Decision-Makers, Institutional Influences and the Role of Ethical issues in the Patenting of Biotechnological Inventions in Europe: Enter the Unitary Patent System.

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Introduction

After many years of discussions and (other failed) proposals around establishing a unitary patent system in Europe,[2] the current Unitary Patent system is set to commence in June 2023.[3] There is much anticipation around the implications of this new adjudicative system for the 'European' patent landscape.[4] Such implications will likely be varied and multifaceted and may take several years to fully discern. Yet, as with the introduction of any new system, it presents us with an opportunity to reflect on the opportunities and challenges ahead, and on how we would like to envisage the role of its new adjudicative body, the Unified Patent Court (UPC). As part of this, we must consider to what extent the UPC will engage with areas of contention in patent law and whether it will maintain or disrupt the status quo in such contexts.

This chapter focuses specifically on one long contested area, namely, the role of ethical considerations in patent decision-making for biotechnological inventions in Europe.[5] More specifically, the chapter examines to what extent the introduction of the UPC– and the unitary patent system more generally – has the potential to influence the current interpretative approach for how ethical issues are considered in the patenting of biotechnological inventions in Europe. It puts forward the case for why a renewed conversation is urgently needed around what normative role ethical issues *should* play in European patent law at this juncture.

The chapter makes three main arguments. First, section one argues - as I have discussed elsewhere[6] - that whilst the role of ethical issues is contested in many fields of patent law,

[2] For a discussion of the history of proposals for a unitary patent system, see: Christopher Wadlow, "An historical perspective II: the unified patent court" in: J Pila & Christopher Wadlow (eds) *The EU unitary patent system*. (OUP, 2015); Aurora Plomer, "A unitary patent for a (Dis)United Europe: the long shadow of history" (2015) 46(5) IIC 508; K Walsh, "Promoting Harmonisation Across the European Patent System Through Judicial Dialogue and Cooperation" (2019) 50 IIC 408.

[3] https://www.epo.org/applying/european/unitary.html correct at the time of writing January 2023.

[4] The word 'European' is used to denote the patent system within European Patent Organisation States, which includes all EU States and several non-EU States.

[5] There is an extensive body of literature examining the role of morality or 'ordre public' in European patent law, this includes: Derek Beyleveld and Roger Brownsword, Mice, Morality and Patents (Common Law Institute of Intellectual Property, 1993); Lionel Bently and Brad Sherman, "The Ethics of Patenting: Towards a Transgenic Patent System" (1995) 3 Medical Law Review 275; Peter Drahos, "Biotechnology Patents, Markets and Morality" (1999) 21(9) European Intellectual Property Review 441; Margo Bagley, "Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law" (2003–2004) 45 William and Mary Law Review 469; Oliver Mills, Biotechnological Inventions: Moral Restraints and Patent Law (revised edn, Ashgate Publishing, 2010); Ana Nordberg, "Patents, Morality and Biomedical Innovation in Europe: Historical Overview, Current Debates on Stem Cells, Gene Editing and AI, and de lege ferenda Reflections" in Daniel Gervais (ed.), Fairness, Morality and Ordre Public (Edward Elgar Publishing, 2020); Karen Walsh and Naomi Hawkins, "Expanding the Role of Morality and Public Policy in European Patent Law" in Paul Torremans (ed.), Intellectual Property and Human Rights (4th edn, Wolters Kluwer, 2021).

[6] Aisling McMahon, 'Institutions, Interpretive Communities and Legacy in Decision-Making: A Case Study of Patents, Morality and Biotechnological Inventions' in: Edward S Dove & Niamh Nic Shuibhne (eds), *Law and Legacy in Medical Jurisprudence: Essays in Honour of Graeme Laurie* (Cambridge University Press, 2022).

there is a clear emphasis on the need for ethical issues to be considered within the EU's Biotechnology Directive 98/44EC (hereafter 'the Directive'). Thus, at a legislative level, I argue that there is a clear mandate for ethical issues to be considered in the patenting of biotechnological inventions. Second, and relatedly, in section two, the chapter highlights that despite this legislative mandate, at a supranational level, multiple adjudicative bodies are involved in the interpretation of these ethical provisions across the EU, European Patent Organisation (EPOrg),[7] and now the UPC contexts. The system was already institutionally complex,[8] and the UPC introduces a further interpretative community within European patent decision-making.[9] As a result, more bodies will be interpreting how ethical issues are considered for patents on biotechnological inventions. It further fragments the supranational European patent adjudicatory landscape,[10] heightening the potential for institutional tensions.[11] Accordingly, with the UPC's introduction, this section argues that a renewed and much deeper interdisciplinary conversation is urgently needed around what role ethical considerations *should* have at patent grant stage for biotechnological inventions in Europe. Finally, third, in section three, I argue that the need for this discussion is heightened because science continues to rapidly develop, thus, the ethical issues presented by patent applications for emerging biotechnological inventions are likely to increase. This in turn will pose complex questions for existing frameworks.

The chapter concludes in section four arguing that the addition of the UPC must give us pause to reflect upon how ethical considerations *are currently,* and *should in future be,* applied within the European patent system for biotechnological inventions. Within such discussions, it is vital that we are cognisant of the important role of decision-making actors, *of who decides*, on how the ethical provisions within the Directive are interpreted and operating in practice. Moreover, given the fragmented landscape applicable, it is vital that there is greater institutional dialogue across and between the relevant European patent institutions on this issue in Europe.[12]

[7]For a discussion of role of the EPOrg and EU in interpreting ethical issues related to the patentability of human embryonic stem cell technologies, and institutional tensions which may arise: see: Antonina Bakardjieva-Engelbrekt, 'Institutional and Jurisdictional Aspects of Stem Cell Patenting in Europe (EC and EPO): Tensions and Prospects' in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents in Europe: European Law and Ethics* (Oxford University Press 2009).

[8] See discussion in Bakardjieva-Engelbrekt, ibid.

[9] On the idea of interpretative communities in this context, see: Drahos (n 5), 441–2. This concept is developed and discussed further in: McMahon (n 6) ; Aisling McMahon, *The Morality Provisions in the European Patent System: An Institutional Examination* (PhD thesis, University of Edinburgh 2016); Aisling McMahon, 'An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: A Fragmented Future Too Far?' (2017) 48 *IIC* 42.

[10] McMahon, 2017, ibid.

[11] This idea of institutional tensions in the European patent framework in the EU and EPO context is discussed in: Bakardjieva-Engelbrekt, (n 7).

[12] On institutional dialogue more generally in the European patent context, see: Karen Walsh, *Fragmentation and the European Patent System* (Hart Publishing 2022); Karen Walsh, 'Promoting Harmonisation Across the European Patent System Through Judicial Dialogue and Cooperation' (2019) IIC 50, 408–440. Karen Walsh, 'Institutional Coexistence: The Necessity of Judicial Dialogue and Cooperation in the UPC' in Duncan Matthews and Paul Torremans (eds), *European Patent Law: The Unified Patent Court and the European Patent Convention* (De Gruyter 2023).

Part 1: Patenting Biotechnological Inventions in Europe: The Embedding of Ethical Considerations within the Biotechnology Directive 98/44/EC

The role that 'ethical' considerations should play in patent grant decisions, particularly, for biotechnological inventions has long been contested within Europe.[13] The term 'ethical' could be used to relate to a range of issues - this chapter uses the term in a broad sense to refer to potential concerns related to the use of a patent right, and/or to the development or use of the proposed invention for which a patent is granted or sought, in terms of the impact of this right or use of the related invention on, for example, humanity, animal life, and the environment we live in.[14]

There are a range of differing views around the role, scope and purpose – if any - of ethical considerations in patent grant decision-making in Europe.[15] Arguments for embedding such considerations in patent law for biotechnological inventions include concerns about commodification of life, human dignity, and the potential impact of patents on access/development/use of biotechnologies.[16] In contrast, others view the patent system as being a technical or inert field,[17] or one which is not configured to engage with ethical considerations.[18] The purpose of this chapter is not to provide a normative framework for how ethical issues *should* be framed in this context, nor is it to provide a normative argument for how the 'European' patent system should engage with ethical issues *per se*. Instead, it argues that although there are multiple contestations around the role of ethical issues at patent grant stage in Europe, the Directive offers a clear mandate for ethical issues to be considered in patenting biotechnological inventions.[19]

(i) Drafting of the Biotechnological Directive and Ethical Issues

The main legal text applicable to patenting technologies generally within the 'European' patent system is the European Patent Convention (EPC), this applies to all fields of inventions, and was originally adopted in 1973. It is not an EU text, instead it applies to 38 Contracting States, which include all EU States. As biotechnologies developed, uncertainties arose about the patentability of biotechnologies in Europe, and fears grew

[13] Discussions include: Beyleveld and Brownsword (n 5); Mills (n 5); Bentley and Sherman (N 5); Justine Pila, 'Adapting the Ordre Public and Morality Exclusion of European Patent Law to Accommodate Emerging Technologies' (2020) 38 *Nature Biotechnology* 555; Amanda Warren-Jones, 'Identifying European Moral Consensus: Why Are the Patent Courts Reticent to Accept Empirical Evidence in Resolving Biotechnological Cases?' (2006) 28 *European Intellectual Property Review* 26.

[14] Ethical considerations could be raised at various levels around the use of a patent right or use/development of the patented technologies. For a discussion, see, also: Cliona Kelly and Rachel Claire Brady, 'Research Ethics and the Patent System' (2022) 44(4) EIPR 209-220.

[15] This is discussed in McMahon (n 6).

[16] See discussion in Mills, (n 5). This is discussed further in: Aisling McMahon, 'The 'Ethical' Regulation of Novel Being Technologies: The Potential Role for Patents as Drivers, Blockers and Ethical Guiders' In: David Lawrence & Sarah Morley (eds). *Novel Beings: Regulatory Approaches for a Future of New Intelligent Life*. (Edward Elgar 2022).

[17] See discussion of arguments in: Bently and Sherman (n 5).

[18] See discussion, in Mills (n 5).

[19] See also McMahon (n 6).

that Europe would fall behind other jurisdictions.[20] To address this, the EU sought to adopt legislation on the patenting of biotechnologies culminating in the Directive. [21] The Directive's negotiations took over ten years,[22] and during this time concerns were raised about the ethical issues posed by patenting biotechnological inventions. This focus on ethical concerns within the drafting process, and that it passed, only after the draft was amended including to address such issues,[23] arguably highlights the concrete role that ethical considerations were viewed as playing by those involved in the legislative process.

(i) Ethical Provisions and the Directive

Notably, the Directive's final text contains several provisions which embed ethical considerations within the patenting of biotechnological inventions in Europe.[24] One of the most discussed provisions is Article 6 of the Directive. Art 6(1) states that inventions "shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation." This so-called general morality provision is similar to the general morality provision within Art 53(a) of the EPC.

However, Art 6(2) of the Directive is a new addition. It lists four categories of biotechnological inventions as unpatentable based on Art 6(1),[25] which denoted areas of contention at the time that the Directive was drafted (late 1980s-1998). However, Art. 6(2)'s list is not exhaustive. It states: "On the basis of paragraph 1, the following, **in particular,** shall be considered unpatentable:" [emphasis added]. The word 'in particular' here denotes inventions falling within these categories are automatically excluded,[26] but other categories could also be excluded from patentability, if considered to fall within the general exclusion under Art 6(1). Recital 38 confirms this, and it also states that: "whereas processes, *the use of* which offend against human dignity… are obviously also excluded from patentability" [Emphasis added]. Importantly, within this recital, the focus appears to be not just on ethical objections to the *patentability* of a technology, but also ethical objections to the *'use'* of the technology which a patent is applied for. Thus, whilst Article 6(1) highlights that patents are excluded where the 'commercial exploitation' of an invention is against *ordre public*/morality, this recital suggests consideration also of the *use* of the technology/process.

Alongside the morality provisions, there are several other references to ethical issues within the Directive. These include, Art 5(1) which states: "The human body, at the various

[20] Gerard Porter, 'The Drafting History of the European Biotechnology Directive' in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents in Europe: European Law and Ethics* (Oxford University Press 2009)
[21] Ibid.
[22] Ibid.
[23] The first draft was rejected, see discussion in Porter (ibid).
[24] This is discussed in detail in: McMahon (note 6).
[25] These are: (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.
[26] See discussion in McMahon (note 6).

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." This provision suggests legislators were concerned about the ethical issues posed by potential patent applications related to the human body, and sought to exclude patents being granted directly over the human body or its parts.[27] Furthermore, several other recitals – which provide guidance on how the legislation is to be interpreted – refer to the need to take ethical considerations into account. These include Recital 16 which refers to the need to apply patent law in a manner that respects "the dignity and integrity of the person,"[28] and Recital 43 which refers to fundamental human rights.

Considered together, these provisions arguably embed a consideration of ethical issues posed by the patentability, development, and use of biotechnologies within the Directive. Accordingly, regardless of broader contestations around whether ethical issues *should* be embedded in patent law, within the EU context reading the Directive's text literally, there are clear references to, and thus, arguably, a clear mandate for ethical issues to be considered in patenting biotechnologies.

Part II: Applying the Directive's Ethical Provisions in Europe: Interpretative Communities, Institutional Overlaps & Influences

Having said this, in practice, the effect of these legal provisions depends on how they are interpreted and applied by the relevant decision-making bodies within the 'European' patent system.[29] At a regional level a complex and overlapping institutional framework applies in this context, and the introduction of the UPC (in its current form) further complicates this framework. Thus, this section argues that it must make us pause to consider how these ethical provisions *should* apply, and relatedly, to what extent the institutional frameworks within European patent law are conducive to this aim.

(a) Ethical Provisions within the Directive & Practical Interpretation – Pre-UPC

Prior to the coming into force of the UPC, the European patent system for how ethical provisions in the Directive are applied already involved a complex overlap of EPOrg and EU functions. This is because even though the Directive is an EU text, the European Patent Office (EPO) is the main patent grant body in Europe. Therefore at a regional level, it is the Examining Divisions and Boards of the EPO, not the decision-making bodies within the EU, that have the most significant role in interpreting how these provisions apply on a day-to-day basis.[30] Under the 'European' patent system – prior to the UPC system coming into effect – there is no unitary 'European' patent per se. Instead, there is a single application route to apply for patents in a range of the 38 EPC Contracting States. An applicant would apply to the EPO, for a patent, and if granted would obtain a bundle of national patents this is the so-called 'classic European patent' route. Under this process, it is the EPO bodies

[27] See also, recital 21-22. The effect of this provision has been narrowed by Art 5(2).
[28] See also recital 39.
[29] McMahon (n 6).
[30] See also discussions in: Bakardjieva-Engelbrekt (n 7), 227; McMahon 2016 (n 9); McMahon 2017 (n 9).

that consider the application's compatibility with the patentability requirements, including considering, the ethical exclusions against patentability. Furthermore, post-grant the EPO has Opposition Proceedings which is a mechanism to challenge a patent at the regional level soon after it is granted, providing an additional avenue for EPO interpretative influence over how such provisions are applied.[31]

In contrast, the EU's adjudicative body, the Court of Justice of the European Union (CJEU), is only involved in adjudicating how such ethical provisions in the Directive are interpreted in a narrow range of circumstances such as, for example, if a preliminary reference by a national EU Member State is made about the interpretation of the Directive. However, such preliminary reference cases are relatively rare in practice in this context, and certainly would not afford the EU the same level of day-to-day practical interpretative influence over how the ethical provisions of the Directive are applied, as the EPO adjudicatory bodies have.

Moreover, the EPO is not an EU entity, and its Contracting States include all EU States, but also non-EU States. After the Directive was adopted, the EPO adopted it as supplementary interpretation for the EPC.[32] Thus, the bodies of the EPO are in theory, informed by these provisions. However, the EPO is not legally bound to follow the EU's approach. Moreover, as will be discussed below, considerable discretion applies for decision-making bodies in relation to setting the threshold and contours of the ethical provisions within the Directive, this widens the potential significance of decision-makers' influence in this context.

(b) Institutional Overlaps & Ethical Considerations – Enter the UPC

The supranational institutional complexity in the current system is increased by the UPC commencement because rather than offering a single patent system for EU States, the new unitary patent and UPC will exist alongside the current EPO and national systems. Moreover, the UPC does not have its own patent grant body, instead such applicants need to apply under the EPO's single application route system for this. Thus, the EPO remains the patent grant body for unitary patents. If the application is granted, it is converted into a European patent with unitary effect, and potentially, also other relevant patents will be granted for States who have not signed the Agreement on a Unified Patent Court (AUPC),[33] depending on the application. However, the key difference is that if granted, the UPC will have jurisdiction over any unitary patents and also for 'classic' European patents granted in States which have signed up to the AUPC.[34]

Thus, once this system commences, it will lead to a scenario where several different overlapping types of patent routes, and differing avenues/implications in terms of which decision-making actor adjudicates over the patent post-grant within Europe. These will include, the possibility of: (1) an application to the national patent office in an EPC

[31] There are also avenues to challenge patents for each national patent granted, at the national level, this is beyond the scope of this paper.
[32] Rule 26, Implementing Regulations to the EPC.
[33] Council Agreement on a Unified Patent Court (2013/C 175/01)
[34] This is unless applicants have opted out of the UPC system during the transitional period.

Contracting State for a national patent whose post grant life is adjudicated over by the national State; (2) an application to the EPO for a European patent with unitary effect whereby the jurisdiction for this patent after grant would be dealt with by the UPC; (3) an application to the EPO for a bundle of patents in EPC Contracting States where post grant each patent is dealt with by the national State for non-AUPC States or in cases where applicants have opted out for the transitional period, and if some of these are applied for in States which have signed/ratified the AUPC the post grant jurisdiction of these patents is overseen by the UPC.[35] It will also be possible, to apply for a combination of these under the EPO route e.g. a single application to the EPO for patents in a range of non-AUPC States alongside a European patent with unitary effect for relevant AUPC States.

As noted, transitional periods will apply after the new system comes into effect which means that applicants can opt-out of the unitary patent system for EPO granted patents in AUPC Contracting States for a certain period, currently proposed as seven years.[36] During the transitional period, where applicants opt-out such European patents will fall under the jurisdiction of the national States, rather than the UPC.[37]

At the post-grant stage, the UPC will have a role in interpreting the ethical provisions within the European patent system, for patents within its jurisdiction such as, if a patent is challenged under revocation proceedings.[38] Currently, revocation proceedings are considered by national courts. After the UPC enters into force, revocation proceedings would fall under its remit for unitary patents and for patents that are granted by the EPO in States which have signed and ratified the AUPC (provided applicants have not opted out during the transitional period). All non-EU States including the UK will fall outside this jurisdiction because only EU States can participate in the unitary patent system. Hence, revocation actions for such States remain under the jurisdiction of their national States. Furthermore, whilst the UPC is not an EU court per se, it has a link with, and may refer questions, to the CJEU aimed at ensuring EU law is applied in a consistent manner.[39]

Alongside this, opposition proceedings under the EPO system will remain possible for all patents granted by the EPO, including patents with unitary effect. As highlighted elsewhere,[40] if a patent is rendered invalid by the UPC, this would only apply to patents in States party to the AUPC, and would not apply to that patent in other EPC Contracting States. This could create further potential for institutional divergence and tensions in the

[35] See McMahon 2017, (n 9), p 51 citing: Hilty RM, Jaeger T, Lamping M, Ullrich H, "The unitary patent package. Twelve reasons for concern" *Max Planck Institute for Intellectual Property and Competition Law*, (17 October 2012).

[36] This is correct at time of writing January 2023.

[37] See: Art. 83(3) AUPC; see also: Luke McDonagh, Exploring perspectives of the unified patent court and unitary patent within the business and legal communities. (UK IPO 2014) at 9.

[38] Art 138(1)(a)EPC states that one ground for revocation is that "(a) the subject-matter of the European patent is not patentable under Articles 52 to 57;" under this it could be argued that a patent should not have been granted on the basis of ethical issues at stake.

[39] Art. 21 AUPC., See McMahon 2017 (n 9), 60.

[40] McMahon 2017, (n 9) 52.

context of how ethical issues are considered for biotechnological inventions and more generally.

Accordingly, once the UPC comes into effect, the ethical provisions within the Directive will be considered at a supranational level by three entities under the following main avenues: the EPO in considering patentability of inventions at patent grant stage, and challenges under opposition/appeal proceedings; the UPC will have a role in deciding matters of revocation for unitary patents and European patents granted by the EPO in AUPC Contracting States; and the CJEU will retain a role in providing guidance on preliminary rulings if the UPC or national courts request this, this could include guidance on questions raised about the interpretation of ethical provisions within the Directive. Thus, three overlapping supranational bodies will be involved in the interpretation of these provisions – each with differing institutional features and differing compositions of applicable State parties.

(c) Interpretative Communities and the UPC's role in interpreting ethical provisions within the Directive

Given this context, it is important to consider, to what extent and how this institutional change might influence how ethical considerations are applied within the European patent system. One could argue that because the legal text – the Directive – applies to various extents in all frameworks, as EU law has primacy within the UPC, and the EPO has adopted the Directive as supplementary interpretation for the EPC, all such bodies should, in theory, be applying the text in a similar manner. However, this section questions this by highlighting the importance of the institutional influences at play.[41] It argues that: (1) as much discretion is left to decision-making actors on these provisions, and (2) due to the differing institutional features of each decision-making framework they will have their own distinct interpretative community for the interpretation of provisions.[42] This in turn, means the three supranational decision-making actors involved could lead to differing approaches on these provisions, and heightened potential for institutional tensions within the system.[43]

(i) Ethical Issues, Discretion & the Interpretative Role of Decision-Makers in the European patent system

If we consider the ethical provisions in the Directive, due to their wording and the concepts within them -around which there is limited consensus - many of these provisions require decision-making actors to exercise discretion in interpreting them. Essentially, such provisions are open-textured and decision-making actors, put the flesh on the bones of such provisions in their application.[44] For instance, take Art 6(1) of the Directive. To exclude a technology from patentability under this provision, decision-makers would need to

[41] See also McMahon 2017, (n 9)
[42] Drahos (n 5).
[43] This concept was discussed in the context of the EPO/EU and hESC patents by Bakardjieva-Engelbrekt (n 7)
[44] See discussion of such open textured principles in: Hart HLA, *The concept of law*. (Oxford University Press, 1961) 199–200, as cited in: McMahon, 2017 (n 7), 56

assess to what extent its 'commercial exploitation' is contrary to 'ordre public' or 'morality'. This is not a straightforward assessment and decision-makers have considerable latitude in assessing what counts as 'commercial exploitation', 'ordre public' and 'morality'. Furthermore, even for the listed exclusions under Art 6(2), technologies are rapidly evolving, and thus, the legal text has not always kept pace with the science. Thus, decision-makers must exercise discretion in how these provisions apply. This is evident in cases involving whether technologies involving the creation of a human embryonic stem cells or parthenotes would be patentable given the exclusion under Art 6(2)(c).[45] Similarly, other ethical provisions in the Directive's text refer to concepts such as dignity and human rights – assessing to what extent granting patents over biotechnologies or using/developing biotechnologies may impact human rights/dignity also requires decision-makers to exercise discretion reinforcing decision-makers interpretative role in such contexts.

As an aside, another important issue in terms of questions of discretion in this context, is that Member States have been recognised as having a margin of discretion in applying the general morality provision under Art 6(1).[46] This 'scope for manoeuvre' is provided to take account States different social and cultural contexts applicable and which Member States are better placed to understand.[47] However, the European patent with unitary effect is unitary in 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 …"[48] This unitary character suggests for such patents there is no avenue for accommodating divergence between States on moral issues, and is likely another issue which will need to be considered as the UPC comes into effect.[49]

(ii) Institutional Influences and Overlapping EPO, CJEU and UPC functions: Interpretating ethical provisions in the Directive

Moreover, as I have argued elsewhere, [50] institutional theories suggest that within any decision-making framework, there will be both legally constraining influences and persuasive influences on decision-making actors which, in turn, may affect how decision-makers interpret legal provisions in practice. Legally constraining factors include the legal competences of that body as contained within its founding legal text and prior case law which may create binding precedents. Whilst persuasive influences include the composition of decision-making actors within that body, as evidence suggests that if such actors come from a similar background e.g., from scientific/technical fields, where ethical issues are either rarely examined within their remit, or marginalised, such actors may continue this status quo when they are required to engage with such provisions. If bodies

[45] Wisconsin Alumni Research Foundation (WARF) (G002/06), Decision of the Enlarged Board of Appeal 25 November 2008; n Case C-34/10 Brustle v. Greenpeace eV [2011] E.C.R. I-9821, and Case C-364/13 International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trade Marks, Judgment of the Court, Grand Camber, 18 December, 2014.
[46] Case C-377/98 Netherlands v. European Parliament and Council, Judgment of the Court, 9 October, 2001,
[47] Ibid, para 37-38.
[48] Recital 7 of Regulation 1257/2012.
[49] McMahon, 2017 (n 9) 62-65.
[50] McMahon 2016; McMahon 2017 (n 9).

such as the EPO, CJEU or UPC are called upon to determine the application of any of the provisions which embed ethical considerations within the Directive for patentability, they will arguably each consider the text of such provisions by filtering these through their own distinct institutional lens to give an application of such provisions.[51]

In contexts where legal provisions require decision-makers to exercise limited discretion[52]– the institutional influence may have limited effect. However, in cases where discretion needs to be exercised, decision-making bodies are more likely to be constrained and persuaded to apply provisions in line with institutional frameworks within that decision-making body.

Furthermore, in terms of the institutional frameworks applicable, each of these three supranational bodies share some similarities, but also key differences. For example, both the EPO and UPC will be comprised of primarily scientific and technical experts, and where legal experts sit on these bodies, they are likely to be experts within patent law, and hence, drawn largely from commercial practice. Such individuals may likely have limited broader engagement with ethical issues previously. This in turn may reinforce a likelihood for such actors to engage in a light touch manner with such provisions/questions. Indeed, the EPO in cases involving the ethical provisions to date, has demonstrated an acute reluctance to engage deeply with ethical issues related to the patentability of biotechnological inventions. [53] In contrast, the CJEU is a generalist legal court composed of legal experts drawn from all legal fields and may likely have broader experience in engaging with questions related to human rights, ethics etc. – and relatedly, less familiarity with specific aspects of patent law which may bring other issues.[54] Based on these features one might predict that the UPC may be likely to adopt a similar light touch approach to the ethical considerations as the EPO has to date. Having said that, much will depend on to what extent the UPC refers questions to the CJEU.[55] This may give the CJEU greater involvement in the field and greater influence over these and other provisions. Furthermore, although the UPC is not an EU supranational court per se, as noted, EU law has primacy within the UPC, and this may influence how it deals with these ethical provisions - only time will tell how the UPC will impact this area.

In short, at a supranational adjudicatory level, the role of ethical considerations in patent grant decisions for biotechnological inventions involves a complex institutional landscape and mesh of functions including the EU and EPOrg and UPC actors. Thus, even though the Directive is an EU legislative text, the EPO is the primary body which interprets the law in practice. To date, the EPO has had the main role in guiding the interpretation of these provisions in everyday patent practice and has done so in a light touch manner. The EPO will continue to have a key role under the unitary patent system as it remains the patent

[51] McMahon 2016, note 9.

[52] For example, under Art 6(2) provisions whereby if an invention falls squarely within the definition of the provision it is automatically excluded.

[53] See discussion in: McMahon 2016 (n 9); Walsh and Hawkins (n 5).

[54] See discussion in Brinkhof J, Ohly A, Towards a unified patent court in Europe. In: Ohly A, Pila J (eds) The Europeanization of intellectual property law. (Oxford University Press 2013) at 215.

[55] See also McMahon 2017, (n 9) 60-62.

grant body for unitary patents. Nonetheless, the UPC will now also have a role at post-grant stage should questions on the ethical provisions related to patents over biotechnological inventions arise before it. How the UPC will engage with these provisions remains unknown, but it will likely be affected by the institutional framework which exists within the UPC, and which differs to both the CJEU and EPO frameworks. This opens new possibilities for divergent interpretations and demands a much more joined up approach and conversation around the role of ethical provisions within and across these institutional frameworks/actors.

Part III. Technological Developments and the need for a renewed conversation on the Role Ethical issues should play within the European Patent System

Alongside the increasing institutional complexity in the European patent system, which the UPC system will exacerbate, the scientific field for biotechnologies is constantly advancing. Accordingly, the ethical issues posed by patent grant (and use) of emerging biotechnologies are likely to intensify in the coming years as the nature of biotechnologies continue to develop at pace. These include, for example, the increase in cell-based therapies for human application such as CAR-T;[56] advances in gene-editing technologies such as CRISPR; and the potential for biotechnologies to be used to develop novel being technologies including using those created via biotechnologies that may resemble humans but not quite be human.[57] A myriad of ethical questions arise over the patentability of such technologies, including re-igniting questions around commodification of the body, around whether such patents would infringe on human dignity, and the broader (bio)ethical questions around the role of patents in encouraging the development of contentious biotechnologies, and around the impact of such patents on access to health-related biotechnologies.

Moreover, within the patent field, there is now also a growing focus on patents potential broader governance functions.[58] Patents give rightsholders the right to stop others using an invention for generally 20 years. However, this in turn allows rightsholders to dictate the terms of access to the invention, and to shape how technologies are used and developed. How patent rights act as governance devices and affect the development, use and access to biotechnologies pose further ethical issues, which may be exacerbated as such technologies develop.

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[56] See also: Luis Gil Abinader, and Jorge L Contreras, The Patentability of Genetic Therapies: CAR-T and Medical Treatment Exclusions Around The World" (2019) 34(4) American University International Law Review 705.

[57] David Lawrence & Sarah Morley (eds), *Novel Beings: Regulatory Approaches for a Future of New Intelligent Life*. (Edward Elgar 2022).

[58] Aisling McMahon, "Biotechnology, Health and Patents as Private Governance Tools: The Good, the Bad and the Potential For Ugly?" (2020) 3 *Intellectual Property Quarterly* 161; Shobita Parthasarathy, '"Use the Patent System to Regulate Gene Editing'" (25 October 2018) 562 *Nature* 486; Duncan Matthews, et al, "The Role of Patents and Licensing in the Governance of Human Genome Editing: A White Paper" (2021) Queen Mary Law Research Paper No. 364/2021; Naomi Scheinerman and Jacob S. Sherkow, "Governance Choices of Genome Editing Patents" (2021) 3 Frontiers in Political Science No. 745898; Jacob Sherkow, Eli Y. Adashi and Glenn Cohen, "Governing Human Germline Editing Through Patent Law" (2021) 326(12) Journal of the American Medical Association 1149.

Furthermore, at a practical level, the Directive marks its 25th year in 2023 and many provisions of this legal text related to ethical issues have been outpaced by scientific developments.[59] This could result in further challenges arising before the adjudicative bodies in Europe, which could require difficult decisions. It could also potentially, in the not-so-distant future, result in pressure for legislative change to amend the Directive or Implementing Regulations to the EPC, addressing ethical issues, depending on how technologies develop.

These developments will place further pressure on the EPO, EU, and now UPC to consider how they engage with ethical considerations posed by patents – and how they are used – over biotechnologies in future. This adds further impetus for a renewed interdisciplinary conversation on the role that ethical considerations should play within the European Patent system, involving dialogue across the EPO, UPC and CJEU and with relevant stakeholders.

Part Four: Concluding Thoughts

In short, even though the role of ethical issues in patent law generally is contested, various provisions within the text of the Directive demonstrate a recognition of the need to consider ethical issues in the patenting of biotechnological inventions within EU States. However, how such provisions play out in practice depends on how they are interpreted by the decision-making actors involved. In this context, at a supranational level, the European system within which such ethical provisions for biotechnological patents apply, is institutionally complex. It involves the overlap of EPO, EU, and now UPC decision-making bodies. Moreover, it remains to be seen how the UPC, and the unitary patent system more generally, will engage with such provisions – only time will tell. There is potential it will offer greater more nuanced engagement with ethical issues in this context, but it is also plausible that the UPC will maintain the status quo light touch approach to such provisions, akin to the EPO's approach to date.

This chapter argues that, given the increasing institutional complexity which the UPC brings, and given the increasing ethical issues likely to arise in the patenting of biotechnologies due to the pace of scientific developments, the time is long over-due for a renewed conversation on the role of ethical issues in this area. It is vital that this conversation would take places across the EPO, EU, UPC institutions and would involve input from relevant stakeholders and interdisciplinary experts in order to consider what role ethical issues are *currently playing* in the patenting of biotechnologies, what is the intended role that *ethical issues should* play in this context in light of obligations within the Directive and other applicable legal instruments, and importantly, within such contexts, what is the role of the various adjudicatory bodies involved in achieving this.

[59] For example, Art 6(2) provisions have required interpretation in light of scientific developments.