg guidance and reports which refer to the relationship of the EPO with the ECHR system; (2) references to the ECHR in decisions of the Boards on the morality provisions; and finally, (3) it will examine the accountability of the EPOrg to ECtHR, and the responsibility of its Contracting States to the ECtHR for actions of the EPOrg. The second and third category overlap considerably with issues discussed above in relation to the EU's

⁸¹² Article 59 of the European Convention on Human Rights sets out those who may become members. The ECHR had to be amended in order to make way for the EU to join it, and now Art. 59(2) states that "The European Union may accede to this Convention." A similar provision would need to be inserted into the ECHR in order for an organisation such as the EPOrg to accede to it.

⁸¹³ Art. 30(2) and (3) of the EPC state that: "Other intergovernmental organisations entrusted with carrying out international procedures in the field of patents, with which the Organisation has concluded an agreement, shall be represented at the meetings of the Administrative Council, in accordance with such agreement. (3) Any other intergovernmental and international non-governmental organisations carrying out an activity of interest to the Organisation may be invited by the Administrative Council to be represented at its meetings during any discussion of matters of mutual interest."

⁸¹⁴ See Administrative Council, Draft Rules of Procedure: Conference for the Revision of the EPC, Munich 2000.

<[http://documents.epo.org/projects/babylon/eponet.nsf/0/6A356B33A1627952C1257281003D5A36/\\$File/draft_rules_mr100_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/6A356B33A1627952C1257281003D5A36/$File/draft_rules_mr100_en.pdf)> accessed 16 July 2015

⁸¹⁵ Directorate of External Relations, 'An Overview of the External Relations of the Council of Europe in 2009' (1 May 2010), 145 <http://www.coe.int/t/der/docs/DERInf_2010_1_EN.pdf> accessed 16 July 2015.

relationship with the EPOrg, and relevant aspects of this discussion will be flagged as it applies.

5.4.1 Early guidance on the relationship between the EPOrg and the ECHR system

A number of early EPOrg sources provide an insight into the relationship of the EPOrg with the ECHR system. For instance, guidance can be gleaned from an EPO Report written in 1999⁸¹⁶ which related to an unsuccessful proposed revision of Art. 23(3) EPC under which the Boards of Appeal would be bound by the TRIPS Agreement and the ECHR. This revision was not carried out, and Art 23 EPC instead now states that: "...in their decisions the members of the Boards shall not be bound by any instructions and shall comply only with the provisions of this Convention [the EPC]..." with no reference to the ECHR or the TRIPS Agreement. Nonetheless, the report issued by the EPO in response to the suggested revision is of relevance for a number of reasons.

First, the report notes that the EPC is an autonomous legal system for the grant of European patents and expressly states that "...neither the legislation of the contracting states nor the international conventions signed by them are part of this autonomous legal system".⁸¹⁷ It alludes to the inter-institutional influence on the EPOrg in the drafting of the EPC stating that the drafting process was influenced by "...the national patent laws of the contracting states and by the international conventions signed by them."⁸¹⁸ However, the report stresses that no direct reference was made in the EPC to external legal sources and that:

"...this procedure has allowed the EPC to develop in harmony with the national laws of the contracting states and the international conventions signed by them, while at the same time guaranteeing the autonomous application of its provisions by the departments of the EPO."⁸¹⁹

⁸¹⁶See European Patent Office, 'Revision of the EPC - Article 23(3) EPC', CA/PL 5/99' 1 February 1999 <[http://documents.epo.org/projects/babylon/eponet.nsf/0/08B98B6FC383EB5AC1257280003EB133/\\$File/capl_99005_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/08B98B6FC383EB5AC1257280003EB133/$File/capl_99005_en.pdf)> accessed 16th July 2015.

⁸¹⁷ Ibid para. 2

⁸¹⁸ Ibid para 3

⁸¹⁹ Ibid para 3

The Report states that it is the task of the Boards to ensure compliance with the EPC, and that they may refer to legal sources outside the EPC including the ECHR. Having said that, the Report then highlights in bold the following points:

“These references show the willingness of the boards to interpret the EPC in the light of international law. However, the boards have **never considered** these references to be **mandatory**. On the contrary: they have been able to call upon these external sources when they felt useful, without in any way being bound by them.”⁸²⁰

[Emphasis *as per* Report]

This is an intriguing statement. It suggests on the one hand that the EPC has taken account of the provisions of international instruments such as the ECHR in its drafting, but maintains that it is up to the Boards of Appeal to decide whether and when references to international law are necessary in their decisions. Thus, the Boards are portrayed as being allowed to call upon international law when it is deemed relevant/useful but not obliged to bind itself to this. This suggests an *à-la-carte* approach to the implementation of international law by the EPOrg which, if this were the case, would be slightly alarming.

However, any alarm is tempered by reading the conclusion which confirms that whilst not in favour of the suggestions proposed:

“...the revision of the EPC offers a good opportunity to examine whether the legal system established by the EPC and the practice of the EPO’s administrative and judicial departments are compatible with principles laid down by the TRIPS Agreement and the ECHR, and if they are not, to amend the EPC accordingly.”⁸²¹

This suggests a desire to bring the EPC in line with the ECHR and TRIPS Agreement, but it is a confusing conclusion to a Report which seems adamant that the Boards should not be directly bound by the provisions of the ECHR. Perhaps a way to see this as compatible with the remainder of the Report, is to consider that the EPOrg seem happy to apply the provisions of international law at their discretion, thereby maintaining the autonomous nature of the EPC legal system, but are not willing to have these provisions directly binding upon them from a top down level. Arguably this mirrors concerns in relation to State sovereignty, which surrounded the initial debates on the ECHR system. This Report was

⁸²⁰ Ibid para 4.

⁸²¹ Ibid para 10.

written in 1999 but is still relevant in highlighting the tensions evident in relation to supranational sovereignty.

5.4.2 Current guidance on the relationship of the EPOrg and ECHR

In terms of the current guidance on the relationship of the EPOrg and ECHR system, the ‘Guidance to the Boards of Appeal’ is instructive. This is explicit on the lack of direct authority of the international courts such as the ECtHR on decisions or actions of the Boards of the EPO. Section H, of this guidance, entitled “Interpretation of the EPC” states that:

“...The boards of appeal *may* take into consideration decisions and opinions given by national courts in interpreting the law (see G 5/83, OJ 1985, 64). Nevertheless, in the proceedings before the European Patent Office, such considerations do not exonerate a board of appeal from its duty as an independent judicial body to interpret and apply the European Patent Convention and to decide in last instance in patent granting matters. *TRIPs provisions, like decisions of the European and International Courts of Justice and national decisions, are elements to be taken into consideration by the boards of appeal but are not binding on them* (T 154/04, OJ 2008, 46).”⁸²² [Emphasis added]

This is another telling statement as to the nature of the relationship between the EPOrg and international instruments such as the ECHR highlighting the independence of the EPOrg, and that it is not directly bound by or answerable to the ECtHR. Arguably, these statements resonate with the traditional perception within patent circles, discussed in chapter one, that moral concerns and arguably also, human rights have no place within the EPOrg framework. The EPOrg traditionally perceived itself as an autonomous body whose work was far removed from ethical considerations. Bently and Sherman claim that:

“[o]ne of the defining characteristics of patent law over the last century has been, not only its highly technical and specialised nature, but also its startling and marked isolation from matters cultural, political and ethical”.⁸²³

⁸²² <http://www.epo.org/law-practice/legal-texts/html/caselaw/2013/e/clar_iii_h.htm> accessed 16 July 2015.

⁸²³ Bently and Sherman, ‘The Ethics of Patenting: Towards a Transgenic Patent System’, note 83, 275.

They refer to this as the “closure of the patent system”, as during earlier times in the 18th or 19th centuries, the system grappled with deeper questions in relation to the nature of creativity. During the twentieth century, these discussions were substituted by economic evaluations focused on issues, such as the balance of trade.⁸²⁴ This sealing off of the patent system from ethical issues, is arguably similar to what is evident here in relation to the Boards guidance on the binding nature of international agreements, which could include human rights instruments. Importantly, the argument is not that the EPOrg seeks to contravene human rights or indeed to contravene human rights treaties. Instead, it is that arguably, it does not perceive human rights considerations as those which fall within the remit of patent grant, and therefore are outside of its role. From an institutional perspective, as discussed in chapter three, the EPOrg’s objectives are grounded in economics, in the harmonisation of patent law with no reference to human rights in its guiding documents and viewed through this lens, these statements are less surprising.

Nonetheless, a change in this perspective may be occurring, as in the recent case of *Case T0149/11*,⁸²⁵ discussed in this context at 5.4.2(a), the EPO alluded to human rights considerations and denied aspects of a claim on such basis. Whilst, as noted, the reasoning in this decision is subject to question, the reference to the ECHR highlights that although the EPO is not party to the ECHR, there may be inter-institutional influences filtering through the EPO decisions in this context. Moreover, it would be foolish to suggest that EPOrg would wilfully ignore the ECHR or jurisprudence of the ECtHR, especially given that all of its Contracting States are party to the ECHR; to do so would give rise to serious questions as to the suitability of the EPOrg to adjudicate patent grant for its Contracting States. Instead, a comparison can be drawn with the early relationship between the ECHR and the EU, which as has been seen, began to incorporate human rights considerations into its jurisprudence and legal framework incrementally, despite the fact that it was not bound directly to the ECHR. Thus, there is nothing to suggest that soft harmonisation in the context of the EPOrg and ECHR will not occur.

However, a number of questions may be raised in this context namely: Firstly, whether the EPO is institutionally configured to assess such considerations; and secondly, whether it is

⁸²⁴ Ibid.

⁸²⁵ Case T0149/11 of 24 January 2013: Method and device for processing a slaughtered animal or part thereof in a slaughterhouse < <http://www.epo.org/law-practice/case-law-appeals/pdf/t110149eu1.pdf> > accessed 16 July 2015.

defensible if the EPO in its role as the granting body for EU patents may be applying a differing level of protection of human rights to the EU, or consideration of these in its application of morality provisions in patent grant. As noted, these issues may be rectified post-grant through national decisions denying patents on certain technology or through CJEU decisions if questions are raised at the EU level on the meaning of the morality provisions. However, it is questionable what the EU perceives as being the role of the morality provisions and whether at an institutional level it perceives, as has been suggested in recent cases, that such provisions should serve to filter human rights considerations such as dignity in some contexts. If so, it is questionable if the EPO can ever deliver on such purposes, given the vast differences between it and institutions such as the ECtHR and CJEU; its more limited interpretative tools for the adjudication of rights; and because underlying concepts such as dignity are absent from the EPO's statutory framework. Indeed, it has been suggested that, in the majority of cases it is institutionally predisposed to deliver a narrow interpretation of the morality provisions. Thus, it is questionable if it as granting body for patents in EU countries, can offer a defensible approach to the application of the morality provisions, if the EU perceives these as filtering broad human rights concerns. It should be stressed again, that this investigation is not arguing in favour of the EPOrg's adoption of a broader approach. Instead, the contribution of this work is to highlight the engrained institutional influences which arise and to question whether it is appropriate to have differing institutions share patent grant/adjudicative functions which involve the application of the morality provisions, if the institutional perception of the functions of such provisions is arguably quite distinct.

Further light is shed on these questions by examining references to human rights in decisions of the EPO concerning in its decisions concerning the morality provisions. This is followed by an examination of the accountability of the EPOrg to the ECtHR and particularly, the accountability of Contracting States of the EPC for actions of the EPOrg or its sub-institutions such as the EPO, on the morality provisions.

a) References to human rights in decisions of the EPO on the application of the morality provisions

References to the ECHR, have featured in three decisions of the EPO concerning the application of the morality provisions. The earliest reference to the ECHR in this context

was in *T 0315/03 (Transgenic Animals/HARVARD)*.⁸²⁶ The ECHR was referred to but not in relation to the application of the morality provisions or how these should be defined, rather it was discussed in relation to whether or not the delay occasioned in the case was of an unreasonable period. The Technical Board of Appeal held that the fact that it took ten years to dispose of the first instance proceedings was unjustified as it was longer than other periods which have been held to constitute an unreasonable delay as defined under Art 6(1) ECHR.⁸²⁷ Thus, the ECHR was referred to, but this consideration related to the procedural regularity of the decision.

The second case of relevance is *Case T 0866/01* which related to a challenge to the patentability of “euthanasia compositions” for use in lower mammals. The appellant suggested that the ECHR should be used “in order to interpret the unspecific legal term “ordre public” in Article 53(a)”.⁸²⁸ Article 2 of the ECHR was cited by the appellant which guarantees the right to life. It was argued that the patent under grant “created at least a real risk to the integrity and protection of life guaranteed in Article 2 ECHR and was therefore unacceptable under the terms of Article 53(a) EPC.” This appellant claimed the compositions in the patent represented toxins which would be used for the destruction of animal and human life which “...was clearly against the principles of Article 2 ECHR, which obliged the legislator and general laws and also any international authority such as the EPO to protect human life.”⁸²⁹ However, contrary to the appellant’s claims, the Board was unable to find a reference in the patent to the toxicity of the euthanasia compositions in humans.⁸³⁰ Instead, the compositions under patent were said to be for the sole purpose of producing humane death in lower animals and that the alleged “additional use of the compositions for the termination of human life is entirely excluded and in no way derivable from the patent description.”⁸³¹ For these reasons the Board felt it was unnecessary to consider whether or not the claims represented “an abstract risk of infringement of certain basic principles of “ordre public”, in particular of the rights as guaranteed by Article 2

⁸²⁶ T 0315/03 (Transgenic Animals/HARVARD, Technical Board of Appeal, Unreported, Decision of 6 July 2004. < <http://www.epo.org/law-practice/case-law-appeals/pdf/t030315ex1.pdf> > accessed 16 July 2015.

⁸²⁷ Ibid para. 15.5.

⁸²⁸ Case T0866/01, Euthanasia Compositions/MICHIGAN STATE UNIV, Technical Board of Appeal, (Unreported), Decision of 11 May 2005, para 16. < <http://www.epo.org/law-practice/case-law-appeals/pdf/t010866eu1.pdf> > accessed 16 July 2015.

⁸²⁹ Ibid para 17.

⁸³⁰ Ibid reasons for decision 6.6.

⁸³¹ Ibid reasons for decision 6.7.

ECHR”.⁸³² Hence, the incorporation of human rights concerns within the morality provisions - although put forward as an argument - were not discussed in any detail by the Board, and thus is not particularly helpful to the discussion at hand.

Finally, the recent decision of *Case T 0149/11*⁸³³ arguably offers suggestions of a move in the EPO to incorporate human rights concerns within the scope of the morality provisions. However, it remains to be seen if this will be followed in subsequent decisions. The decision, as discussed in chapter three, concerned the patentability of a method and the device for processing an animal in a slaughterhouse. As noted, part of the patent provided for the presence of an observer on the slaughter line in order to oversee the process. The reference to the observer as a feature of the claim was challenged as being against *ordre public* as it was claimed that on reading of the application, the observer appeared part of the device which would contravene basic human rights such as human dignity. The appeal was upheld on this ground, in what was a questionable line of reasoning, discussed previously in chapter three at section 3.4.2(b)(ii). The Board stated that “ordre public” must be seen as defined “by norms that safeguard fundamental values and rights such as the inviolability of human dignity and the right of life and physical integrity.”⁸³⁴ The Board cited Singer/Stauder⁸³⁵ as authority for the opinion that:

“[h]uman and civil rights, such as those guaranteed by international treaties and national constitutions, are to be regarded as the principal foundations of the legal order of the contracting states, and as such also the foundations of “ordre public”.”⁸³⁶

It stated that fundamental rights and freedoms are codified in Arts 4 and 5 of the ECHR according to which everyone has the right to liberty and should not be held in slavery,⁸³⁷ and this in turn corresponds with the prohibition of slavery and the right to liberty under the Charter of Fundamental Rights of the EU Arts 3-6. Surprisingly, there was no discussion of how these articles might apply to the claim under patent, the scope of the

⁸³² Ibid reasons for decision 6.8 (c).

⁸³³ Case T0149/11 of 24 January 2013: Method and device for processing a slaughtered animal or part thereof in a slaughterhouse < <http://www.epo.org/law-practice/case-law-appeals/pdf/t110149eu1.pdf> > accessed 16 July 2015.

⁸³⁴ Ibid para 2.5.

⁸³⁵ Singer/Stauder, *Europaisches Patentubereinkomen* (6th ed. 2013), Art. 53 note 7, as cited Ibid para 2.5.

⁸³⁶ Ibid para 2.5.

⁸³⁷ Ibid para 2.5.

rights in question, the status of the observer in the claim, or whether slavery was likely the intention of the claim. Instead the Board simply stated, that:

“Since patents are instrument of private property and as such freely transferable, a patent for an invention that includes one or more human beings among its features gives rise to serious concerns as to these fundamental rights and freedoms of the particular human beings that would be the subject of such a patent when commercialized, however, farfetched such an interpretation may seem. These serious concerns regarding human liberty and the prohibition of slavery lead the Board to conclude that claims 13 and 14 of the main request contravene Article 53(a) EPC.”⁸³⁸

This reasoning can at best be described as superficial and is arguably wholly at odds with reasoning which one might expect in relation to human rights concerns which generally requires one to take into account and balance relevant interests at stake. If one did so in this case, it is submitted that it would be unlikely that it would be inferred from the application that individuals could be subject to slavery. Plomer has argued that the “dearth of legal argument [evident in the decision] would simply be inconceivable had an alleged breach of Article 3 and 4 been subject of adjudication at the European Court of Human Rights.”⁸³⁹ She notes that there is no reference in the decision to any jurisprudence of the ECtHR on the prohibition of torture or slavery, or to regulatory frameworks applicable in relation to animal slaughter.⁸⁴⁰

Nonetheless, the judgment is significant for the purposes of this discussion, as it signals an explicit indication from the EPO of an understanding of ‘ordre public’ as incorporating human rights concerns present within the territories of the EPC. It is conceded that this is merely one decision, and so it is difficult to draw firm conclusions as to what this case may mean for the future application of the morality provisions. However, as noted, this decision again raises the question of whether the EPO is a suitable institution to address human rights concerns of developing technologies, if these are to be incorporated into the consideration of morality provisions, and particularly whether it is a suitable institution to

⁸³⁸Ibid para 2.5.

⁸³⁹ Plomer, ‘Human Dignity and Patents’, note 328, 493.

⁸⁴⁰ Ibid.

do so for patents applied for in EU States, as its interpretation of human rights may differ from the EU's perception of same.

As argued throughout this thesis, the decision-making bodies of the EPO are not institutionally configured to consider human rights concerns in the way in which we are accustomed to institutions like the ECtHR or CJEU (to a lesser extent) doing. If charged with doing so, this thesis suggests that the EPO will filter human rights questions through its institutional matrix and arrive upon institution-specific understanding of rights. This is problematic as the EPO's own goals may be in conflict with the scrutiny of human rights. In particular, as has been seen, its main aim is to grant patents for which it receives financial incentives. This, along with the other characteristics alluded to in chapter three suggest the EPO has an institutional predisposition that is entirely at odds with adjudication upon human rights concerns which we have grown accustomed to for two reasons.

Firstly, there may be institutional influences surrounding the identification of which rights may be engaged. It has been submitted in chapter three, that it will arguably only be in instances which give rise to particularly controversial issues such as those concerning patents on life, or hESC technology that the EPO will be prompted to apply the morality provisions in a broader manner. Arguably in such cases, it is prompted to act in order to ensure public acceptance of its decisions, as such contexts attract greater public interest. Thus, the EPO may be forced to step outside its institutional space and engage with human rights issues in order to align its position with its perceived understanding of the EU and ECtHR position in an area. In other instances, it will arguably filter such questions through its institutional matrix and in doing so will be predisposed to offer a limited application of human rights. Again, this is not to suggest that the EPO is deliberately avoiding the application of human rights; instead the point is that: (a) it generally arguably does not perceive its role as involving the application of human rights, and (b) even if it does perceive this as part of its role, given its institutional configuration it may not identify the same instances as involving human rights as the CJEU would, and arguably would not approach human rights with the same methodology as the CJEU. In order words, the institutional context of the CJEU, ECtHR and EPO dictates how judicial/quasi-judicial actors within these institutions approach, engage with and adjudicate upon human rights

issues which becomes relevant in the context of the morality provisions, if these incorporate human rights concerns.

A second issue is that the reasoning of the EPO in the application of the morality provisions to date has been superficial and often fails to delve into the various interests at stake; instead in some instances it presents argument as facts. As noted, this tendency is replicated in the guidance of the EPO on the application of the morality provisions, which makes statements such as anti-personnel mines are an ‘obvious’ example of inventions which are against ‘ordre public’ but fails to engage with why this is the case, or what other inventions may be perceived as such.⁸⁴¹ Arguably, similar institutional influences and constraints apply in the human rights context, to the extent that the EPO is configured in a manner which means that it will engage with rights on a more superficial level. This point is supported by the limited reasoning provided by the EPO in the recent decision in *Case T0149/11*. These issues are compounded by the fact that, unlike the EU, the EPOrg has no instrument or provisions relating to human rights, is generally not involved in the adjudication of rights in other contexts – other than to ensure that its decisions are procedurally appropriate. Thus, the way in which rights will be interpreted within the institutional context of the EPO is likely to differ substantially with how the CJEU or ECtHR would reflect upon such issues. Moreover, the central argument raised in this thesis suggests that the EPO is *institutionally predisposed* to consider human rights in a manner that is, at best, troubling for other institutional and legal understandings, and at worst, at odds with the fundamental tenets of human rights as they have been understood until now.

All of the above suggests that if the provisions are to incorporate human rights concerns in the way suggested by recent case law, then it is crucial that some discussion takes place around the differing institutional contexts involved in the ‘European’ patent system, and how these differing contexts may affect the ‘defensibility’ of the application of the morality provisions. These questions are particularly timely in light of the planned unitary patent scheme discussed in chapter six, as this adds a third supranational adjudicatory body the UPCt for post-grant issues which will bring its own institutional influences to bear.

⁸⁴¹ See chapter three, 3.4.1 (c).

b) Accountability of the EPOrg to the ECtHR

The relationship between the EPOrg and the ECtHR has been examined in a number of ECtHR cases.⁸⁴² Generally, the principles outlined above in relation to the accountability of the EU, will also apply and as the EPOrg is similarly not party to the ECHR it cannot be held directly accountable. However, its Contracting States who are also party to the ECHR remain responsible for violations in this context, provided that national actions are involved. This was confirmed in *Heinz v the Contracting States party to the European Patent Convention*⁸⁴³ concerning an alleged breach of property rights of the applicant due to Art 86 of the EPC. This states that a patent application would be withdrawn if the renewal fees were not paid, the applicant had requested an extension of time to pay the fees but this had been refused by the EPO. The applicant subsequently brought a challenge against this to the European Commission on Human Rights, as it was then, arguing that this was in breach of his property rights under Art. 1(1) of Protocol 1 of the ECHR and that the Contracting Parties to the ECHR were responsible having drawn up this Article.

The Commission recalled case law in other contexts which stated it would not be competent to examine complaints about decisions of organs of the European Communities, as the European Community (as it was then) was not party to the ECHR, nor did its decisions amount to an exercise of national jurisdiction and so the ECtHR had no jurisdiction over these.⁸⁴⁴ Applying this line of reasoning to decisions of the EPO, the ECtHR held that similarly as the EPOrg was not party to the ECHR, and as decisions taken by the EPO or EPOrg did not amount to an exercise of national jurisdiction, these were not under its jurisdiction. Therefore, it held that it was not competent to examine the applicant's complaint.

Interestingly, in the course of the decision, the Court also confirmed that in adopting the EPC, the Contracting States to the ECHR transferred jurisdiction on patenting issues to the EPOrg creating a system of law common to Contracting Parties on the grant of patents. It

⁸⁴² It was also discussed at a national level, see the Scottish decision in *ITP SA v Coflexp Stena Offshore Ltd* CS A3606/00, where it was held that the ECtHR had no jurisdiction over the EPO decisions directly stating at para. 28 that "even if the application were held to be both admissible and well-founded, this would not, of itself, have any effect on the revocation of the pursuers' European patent. The ECtHR cannot require the European Patent office to reinstate the pursuers' patent. It might, at most, award monetary compensation for loss of the patent. Whether, and with what effect, any measures might subsequently be introduced to enable the decision of a Board of Appeal to be reviewed cannot, at this stage, be more than a matter for speculation."

⁸⁴³ (1994) 18 EHRR CD168.

⁸⁴⁴ *Ibid.*

confirmed, as noted above, that it is permissible under the ECHR for States to transfer their powers to an international organisation, however, Contracting States remain accountable for treaty obligations to the ECHR. Nonetheless, the ECtHR noted various safeguards contained in the EPC which guaranteed equivalent protections by EPOrg of Convention rights.

This was subsequently confirmed in *Lenzing AG v Germany*⁸⁴⁵ and was further expanded upon in the recent case of *Rambus Inc v Germany*⁸⁴⁶ which pertained to a patent in the area of chip technology which was revoked by the Board of Appeal of the EPO. The applicant company challenged this in the German courts on the grounds of procedural deficiencies in the EPO process however, the claim was ruled inadmissible. The company then complained to the ECtHR against Germany relying on Art 6 ECHR, and Art 1 of Protocol No. 1, claiming that it was denied a fair trial with regard to patent rights and that Germany, a party to the ECHR, had transferred powers without ensuring adequate safeguards under the ECHR in the EPO process. It also claimed that Germany failed to give an effective remedy in such circumstances. The application was dismissed by the ECtHR.

In doing so, the ECtHR also cited the decision *Behrami*⁸⁴⁷ which highlights the reluctance of the ECtHR to hold States liable for actions conducted by an international organisation.⁸⁴⁸ The impugned acts in *Behrami* did not involve a decision by national authorities but rather a decision by the NATO Kosovo Force and the UN Mission in Kosovo. However the national States had provided some of the troops involved in the impugned acts. Nonetheless, according to the ECtHR in *Behrami*, the impugned acts and omissions in *Behrami* were actions of “an international security force and a subsidiary organ of the United Nations could not be attributed to the respondent States”⁸⁴⁹ in spite of the provision of troops. Therefore, States could not be held responsible for non-compliance with the ECHR. Applying this principle to the facts in *Rambus*, the ECtHR stated that in terms of the impugned act, the revocation of a patent by the EPO, the “German authorities have

⁸⁴⁵ (1994) 18 EHRR CD168.

⁸⁴⁶ *Rambus Inc v Germany* [2009] ECHR 40382/04; as discussed in T Murphy and G O’Cuinn, ‘Words in Progress: New Technologies and the European Court of Human Rights [2010] HRLR 601, 616.

⁸⁴⁷ *Behrami and Behrami v France; Saramati v France, Germany and Norway* (2007) 45 EHRR SE10.

⁸⁴⁸ This case is discussed in B Ní Ghráinne, *Challenges in the Relationship between the Protection of Internally Displaced Persons and International Refugee Law* (PhD Thesis, Oxford University, October, 2014).

⁸⁴⁹ This was subsequently applied in *Boivin v. 34 Member States of the Council of Europe*, Application no. 73250/01, 9 September 2008; *Connolly v. 15 Member States of the European Union*, Application no. 73274/01, ECHR, 9 December 2008.

neither intervened in the proceedings before the EPO nor, unlike the situation in *Bosphorus*, taken any subsequent measures of implementation.” This appears to suggest the *Behrami* case law would apply. Nonetheless, the ECtHR introduced an element of uncertainty to this, as it then stated that:

“Admittedly, the grant of a European Patent as well as its revocation in opposition proceedings have direct effects within the legal system of Germany as well as of all other Contracting States of the European Patent Convention. However, even assuming therefore the applicability of the *Bosphorus* case-law to the present case, the applicant did not put forward any arguments to depart from the Federal Constitutional Court’s finding that the protection of fundamental rights within the framework of the European Patent Organisation was in general equivalent to the standard of the German Constitution.”⁸⁵⁰

Thus, it is questionable to what extent EPO Contracting States can be held accountable for EPO actions, such as revocation actions, where no implementing measures or national measures are required. This statement suggests that they may still be, given that revocation has a direct effect in the national system, as the national patent is revoked. If this is the case, *Bosphorus* principles apply but given the presumption of equivalence of the EPOrg with ECHR protections, only if this is proven to be ‘manifestly deficient’ will MSs be held not to comply with the ECHR. In other cases, where a national act is required, such as where national law changes as a result of the EPC, or an interpretation by the EPO, then *Bosphorus* will always apply and States can be held accountable if there is evidence that protections are ‘manifestly deficient’, which is also in line with *Behrami*.

As an aside, the gap in protection created by *Behrami* has been criticised in the literature.⁸⁵¹ For instance, Sari⁸⁵² argues that *Behrami* is contrary to what the *Bosphorus* ruling was seeking to achieve, as the decision creates a scenario which means that neither the international organisation nor States can be held accountable for breaches of the ECHR which may arise. For instance if *Behrami* were to apply in the context of patents revoked

⁸⁵⁰ *Rambus Inc v Germany* [2009] ECHR 40382/04

⁸⁵¹ M Milanović, and T Papić, ‘As Bad as it Gets: The European Court of Human Right’s *Behrami* and *Saramati* Decision and General International Law’ (2009) 58 ICLQ 267; A Sari, ‘Jurisdiction and International Responsibility in Peace Support Operations: The *Behrami* and *Saramati* Cases’ (2008) 8 HRLR 151.

⁸⁵² Sari, *Ibid*.

by the EPO, as the effect of EPO revocation is for national patents to be automatically revoked thereby potentially infringing on the property rights of the applicant but any challenge to Convention rights could not be challenged to the ECtHR as the Contracting States would not be liable and equally as noted above the EPOrg is not party to the ECHR complaints against it are inadmissible.

It is conceded, that the likelihood of such a scenario arising is slim in the context of the morality provisions, given that the EPO provides a narrow interpretation of these provisions and it is unclear, in any case, if *Behrami* applies in such cases. Nonetheless, if it does, questions may be raised should the EPO decide to incorporate human rights considerations more broadly within the morality provisions as its decision in *Brustle* suggests. To avoid this scenario it arguably would be best for the EPO to retain a narrow interpretation of the morality provisions and to maintain the current position whereby divergence may be achieved at a post-grant stage as Contracting States retain post-grant discretion for patents granted.

In short, the presumption of equivalence of human rights protection between the ECHR applies to the EPOrg which suggests it is compliant with base line ECHR standards of protection. This presumption can only be rebutted if the protection is deemed 'manifestly deficient', which appears to be a relatively high threshold. If rebutted, applying *Bosphorus*, the State party to the ECtHR could be found in breach. Arguably, as all current States party to the EPC are also party to the ECHR, pressure may be exerted on the EPO by States to maintain compatibility with the ECHR which in turn may act as a means of soft harmonisation.

5.5 Reflection on the Role of the ECtHR in Bridging the Institutional Divide between the EPOrg and the EU

As currently institutionally configured, the main way in which the ECHR and ECtHR can act as a mediating bridge in this context is by ensuring a baseline standard for the protection of human rights in the ECHR applicable in all CoE Contracting States. These will bind the EU directly in the event that its accession to the ECtHR goes ahead. It will also arguably be inferred to apply in the EPOrg territory given that the ECHR could be considered part of the 'ordre public' of the Contracting States. Furthermore, although the EPOrg is not

bound to the ECtHR nor can it be held responsible for any failings in this context, a process of soft harmonisation is evident. Given that the Contracting States of the EPOrg are all party to the ECHR, it would be politically questionable for it or the EPO to act contrary to the ECHR. Its compliance in this respect is confirmed by decisions of *Heinz* and *Rambus* discussed above where it was held the EPOrg offered equivalent protection for rights as within the ECHR, but this can be rebutted should protections be ‘manifestly deficient.’ Similar, arguments can be raised in the context of the EU as it currently operates in the absence of accession. Moreover, the jurisprudence of the CJEU and EPO has referred to ECtHR jurisprudence which supports this idea of soft harmonisation.

Having said this, the main difficulty presented in the context of the morality provisions, is that if these are to incorporate human rights concerns more broadly, the EPO will arguably interpret rights in a manner which differs from the EU’s interpretation of same. However, offering a margin of appreciation to States may provide a solution, or at least may be the most defensible approach. Thus, a lesson which can be learnt from the ECHR framework is the need to preserve a space for Contracting States action on issues relating to the morality provisions. Adopting and maintaining such an approach would also help limit the institutional influences coming from the EPOrg and EU on the application of the morality provisions in these contexts. However, the use of such an approach is complicated given the overlapping supranational actors and multiple States which exist. This point is worthy of further discussion, as a key contribution of the ECtHR is how its margin of appreciation doctrine could filter through to the other supranational context to mediate tensions which may arise.

5.5.1 Multiple Margins of Appreciation, Institutional Divergences and Differing Conceptions of Human Rights

Chapters three and four have argued that institutional characteristics can influence the application of open textured principles such as morality, of which rights are another prime example. Given their malleable nature, similar to the morality provisions, the contours of rights depend on the concrete application given to them by the actors charged with their adjudication, as discussed, institutional influences are integral to this. The analysis above suggests that the ECtHR embraces divergence on the interpretation of rights in some

contexts in order to ensure it does not encroach upon Contracting States sovereignty. This has been central to the ECtHR's success in maintaining the trust and compliance of Contracting States. Arguably, the main route which the ECtHR would have to act as a bridge between the EU and EPOrg would be to further engrain the margin of appreciation concept within the supranational framework for the application of the morality provisions. This would give rise to a more pluralistic understanding of rights and morality in this context. Thus, rather than seek to limit the divergence which may arise in relation to the application of morality provisions in the EPO, this route would suggest that it should be preserved.

Of resonance in this context is Nic Shuibhne's work, discussed above. She alludes to the possibility of having multiple margins of appreciation existing in any one context and also highlights the complexities in relation to the adjudication of human rights when multiple norm setting actors are involved. Nic Shuibhne focuses on the EU relationship with the ECHR, and states that:

“...the idea that when movement occurs between Member States, *this can involve movement between different systems or versions of rights*. Taking this further, ideas about conflict of rights—a standard device in the context of adjudication between competing claims, even within one constitution system—can be refined by looking at the dynamics of various connections between the Member States, the EC and the Council of Europe. This enables us to visualise just how densely tied the different sources of rights protection operating with the Community legal order actually are. By building from a bilateral to, ultimately, a four way connection, we can also understand more clearly that the involvement of more norm-setting actors in any given situation will inherently and inevitably shift the responsibility for resolution of conflicts to the site of supranational decision-making—the only player within these groups that has genuine jurisdictional oversight of the variety of potentially competing rights and values.”⁸⁵³ [Emphasis added]

If we apply such analysis to mapping the actors evident in the patent context, it highlights the complexity of the framework in terms of the multiple margins of appreciations but also

⁸⁵³ Nic Shuibhne, 'Margins of Appreciation', note 622, 245.

the potential for a shift in thinking to arise. It suggests a need to consider whether the ECtHR has supranational oversight in this area and if so how this might be used to mediate conflicting rights/versions of rights. There are more actors involved in the European patent context than in the EU/MS/ECHR context, and there are also differing levels of relationships in question. In the patent context, three supranational actors⁸⁵⁴ are involved which have with differing and overlapping State compositions. The CoE has 47 members, the EPOrg has 38 members all of which are also now party to the ECHR and the EU has jurisdiction over 28 of the 38 EPOrg members, so its norms will only apply to these countries. Furthermore, the EPOrg is the norm setting actor for all classical EPs which can be obtained in all EPC Contracting States, which includes the 28 EU States. It will also act as granting body for the unitary patent once this comes into effect in the 26 EU countries party to this system. Although, as discussed in chapter six, the Unitary Patent Court (UPCt) will deal with post-grant issues. The UPCt can be seen as a fourth supra-institutional actor, as even though it has links to the EU, it is not an EU court, and institutionally is more similar to the EPO.

Thus, not only is there overlapping jurisdictions evident, but also an intertwined interaction between the EPOrg and EU, whereby the EPO is charged with granting patents thereby assessing the application of the morality provisions for a significant portion of EU patent applications. However, the States involved in the 'European' patent system are also bound by the ECtHR. Thus, decisions of the ECtHR arguably have significant influence in this context. As has been seen the ECtHR generally gives a margin of appreciation to States on moral issues, and this aspect has been picked up by the CJEU in terms of how it approaches the general morality provisions, confirming cross fertilisation between the EU and ECtHR at the adjudicative level.

In thinking about the differing connections which arise, the cross fertilisation which may occur is evident from the CJEU/ECtHR context, and although the EPO is not bound by the ECHR, it is arguable that the decisions of the ECtHR will also influence the EPO. The main difficulty is that the EPO has not shown itself to date to be institutionally configured to engage in the principled analysis needed. However, arguably if it were to follow the ECtHR

⁸⁵⁴ Obligations are also owed under TRIPS so Contracting States party to the TRIPS Agreement are accountable to the WTO. However, as noted in chapter one, the WTO has not been active in this context to date.

approach, and grant discretion to Contracting States, or retain the current position where its post-grant stage allows for deference, this would avoid situations of conflicting interpretations. It is conceded, that the thesis has questioned the defensibility of the EPO's applications of morality if in patent grant the EPO is not applying the morality provisions based on the same level of protection the EU might apply. However, to this it could be argued, that if there is a need to have one supranational granting body in the 'European' patent system for commercial reasons, in light of the fact that moral issues only impact upon a small proportion of patent applications, it would be disproportionate to suggest that these issues give rise to broader questions as to the defensibility of the current system. From a logistical point of view it would be problematic to seek submissions from the EU and other Contracting States to the EPO to be considered in the grant process. Arguably, although by no means perfect, if the current framework is maintained, and deference is given to States at the post-grant stage on the application of the morality provisions, it may strike the appropriate balance. Allowing for deference to States and the EU, means that they may apply the morality provisions more broadly should they choose to do so to deny patents in specific cases should they feel such patents encroach upon human rights – which is only likely to occur in rare cases. Notably, the EPO or EPOrg has never applied a margin of discretion on the interpretation of morality provisions under the EPC for Contracting States but has interpreted provisions in a narrow manner to date which has indirectly achieved the same as this provides discretion to States by allowing for divergence at a post-grant level.

To render this process more defensible, arguably competing margins of appreciation should be more wholly embraced within the decision making structure of the EPO. This would foster greater pluralism and respect for State traditions. At the grant stage for the logistical reasons discussed, it may be difficult for the EPO to apply such a margin of discretion. Instead, allowing for a minimum threshold for morality provisions allows for greater scope for Contracting States to later diverge on the application of same. However, a margin of appreciation could be employed by the EPO in cases where the patent may be challenged on the basis of morality provisions such as in Opposition Proceedings. In such contexts, decisions could be reverted back to Contracting States where the patent has been granted in, in order to allow Contracting States to consider the application of the morality provisions in these jurisdictions. Alternatively, to avoid increasing litigation costs, in the event of challenge on the basis of the morality provisions, the EPO could ask for an opinion from

each country the patent is granted for (when challenged on this basis) and then apply the country position.⁸⁵⁵ This represents a more concrete adoption of a margin of appreciation type approach. It would be dependent on patents being challenged so would not act as a check on EPO action, but would arguably offer a suitable balance in such cases.

Finally, in order for margins of appreciation to be effective in the 'European' patent system, actors within the system need to engage in greater mutual recognition of each other. As noted, the EPO is not bound by the ECtHR so this could not act as a judicial check on EPO action. However, it is in the EPO's interest to abide by ECHR law, so as noted, arguably a process of soft harmonisation will arise. In cases where conflict occurs, dialogue amongst supranational actors could be engaged in to discuss opinions of these actors and reach an agreement, this would operate as a means to mediate difference within the overlapping territories. This would exert political, rather than binding pressure on the supranational actors, and it would be in their own interests to collaborate to avoid conflict.

5.6 Conclusion

In light of these factors, it is argued that as currently structured, the ECHR system may provide a bridge if the dialogue between the CoE, EPOrg, and EU is increased. To this it might be argued that there would be difficulties in generating this dialogue between the EPOrg and CoE as the EPOrg is not a member of the CoE. However, precedent is set for this as the EPOrg already interacts with a number of bodies, including the EU, which it has no formal legal relationship with, the role of the Administrative Council is crucial to this, as discussed in chapter one. Of further benefit is the role of the margin of appreciation doctrine which allows States to maintain a position in line with their own moral frameworks. This is an important feature which should be promoted particularly at a national level to minimise institutionally tailored applications of the morality provisions by supranational institutions in favour of applications which reflect any concerns as to the morality of a patent within a State if these arise.

⁸⁵⁵ P Torremans, 'A Transnational Institution Confronted with a Single Jurisdiction Model: Guidance for the EPO's Implementation of the Directive from a Private International Law Perspective' in A Plomer and P Torremans, (eds.), *Embryonic Stem Cell Patents: European Law and Ethics* (OUP 2009) 300-301. This approach has been criticised by Bakardjieva Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting', note 8, 260.

A final aspect which must be considered is the future unitary patent scheme and how it may influence the application of the morality provisions, examined overleaf in chapter six. Two main issues arise in this context: Firstly, the difficulties the unitary patent scheme may pose in terms of allowing for Contracting State discretion give the unitary nature of such patents. Secondly, the role of the UPCt and whether it will act as a bridging force between the EPO and CJEU, or exacerbate current issues. It will be argued that it has the potential to do both, and much will depend on its openness to engage in dialogue with the CJEU.

Chapter six: The Unitary Patent Package: Implications for the Morality Provisions

6.1 Introduction

This thesis has argued that the decision-making bodies within the EPOrg and EU are heavily influenced by the institutional frameworks in which they are situated when interpreting the morality provisions. These overarching institutions have been conceptualised as prisms, through which morality is filtered by decision-makers. Given the differing institutional frameworks evident in the EU and EPOrg, and the malleable nature of morality, the scope for divergence and conflicting interpretations of the morality provisions has been highlighted. The planned unitary patent package (UPP) will alter the institutional framework within the 'European' patent system by introducing a third supranational decision making forum, the Unified Patent Court (UPCt). In doing so, it further complicates the current system increasing the institutional overlaps which arise. Despite extensive discussions on the unitary package,⁸⁵⁶ there has been little discussion of the relevance of this institutional change for the interpretation of the morality provisions within the patent system.⁸⁵⁷

⁸⁵⁶ This includes: K Kaesling, 'The European patent with unitary effect - a unitary patent protection for a unitary market?' (2013) 2(1) UCL Journal of Law and Jurisprudence 87; Z Zawadska, 'The unitary patent protection - a voice in the discussion from the Polish perspective' (2014) 45(4) International Review of Intellectual Property and Competition Law 383; RM Hilty, T Jaeger, M Lamping, and H Ulrich, 'The Unitary Patent Package Twelve Reasons for Concern' (2012) 12(12) Max Planck Institute for Intellectual Property & Competition Law Research Paper 1; A West, S Kusumakar, T Powell, 'Unitary patents and the Unified Patent Court' (2013) 19(4) Computer and Telecommunications Law Review 105; A Kaisi, 'Finally a single European right for the EU? An analysis of the substantive provisions of the European patent with unitary effect' (2014) 36(3) EIPR 170; R Aerts, 'The unitary patent and the Biotechnology Directive: is uniform protection of biotechnological inventions ensured?' (2014) 36(9) EIPR 584; A Ohly and J Pila, (eds.) *The Europeanization of Intellectual Property Law: Towards a European Legal Methodology* (OUP 2013); J Pila, C Wadlow (eds), *The Unitary Patent System* (Hart Publishing 2014).

⁸⁵⁷ This is examined briefly in C Petersen, T Riis and J Schovsbo, 'The Unified Patent Court (UPC) in Action – How with the Design of the UPC Affect Patent Law' in *Transitions in European Patent Law – Influences of the Unitary Patent Package* (Kluwer Forthcoming) pre-print <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2450945> accessed 16 July 2015; Kaisi, 'Finally a single European right for the EU?', note 856; R Aerts, 'The patenting of biotechnological inventions in the EU, the judicial bodies involved, and the objectives of the EU legislator' (2014) 36(2) EIPR 88. For a discussion of the potential implications of a unitary system for the morality provisions as considered prior to the adoption of the current proposals, see: Warren-Jones, 'Finding a "common morality codex for biotech" note 76; A Warren-Jones, 'Morally regulating innovation: what is "commercial exploitation"?' (2008) 2 IPQ 193-212; E Bonadio, 'Biotech patents and morality after Brüstle' (2012) 34(7) EIPR 433, 440; Warren-Jones, 'Identifying European moral consensus' note 76.

This chapter fills this gap by examining how this planned scheme will affect the application of the morality provisions. In doing so, the analysis draws on insights from institutional theory developed in the thesis thus far which have highlighted the importance of institutional factors in the application of the morality provisions, and how these may play out in the UPP context. Part one commences by giving an overview of the UPP which sets the background for this analysis. Following this, the likely changes the UPP will create for the application of the morality provisions are divided into three overlapping lines of inquiry and examined in parts two, three and four respectively: Firstly, the establishment of the UPCt will create further institutional overlaps in the already complex institutional framework for the application of the morality provisions. The increasing institutional overlaps are examined in part two which investigates whether it may alleviate or exacerbate questions surrounding the defensibility of the morality provisions in this context. Secondly, as noted, the UPP will add the UPCt a third supranational decision-making forum for the adjudication of the morality provisions. Therefore, the institutional influences on this court will arguably impact upon its interpretation of the morality provisions in future. This aspect is examined in part three. Thirdly, the scheme will create a European patent with ‘unitary’ effect (EPUE) at post-grant stage in Contracting States which is problematic in this context for a number of reasons, including the difficulties documented in chapter five in terms of obtaining a consensus on ‘morality’ in the ‘European’ patent system and the need to maintain a certain level of discretion for MSs to respect differing State’s moral traditions and to align with the ECtHR practices in this area. This issue will be examined in part four. The chapter concludes by arguing that deeper consideration must be given to how the adoption of the UPP and the institutional changes which this gives rise to, will influence the application of the morality provisions.

6.2 Overview of the Unitary Patent Package

The attempt to establish a unitary patent for Europe spans at least the last forty years.⁸⁵⁸ However, the end point now appears in sight as on the 17th December 2012, the Council

⁸⁵⁸ D Cremers, et al, ‘Patent Litigation in Europe’ ZEW Discussion Paper No. 13-07 (2013) as cited in L McDonagh, *Exploring Perspectives of the Unified Patent Court and Unitary Patent Within the Business and Legal Communities* (UK IPO, July 2014) 7. See also: K Mahne, ‘A Unitary Patent and Unified Patent Court for the European Union: An Analysis of Europe’s Long Standing Attempt to Create a Supranational Patent System’ (2012) 94 *Journal of Patent and Trademark Office Society* 162; R Jacob, ‘Creating the Community Patent and its Court’ in D Vaver and L Bently (eds) *Intellectual Property in the New Millennium in Honour of William R Cornish* (CUP 2004); S Luginbuehl, *European Patent Law: Towards a Uniform Interpretation*

for the EU signed two regulations⁸⁵⁹ which have paved the way for the development of an EPUE in participating EU States. Originally, the unitary patent was intended to include all EPC Contracting States⁸⁶⁰ but following a number of unsuccessful initiatives,⁸⁶¹ plans commenced for the adoption of a unitary patent for EU MSs. However, these plans also ran into difficulties in light of disagreements relating to translation and language arrangements which made it impossible to reach a unanimous agreement on the package;⁸⁶² with Spain and Italy objecting to the final proposal. Consequently, an enhanced cooperation scheme was employed,⁸⁶³ which allowed the UPP to go ahead with the remaining twenty five EU States.⁸⁶⁴

As an aside, although initially Italy opted out of the scheme, following a number of unsuccessful challenges to the legality of the scheme,⁸⁶⁵ Italy sent a notification on 7th July 2015 to the EU confirming its intention to join the scheme.⁸⁶⁶ Moreover, Croatia joined the EU on the 1st July, 2013 and may also join the UPP⁸⁶⁷ but it has not yet signed the agreement on enhanced co-operation required for participation in the scheme. Therefore, whilst there are currently 25 EU States party to the UPP, it is expected Italy and Croatia will join shortly.

(Edward Elgar 2011) 185, 252-264 as cited in J Brinkhof and A Ohly, 'Towards a Unified Patent Court in Europe' in A Ohly and J Pila, (eds) *The Europeanization of Intellectual Property Law* (OUP 2013) 199-216.

⁸⁵⁹ Regulation 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, OJ L 361/1 of 31.12.2012 (Regulation 1257/2012); Council Regulation 1260/2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to applicable translation arrangements (Regulation 1260/2012).

⁸⁶⁰ The most recent attempt planned to create a Court within the EU system which had jurisdiction for both EU and non-EU EPC Contracting States. This was deemed incompatible with EU law in Opinion 1/09 [2011] ECR I-1137.

⁸⁶¹ See, Brinkhof, and Ohly, 'Towards a Unified Patent Court', note 858, 200; Kaisi, 'Finally a single European right for the EU?', note 856, 173.

⁸⁶² Council Decision of 10 March 2011 authorising enhanced cooperation in the area of the creation of unitary patent protection (2011/167/EU).

⁸⁶³ Regulation 1257/2012.

⁸⁶⁴ For an overview of the process leading to the adoption of the current model and subsequent challenge of this by Spain and Italy, see E Pistoia, "Enhanced cooperation as a tool to enhance integration? Spain and Italy v. Council" (2014) 51 CML Rev 247.

⁸⁶⁵ Spain and Italy challenged the enhanced cooperation process necessary to allow the patent package to proceed in Joined Cases C-274/11 and C-295/11 [2013] 3 CMLR 24.

⁸⁶⁶ Council of the European Union, General Secretariat of the Council 'Notification by Italy of its intention to participate in the enhanced cooperation in the area of the creation of unitary patent protection and in the enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements' (7th July, 2015) <<http://data.consilium.europa.eu/doc/document/ST-10621-2015-INIT/en/pdf>> accessed 16 July 2015. See M Brenn, 'Italy asks can we join the unitary patent scheme?' *Delta Patents* (13 July 2015) <<http://unitary-patent.blogspot.nl/2015/07/italy-asks-eu-can-we-join-unitary-patent.html>> accessed 16 July 2015.

⁸⁶⁷ The EPO has suggested that Croatia will join: B Battistelli, 'Croatia's EU Accession: Good News for Europe' (EPO, 1st July 2013) <<http://blog.epo.org/unitary-patent-2/croatias-eu-accession-good-news-for-europe/>> accessed 16 July 2015.

More, generally, the UPP is open to any EU MSs who wishes to join⁸⁶⁸ but is not open to non-EU States; for instance other EPC Contracting States. In this vein, following the UK general election, questions have been raised as to what would happen in the future should the UK leave the EU; if it did so, it would not be allowed to join the UPP. However, given the uncertainty surrounding this possibility, it will not be considered in the analysis which follows.⁸⁶⁹

Under the UPP, the EPO will retain a central role in the granting process. In fact, nothing changes from the classical 'European' patent system at the pre-grant stage. Applicants apply to the EPO under the same process as they would for a classical 'European' patent designating States in which they desire a patent.⁸⁷⁰ Once granted, if the applicant wants a EPUE, they must file a request to the EPO for unitary effect in the participating EU MSs within one month of the publication of the patent grant in the European Patent Bulletin.⁸⁷¹ Thus, despite the fact that it is an EU initiative, at the grant stage the system is dependent upon the EPO and operation of the EPC. One author has aptly described the EPUE as being grafted onto the EPO decision to grant a patent bundle.⁸⁷² This dependence on the EPO system and the fact that the compliance of an invention with patentability requirements, including the morality provisions is assessed in the first instance by the EPO highlights the comparatively limited role of the UPCt in comparison to the EPO in this context, a point returned to at 6.3.1.

The central change brought about by the UPP is the creation of the EPUE which will have unitary post-grant effect in participating MSs.⁸⁷³ This contrasts with the classical European patent (EP) which once granted is refracted into a bundle of national patents, for which post-grant issues are dealt with by national Contracting States. The EPUE will be

⁸⁶⁸ Select Committee of the Unified Patent Court, *An Enhanced European Patent System* (2014) 7 <<http://www.unified-patent-court.org/images/documents/enhanced-european-patent-system.pdf>> accessed 16 July 2015.

⁸⁶⁹ See generally, A Johnson, 'The UK general election and the UPC', *Bristows UPC*, 8 May 2015 <<http://www.bristowsupc.com/commentary/UK-General-Election-and-the-UPC/>> accessed 16 July 2015.

⁸⁷⁰ For a discussion of the role of the EPO as the granting body see H Ulrich, '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*.

⁸⁷¹ Recital 18, Regulation 1257/2012.

⁸⁷² T Jaeger, 'What's in the Unitary Patent Package?' (2014) *Max Planck Institute for Innovation and Competition Research Paper Series, No. 14/08, 18* <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2435125> accessed 16 July 2015.

⁸⁷³ Recital 5, Regulation 1257/2012.

supplemented by the Unified Patent Court (UPCt) whose establishment is set out in the Agreement on a Unified Patent Court⁸⁷⁴ (AUPC) signed on the 19th February 2013⁸⁷⁵ by 25 of the 28 EU MSs,⁸⁷⁶ noted above.

From an institutional perspective, the UPCt is not an EU Court but rather has been designed akin to a national court of the MSs, and is modelled on the Benelux Court.⁸⁷⁷ Nonetheless, EU law has primacy in decisions of this court as expressly confirmed in the AUPC.⁸⁷⁸ Thus, as will be discussed below; unlike the EPO, the UPCt is bound by EU law and has a direct link with the CJEU. However, it is a specialised court dealing only with patent issues with members drawn from within the pool of patent practitioners, thus in form - as will be seen - arguably it has more resemblance to the EPO Boards of Appeal than the CJEU. These factors will potentially impact upon how it may interpret and apply the morality provisions and are examined in parts two to four below.

The UPP will operate from the date of the entry into force of the AUPC.⁸⁷⁹ This will come into effect four months after the AUPC has been ratified by thirteen of the Contracting States, providing that these thirteen signatory states include the three States which have the highest number of European patents in force in the preceding year, namely, Germany, the United Kingdom and France.⁸⁸⁰ The Brussels I Regulation was amended⁸⁸¹ in order to clarify the jurisdictional rules in relation to UPCt and this was signed in May 2014,⁸⁸² and came into force on 10 January, 2015.

⁸⁷⁴ Council Agreement on a Unified Patent Court (2013/C 175/01).

⁸⁷⁵ For a discussion of the stakeholders perspectives, see, UK Intellectual Property Office, "Exploring Perspectives of the Unified Patent Court and Unitary Patent Within the Business and Legal Communities" (Intellectual Property Office, 2014) <https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/328035/UPC_Study.pdf > accessed 16 July 2015.

⁸⁷⁶ Spain and Poland have opted out of the scheme whilst Croatia which recently joined the EU has not yet signed this agreement but may do so in the future.

⁸⁷⁷ Brikhof, and Ohly, 'Towards a Unified Patent Court', note 858, 211.

⁸⁷⁸ Art. 20 AUPC.

⁸⁷⁹ Art. 18(2) Regulation 1257/2012.

⁸⁸⁰ Select Committee of the Unified Patent Court, An Enhanced European Patent System (2014), note 868, 19.

⁸⁸¹ For the reasons requiring this amendment see, A Horns, Compatibility Of Draft Agreement On Unified Patent Court with EU acquis (KSNH:Law, 3rd October, 2011) <<http://blog.ksnh.eu/en/2011/10/03/compatibility-of-draft-agreement-on-unified-patent-court-with-eu-acquis/>> accessed 16 July 2015. This point is alluded to in P Torremans, 'Intellectual property puts art.6(1) Brussels I Regulation to the test'(2014) 1 IPQ 1.

⁸⁸² Regulation (EU) No. 542/2014 of the European Parliament and of the Council of 15 May 2014 amending Regulation (EU) No. 1215/2012 as regards the rules to be applied with respect to the Unified Patent Court and the Benelux Court of Justice.

At the time of writing, the AUPC has been ratified by seven countries.⁸⁸³ However, having the system up and running in 2015 as previously predicted⁸⁸⁴ is highly optimistic.⁸⁸⁵ This is particularly the case in light of the work which will be needed to establish a new court system, including the development of the court buildings and infrastructure, recruitment of the judicial body, development of the rules of procedure etc.⁸⁸⁶ A recent progress report on the implementation of the UPP suggests that revised date for implementation will be drawn up later in 2015.⁸⁸⁷ This suggests that it will be 2016, at the earliest, but more likely 2017 when the scheme is in place.⁸⁸⁸

However, far from being welcomed, this package and the compromises that have been necessary to bring it to this stage have been criticised extensively.⁸⁸⁹ The UPP has also already been the subject of a number of unsuccessful judicial challenges⁸⁹⁰ including a recently concluded challenge by Spain which was dismissed.⁸⁹¹ Nonetheless, if the scheme goes ahead as currently set out, it will have significant implications for the morality provisions examined in the sections which follow.

⁸⁸³ Current signatories are: Austria, Belgium, Denmark, France, Malta, Sweden and Luxembourg <<http://www.consilium.europa.eu/en/documents-publications/agreements-conventions/agreement/?aid=2013001> > accessed 16 July 2015.

⁸⁸⁴ 'Delay to the operation of the new unified patent court' (Out-law, 24th March, 2014) <http://www.out-law.com/en/articles/2014/march/delay-to-the-operation-of-new-unified-patent-court/> > accessed 16 July 2015.

⁸⁸⁵ T Cook, 'The Progress to Date on the Unitary Patent and the Unified Patent Court for Europe' (2013) 18 JIPR 584.

⁸⁸⁶ Cook, *Ibid*, 585.

⁸⁸⁷ General Secretariat of the Council of Europe, European Patent with Unitary Effect and Unified Patent Court- Information by the Presidency (21 May, 2015) 17 <<http://data.consilium.europa.eu/doc/document/ST-9107-2015-INIT/en/pdf> > accessed 16 July 2015.

⁸⁸⁸ K Egbuonu, 'Unitary Patent and the UPC: A Progress Report' *Managing Intellectual Property* (3 June 2015) <<http://www.managingip.com/Article/3459207/Unitary-Patent-and-UPC-a-progress-report.html> > accessed 16 July 2015.

⁸⁸⁹ This includes: Hilty, Jaeger, Lamping and Ulrich, 'The Unitary Patent Package Twelve Reasons for Concern', note 856; H Ulrich, 'Harmonising Patent Law: The Untameable Union Patent' in M Janssens, and G Van Overwalle (eds) *Harmonisation of European IP Law* (Bruylant 2012); T Jaeger, 'All back to Square one?' note 80; H Ulrich, 'Select from within the System', note 869.

⁸⁹⁰ Joined Cases C-274/11 and C-295/11 [2013] 3 CMLR 24.

⁸⁹¹ Case 146/13 *Kingdom of Spain v European Parliament and Council of the European Union*, Judgment of the Court 5th May, 2015. For discussion, see A Plomer, 'Spain v Parliament & Council (C-146/13) – a giant step towards (dis)integration of the European patent system', *Eutopia Law*, 11 May, 2015 <<http://eutopialaw.com/2015/05/11/spain-v-parliament-council-c-14613-a-giant-step-towards-disintegration-of-the-european-patent-system/>> accessed 16 July 2015.

6.3 The Institutional Landscape for the Unitary Patent: Implications for the Application of the Morality Provisions

The proposed UPP alters the institutional landscape, introducing a third supranational actor, the UPCT, and further layers to the already fragmented “European” patent system. In doing so, it changes the institutional framework within which the morality provisions are adjudicated upon, particularly at the post-grant stage where the changes create further possibilities for overlapping interpretations of morality at a supranational level. This section examines separately the pre-grant and post-grant stages of the proposed framework, exploring how the planned institutional may filter into questions surrounding the defensibility of the morality provisions raised in earlier chapters.

6.3.1 Implications at Pre-grant Stage

As noted, an EPUE is obtained in the same way as the classical EPs whereby the EPO acts as a granting body which assesses the compliance of inventions with patentability requirements, including the morality provisions. The EPO takes on this role in spite of the fact that the EPUE will only be available in participating EU States and that EU law has primacy within the UPCT system. This raises questions as to the defensibility of the application of the morality provisions in light of the arguments raised in this thesis, which have suggested that the decision-making bodies of the EPOrg and EU are not institutionally configured to interpret the morality provisions in the same manner.

The EU Commission has stressed that there will be no change to the application of the morality provisions, noting that the UPP will not change the patentability requirements.⁸⁹² It also claimed that the Biotechnology Directive has been “fully integrated in the legal framework of the European Patent Organisation”.⁸⁹³ However, this research has demonstrated that despite the voluntary convergence between the EPOrg and EU at a legislative level, the interpretation of the morality provisions at a decision-making level is deeply bound to, if not contingent upon, the institutional framework within which decision-makers operate. Considered from this perspective, it suggests that it would be impossible

⁸⁹² EU Commission, Patent Reform Package – frequently asked questions, (Brussels, 11 December 2012) see question 20 < http://europa.eu/rapid/press-release_MEMO-12-970_en.htm?locale=en > accessed 16 July 2015.

⁸⁹³ Ibid.

to integrate the interpretative practices of the CJEU into the EPO's decision-making framework, without fundamentally reconfiguring the institutional framework within the EPOrg. Thus, whilst it is accepted that the UPP does not alter the patentability criteria at a legislative level, there are already significant distinctions between the EU and EPO decision-makers' interpretative approaches to the morality provisions highlighted in this work which give rise to questions surrounding the defensibility of the application of the morality provisions, across and between the EPO/EU systems. The UPP in retaining the same granting process, will arguably further undermine the defensibility of the morality provisions.

6.3.2 Implications at a Post-grant Stage

Turning to the post-grant stage, the EPUE which will come into existence is ancillary to the current system, and does not in any way replace the classical EP or national patent scheme; instead it exists in parallel to these.⁸⁹⁴ Once adopted, the UPCt will have jurisdiction for all EPUEs, and following a transitional period, it will have jurisdiction for all EPs granted to Contracting MSs.⁸⁹⁵ Therefore, once this package comes into force, four overlapping levels of protection for patents will exist within the 'European' patent system, namely: (1) a national patent granted by national EPC Contracting States;(2) a EPUE granted by the EPO with post-grant jurisdiction vested in the UPCt; (3) a classical EP which is granted by the EPO but with post-grant jurisdiction governed by the national States; and (4) a EP granted by the EPO valid in the AUPC Contracting States whose post-grant life will be governed by the UPCt.⁸⁹⁶

These changes therefore alter the decision-making bodies charged with the interpretation of the morality provisions should a challenge arise on this basis at the post-grant stage through revocation actions,⁸⁹⁷ and will also pose further institutional complexities in terms of opposition proceedings.⁸⁹⁸ At this juncture, an overview of the actors involved at the post-grant stage under the planned scheme is provided. This is followed by a discussion of

⁸⁹⁴ Regulation 1257/2012, recital 26.

⁸⁹⁵ Art. 3 AUPC.

⁸⁹⁶ Hilty, Jaeger, Lamping and Ulrich, 'The Unitary Patent Package Twelve Reasons for Concern', note 856, 1.

⁸⁹⁷ Art. 138(1)(a) EPC.

⁸⁹⁸ Art. 99-100 EPC.

the implications of the new institutional structure for the application of the morality provisions.

a) Revocation Proceedings

The UPCt will not be involved at grant stage for EPUEs and so it will have less direct influence in shaping these provisions than the EPO. Instead, in practice, the UPCt will only have an opportunity to shape these provisions if a patent is challenged and therefore, its role is akin to the role national courts currently play. Hence, revocation proceedings will provide the main avenue for the UPCt to shape the morality provisions.

Currently, revocation proceedings are dealt with by the national court in the case of national patents and classical EPs, as the EPO has no post-grant jurisdiction in this context. However, once the UPCt is operational, this will change as the AUPC provides that EPUEs and all classical EPs validated in the Contracting States of the AUPC fall under the jurisdiction of the UPCt.⁸⁹⁹ Therefore, assuming all current signatories ratify the agreement and it comes into force, if an applicant obtains a classical EP as opposed to a EPUE, this will still be refracted into a bundle of national patents. However, the UPCt will become responsible for the post-grant life of EPs granted in Contracting States which have ratified the AUPC. The decisions of the UPCt in respect of a challenge raised against such patents will bind all Contracting States to the AUPC.⁹⁰⁰

Only Contracting States not party to the AUPC will retain post-grant jurisdiction for EPs. Therefore, should the current signatories remain the same and these States all ratify the agreement, the only EU States which will retain national jurisdiction are those which have not signed up to the AUPC, namely: Spain, Croatia and Poland. National jurisdiction is also retained for Contracting States to the EPC who are not in the EU because as noted, these States are not entitled to join the AUPC.⁹⁰¹ Italy currently occupies an unusual place as it

⁸⁹⁹ Art. 3(c)-(d) AUPC include European patents in its scope of application. However, it only applies in respect of EPs granted in Contracting States of the AUPC as confirmed by Art. 34 AUPC on the territorial scope of decisions.

⁹⁰⁰ Art. 38 AUPC.

⁹⁰¹ The Preamble to the AUPC states that “Considering that this Agreement should be open to accession by any Member States of the European Union, Member States which have decided not to participate in the enhanced cooperation in the area of the creation of unitary patent protection may participate in this Agreement in respect of European patents granted for their respective territory”.

has signed the AUPC but (as yet) it has not signed the Regulation adopting the unitary patent (although as noted it has recently indicated it would like to do so). However, if it does not, and should it ratify the AUPC, the post-grant jurisdiction for classical EPs validated in Italy would fall to the UPCt but one could still not obtain a EPUE designating Italy.

To further complicate matters, as noted above, there will be a transitional period of seven years⁹⁰² after the AUPC comes into force during which time patentees who obtain an EP validated in States party to the AUPC can decide if they wish to opt-out of the UPC system.⁹⁰³ If a patentee decides to opt out they must notify the Registry and this opt out will take effect on its entry on to the register,⁹⁰⁴ and this will then be applied to all Contracting States in which the EP has been granted.⁹⁰⁵ An opt-out once registered, will mean that the UPCt has no jurisdiction over the EP bundle and instead, the bundle of patents will be subject to relevant national jurisdictions.⁹⁰⁶ Thus, a complex institutional framework arises whereby EPs are granted by the EPO, and then decisions on revocation will be governed either by national courts or the UPCt depending on whether the State is party to the AUPC and during the first seven years - the transitional period - it will also depend on whether the patentee has decided to opt out. It should also be borne in mind, that when it first comes into force, the UPP needs just the required 14 ratifications to come into effect. This means that initially it could be a EPUE in 14 States, increasing to a EPUE in 15, 16 States etc. depending on when States ratify, this further increases the institutional complexity within the system, as until States ratify only classical EPs can be obtained in that jurisdiction. The diagram below offers a basic overview of decision-making forums for revocation actions.

⁹⁰² Art. 83 AUPC.

⁹⁰³ L McDonagh, *Exploring Perspectives of the Unified Patent Court and Unitary Patent Within the Business and Legal Communities* (United Kingdom Intellectual Property Office, July 2014) 9.

⁹⁰⁴ Art. 83(3) AUPC.

⁹⁰⁵ Art. 83(3) AUPC.

⁹⁰⁶ Preparatory Committee of the Unitary Patent Court, 'Unitary Patent Court Q&As' < <http://www.unified-patent-court.org/about-the-upc/17-category-d> > accessed 16 July 2015.

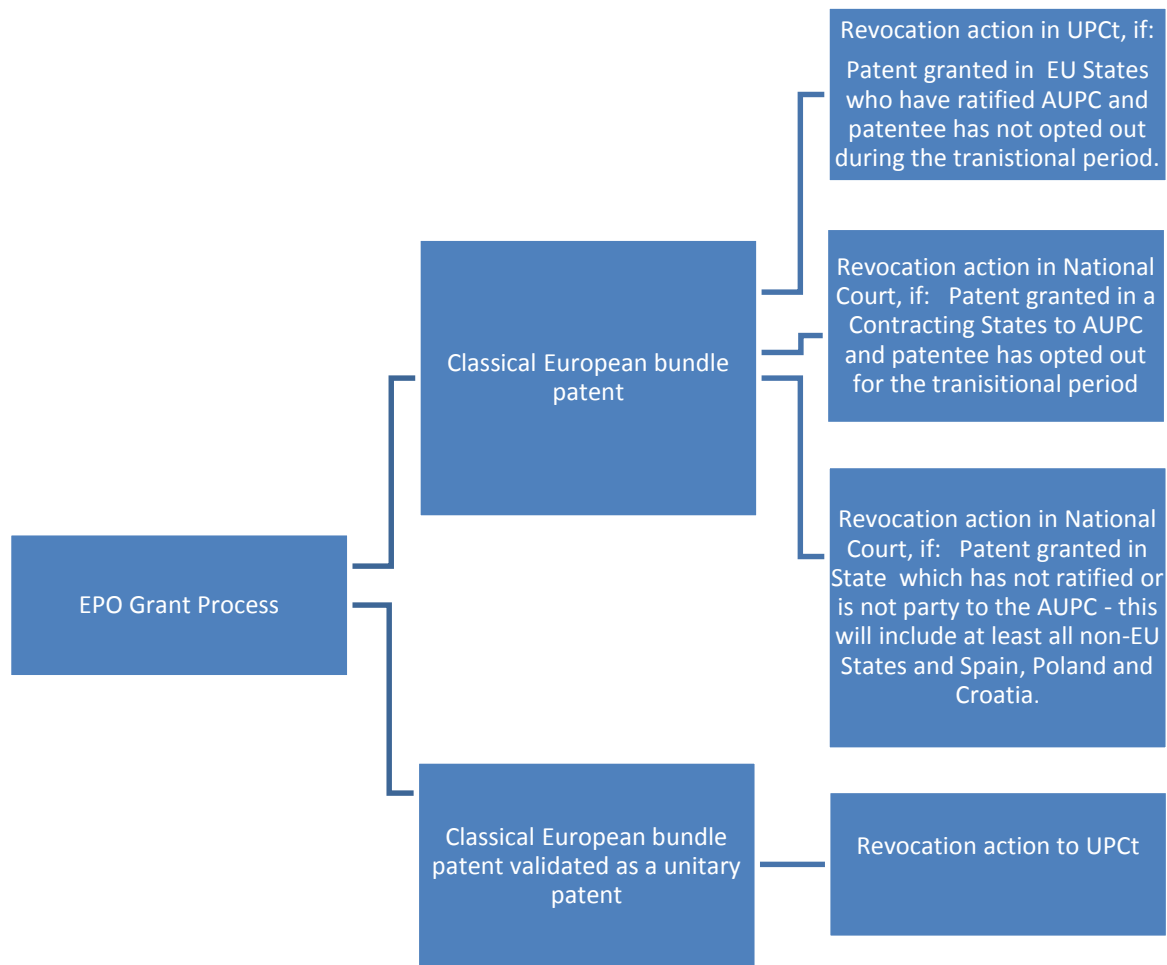


Fig. 3: Decision-making forums for revocation actions following patent grant by the EPO under the UPP.

b) Opposition Proceedings

Prior to examining the implications of the above institutional changes for the application of the morality proceedings, the Opposition Proceedings in the EPO should be considered in order to form a complete picture of the planned institutional system. Under the proposed unitary patent scheme, the unitary patent created has an ‘accessory’ nature explained by Recital 7 of Regulation 1257/2012 which states that:

“...the unitary effect attributed to a European patent should have an accessory nature and *should be deemed not to have arisen to the extent that the basic European patent has been revoked or limited*”⁹⁰⁷. [Emphasis added]

As a result of this, if an EP is successfully challenged by way of Opposition Proceedings after its grant by the EPO, the EPUE validated as a result will also be deemed not to exist. Thus, despite the fact that generally post-grant issues in relation to the EPUE are dealt with by the UPCt, Opposition Proceedings in the EPO continue to exist under the UPP. Therefore, at any one time a patent could be challenged on the grounds of the morality provisions through Opposition Proceedings in the EPO, and also revocation proceedings in the UPCt or national court. The UPCt, as examined below, must be informed of any pending opposition proceedings before the EPO and may decide to stay proceedings if a rapid decision may be expected from the EPO.⁹⁰⁸ However, if it does not stay proceedings and upholds a patent subsequent to challenge, this patent may be subsequently revoked by the EPO. This gives rise to the potential for conflicting interpretations of these provisions.



Fig. 4: Simplified representation of the interaction of opposition and revocation proceedings when the UPP comes into effect.

⁹⁰⁷ Recital 7, Regulation 1257/2012. This is reinforced by Art. 3(3) of the Regulation which states that “The unitary effect of a European patent shall be deemed not to have arisen to the extent that the European patent has been revoked or limited.”

⁹⁰⁸ Art. 33(1) AUPC.

Having said this, this thesis has highlighted that the EPO will generally take a light touch approach to the morality provisions favouring patent grant where possible. Therefore, it is unlikely that this situation would arise. Of more concern in terms of potential divergence is if the EPO dismisses an opposition proceeding and upholds the patent, and a subsequent challenge to the patent through revocation proceedings in the UPCt is accepted. This creates the possibility of conflict as this would render the patent invalid in all AUPC Contracting States, which is the majority of EU States but the patent would remain valid in non-AUPC States which is all non-EU States and also EU States who have not ratified the AUPC.

6.3.3 Implications of Proposed Institutional Changes

These proposed changes significantly alter the decision-making bodies responsible for revocation proceedings. The process gives rise to increased institutional messiness and overlaps as the post-grant process will involve three supranational decision-making actors; the Boards of the EPO, UPCt and the CJEU. In this context, the UPCt and CJEU are described separately as although the UPCt has links to the CJEU and the UPCt – at least indirectly as it is not an EU court itself - is arguably embedded in the EU system as will be discussed in 6.4.3 below; this does not mean it will share the CJEU's interpretative approach to the morality provisions. Thus, the proposed system creates the possibility of further fragmented moral spaces at the supranational level as one will have overlapping areas governed by the UPCt, the CJEU and Boards of the EPO, and as discussed each of these decision making bodies may offer differing interpretations of these provisions, given their differing institutional contexts and frameworks.

In order to illustrate the potential difficulties which may arise, consider a decision of the UPCt in a revocation action which invalidated a EPUE on the basis of the morality provisions. If rendered invalid by the UPCt, the patent would be invalid in all Contracting States to the AUPC but would remain valid in other countries where it was originally validated in as an EP. Further national challenges would be required to invalidate these EPs. In the absence of such challenges, under the current membership, one would have a patent invalid for 25 of the 38 EPC countries but valid in the remaining. This creates a sticky situation for non-AUPC countries if we presume - in light of the primacy of EU law within the UPCt system and the fact that the EPC is also a source of law for the UPCt - that the UPCt was applying EU law along with the EPC in its decision. If this can be presumed,

the denial of a patent by the UPCt in AUPC States would give rise to questions as to its validity in other EU States not party to the AUPC, and also arguably in other EPC States. To justify a differing approach, it could be argued that the consensus on morality within AUPC States differed from non-AUPC States. However, it is unlikely that one would have one overwhelming consensus on the morality provisions in 25 EU States, but not in the remaining 3 EU States not currently party to the AUPC or the remaining non-AUPC EPC States.

In terms of resolving conflicting interpretations should they occur, the only way in which a ruling relating to the UPCt would bind non-participating EU States is if the UPCt made a referral to the CJEU, as the CJEU's decision in such a case would be binding on all EU States. Aside from this, a further challenge of the patent in each national court would be necessary to render it invalid in EU States not party to the AUPC. Moreover, as there is no direct link from the UPCt to the EPOrg, the only means to render such a patent invalid in non-participating EPC States who are not in the EU, is through a similar national challenges to the patent grant or a challenge on foot of opposition proceedings to the EPO.

In short, the overlapping supranational layers add considerable complexity to the already multi-layered system leaving open the possibility for differing overlapping and conflicting supranational interpretations of the morality provisions. It must be acknowledged that the difficulty created is not the risk of divergent interpretation *per se*; already Contracting States have post-grant jurisdiction which allows divergence amongst States on the application of the morality provisions. However, this current approach allows differing national moral and historical traditions to be respected. In fact, as discussed in chapter five, allocating a margin of discretion to States in this context has been espoused by the CJEU and is supported by the jurisprudence of the ECtHR which generally offers a margin of appreciation on questions relating to morality. Instead, the difficulty created by the UPP is that the morality provisions will be applied by three supranational decision-making bodies, which are institutionally configured to apply the morality provisions in a differing manner – a point supported through the discussion of the institutional framework within the UPCt in 6.4 below. If these bodies choose to give unilateral or unitary interpretations of these provisions denying patents on the basis of the morality provisions in all of their Contracting States, this could give rise to conflicting interpretations and tensions as Contracting States have overlapping obligations to the Biotech Directive, EPC and AUPC. This reinforces

questions over the defensibility of the application of the morality provisions. Arguably, in order to avoid the difficulties highlighted, and to facilitate the protection of national moral traditions, a system maintaining deference for MSs in this context would be preferable. However, a difficulty in this context is that the EPUE must have unitary effect and cannot be limited or denied in respect of individual jurisdictions, this point will be returned to in 6.6 below.

6.4 Institutional Influences on the UPCt in the Application of the Morality Provisions

Turning to the second implication of the UPP for the morality provisions, as highlighted above, the UPCt will become a third supranational decision-making forum within the ‘European’ patent system and will interpret the morality provisions at post-grant stage if this forms the basis of challenge in revocation proceedings. Thus, it is important to gain an understanding of the institutional framework within the UPCt and the institutional factors which may influence it in its application of the morality provisions. As the unitary patent system is not yet in place, this is in many ways a foresighting exercise⁹⁰⁹ which seeks to assess the applicable legal framework and relevant institutional characteristics planned for the UPCt, in order to predict influences and hence the interpretative approach of the UPCt in relation to the morality provisions. In doing so, the analysis draws on insights from institutional theory documented in chapter two, along with the template for assessing the institutional influence which was used to assess the institutional influences on the EPORG/EU in the application of the morality provisions. It can be recalled that this template set out four categories of institutional influences, namely: (1) *the central objectives* of the overarching institution and decision making body; (2) *the institutional structure, role and composition of the judicial/quasi-judicial institutions* charged with the application of the morality provisions; (3) *the path dependency* which may influence the morality provision both in terms of legislative path dependencies and judicial path dependencies; and (4) the inter-institutional relationships/agreements of the over-arching institution with external institutions.

⁹⁰⁹ G Laurie, S Harmon, F Arzuaga, ‘Foresighting Future: Law, New Technologies, and the Challenges for Regulating Uncertainty’ (2012) 4(1) *Law, Innovation and Technology* 1.

In relation to the third factor of path dependency, it is not possible to examine this at this juncture, self-evidently, because the UPCt has yet to be established and so there are no cases or past actions of the UPCt upon which to base this analysis. Thus, this section will be omitted from the analysis. Having said this, some insights can be gleaned in terms of the constraints on the court by examining the applicable law. These will be assessed under the decision making framework for the UPCt considered at 6.4.2 below. In short, this section applies the remaining three categories of the template to sketch what type of institutional influences may arise within the UPCt which may influence its interpretation of the morality provisions.

6.4.1 Objectives of the Overarching Institution and the UPCt

In terms of relevant objectives which may influence the UPCt, of particular consequence are the objectives of the EU and more importantly, the objectives of the statutory framework setting up the UPCt. The objectives of the EU are of relevance because as highlighted, the UPP is an EU initiative, and as noted above it was agreed upon by the Council of the European Union and the European Parliament, and solidified with the adoption of two EU regulations in December 2012. It is conceded that the UPCt is not an EU court *per se*; rather it is a Court common to the Contracting States of the AUPC and is subject to the same obligations to the EU as national MS courts.⁹¹⁰ Nonetheless, EU law has primacy within this Court,⁹¹¹ discussed in further detail below, and it could arguably be described as broadly connected to the EU institutional framework and therefore it would be expected that the overarching objectives of the EU would filter into the UPCt framework.

The general EU objectives have been discussed in chapter four. These objectives include the furthering of the internal market within a framework which protects and maintains fundamental rights. The EU internal market objectives are reflected at a number of points in the Preamble to the AUPC. For instance, it states that:

⁹¹⁰ Art 1 AUPC which states: “The Unified Patent Court shall be a court common to the Contracting Member States and thus subject to the same obligations under Union law as any national court of the Contracting Member States.”

⁹¹¹ Preamble AUPC, Art. 20 AUPC.

“...the cooperation amongst the Member States of the European Union in the field of patents contributes significantly to the integration process in Europe, in particular to the establishment of an internal market within the European Union characterised by the free movement of goods and services and the creation of a system ensuring that competition in the internal market is not distorted.”⁹¹²

In terms of the broader EU objectives, the Preamble to the AUPC also refers to the Charter of Fundamental Rights, noting that it is part of the sources of law applicable to the UPCt.⁹¹³ However, outside of this reference there is no discussion of the role of human rights or dignity in the application of the AUPC nor are the broader social goals of the EU mentioned. This is perhaps unsurprising given that the AUPC deals with all inventions and not just biotechnological inventions and it is in the latter context, that human rights issues have been particularly contentious. Nonetheless, the absence of references to broader EU goals in the AUPC alongside the repeated references to the harmonisation goals and the fact that the UPCt sits in a somewhat disjointed manner to the EU judicial system, suggests that these broader social objectives may not be channelled as directly through the UPCt as they would within the CJEU context. These aspects are explored further in the next section.

The objectives set out in Regulation 1257/2012 and the AUPC which set up the UPCt arguably have the greatest influence on the likely interpretative role of the UPCt in this context. Given the specialisation of the UPCt, these objectives are understandably quite narrow. The primary aim of the Regulation 1257/2012 is to achieve unitary patent protection in Contracting States,⁹¹⁴ whilst the AUPC seeks to set up one decision-making body for the adjudication of patents within Contracting States in order to reduce fragmentation and achieve this unitary goal. This is affirmed in the Preamble to the AUPC, which highlights the detrimental effects of variation across countries in the patent context and the desire to improve the enforcement of patents. Thus, these legislative instruments set out primarily economic objectives which prioritise removing fragmentation within the ‘European’ patent system. If the UPCt perceives as its main function the harmonisation of patent law within a ‘European’ market, then it will arguably perceive any broader rights based functions narrowly, particularly as no detailed reference to these is alluded to in any

⁹¹² Preamble AUPC.

⁹¹³ Ibid.

⁹¹⁴ Recital 26, Regulation 1257/2012.

of these statutory instruments. This point is reinforced by considering the decision-making framework provided by the UPCt.

6.4.2 Decision making-framework within the UPCt: A specialised forum

The UPCt is a specialised court⁹¹⁵ which deals solely with “the settlement of disputes relating to European patents and European patents with unitary effect”.⁹¹⁶ In light of this specialised nature, the UPCt may arguably become insulated from broader considerations which generalised courts such as the CJEU have to adjudicate on a daily basis. In this respect, the UPCt’s role is more similar to the Boards of Appeal of the EPO than the CJEU. As has been argued in respect of the EPO, if decision-makers such as the UPCt are unaccustomed with adjudicating on moral or human rights issues they may be reluctant to decline patents on this basis, particularly, if they are operating within a framework which prioritises market goals and the furtherance of the internal market. This is reinforced when one considers, as will be examined below, that the UPCt’s judicial members - similarly to those in the EPO - are drawn from within the patent community, and hence comprise of patent specialists who may have little expertise in examining bioethics or moral issues in other contexts.

This argument is supported by Petersen, Riis and Schovsbo who highlight that the main risk of specialisation is that the UPCt may develop:

“...certain biases that lead the court to downplay or even disregard issues of a general societal nature unrelated to the technical issues of patent law.”⁹¹⁷

In light of the objectives of the UPP, they argue that a bias may result which favours achieving agreement and avoiding diversity.⁹¹⁸ Petersen et al also note that specialised courts have been recognised as being more likely to follow or identify with the objectives and statutory scheme they are administering and may identify too strongly with their

⁹¹⁵ A court whose jurisdiction can be described in terms of the subject matter it deals with rather than geographical factors is, see: Petersen, Riis and Schovsbo, ‘The Unified Patent Court (UPC)’, note 857, 6 citing Gugliuzza, P.R., “Rethinking Federal Circuit Jurisdiction” (2012) 100 Georgetown Law Journal 1437, 1445.

⁹¹⁶ Art. 1 AUPC.

⁹¹⁷ Petersen, Riis and Schovsbo, ‘The Unified Patent Court (UPC)’, note 857, 7.

⁹¹⁸ Ibid 7.

litigants.⁹¹⁹ Similarly, they claim that such judicial members may “develop a tunnel vision and become overly sympathetic to policies furthered by the law that they administer or who are overly sympathetic to “capture” by the bar that regularly practices before them.”⁹²⁰ Institutional theories discussed in chapter two have previously been employed to develop similar arguments in the context of the EPO. Taken together, these arguments suggest the UPCt may focus closely on the objectives set out in the statutory scheme setting up the UPCt and in doing so may seek to preserve a narrow harmonised interpretation of the morality provisions.

These points are reinforced by considering the specific aspects of the decision-making structure within the UPCt and also composition of the court. For the purposes of clarity prior to delving into the decision-making framework, the applicable law within the UPCt is of note.

a) Applicable law within the UPCt

The main sources of law which the UPCt can have recourse to are: EU law, the AUPC, the EPC, and other relevant international agreements such as TRIPS, and national law.⁹²¹ The primacy and respect for EU law is expressly guaranteed in the AUPC,⁹²² and the decisions of the CJEU are also binding upon the UPCt.⁹²³ This is particularly relevant in the context of biotechnological patents, given the existence of an EU instrument governing this area; the Biotechnology Directive. In line with this, the UPCt may make requests for preliminary rulings to the CJEU on the interpretation of the morality provisions in order to ensure the consistent and uniform application of EU law.⁹²⁴ However, much like the current scenario involving national courts, the CJEU’s role in shaping the interpretation of the morality provisions will depend on what questions the UPCt decides to raise and its level of trust in the CJEU which will influence whether it uses this facility to refer questions to the CJEU. This point is discussed at 6.4.3 below.

⁹¹⁹ Ibid 9, citing R A Posner, *The Federal Courts: Crisis and Reforms* (1985) 150-157; P R Guidliuzza, ‘Rethinking Federal Circuit Jurisdiction’ (2012) 100 *Georgetown Law Journal* 1437, 1149; R C Dreyfuss, ‘The Federal Circuit: A Case Study in Specialized Courts’ (1989) 6(1) *New York University Law Review* 3.

⁹²⁰ Petersen, Riis and Schovsbo, ‘The Unified Patent Court (UPC)’, note 857, 9.

⁹²¹ Art. 24(1) AUPC.

⁹²² Art. 20 AUPC.

⁹²³ Art. 20 AUPC.

⁹²⁴ Art. 21 AUPC.

b) Decision-Making Structure of the UPCt

Turning to the structure of the UPCt, once established it will consist of a Court of First Instance (CFI), a Court of Appeal and a Registry.⁹²⁵ The Registry is not relevant for the purposes of this study as it is not a decision-making body, but rather is where the register of the Court is kept⁹²⁶ so it will not be examined. The section commences by setting out the role/structure of the Court of First Instance and the Court of Appeal. This is followed by an overview of the composition and eligibility of decision-making actors sitting within the UPCt and how this may influence the interpretation of the morality provisions. The role of the CJEU in this context is examined separately at the end of this section as in order to gain an understanding of the likely interactions in this context, one must first have an understanding of the system within the UPCt as a whole, including the composition of judicial actors.

i. Court of First Instance (CFI)

The CFI will have a number of divisions, comprising one central division which will be in Paris with sections in Munich and London, and a number of local and regional divisions.⁹²⁷ Each Contracting State will be entitled to have at least one local division, and depending on the number of patent applications in the previous year, they may increase this number up to a maximum of four divisions.⁹²⁸ Regional divisions are set up by two or more Contracting States⁹²⁹ in a joint fashion. The Central Division has three branches, each is responsible for a different subject matter,⁹³⁰ whilst the Paris branch will also be the President's Office.

⁹²⁵ Select Committee of the Unified Patent Court, An Enhanced European Patent System (2014), note 868, 10.

⁹²⁶ The functions of the Registry and Registrar are set out in the Art 10 AUPC and also Art 22-25 Statute of the Unified Patent Court, Annex I AUPC, <[http://documents.epo.org/projects/babylon/eponet.nsf/0/A1080B83447CB9DDC1257B36005AAAB8/\\$File/upc_agreement_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/A1080B83447CB9DDC1257B36005AAAB8/$File/upc_agreement_en.pdf)> accessed 16 July 2015 ('Statute of the UPCt').

⁹²⁷ Select Committee of the Unified Patent Court, An Enhanced European Patent System (2014), note 868, 11.

⁹²⁸ Art. 7(4) AUPC. For discussion see Brikhof, and Ohly, 'Towards a Unified Patent Court', note 858, 209

⁹²⁹ Art. 7(5) AUPC.

⁹³⁰ Select Committee of the Unified Patent Court, An Enhanced European Patent System (2014), note 868, 12.

The competence of the CFI is governed by Article 33 of the AUPC. The local/regional division will deal with infringement actions which relate to any infringement alleged to have occurred in the Contracting States(s) of the division.⁹³¹ It may also deal with infringement actions where the alleged defendant(s) resides, or has a place of business in the Contracting States(s).⁹³² This division also deals with provisional and protective measures and injunctions, and damages or compensation which arises from provisional protection and/or prior use.⁹³³ The Central Division deals with revocation and non-infringement issues, providing there is no pending infringement action at the local/regional division which generally would occur if an infringement action was raised and answered by a counter-claim for revocation. If there is a pending action in this context, the local/regional division has discretion on what to do, they may: proceed with the action and also hear the revocation claim where they would request the President to allocate a suitably technically qualified judge to assist with the hearing;⁹³⁴ refer the counter claim for revocation to the Central Division and in the meantime they can suspend or proceed with the action; or they may refer the case for decision to the Central Division. This is of relevance in the context of the morality provisions, as any challenges on this basis through revocation proceedings will be dealt with either by the local/regional or central division.

ii. Court of Appeal

Decisions of the CFI may be appealed to the Court of Appeal, the seat of which will be in Luxembourg.⁹³⁵ The procedure of the Court is governed by the Rules of Procedure which have yet to be finalised, but this is expected to happen in October 2015.⁹³⁶

⁹³¹ Art. 33(1)(a) AUPC.

⁹³² Art. 33(1)(b) AUPC.

⁹³³ Select Committee of the Unified Patent Court, An Enhanced European Patent System (2014), note 868, 12.

⁹³⁴ Art. 33(3)(a) AUPC.

⁹³⁵ Art. 9(5) AUPC.

⁹³⁶ Preparatory Committee to the Unified Patent Court, '10th Meeting of Preparatory committee', (10 July 2015) <<http://www.unified-patent-court.org/news/93-10th-meeting-of-the-preparatory-committee-3-september-2015>> accessed 16 July 2015.

c) Composition and Eligibility of the Judiciary in UPCT

In terms of the judicial composition of the CFI, local divisions in a Contracting State which have heard less than fifty patent cases per year in the three years prior to or subsequent to the entry into force of the AUPC will be presided over by three legally qualified judges, one who is a national of the Contracting State hosting the local division concerned and two judges from outside the hosting Contracting State.⁹³⁷ If fifty or more patent cases had been commenced in the three years prior or after the entry into force of the AUPC, the local division would sit as two legally qualified judges who are nationals of the hosting Contracting State and one legally qualified judge who is not a national of the Contracting State. Regional divisions are also composed of three legally qualified judges, two from a list of regional judges, and one who is not from the Contracting States involved.⁹³⁸ Parties to the case can also request that a local or regional panel request the addition of a technically qualified judge who is qualified in the area in question.⁹³⁹ Following a hearing of the parties, the local or regional divisions can submit a request for a technically qualified person, if deemed appropriate.⁹⁴⁰ If the CFI is examining a counter claim for revocation they will also be allocated a technically qualified judge.⁹⁴¹

The Court of Appeal sits in panels composed of five judges to include: three legally qualified judges of differing nationalities and two technically qualified judges with experience in the areas under consideration.⁹⁴² These panels are chaired by a legally-qualified judge.⁹⁴³ Thus, in terms of composition, the UPCT will be made up of a majority of legal experts and to a lesser extent, technical experts. This is particularly evident in the CFI which is composed entirely of legal experts, unless a technical expert is requested or in the event of a revocation counter claim to an infringement action.

In terms of the eligibility of the judiciary sitting in the UPCT, a central requirement is that judges both legally and technically qualified shall “have proven experience in the field of

⁹³⁷ Art. 8(2) AUPC.

⁹³⁸ Art. 8(4) AUPC.

⁹³⁹ Art. 8(5) AUPC.

⁹⁴⁰ Ibid.

⁹⁴¹ Art. 33(3)(a) AUPC.

⁹⁴² Art. 9 AUPC.

⁹⁴³ Art. 9(3) AUPC.

patent litigation”.⁹⁴⁴ Legally-qualified members must “possess the qualifications for appointment to judicial offices in a Contracting Member State”⁹⁴⁵ whilst technically qualified members must “have a university degree and proven expertise in a field of technology. They shall also have proven knowledge of civil law and procedure relevant to patent litigation”.⁹⁴⁶ The required patent experience can in some cases be acquired by going through the training framework of the UPCt.⁹⁴⁷ Nonetheless, generally members of the UPCt like members of the EPO will be drawn from within the patent community. As has been argued in chapter three in relation to the EPOrg, having members drawn from within the patent community, which has a general disposition in favour of patent grant and where moral and ethical issues generally are seen as having marginal role, may in turn foster an institutional disposition amongst UPCt members in favour of offering a similarly narrow interpretation of the morality provisions.

Judicial independence is enshrined in the AUPC;⁹⁴⁸ expanded upon in the Statute to the Court⁹⁴⁹ which includes a requirement that judges cannot hold any conflicting positions for the duration of their role on the UPCt. However, there is a facility to appoint part-time judges who can be included in a pool of judges which will be set up. These appointments serve to ensure that all fields of technology are covered⁹⁵⁰ but the impartiality of such judges, although enshrined in the legislation, may prove more difficult to guarantee.⁹⁵¹ Finally, the term of office for each judge is six years, although they may be reappointed.⁹⁵²

In terms of the judicial appointment, there is an Advisory Committee which assists the Administrative Council in the preparation of the appointment of judges and who can also make proposals on the guidelines for the training programme for the judiciary.⁹⁵³ Each

⁹⁴⁴ Art. 15 AUPC. See: C Thornham, and R Küppers, ‘Judges in the Unified Patent Court’, *Intellectual Property Magazine* (February, 2014) 57-59.

⁹⁴⁵ Art. 15(2) AUPC.

⁹⁴⁶ Art. 15(3) AUPC.

⁹⁴⁷ Art. 2(3) Statute of the UPCt. This states: “Experience with patent litigation which has to be proven for the appointment pursuant to Article 15(1) of the Agreement may be acquired by training under Article 11(4)(a) of this Statute.”

⁹⁴⁸ Art 17(1) AUPC.

⁹⁴⁹ Art. 7 Statute of the UPCt.

⁹⁵⁰ Art. 3 Statue to the UPCt.

⁹⁵¹ See: S Holzer and M Lachenal, ‘Ensuring the impartiality of part-time judges at the Unified Patent Court and the Swiss Federal Patent Court’ *Kluwer Patent Blog*, 28th February, 2013 <<http://kluwerpatentblog.com/2013/02/28/ensuring-the-impartiality-of-part-time-judges-at-the-unified-patent-court-and-the-swiss-federal-patent-court/>> accessed 16 July 2015.

⁹⁵² Art. 4(1) Statute of the UPCt.

⁹⁵³ Art. 14 AUPC

Contracting State will propose an individual for appointment to the Advisory Committee⁹⁵⁴ and these individuals must “comprise patent judges and practitioners in patent law and patent litigation with the highest recognised competence.”⁹⁵⁵ All of the above demonstrates that the UP Ct, although situated within the EU, is very much embedded also within the patent community with both the judiciary and members of the advisory committee who feed into the appointment of judicial members, being drawn arguably almost exclusively from within the patent system. This reinforces the perception of this body as a somewhat hybrid institution – legally set up under EU, but in features is more akin to the EPO, which suggests from an institutional perspective that behaviourally, it is likely to act like EPO favouring a narrow interpretation of the morality provisions.

i. Training of judiciary and expert appointments

Interestingly, the AUPC provides a training framework for the judiciary⁹⁵⁶ which aims to “improve and increase available patent litigation expertise and to ensure broad geographic distribution of such specific knowledge and experience”.⁹⁵⁷ However, there is no reference to training on broader aspects of law or ethics which may be applicable in deciding upon the morality provisions. Moreover, this thesis has suggested training would not be sufficient to shift institutional predispositions towards narrow conceptions of the morality provisions. Instead, a bottom up change in institutional thinking would be necessary which would take time to filter through an institution and to the decision-making body. This could be facilitated by training, and institutional linkages may encourage the consideration of broader aspects in the application of the morality provisions, but an institutional disposition favouring a narrow application of the morality provisions, or any other predisposition for that matter, cannot be resolved by training *per se*. Nonetheless, the fact that ethics are not referred to in the AUPC in relation to training arguably reinforces the marginalisation of such issues.

In terms of external influences which may be brought into the system, there is a facility to appoint experts in a case to provide expertise on specific aspects,⁹⁵⁸ and it is questionable

⁹⁵⁴ Art. 5 Statute of the UP Ct.

⁹⁵⁵ Art. 14(2) AUPC.

⁹⁵⁶ Art. 19 AUPC.

⁹⁵⁷ Ibid.

⁹⁵⁸ Art. 57 AUPC.

whether this facility could be used to appoint ethicists or human rights specialists. However, if this were the case it is unclear how, and whether, the court would decide to request this and also how this would operate in practice. Furthermore, as discussed previously, the difficulties surrounding bringing in external ethical expertise within patent law should be noted.⁹⁵⁹

ii. Interim Reflections on the composition of the UPCt

In short, the UPCt is composed of actors drawn primarily from within the patent system which includes both legally and technically qualified members. There is no reference to ethics in the AUPC in terms of training, experts, or requirements for appointment as a member of the judicial panel. Overall, in form the UPCt appears more akin to the EPO than the generalist CJEU or national courts, which will therefore arguably be similarly institutionally predisposed to give a narrower interpretation to the morality provisions. Nonetheless, unlike the EPO it has direct links with the CJEU which require investigation to ascertain if these links could be used as a potential bridge to mediate differences between the EPOrg and EU in the application of the morality provisions.

6.4.3 Relationship of the UPCt with the Court of Justice of the EU

The UPCt may refer questions to the CJEU⁹⁶⁰ if these concern EU law. However, much like the current scenario involving national courts, the CJEU's role in shaping the interpretation of the morality provisions in this context will depend on what questions the UPCt decides to refer to the CJEU. Referrals can be made by the CFI or Court of Appeal and in such cases, there will be a stay on the proceedings⁹⁶¹ until the CJEU has delivered its opinion. Having said this, current discussions suggest a reluctance to involve the CJEU in decisions of the UPCt, with many commentators from within patent law expressing reluctance for patent law to come under its influence.⁹⁶² Robin Jacob expressed this view quite starkly, stating that: "I know of no one in favour of involvement of the CJEU in

⁹⁵⁹ Busby, Hervey and Mohr, 'Ethical EU law?', note 513; Petit, 'An Ethics Committee for Patent Offices', note 329.

⁹⁶⁰ Art. 38 Statute to the UPCt.

⁹⁶¹ Ibid.

⁹⁶² For a discussion see, Brikhof, and Ohly, 'Towards a Unified Patent Court', note 858, 215.

patent litigation. On the contrary all users, lawyers and judges are unanimously against it.⁹⁶³

One of the main objections to the CJEU's role in this area is on the grounds that it is a generalist court whose judiciary do not have the required expertise and knowledge of patent law. This is deemed to be problematic given the specialist and technical nature of patent law and questions have been raised in relation to the quality of judgments the CJEU would deliver in this context.⁹⁶⁴ Other concerns include the potential for the CJEU to cause delay and increase the costs of proceedings.⁹⁶⁵

In order to minimise the influence of the CJEU, there has been an effort to limit the substantive legal provisions in the AUPC. However, unlike other areas of patent law not covered by EU provisions, the Biotechnology Directive already provides a number of substantive provisions on patent law, including the morality provisions. Therefore, decisions of the UPCt concerning the meaning of the morality provision under Art 6 of the Directive, fall directly within the remit of the CJEU, in the same manner as operates currently in national EU States decisions on the morality provisions.

Nonetheless, as others have noted, the UPCt has significant responsibility in this context because once the UPCt becomes operational, it will not be different national courts referring matters; rather it will be the UPCt which will decide exclusively on such issues⁹⁶⁶ for EPUEs and EPs granted in EU States party to the AUPC. If reluctance is already being expressed in relation to the CJEU's role, this arguably does not bode well in relation to how the UPCt may rely on the CJEU in future. This reluctance appears to stem from a mistrust of the CJEU in the 'technical' field of patent law. This again confirms a view of the patent law as insulated from other areas; portrayed as fenced off from the broader legal framework and issues, reinforcing the very hypothesis of this thesis. It is conceded, that there is a need for scientific expertise when one is examining technical issues. However, the application of the morality provisions is arguably an issue which explicitly calls for a broader overview

⁹⁶³See R Jacob, Opinion (2nd November, 2011), 3 <<http://www.eplawpatentblog.com/2011/November/Robin%20Jacob%20Opinion%20re%20Arts.pdf>> accessed 16 July 2015.

⁹⁶⁴ Brikhof, and Ohly, 'Towards a Unified Patent Court', note 858, 215.

⁹⁶⁵ Ibid.

⁹⁶⁶ Ibid 216.

of the issues involved, which may be served well by input from the CJEU. This is particularly true if, as suggested by recent case law, the morality provisions are to incorporate human rights considerations in a broader manner. In this vein, Ohly and Brinkhof have argued that a balance is required between the UPCt and the CJEU in order to ensure that:

“...issues which concern fundamental freedoms, human rights, or the balance between patent protection and countervailing interests reach the CJEU, while practical issues of patent law will be decided by specialist judges.”⁹⁶⁷

In order to achieve such a balance, the UPCt must remain cognisant of its responsibilities to enforce the morality provisions as set out in the Biotech Directive, and must show an openness to refer questions in relation to their application to the CJEU where necessary. If the UPCt were to use this facility to refer questions to the CJEU it could form a useful bridge between the EU and the EPOrg. This is because as even though the UPCt is not responsible for all EU MSs, an interpretation of the CJEU of the morality provisions would involve an interpretation of the Biotech Directive, and therefore would be influential on all MSs. Furthermore, given the UPCt’s jurisdiction and link with the CJEU, it could act as a judicial check on the functions of the EPO in its application of the morality provisions. This is because decisions of the UPCt have automatic effect in all Contracting States to the AUPC and hence the denial of a patent by the UPCt would be an extremely influential act which may place pressure on the EPO to conform to the UPCt approach; as to do otherwise could jeopardise the EPO’s function in terms of patent grant. Thus, the UPCt could forge a mechanism to increase soft harmonisation at an adjudicative level between the EPOrg and EU adjudicative branches’ interpretations of the morality provisions. As an aside, it is conceded that a difficulty which arises in this context is how a margin of appreciation would operate within the EPUE context in light of the unitary nature of such patents, and this point would need to be addressed and is examined in 6.6 below.

Currently, following patent grant by the EPO, aside from a referral to the CJEU which denies a patent and is applicable in all EU MSs, a patent needs to be challenged individually in each Contracting State to render it invalid. In contrast, the UPCt system offers a single

⁹⁶⁷ Ibid 216.

track to invalidation in 25 States, should a revocation action before the UPCt succeed. Thus, the way the UPCt will approach the morality provisions offers an important judicial avenue to challenge EPO practice. It is conceded in this context that UPCt decisions are not directly binding on the EPO, but given the number of States party to the UPCt, it will have significant persuasive influence on EPO practice. This is confirmed by Petersen; et al have argued it could operate a watchdog role in respect of decisions of the EPO.⁹⁶⁸

However, the only way such a link would work to mediate potential differences between the EU and EPOrg is if the UPCt were to interpret the morality provisions using a similar interpretative framework as the CJEU which appears unlikely in light of its institutional characteristics which differ substantially from the CJEU. Alternatively it could seek to develop strong links with the CJEU by using its referral procedure in dealing with any questions which arise as to the interpretation of the morality provisions, thereby bridging the divide between it and the CJEU in this context. This proposal is not without its difficulties and there is no denying that this process would be more institutionally coherent if all EU States were party to the UPCt, because as demonstrated above, the proposed system leaves open questions in relation to non-AUPC States. It would also be the case that the UPCt would have to wait for a patent to be challenged to exert influence. In short, much depends on how the UPCt is likely to approach the interpretation of the morality provisions, and whether it is likely to forge links with the CJEU in this context.

6.5 Inter-Institutional Influences: The UPCt, the EPO and the ECtHR

In order to complete the picture of the institutional framework which will be operable in the UPCt, it is important to briefly map the main links between the UPCt and the EPO; and ECtHR, respectively.

6.5.1 Relationship with European Patent Office

The EPO has been charged with a number of functions in the unitary patent scheme, including responsibility for the granting process.⁹⁶⁹ Alongside this, the EPO is charged with

⁹⁶⁸ Petersen, Riis and Schovsbo, 'The Unified Patent Court (UPC)', note 847, 4.

⁹⁶⁹ Recital 5, Regulation 1257/2012.

functions in relation to patent licenses whereby patent proprietors of EPUE will have to file a statement with the EPO if they wish to license the patent to others. Importantly, the EPO will also be responsible for a number of administrative tasks relating to the unitary patent package set out in Art 9 of the Regulation on Enhanced Cooperation. These can be paraphrased as including: the administration of requests for unitary effect; including the register for unitary patent protection with the European Patent Register, and administering the register for unitary patent protection; processing licensing requests including the registration of these; publishing translations during the transitional period; collecting and administering renewal fees for EPUEs and dealing with appropriate distributions to MSs; administering the compensation scheme for the reimbursement of translation costs; ensuring the request for unitary effect is submitted in the appropriate language; ensuring the unitary effect is indicated in the Register for unitary patent protection and for the transitional period, ensuring that this has been submitted along with appropriate translations and that the EPO is informed of any licences, revocations, transfers of EPUEs.

Thus, a number of links are evident between the EPO and this unitary patent scheme. According to Art 9(2) of the Regulation, the participating MSs will supervise the actions of the EPO by setting up a Select Committee of the Administrative Council of the EPOrg⁹⁷⁰ within the meaning of Art 145 EPC. The first meeting of the Committee was held in March 2013 and it adopted rules of procedure which entered into force on 25th June, 2013.⁹⁷¹ The Select Committee is composed of representatives of the participating Contracting States and also a member of the European Commission as an observer. The Committee may also be assisted by experts or advisors.⁹⁷² Importantly, the President of the EPOrg takes part in all deliberations of the Select Committee as set out in the Rules of the Court.⁹⁷³ Other observers may also be invited to participate in the meetings of the Select Committee. At the moment, these observers include: Business Europe, the Institute of Professional Representative before the European Patent Organisation (epi) and the following observer States: Albania, Croatia, Italy, Monaco, Norway, San Marino, Serbia, Spain, Switzerland, and Turkey.⁹⁷⁴

⁹⁷⁰ For further details on its composition see < <http://www.epo.org/about-us/organisation/select-committee.html> > accessed 16 July 2015.

⁹⁷¹ Decision of the Select Committee of the Administrative Council of 25 June 2013 approving the Rules of Procedure of the Select Committee of the Administrative Council SC/D/1/13.

⁹⁷² Art. 9(2) Regulation 1257/2012.

⁹⁷³ Art. 6 Regulation 1257/2012.

⁹⁷⁴ See <<http://www.epo.org/about-us/organisation/select-committee.html>> accessed 16 July 2015.

This Committee performs an important bridge between the EPOrg and participating AUPC Contracting States in overseeing the actions of the EPO in relation to the EPUE. This forum could be used to coordinate the approaches of the EPO and the Contracting States of the AUPC. As these MSs are all EU States, and as the European Commission is an observer, it could also arguably be used to try to increase convergence between the EU and EPOrg more generally and to deal with conflicts which may arise in relation to the patentability process including in relation to the morality provisions.

6.5.2 Relationship with the European Court of Human Rights (ECtHR)

In terms of the relationship of the UPCt with the ECtHR, as noted the UPCt is not an EU Court. Instead it is a Court of the MSs which is bound by EU law. However, it will have the same obligations as enshrined in EU law to observe the ECHR, and also the Charter of Fundamental Rights which is referred to as a source of applicable law in the Preamble of the AUPC. This suggests a need for the UPCt to consider human rights implications in the application of the morality provisions and also the need to observe MSs' moral traditions, a point expanded upon in section 6.6 below.

Nonetheless, given the institutional framework set out above it is unclear how open the UPCt may be to using the morality provisions to filter human rights concerns. Referrals to the CJEU in this context may ensure decisions of the UPCt align with the EU and ECHR. However, as noted, much will depend on the relationship the UPCt develops with the CJEU. In light of the planned accession to the ECtHR, it may also be of interest to see if the UPCt could refer decisions to the ECtHR in the future. However, this point is beyond the scope of this current work.

6.5.3 Reflection: The Influences on the UPCt in the interpretation of morality

The UPP creates further complexity in the 'European' patent system introducing another supranational jurisdiction which increases the overlapping institutional framework in the 'European' patent system and may exacerbate the potential for conflicting interpretations on the morality provisions. This may prove particularly difficult given the fact that not all EU States are participating in the AUPC, as questions may arise as to the validity of patents

granted in non-AUPC States if such patents are denied by the UPCt. The above application of the template for assessing institutional influences within the UPCt's which may affect its application of the morality provisions has been used to suggest that left to its own devices, it is likely to behave in a manner similar to the Boards of the EPO rather than the CJEU – depending on the links it develops with the CJEU – and will be institutionally disposed to offer a narrow interpretation of these provisions.

Reflecting on this analysis, the following has been observed in respect of each element of this template: (1) In terms of its central objectives, as noted it has links with the EU, although it is not an EU court. Nonetheless, given that it is an EU initiative the EU objectives will arguably be influential. However, given its specialised functions, the AUPC and Regulation 1257/2012 which set up the scheme, refer extensively to the EU internal market and economic aims, with little to no reference to broader social objectives of the EU. This in turn suggests a marginal role for such broader objectives within this specialised forum; (2) Turning to the structure and composition of the UPCt, its judicial members will be drawn primarily from within the patent system with little outside influence discernible, and it has been argued that the body is institutionally more akin to the Boards of the EPO than the CJEU. Accordingly, if the experience of the EPO is anything to go by, this suggests that the UPCt will approach the morality provisions in a narrow manner blinkered from external considerations. The difference being that there is the possibility for the UPCt to refer question to the CJEU. However, the current discussions on the role of the CJEU within the UPCt system, suggest a reluctance to involve the CJEU. A clear delineation is evident in the portrayal of patent law as a technical specialist field which should remain within the sole remit of the specialist patent courts, and more generalist issues which should be the preserve of the CJEU. This is problematic as the morality provisions arguably relate to broader considerations but it is unclear whether the UPCt will be likely to refer questions on these to the UPCt; (3) The path dependencies of the institution are also a factor outlined in the template, but these were not examined in the context of the UPCt as it has not come into operation yet, so this examination is not possible; (4) Finally, in terms of inter-institutional influences and how these may influence the application of the morality provisions, arguably much will hinge on this, and particularly on the UPCt's relationship with the CJEU. Arguably, the UPCt approach has the potential to offer a bridge to mediate differences between the EPO and EU, if the UPCt were to view the morality provisions as an area where the CJEU should have an influence and consequently developed a closer

relationship with the CJEU in this context. This process could be used to ensure the EPO's initial application of the morality provisions complied with the CJEU approach as the UPCt as noted above would have significant influence on the EPO. This is because the UPCt's denial of a patent has unilateral effect in all Contracting States to the AUPC which form a substantial proportion of EPC States thereby putting pressure on the EPO. Another feature of the unitary patent system which could be used to further increase dialogue between the EU and EPOrg in this context is through the Select Committee which provides a means for coordination at a legislative level. It has been argued that legislative coordination has a questionable impact at a decision-making level but nonetheless, it could be an important forum for the discussion of the trajectory of the morality provisions and bridging of conflicts which could occur.

Thus, whilst the UPP is by no means a perfect one, if it were to approach the morality provisions in an open manner and involve the CJEU in such decisions, it has the potential to introduce both judicial and legislative checks on the EPO in the grant of unitary patents. Having said this, if it chooses to adjudicate on the morality provisions with limited input from the CJEU, its institutional characteristics as examined above suggest that it will be institutionally predisposed to apply the morality provisions in a narrow manner which is similar to the EPO's approach. It is also not at all clear whether the UPCt itself is institutionally structured to deliver on the goals of the Biotech Directive in its interpretation of the morality provisions which may give rise to further questions surrounding the defensibility of the morality provisions.

6.6 The Morality Provisions and the 'Unitary' nature of the EPUE

Finally, the third implication of the UPP which must be alluded to in any discussion of its implications for the application of the morality provisions, is the unitary nature of EPUE. This is enshrined in Recital 7 to the Regulation which states that:

“The main feature of a European patent should be its unitary character, i.e. providing *uniform protection* and having *equal effect in all the participating Member States*. Consequently, a European patent with unitary effect should *only be*

limited, transferred or revoked, or lapse, in respect of all the participating Member States ...” [Emphasis added]

This provides for a system where the EPUE will either stand or fall as a whole and cannot be revoked or limited in respect of particular Contracting States which may object. The UPCt could still arguably allow for divergence in respect of EPs under its jurisdiction which are not EPUEs. However, there does not appear to be any means to accommodate divergence amongst States in respect of EPUEs. It can also be inferred from the recital above that a UPP cannot be converted back to an EP bundle if it is subsequently objected on the basis of moral concerns in a particular Contracting State after registration as a EPUE, as this would appear to render this recital unnecessary. Instead, EPUEs can only be limited, revoked or lapsed in all Contracting States.

6.6.1 Uniformity under the UPCt Scheme

This uniformity proves problematic in the context of the morality provisions as moral questions may give rise to divergent and entrenched polar opinions and the opinion within different States on such issues can vary widely. Furthermore, as discussed in chapter four, the EU has obligations in terms of allowing for MS divergence and respect for national identity which indicate a need for some leeway for MSs on questions relating to morality. This is reinforced by the EU’s obligations under the ECHR, discussed in chapter five and the margin of discretion generally provided by the ECHR to allow MSs to decide on such issues. Indeed, the need for deference towards MSs in respect of the general morality provision in Art 6(1) of the Biotechnology Directive was confirmed by the CJEU in the *Netherlands* decision.⁹⁷⁵ Furthermore, the wording of the Biotechnology Directive suggests that morality should be assessed on the basis of the consensus in a MS affirmed by recital 39 of the Directive which states that:

“Whereas *ordre public* and morality correspond in particular to ethical or moral principles recognised *in a Member State*, respect for which is particularly important in the field of biotechnology...” [Emphasis added]

⁹⁷⁵ Case 377/98 *Netherlands v European Parliament and Council* [2001] ECR I-07079.

The use of a MS in the singular in this recital, suggests that the principle was envisaged as being assessed on a national level⁹⁷⁶ which could provide for a means to allow for national differences in terms of some patents. However, it is unclear how the unitary patent system can maintain discretion for individual States who may object to patentability on moral grounds. Alongside these difficulties, it is also unclear which territory it should seek to judge the moral stance in, given that the Contracting States to the AUPC are also party to the EPC and Biotech Directive. In particular, it is not clear whether it will seek to ascertain moral consensus in the current 25 AUPC Contracting States, the 28 EU States or the 38 EPC States. The UPCt will need to either adopt a lowest common denominator approach granting a patent unless deemed absolutely abhorrent and consensus on this was held by all MSs, or a maximalist approach which would prohibit patents if any MS objected.

An added complication to this is Art 7 of the Regulation 1257/361, which states that:

“A European patent with unitary effect *as an object of property* shall be treated in its entirety and in all the participating Member States as a national patent of the participating Member State in which that patent has unitary effect”. [Emphasis added]

This provision applies in relation to the treatment of patent law where there is no substantive law⁹⁷⁷ within the AUPC, Biotech Directive or EPC governing an area and applies specifically to the property aspects of patents which have been suggested as referring to transfer, licensing, encumbrance, enforcement and other aspects where the legal ownership of patents is in issue.⁹⁷⁸ Therefore, it is questionable whether this would apply in the UPCt’s application of the morality provisions. Whilst there is an applicable legislative provision in the context of the morality provisions which is contained in both the EPC and Biotech Directive. However, as noted these provisions are open textured in nature and it is not clear which area morality should be judged upon, whether it should be the moral standard within national, AUPC, EU or EPC areas. Moreover, a property right is

⁹⁷⁶ E Bonadio, ‘Biotech patents and morality after Brüstle’ (2012) 34(7) EIPR 433, 439.

⁹⁷⁷ Brikhof, and Ohly, ‘Towards a Unified Patent Court’, note 858, 212.

⁹⁷⁸ T Mullerstoy and F Paschold, ‘Unitary Patent and National law’ IP Report 2014 Special/I, *Bardehle Pagenberg* <<http://www.bardehle.com/index.php?id=1&uid=407&type=1001&L=1>> accessed 16 July 2015. This is discussed in detail by H Ulrich, ‘The Property Aspects of the European Patent with Unitary Effect: A national perspective for a European Prospect?’ (2012) Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 13-17, 1-17.

in issue, as morality provisions can be invoked to challenge a patent via revocation proceedings which relate to the removal of a patent and therefore arguably property rights. Hence, it is at least arguable that Art 7 may apply in this context.

The significance of this is if Art 7 did apply it would mean that the UPCt must adjudicate any actions on the basis of the national law in one MS. In terms of the applicable national law, this will be the law of the State where the applicant had his/her residence or principal place of business on the date of filing the application for a European patent. If this does not apply, then it will be where the applicant had a place of business at the date of filing. If neither of these apply, then the EPUE shall be treated as a national patent of the State where the EPORG has its headquarters, which is Munich, and hence treated according to German law.⁹⁷⁹ Also of relevance in this context is Art 5(2) which as discussed states that the unitary patent right and limitations shall be uniform to all participating MSs. Kasis argues that taken together, Art 5(2) and Art 7 does not mean the unitary patents must be interpreted in a uniform way in all cases involved. Instead, he argues that they mean that a particular EPUE must be treated in a uniform way and must be interpreted according to the national law of one MS for the entire territory of the enhanced co-operation.⁹⁸⁰ It has been questioned whether this complies with Art 118 of the TFEU⁹⁸¹ as it fails to provide for uniformity between patents in respect of the property aspect. Moreover, in the context of the morality provisions the reference to “Member State” in the singular in recital 39 of the Biotech Directive, quoted above, is significant as whilst the provision to date had been interpreted as giving discretion to MSs should they wish to deny patents, it is questionable whether Art 7 applied in this context could be used to suggest that the law of one MS would apply.

Hence, if this provision applied to the morality provisions it would be highly problematic. As it would mean that the UPCt would be required to judge the challenge by reference to the law of one MS, which would apply the moral tradition of one MS to the patentability of a particular patent in all States, leading to a scenario where the moral tradition of one MS would be brought to bear on all MSs. This would be adverse to EU responsibilities to

⁹⁷⁹ Art. 7(3) AUPC.

⁹⁸⁰ Kasis, ‘Finally a single European right for the EU?’, note 856, 179.

⁹⁸¹ Ibid 179. See also H Ulrich, ‘The Property Aspects of the European Patent with Unitary Effect’, note 978.

protect MS's moral traditions⁹⁸² and also arguably contrary to obligations under the ECHR. Article 6(2) of the Biotech Directive, detailing the specific morality provisions is not in issue in this context as it has previously been accepted that this provision must be interpreted in a uniform manner in all EU MSs. However, Art 6(1) of the Biotech Directive requires further attention from policy-makers as should Art 7 apply it would raise serious questions as to the defensibility of the morality provisions, as it would lead to the UPCT having to enforce a uniform interpretation in all MSs, using the standard of one MS as a baseline. It could also engender uncertainty and forum shopping, whereby States perceived as holding strict moral traditions could arguably be avoided in patent disputes by changing one's place of business.

6.6.2 Current Post-grant Divergence

Moreover, even if Art 7 does not apply, the unitary nature required if based on a perceived uniform interpretation in all MSs is still problematic. Currently, there is scope for national divergence to be introduced post-grant through revocation proceedings discussed above; the importance of which was highlighted in the *Stem Cell Patent Report*⁹⁸³ which focuses specifically on hESC inventions, and recommended that the EPO adopt a wide interpretation of patentability, whereby patents would be granted unless there was a wide European moral norm which supported their denial. This Report claimed that objections of individual MSs could then be accommodated post-grant through national revocation proceedings which could thereby preserve national moral traditions.⁹⁸⁴ This mechanism for allowing divergence at the post-grant stage will be removed by the UPP in respect of EPUEs.

6.6.3 Reflections on the unitary nature

There was hope that the UPP would offer a more institutionally sound basis for assessing the morality provisions than currently provided by the EPO under the classical EP route.

⁹⁸² Kaisi, 'Finally a single European right for the EU?', note 856, 179.

⁹⁸³ Plomer (Co-ordinator), *Stem Cell Patent Report*, note 47.

⁹⁸⁴ *Ibid* 133.

In this vein, Plomer writing in 2008 noted that:

“Institutionally, the European Patent Organisation and its tribunal system lack the appropriate constitutional structure to confer the required legitimacy and authority to take patent law further into unchartered legal experiments in this legally fraught field. For the time being, procedures are in place within the EPC and national laws for Member States to invalidate a European patent granted by the EPO on moral grounds. These procedures should be relied upon until a better integration of European patent courts, staffed by professional judges and with a clear hierarchy ending in the European Court of Justice, has been achieved”⁹⁸⁵

However, this statement was written when the proposed UPP was a very different proposition than the package we have today. It is questionable whether the current UPP and the compromises made to achieve this, offer a more defensible approach than the classical EP scheme. If anything, as the proposal currently stands, arguably the UPCt will give rise to similar institutional questions as the EPOrg in relation to its application of the morality provisions. The EPO remains a granting body so none of the institutional questions raised above in this context have been addressed, and at post-grant stage the UPP results in further fragmentation of the ‘European’ patent system, with increasingly complex institutional overlaps and the introduction of a third hybrid supranational forum, the UPCt. Depending on how the UPCt evolves this could further exacerbate the institutional divides already evident. This is likely unless the UPCt develops a closer relationship with the CJEU, which, if it were to do so, could act as a bridge between the EPO and EU in this context. However, even if this occurs, a more difficult issue in the context of the morality provisions is the ‘unitary’ nature of the EPUE. As currently constructed it does not appear to leave any means for MSs divergence, if challenges arise to the EPUE, accordingly, it is arguably incompatible with the need to respect MS divergence in relation to moral questions. A potential solution to this, would be to allow the EPUE to be converted to a classical EP in cases where challenges were raised on the basis of Art 6(1) of the Directive, in order to accommodate a margin of discretion for States given the sensitive moral issues at stake and the CJEU’s policy of allowing some manoeuvre on such issues.

⁹⁸⁵ Plomer, ‘Human Dignity, Human Rights, and Article 6(1)’, note 422.

6.7 Conclusion

In short, the ‘unitary’ nature of the EPUE is rubbing against the need to accommodate States divergence in cases involving the application of the morality provisions. These cases may be rare occurrences but they are nonetheless significant, and should be accommodated. This thesis suggests that further thought must be given to the institutional structure for the proposed UPCt and how this may affect the application of the morality provisions. On the one hand, the UPCt presents some useful features that could be used to increase the defensibility of morality in this context. However, on the other hand, its current institutional structure also raises serious issues, which could further exacerbate current tensions depending on how the UPCt operates in this context. Further thought is given to potential recommendations that could be adopted in the conclusion overleaf.

Thesis Conclusion

The thesis has argued that the adjudicative actors within the European Patent Organisation, Court of Justice of the European Union, and Unitary Patent Court – should this come into existence – are (and in the case of the Unitary Patent Court will be) significantly influenced by the institutional framework within which they are situated in their application of the morality provisions. Each adjudicative body is institutionally configured to filter and view the morality provisions through an institutional lens which, in turn, directly affects their interpretation of these provisions. In this context, it has been argued that it is futile to expect decision-making bodies within differing institutions to deliver the same interpretations of the morality provisions. Instead, the thesis has drawn on institutional theories outlined in chapter two to develop a novel analytical template for assessing institutional influences.

This template argues that decision-making bodies' interpretations will reflect the following factors: (1) the *central objectives* of the overarching institution within which they sit, and their own objectives. This factor was developed by drawing on MacCormick's work which highlights that such objectives act as constraints on judicial/quasi-judicial decision-makers as they must act in line with the functions/aims of the body in which they are situated in; (2) the *institutional structure, role and composition* of the judicial/quasi-judicial bodies which was devised with reference to Clayton and May's institutional theory and drawing also on political and sociological institutionalism. Analysing this feature offers insights into how decision-making bodies can be predicted to act and how external factors might influence decision-making in a particular context; (3) the *path dependencies* of both the overarching institution and the judicial/quasi-judicial body. This factor draws on historical institutionalism and MacCormick's work highlighting the institutionalised nature of legal adjudication on moral issues. The thesis highlights that judicial/quasi-judicial decision-makers are *legally constrained* by the past decisions of the adjudicative body within which they sit particularly if decisions have already been given on the morality provisions. They are also influenced by decisions in related areas to which analogies might be drawn given the need for consistency and coherence within a legal framework. Moreover, past decisions at a legislative level are also significant as adjudicative bodies must interpret the underlying legal framework by reference to the purpose of the legislation and principles set out within it and related legislation; and finally, (4) *inter-institutional influences* exerted on decision-making bodies. This factor was included by drawing on sociological institutionalism which

highlights the potential for diffusion across institutions operating in the same area. In the legal context, this may be a constraining factor if there are hierarchies existing between institutions such as the obligations the EU would have to the ECHR system post accession. Relationships between institutions may also be highly persuasive such as the EPOrg's relationship with the ECHR system, where although the EPOrg is not party to the ECHR it arguably will still seek to abide by Convention law given that all of its Contracting States are Convention parties. Analysing inter-institutional relationships can offer predictions as to the behaviour of judicial/quasi-judicial decision-making bodies situated within these overarching institutions.

The main research question that has been explored in this context is whether the current application of the morality provisions is a defensible one in light of such influences. In examining this question, this novel template was applied to both the EPOrg and EU in chapter three and four, respectively, to assess the extent to which the institutional influences - both constraining and predictive – evident within these frameworks are likely to influence these decision-making bodies in their application of the morality provisions. The potential influences of the ECHR system on both frameworks was then considered in chapter three. This analysis demonstrated that there are significant differences in the constraining and predictive factors applicable in the respective frameworks which it has been argued will influence the adjudicative bodies in the EPOrg/EU in their application of the morality provisions in different ways. In particular, the following differences in *constraints* were identified: differing central objectives in the EPOrg versus the EU framework; differing legal competences of the CJEU and EPO; differences in the interpretative principles applicable in each framework; differences in the relationships between the overarching institutions the EPOrg/EU and their Contracting States; and differences in path dependencies, in terms of the previous judicial/quasi-judicial decisions of the EPO/CJEU on the morality provisions and related issues - or in the EPO context the lack of familiarity of examining moral issues in other contexts. Similarly, differences have been identified in the *predictive factors* which may influence adjudicative bodies in these respective frameworks, including: differences in the composition/eligibility/structure of the CJEU/EPO; differences in the independence of the CJEU/EPO and the likely financial/external influences on both bodies; and differences in the inter-institutional relationships between these bodies and the ECHR system.

Accordingly, it has been argued that there are fundamental difficulties with the adjudicative framework for the application of the morality provisions, and indeed that the expectations placed upon decision-makers, especially on the decision-making bodies in the EPO to apply the morality provisions in the same manner as the EU, fails to take these institutional differences into account. The thesis argues that given the differences between the EU and EPOrg systems, that institutional influences will give rise to divergences at an adjudicative level between decision-making actors in these institutions in their interpretation of the morality provisions. This will occur regardless of whether convergence is evident at a legislative level, as influences on adjudicative actors are long-standing and engrained within an institutional framework. Equally, it has been argued that it is only through incremental development (and depending on the change desired this may require changes to the competences/legal interpretative principles set out in the underlying legislation in the EPOrg/EU context, which in turn may not be possible), institutional reflection, and inter-institutional dialogue that institutional change can be generated. This is particularly the case in the context of the morality provisions, as the open-textured nature of these provisions requires adjudicative actors to shape such provisions in order to give them effect.

It has been argued that a difficulty presents itself in terms of the defensibility of the application of the morality provisions, as the EPO acts as the patent grant body for all classical European patents, and will also be the granting body for the new EPUE when this comes into effect. Thus, it has been questioned whether the fact that the EPO/CJEU are arguably applying the morality provisions in a differing manner undermines the defensibility of morality in this context. It is conceded on this point that the current approach is not a perfect one, because the EPO in assessing patent grant is arguably granting patents that the EU decision maker - if called upon to consider - might not grant. Having said this, on a pragmatic and logistical level, the current system allows for a supranational patent grant scheme for all EU/EPOrg Contracting States which is of commercial benefit and also provides a means for divergence amongst States at a post-grant level as after grant, the patent is dealt with by individual Contracting States. Thus, although questions arise as to defensibility in the current system, these are arguably ameliorated in this context by this post-grant mechanism.

Moreover, a further bridge between the EPOrg and EU, which could be engaged with in this context is the ECHR framework which was examined in chapter five. Given that the ECHR is something which all EPOrg and EU Contracting States are party to, it arguably has significant influence to provide for the diffusion of common principles in the application of the morality provisions. Furthermore, the ECtHR's jurisprudence could generate cross fertilisation of principles and in this respect of particular significance is the margin of discretion approach, which the ECtHR adopts in relation to moral or sensitive issues. This has already filtered into the EU's jurisprudence in this area, but not yet featured expressly in the EPOrg case law. Further attempts should arguably be made to generate dialogue across and amongst the CoE, EPOrg, and EU in the context of the morality provisions in an attempt to generate a pattern of mutual recognition and dialogue on the scope, purpose and principles to be applied in the application/adjudication of the morality provisions.

In terms of the future development, the thesis contribution highlights the significant role of institutional factors in the application of the morality provisions, and this should be incorporated into discussions surrounding the planned EPUE which was examined in chapter six. As has been seen, it is not yet entirely clear how this framework will play out in practice, but two particularly significant issues are: the unitary nature of the proposed EPUE, and the developing relationship between the CJEU and the UPCt in this context. Firstly, in relation to the unitary nature of such patents, this factor arguably precludes Contracting States from being granted a breathing space for the application of the morality provisions, preventing the application of a margin of appreciation in this context. This is arguably problematic in light of the need to respect Contracting State traditions, which is one of the primary reasons behind the morality provisions. Furthermore, it is not clear which Contracting State's view on the morality of patentability should be taken into account, or if it is an EPOrg, UPCt or EU wide consensus which will apply. Moreover, as has been seen, given the institutional influences on supranational actors in this context, and given that national courts are closer to the site where moral concerns may arise, allowing for discretion on the application of the morality provisions where necessary to preserve Contracting States moral traditions is arguably a necessary feature of these provisions. This

aspect has not been discussed in the debates surrounding the EPUE to date, and needs to be debated in full.

Secondly, the relationship between the UPCt and the CJEU needs to be considered in the context of the morality provisions, and whether in spite of the reluctance to involve the CJEU in the EPUE generally, if the UPCt will be open to referring decisions to the CJEU in the context of the morality provisions. If it were to do so, this would arguably offer a bridge between the UPCt and CJEU, and the UPCt could also act as a judicial check on the EPO's application of the morality provisions. As noted, this would be a very effective soft harmonisation mechanism as decisions of the UPCt would be automatically effective in all Contracting States, and this would be likely to put pressure on the EPOrg to converge with the CJEU position.

To conclude, the core original contributions of this thesis are the novel analytical template outlined in chapter two which is transplantable to other contexts, and the analysis of the EPOrg/EU adjudicative frameworks conducted using this template which has demonstrated the fundamental importance of institutional frameworks on the application of the morality provisions. It is crucial that such institutional considerations are borne in mind in relation to any normative proposals or reform of this area, as the institutional framework within which the morality provisions are interpreted, arguably fundamentally effects how these provisions are shaped and, in turn, are given effect. It is submitted that this contribution is particularly timely in light of the significant institutional changes proposed by the EPUE. Moreover, the stark absence of any discussion of how these institutional changes are relevant to or may affect the application of the morality provisions in this context lends support for the relevance of, and the need for, this contribution.

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