Cambridge Quarterly of Healthcare Ethics (2021), 30: 3, 529–542
doi:10.1017/S0963180120001073

CAMBRIDGE UNIVERSITY PRESS

ARTICLE

Patents, Governance and Control: Ethics and the Patentability of Novel Beings and Advanced Biotechnologies in Europe

Aisling McMahon

Assistant Professor in Law, Maynooth University, Mariavilla Maynooth, Co. Kildare, Ireland
Corresponding author. Email: aisling.mcmahon@mu.ie

Abstract
This article focuses primarily on to what extent novel beings, and particularly, beings which display something akin to human consciousness or agency would be (or should be) patentable under current European patent law. Patents grant the patent holder a right to exclude others from using the patented invention for the period of patent grant (usually 20 years). This allows the patent holder to control how that invention can or cannot be used by others downstream, granting patent holders a governance like function over the patented technology for the duration of the patent. Accordingly, the potential for patentability of novel beings gives rise to a myriad of ethical issues including: to what extent is it appropriate for patent holders to retain and exercise patents over "novel beings"; how issues of "agency" displayed by any "novel beings" would fit within the current patent framework, if at all; and to what extent existing exclusions from patentability might exclude patents on "novel beings" or whether changes within patent law may be needed if patents in relation to "novel beings" are deemed ethically problematic. This article focuses on such issues, and in doing so, also sheds light on the role of ethical issues within the patenting of advanced biotechnologies more generally.

Keywords: Patents; Patent ethics; biotechnology; novel beings; morality provisions; European patent law

Introduction

A patent gives the patent holder the right to exclude others from using the patented invention for the period of patent grant (usually 20 years)without the patent holder's permission (via a license). This creates the potential for the patent holder to obtain a monopoly over the invention, as it allows the patent holder to decide whether to license an invention for use to third parties, and how much to charge for such licenses. However, the nature of patents, and the control they divest over the patented invention can create considerable ethical issues—this has been particularly evident in the context of patents over medicines, as depending on the patent holders actions, such patents can be used to give rise to increased costs of medicines and/or limit supplies of medicines available, thereby hindering access to medicines.[1] Moreover, ethical issues posed by patents go far beyond issues of access, including questions around the appropriateness of patenting certain technologies. The potential for the development of "novel beings" and patent applications arising in relation to such beings is an example of a scenario likely to give rise to a myriad of ethical questions, including to what extent is it appropriate for patent holders to retain and exercise patents over such technologies or "novel beings?" This article focuses on how such questions may be accounted for, if at all, within European patent law. In this context, "novel beings" is used to denote beings/technologies which may in future display something akin to "consciousness," albeit they are not human beings, and/or beings/technologies which display characteristics of agency akin to human agency or "will."[2] Thus, such beings/technologies could act in a way that appear "conscious" or could exercise their own actions with agency. Based on current technologies, it is envisaged that, if such

"novel beings" were to arise, they are most likely to be developed in the context of advanced artificial intelligence technologies or advanced biotechnologies.

Moreover, whilst science is not yet at the stage of "novel beings" and it is conceded such beings may never be developed, such questions are still important to anticipate and to foresee challenges which may arise should technologies develop to this extent. Furthermore, even if technologies do not develop to the stage of creating "novel beings" *per se*, emerging technologies in the artificial intelligence and biotechnological sphere, are often highly ethically contentious and the arguments raised in this article provide broader insights for the role of ethics in the patenting of such technologies. In particular, the development of ethically contentious technologies gives rise to important questions for patent law, including: (1) to what extent such technologies should be incentivized via patent grant if they are ethically contentious; and (2) how patent holders' control over the development of such contentious technologies should be regulated downstream, if at all. For example, if technologies give rise to significant ethical questions, such as recent debates around the use of CRISPR gene-editing technologies in the human embryo context,[3] then should we be encouraging the development of technologies or related processes via patents? Alongside this, if patents are granted over ethically contentious technologies, to what extent should patent holders be allowed control over how such patented "inventions" are used downstream via licensing, and should patent holders retain the largely unfettered discretion which they generally have over the use of patented inventions in such contexts? Alternatively, should the patent system be used as part of a broader approach to regulate and govern contentious technologies such as gene-editing, or to complement regulatory approaches related to such technologies?[4]

This article focuses primarily on the question of to what extent novel beings, and particularly, beings which display something akin to human consciousness or agency would be patentable in Europe. This includes a discussion of the ethical issues that patenting "novel beings" would be likely to pose, and the extent to which current patent practice could accommodate such ethical considerations. In taking this focus, the related issue of how patent holders should use patents over such technologies (if granted), including how they choose to license such technologies is also a significant one. In this latter context, many patent holders in the biotechnological field particularly are likely to be companies, or large corporate entities given the costs/resources needed to conduct biotechnological research and funding needed to translate such research into practical applications. Company directors' primary duty is toward the welfare (and profit maximization) of the company's shareholders, and therefore a key concern in technology development from a company perspective is how to ensure an investment stream from the development of technologies. In this context, intellectual property, including patent law—the primary focus of this article—comes into play. Companies will often seek to obtain intellectual property protections, such as patents over such new inventions, including where possible advances in biotechnologies, artificial intelligence, and potentially in future "novel beings" to retain control over and develop an income from such "technologies." The role of companies as patent holders, and the appropriateness of their decision-making role over the patented invention, particularly when the technology under patent is ethically contentious, is an important issue. As the author has argued elsewhere patent holders effectively exercise a private governance role over the invention for the duration of the patent dictating how the invention is used downstream with knock-on impacts for a range of related technologies, however, due to limits of space, this latter issue is beyond the scope of this current article but should be borne in mind in the arguments discussed.[5]

The article is the first to examine the extent to which "novel beings" would be patentable and the extent to which having consciousness or agency (albeit non-human) would be an exclusionary factor against patentability. In doing so, the arguments raised here, given that they explore issues of whether agency and qualities of consciousness may be considered as factors which limit patentability of an invention under European patent law, have broader potential implications and resonance for debates in patent law over the patentability of sentient transgenic animals. Such arguments also have resonance for future possibilities within biotechnology, such as, for example, de-extinction—which seek to re-introduce or develop extinct species or animals which look akin to extinct species.[6] In such contexts, for example, a myriad of ethical issues would arise if de-extinction projects were applied to the context of

resurrecting de-extinct early human species, including questions around the potential patentability of such beings, where issues including agency and consciousness will likely be argued as factors which should exclude patentability.[7] Furthermore, the article provides broader insights into the marginalization of ethical issues within patent law, and the disjoint between how ethical issues are examined within patent law— often in a light touch superficial manner—in comparison to how analogous ethical issues are considered within other contexts such as within medical law or bioethics.

In making these arguments, the article is structured as follows: Part I sets the foundations for the arguments by briefly outlining the nature of patents and requirements for patentability in Europe. Part II draws on this background to argue that exclusions from patentability exist and could be used to incorporate ethical concerns around patentability. However, such exclusions tend to be interpreted highly restrictively by patent offices and it is unlikely these provisions would exclude the patentability of non-human "novel beings" on the basis of consciousness or agency *per se*, if current interpretative patterns within European patent law prevail. Part III then concludes arguing that the scope for considering ethical issues in the patenting of novel beings (should they be developed) requires reconsideration, as does the way in which ethical issues more generally are considered within European patent law.

Part I: Patents, Incentives, and Control: The Power of Patent Holders

To be patentable, an invention must fulfill three main criteria: novelty, inventive step, and it must have an industrial application (i.e., technical effect).[8] The object or process which is the subject matter of the patent application must also fall within the definition of an "invention" for the purposes of patent law.[9] It cannot for example be a discovery or something naturally occurring in nature *per se*. Although, the idea of a discovery has been interpreted by the European Patent Office in a relatively narrow manner,[10] and patents are allowed in some contexts on naturally occurring substances provided they are made available in isolated form and have a technical application, for example, genes isolated from the human body.[11]

The grant of a patent divests significant control to the patent holder, as once granted, the patent holder can decide if they will license the invention to third parties, and to which third parties, or they refuse to license the technology/process. If they decide not to license the invention, or if they decide to license it only for a high cost, this can significantly affect access to the invention. The patent holder could also impose restrictions on how the invention is licensed including restrictions on downstream use of that invention. The latter type of restrictions could, for example, affect the development of the technology downstream, and accordingly, indirectly shape other fields contingent upon the use of that patented invention. If a third party uses a patented invention without permission from the patent holder, they would be infringing the patent, which could lead to legal sanctions, including financial awards against them. In short, patents have important downstream consequences for the use and subsequent development of patented technologies and related technologies and the author has argued elsewhere these can amount to a private governance function as patents allow the patent holder to steer downstream development and use of a patented invention for the duration of the patent.[12]

From a legal jurisdictional perspective, there is no global patent system *per se*;instead, patent law is governed separately by each country or jurisdiction – although some regional legal instruments apply. An example of a regional patent instrument is the European Patent Convention 1973 (EPC) which applies in 38 European States, including all European Union States. The EPC sets out minimum standards for patenting in Europe. It also established a single patent application route for individuals seeking patents in more than one EPC State. Alongside such regional and national systems, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was adopted in 1995 and sets out minimum standards for patentability for all Contracting States. Participation in the TRIPS Agreement was necessary for all World Trade Organization (WTO) Members to gain access to the other WTO benefits, hence it has wide global participation.[13] Importantly, Article 27 TRIPS Agreement

provides that patents "shall be available …*in all fields of technology*." This means WTO Member States cannot refuse patents on particular areas.[14] Thus, at least in theory, States could not provide a blanket refusal for patents on technologies deemed to be "novel beings" *per se*.

This article focuses primarily on European patent law and on the context of biotechnology (or novel beings arising from biotechnological developments) in discussing questions around the patentability of novel-beings. This focus was chosen as a case study because in Europe there is tailored legislation dealing with the patenting of biotechnology which contains specific exclusions against patentability based on ethical issues. Many other jurisdictions do not have similar exclusions from patentability based on morality or ethical issues for biotechnologies or other technologies. Hence, European patent law, and particularly as it applies to biotechnologies, at least on paper, is one of the jurisdictions most open to considering ethical issues in the grant and refusal of patents. Therefore, an examination of the European framework should in theory demonstrate considerable potential for ethical issues to be considered in the patenting of "novel beings." Patents applied for in many other jurisdictions or other contexts are arguably even more likely to be patentable given the lack of provisions accounting for ethical issues in many other jurisdictions.

Part II: Patents and Novel Beings: Non-human Consciousness as a Bar to Patentability?

The potential for the future development of novel beings via biotechnologies or artificial technologies raises a multitude of ethical questions, including to what extent such novel beings should be patentable? It is useful to consider at the outset the likely consequences of granting patents on such beings (if developed). A patent, as noted, gives the patent holder the right to determine who uses that "invention" subject to patent. The patent holder can refuse to allow others to use the invention and can determine how the invention is used via licensing. They can also place conditions on the use of the invention in patent licenses. If the patented technology were a novel being, exhibiting something akin to consciousness, the patent holder would be entitled to control who used that invention, how the invention was used, and who could not use it for the duration of the patent.

To further complicate issues, we can imagine a scenario where the invention itself—the novel being—demonstrated something akin to human agency; this would raise tricky ethical and legal questions. For example, what if the patent holder refused to allow a third-party X use the "invention" (the novel being), but the novel being subsequently agreed to work for or be used by X? Could the novel being be held responsible for patent infringement? This would be highly unlikely as the novel being is the invention in the example given; it is not the party using the invention in a manner constituting the alleged infringement. Moreover, even if it were possible to raise such a challenge, if the novel being has no legal status then infringement litigation would be legally impossible as one could not enforce a judgment against an entity that has no legal status. Instead, if any infringement were found it would be more likely that the third party X would be liable for patent infringement if they should have known this use was not approved by the patent holder.

Nonetheless, if a novel being had agency of this kind, an arguably more pressing ethical question, would be to what extent it would be ethically desirable/appropriate to allow patentability of that being? Would this amount to an illegitimate exercise of control over a being—akin to, for example, slavery in the human context?[15] In this vein, the EPO has stated that patents cannot be provided on human beings as this could amount to slavery.[16] This idea of patents potentially amounting to slavery was discussed in the *Relaxin* case, where a patent was sought over the gene encoding for the human hormone Relaxin, naturally released during childbirth, and investigated for pain relief purposes.[17] One of the objections raised against the patent was that patents on human genes could lead to "a form of modern slavery." This objection was rejected by the EPO which held that such patents did not give rights over individual human beings, rather they related to isolated genes in that context. Yet the scenario presented by novel beings examined here differs in that a patent could plausibly be applied for over a novel being, if that being did not exist in nature and therefore was deemed to be an invention as opposed to a discovery. A patent over a

novel being could potentially, under the example given, be used to seek to curtail actions of that being, yet nothing within patent law preventspatents on such novel beings due to their potential agency *per se*. Moreover, there have been no statements on patents and potential issues of slavery in the non-human context (undoubtedly because technology has not developed this far and indeed might never but if it does so—or also arguably, if, for example, de-extinction attempts are ever used to produce beings akin/resembling former human species[18]—this will need reconsideration).

Another question is whether it would be practically futile to allow patents in such contexts, as if the object of the patent had agency and was capable of granting permission or indeed agreeing to being used by others, then how could/should patent law operate in such contexts? It is conceded, that science is not at this stage yet, and many of these questions may never arise in reality. Nonetheless, given ongoing discussions about autonomous technologies that will likely be developed further in the future, such questions deserve careful consideration to pre-empt such possibilities, especially given the difficulties in foreseeing technologies.[19] For now, careful monitoring of technologies are needed, and in particular, monitoring of the extent to which any technological developments displaying features akin to human consciousness/agency are perceived or are being developed. Should technologies displaying such features develop this will reignite questions on the ethical probity of patents in relation to such "technologies" and how such ethical issues should be accounted for in patent law.

Assuming that such novel beings were developed, it is questionable whether existing exclusions from patentability would exclude the patents on "novel beings," or whether patent law would need to be reconfigured to exclude patents on such "technologies" (if a consensus developed that such novel beings should not be patentable). There are several avenues within European patent law where such arguments could be raised which the article now turns to consider.

1) Novel Beings as Patentable "Inventions"?

The patentability of novel beings would depend on whether such technology fulfilled the general patentability criteria of being novel, demonstrated an inventive step, and showed industrial application. However, a patent can also only be applied for on something which falls under the definition of an "invention." The EPC, as in other jurisdictions, has a wide interpretation of what can amount to an "invention" for the purpose of patentability set out in Art 52 EPC.[20] None of these patentability criteria or the definition of the invention under the EPC exclude patents on novel beings *per se*, but could, for example, have implications depending on the type of technologies used to create the novel being. For instance, Art 52(c) EPC states that "schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers" are not considered inventions under the EPC and this could have implications for patents on algorithms should this be how such "novel beings" were created.[21] However, nothing in Art 52 EPC would exclude patents on novel beings *per se* by virtue of them demonstrating something akin to consciousness.

Having said this, Art 52 EPC states that "[t]he following *in particular* shall not be regarded as inventions" [emphasis added]. This implies that the list of technologies not regarded as an invention for the purposes of patent law under the EPC is not an exhaustive list and could include other categories or objects outside the list. However, to deem anything excluded from patentability under Art 52 would require significant consensus within EPC Contracting States, and could risk non-compliance with the TRIPS Agreement which as noted provides patents are available in all fields of technologies in all World Trade Organisation States. It would also require a precise definition of what the category to be excluded covered and what characteristics would have to be met before an object purporting to fall within that category would be excluded from patentability. Moreover, there is nothing to suggest that the categories under Art 52 are excluded because of ethical issues related to the patentability of the technology. Instead, many of the categories are excluded under Art 52 from being considered an invention for patent law on the basis that they are not man-made inventions and instead are seen as discoveries, or that they are abstract ideas and hence protectable by other branches of intellectual property; for example, aesthetic creations are protected by copyright. Therefore, it is questionable on what basis one could exclude

patentability of "novel beings" under Art 52 EPC and there is nothing to suggest that the criteria limiting what is an "invention" under this provision is linked to ethical issues.

2) Exclusion of "Novel Beings" from Patentability Under the Morality Provisions

One of the primary avenues in Europe to challenge the patentability of ethically contentious technologies to date has been the morality provisions under Art 53(a) EPC. However, invoking such provisions to deny patentability is rarely successful in practice and the EPO decisions to date have generally shown a reluctance to engage with ethical issues, and a very narrow construction of the role of morality/ethics within patent law. Art 53(a) of the EPC states that: 'European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality…' This provision applies to all fields of technologies, and can be used to exclude patentability if the commercial exploitation of an invention was seen as contrary to *ordre public* or morality in any technological field. In the context of a "novel being" depending on the extent of consciousness/agency demonstrated by this being, an argument could be raised that commercial exploitation of such a being would be against morality or "ordre public" and hence unpatentable; however, the likelihood of success is questionable as will be demonstrated.

To date, the morality provisions have proven most controversial in the context of biotechnologies and the provisions in the EPC have been supplemented by Art 6 of the EU's Biotechnology Directive,[22] which was adopted as supplementary interpretation for the EPC.[23] Art 6(1) of the Directive repeats the wording of the general morality provision in the EPC. However, Art 6(2) also includes a list of four specific inventions/processes that are unpatentable on this basis.[24] Once an invention falls within the definition of Art 6(2) it is automatically excluded from patentability. None of the specific four categories under Art 6(2) excludes patents on "novel beings" *per se*– although, should the creation of a novel being involve processes/elements listed under Art 6(2), that may cause them to be excluded from patentability. For example, if uses of human embryos were required in the creation of novel beings, they would likely be excluded from patentability.

However, the specific exclusions under Art 6(2) do not exclude patentability based on characteristics such as non-human "consciousness" etc. To include specific exclusions applicable to "novel beings" a legislative change would be needed which legislators may be wary of introducing given the tumultuous background of the Directive.[25] No similar list of specific exclusions based on morality provisions is provided for other technologies outside the biotechnology sector. Thus, the general morality provision would be the main potential avenue which could be argued to exclude "novel beings" from patentability based on ethical issues.

As noted, the general morality provision provides that any invention whose exploitation is against *ordre public* or morality is excluded from patentability and this could therefore in theory be used to exclude patents on "novel beings." However, an examination of: (1) the EPO guidelines on the morality provisions; (2) the previous EPO decisions and statements on these provisions; and (3) the limited application of these provisions to deny patents on transgenic animals (which arguably is the most analogous scenario to novel beings that has been considered by the EPO to date) demonstrates the limited potential of the morality provisions to exclude patentability of novel beings.

Firstly, the EPO Guidelines for Examination of patents on the morality provisions demonstrate that the EPO has adopted a light touch and exceptionalized application of these provisions in practice,[26] which are unlikely to be used to deny patentability to technologies unless very high thresholds are met. The EPO guidelines state that the purpose of the morality provision is "to deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour." The guidelines cite antipersonnel mines as an "obvious example" of technology which would be excluded from patentability but no further explanation or rationale is provided for this. The guidelines also state that the morality provision "is likely to be invoked only in rare and extreme cases" and 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."[27] Thus, even if moral objections were raised against the commercial

exploitation of "novel beings," patentability would only be denied under these tests if the invention was regarded by the public "as so abhorrent that the grant of patent rights would be inconceivable." This is an extremely high threshold to meet.[28] Moreover, translation of scientific knowledge into the public domain, and obtaining consensus on ethical positions around scientific developments, is notoriously difficult, especially for contentious technologies. Thus, it would arguably be difficult to demonstrate that "novel beings," should they be developed—depending on the type of entity this involved—met the required tests to be denied patentability on this basis. An added difficulty is that the claimed invention would be, given the nature of the patent process, at a very early stage at the point of patent application given that technologies must be novel to obtain patent protection, thus, the potential for ethical issues to arise in relation to its patentability may be unknown at that point. Hence it is likely that the extent of the potential ethical concerns around patentability and in turn a challenge based on the morality provisions would not arise until (potentially long) after the invention was patented.

Secondly, the EPO decisions to date on the morality provisions, confirm a highly restrictive application of the provisions,[29] demonstrating the EPO's reluctance to engage with these provisions. For example, in *Leland Stanford*[30] the Opposition Division of the EPO held that the role of the EPO was not to act as a moral censor. It stated that as there was no consensus on the desirability of the technology in question in the case in Europe (the application related to a modified mouse) then 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 antipersonnel mines which "would be regarded by the public as so abhorrent that the grant of a patent would be inconceivable."[31] As this was not the case with the technology in question, the patent grant was allowed. No further justification is provided in the decision for why the abhorrence standard was adopted or why the provisions would only to apply in rare cases. The EPO also provided little elaboration on why a patent on a modified mouse in the case was acceptable but letter bombs were not or the criteria used to justify such choices. In short, there was limited elaboration of the reasoning within the decision, instead the EPO findings are often presented as self-evident truths in a similar fashion to the ethical stances taken in the Examination Guidelines discussed above. Such limited engagement with ethical issues suggests engrained perceptions of the role morality/ethics within patent law by the European Patent Office. It belies a light touch engagement with such issues and a reluctance of the EPO to involve itself in such debates.[32] Arguably, the EPO, would similarly, be reluctant to engage with the morality provisions should they arise in the context of "novel beings."

This restrictive approach to the morality provisions is not confined to the Leland Stanford case, it is also evident in *Greenpeace U.K. v Plant Genetic Systems N.V.*[33] where the Technical Board of Appeal in the EPO opined that the exceptions to patentability should be narrowly construed. 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.[34] Similarly, in *Novartis*[35] the Enlarged Board of Appeal of the EPO acknowledged that the technology in question in the case 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. Furthermore, in T 0866/01 *Dr. Knotgen & Ors. v Michigan State University*[36] the Technical Board of the EPO held that:

> "Article 53(a) is thus an exception *to the general entitlement to a patent* in Article 52(1) EPC and is to be construed narrowly, given the EPC's underlying objective of establishing a comprehensive patent protection between the contracting states (see Preamble of the EPC, paragraph 2)."[37] [emphasis added]

The Board stated that it is generally accepted that "Article 53(a) is to be construed narrowly and that such a restrictive interpretation is, whereas having regard to the particular circumstances of each individual case not only correct but also justified."[38] 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."[39] These statements were not accompanied with detailed reasoning; rather, the Board presented such

statements in a self-evident manner, highlighting a sharp disjoint between how such ethical issues might be investigated in other contexts such as within bioethics/medical law, and how they are dealt with within the EPO patent law context. Put simply, past decisions of the EPO on the general morality provision in Europe demonstrate these provisions tend to be interpreted narrowly in a highly superficial manner showing a reluctance of the EPO to use the provisions to deny patents.

Thirdly, one of the main ethical objections to patents on "novel beings" is likely to be the "consciousness" of that being. However, the fact an invention is living *per se* or shows consciousness is not a bar to patentability under the morality provisions. For example, transgenic animals are patentable provided certain criteria are met[40]; for instance, it must be demonstrated that the transgenic animal was man-made, and there must be justification of any suffering caused to the animal (if applicable) with reference to the benefits to humans or animals.[41] The patentability of transgenic mice was confirmed in the controversial *Onco-Mouse* decision.[42] In that case, a patent was allowed in respect of transgenic mice that had been modified to be more susceptible to cancers, and hence could be used as animal models, for example, for testing of treatments for cancer. The EPO discussion of whether the patent should be excluded on the *Onco-Mouse* based on the morality provisions focused on risks to the environment and the potential for causing the animal suffering. However, there was limited engagement with the broader ethical question of whether patents are ethically appropriate to be granted in respect of living animals – or the implications of patents if these were higher order animals. The EPO noted that "patent law is not the right legislative tool for regulating problems arising in connection with genetic manipulation of animals." However, no justification was provided for why patent law could not be used as a regulatory tool or why, for instance, it could not be used to complement regulatory approaches. The EPO Board concluded by noting that the patentability of transgenic animals would be decided on a case by case basis, and would depend

> "…mainly on a careful weighing up of the suffering of animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other."[43]

By analogy, arguably, a claimed invention which is non-human but which demonstrates something akin to consciousness would not necessarily be deemed unpatentable by virtue of it being conscious alone, as transgenic animals share this characteristic and can in some circumstances still be patentable. Of course, depending on how "novel beings" developed, it could be argued they could demonstrate a different or higher level of consciousness or awareness to animals *per se* and therefore should be excluded from patentability under, for example, the morality provisions if they were distinguished from transgenic animals in this way. However, there is nothing within the text of the EPC or other European patent laws which would automatically exclude patentability of "novel beings" on the basis of consciousness.

Thus, as current interpretative patterns stand the morality provisions are unlikely to be a fruitful avenue to deny patents on "novel beings." Instead, patent law is arguably normatively isolated from broader (bio)ethical objections to ownership/tangible property rights in bodies or living material that has played out in other domains.[44] Overall, a marginalization of ethical issues within patent law is often evident,[45] and an institutional disposition toward patent grant rather than the denial of patents appears to exist, where ethical exclusions are interpreted narrowly, and the EPO has demonstrated an acute reluctance to engage with such issues in practice.[46] As past decisions of the EPO suggest the morality provisions are treated as marginal or exceptional provisions within patent law, and all of this suggests that it is unlikely – in the absence of a fundamental institutional (and interpretative) shift within patent law – that the morality provisions would be used to deny patents on "novel beings."

Of course, if technology developed to the stage of "novel beings" this could arguably give rise to a fundamental shift within patent law. The morality provisions were initially designed in a context of mechanical or industrial type inventions and not in context of current advances in biotechnology,[47] or indeed, in context of potential "novel beings." Thus, there is arguably a mismatch between the initial purpose of such morality provisions in the drafting of the EPC and the types of inventions that are now being patented, and which could be patented in future. Furthermore, at least on paper, there is scope for

the morality provisions to be used as a site of broader consideration of ethical or moral issues posed by technologies within patent law. This is confirmed in Recital 39 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 in view of the potential scope of inventions in this field and their inherent relationship to living matter; whereas such ethical or moral principles supplement the standard legal examinations under patent law regardless of the technical field of the invention;"

This implies that at least in theory such provisions could be used to deny patentability to "novel beings' should they arise as it confirms that ethical/moral principles supplement patent examination. Edward Armitage and Ivor Davis who were involved in the initial drafting of the EPC,[48] stated that the morality check at that time of drafting the EPC was seen as merely an optional, conventional, feature on the margins of the system"[49] and that when the EPC was drafted the morality provision was adopted without controversy seen in many ways as "unremarkable but necessary marginal safeguard."[50] Nonetheless, they recognized circumstances could change, and that a change in the way in which the morality provision was applied could be justified if three conditions were met: 1) "some event compelling a re-think and consequent change 2) some significant benefits for society 3) no impairment of the patent system in serving its primary purpose."[51] Arguably, biotechnology and particularly current advances within biotechnology amount to such a change. Furthermore, if technology developed to the stage of "novel beings" this would amount to a significant change and would justify a significant rethink of patent law and a change of approach on the morality provisions. Moreover, denying patents to "novel beings" would not necessarily impair the patent system and could have benefits for society as a whole (e.g., if there were questions over whether such technologies should be incentivized removing the patent incentive may discourage commercial projects in such fields). In such circumstances, there would be nothing to preclude a blanket exclusion on patents over "novel beings" based on the morality provisions or a more critical examination of how the morality provisions should apply to particular types of "novel beings."

Nonetheless, to achieve such change and to use the morality provisions to engage with ethical issues posed by patenting emerging technologies, would arguably require a fundamental change of thinking within patent law. It would likely require bottom up institutional change to provide a nuanced reflection on ethical issues within patent law.[52] Even if technology never develops to the stage of novel beings, given the rapid development of biotechnologies and broader implications of these for human health and lives, this article argues we have come to the stage where we need to reconsider if the current interpretative approach to the morality provisions within European patent law is still fit for purpose. Further consideration is needed on whether the light touch, minimalistic approach to ethics within patent law is appropriate in the current context, and for future advances in biotechnologies.

3) Exclusion of "Novel Beings" from Patentability Based on Ethical Principles Within the Biotechnology Directive

Aside from the morality provisions, the text of the Biotechnology Directive applicable in EU States, contains several provisions reiterating the non-patentability of humans from which one can gain further insights into how ethical issues are considered within patent law. However, when one examines these provisions, it appears to be the quality of being human *per se*, and not broader ethical objections concerning consciousness or agency which underpin these exclusionary provisions. Moreover, even in the context of human beings, such provisions have had limited weight in practice, which suggests it is unlikely such provisions would be fruitful avenues to challenge patents in respect of non-human novel beings.

For example, there are specific references in the Directive to broader ethical principles such as dignity or integrity that should be respected, but these guiding principles are referred to in the context of human beings only, and arguably broader principles cannot be drawn from such references to apply to "novel beings." Recital 16 states: "Whereas patent law must be applied so as to respect the fundamental

principles safeguarding the dignity and integrity of the person."[53] The term "person" is arguably confined here to human persons; for non-human beings including "novel beings" to be recognized within this, it would require reinterpretation and recognition of the non-human being as persons, which is unlikely. It would also need to be proven that patenting of the non-human being offended against or failed to respect dignity/integrity of persons; however, both dignity and integrity are generally treated as concepts related to human dignity and human (bodily) integrity which again would not apply in the novel (non-human) being context. Moreover, to date, such provisions around dignity have had little weight in terms of being used to exclude patents in the context of inventions related to the human body,[54] and under current interpretative approaches their potential use in the context of novel beings would arguably be slim. An avenue where such provisions might have considerable weight however, would be for example, if de-extinction attempts were ever attempted to re-create a former human species or something resembling a former human species. In such contexts, it would likely be argued the recreation of a former human species would threaten human dignity and could also pose risks for the current human species. It may also likely be argued that the recreation of former human species, or any living organism akin to this should not be encouraged via a patent incentive. However, this example is arguably an exceptional one, and distinguishable from "novel beings" generally, given its connection with humans. Moreover, ethical objections if framed in this manner, relate to risks/interests of the current human species effected by recreating former species, and arguments based on dignity/integrity arguably (under current patent law interpretative approaches) would not have similar weight where the novel-being had consciousness but no connection to human species *per se*.

Furthermore, even in the context of the patentability of elements related to the human body, some exclusionary provisions in the Directive have arguably been watered down, by further provisions in the Directive or when interpreted by the EPO. For example, Art 5(1) states that: "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." However, Art 5(2) states that: "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 identical to that of a natural element." This in turn means that despite the wording of Art 5(1), 5(2) provides that if isolated from the body an element of the body may be patentable, even if such patents curtail what third parties can do with their bodily material. For example, patents on isolated genes (depending on how these are used by the patent holder, have the potential to limit how/if genetic testing can be conducted on samples from other human bodies, and by whom.[55] Moreover, the application of the morality provisions in the gene patent context by the EPO has tended to focus on whether the individual whose bodily material was used to isolate the gene originally gave informed consent, and whilst this is a significant issue, the lack of engagement with the broader implications of providing patents on genes and the potential impact of such patents on diagnostic treatments which can be provided to others bodies downstream is absent from EPO discussions on this issue.[56] This example, and how Art 5(2) has been interpreted by the EPO demonstrates that even if exclusions from patentability were provided for novel beings, the interpretation of such provisions would need to be monitored as their effect could be watered down in practice. It also arguably demonstrates the blinkered view within European patent law to ethical issuesas it fails to assess the broader implications of patentability on third parties.

Finally, it must be noted that the Directive confirms that human rights considerations are relevant to patentability decisions, as emphasized in several provisions.[57] However, if a novel being was non-human in origin this would also not be applicable in this context, as human rights only apply to humans as currently interpreted.

Conclusion

"Novel beings" should they arise and depending on the nature of such beings and how they are created, could likely be patentable under European patent law based on the current provisions applicable and the

interpretative approach to these. Key questions in terms of patent grant assessment would include whether the "novel being" satisfied the quality of being an invention, and whether it met standards of novelty, inventive step, and industrial applicability (technical application). The tests of novelty and inventive step are likely to be met by such technology, but more problematic could be whether the "novel being" demonstrated relevant industrial application to be patentable. For patentability, much would also depend, on the origins of the "novel being" but importantly, there is nothing within patent law criteria which would automatically exclude an "invention" from patentability based on consciousness (if non-human). Although practical problems would likely arise with how to enforce such patents on "novel-beings" depending on the level of consciousness or potential for agency that the being demonstrated. This would also give rise to serious ethical questions from a patent perspective.

As noted, the morality provisions provide a potential avenue to consider ethical issues arising from the patentability of a technology and arguably would be the most fruitful (and likely) avenue to seek to exclude patentability of novel beings (should they be developed). However, such provisions are generally applied in a light touch manner by the EPO which has demonstrated a strong reluctance to engage with ethical issues within patent law other than in an extremely narrow range of circumstances. If technology reached the point of the "novel being" this would be highly disruptive of patent law and arguably would fit within the criteria suggested by Armitage and Davies warranting a different approach to the morality provisions. However, given the EPO's current interpretative approach to these issues, gaining consensus against patentability is likely to be an uphill struggle in such contexts.

Furthermore, although ethical objections to patentability are evident within the text of the Directive, which includes references to patent law aligning with human rights, these rights and provisions are currently defined by reference to the quality of being "human" and would argubaly not apply to novel (non-human) beings unless fundamentally reinterpreted.

In short, questions around the patentability of novel beings currently is an exercise in blue skies thinking, as technology has not yet (and possibly never will) develop to the stage of demonstrating (non-human) consciousness or agency. Nonetheless, the possibility of such technology in future cannot be dismissed. Moreover, questions around patentability of novel beings, gives rise to important broader questions on the role of ethical issues generally within patent law and also the appropriateness and extent of the role of patent holders in shaping and governing the use and development of such technologies downstream. Such questions warrant much closer and deeper consideration around the role of ethics within patent law in Europe and elsewhere.

Acknowledgments. An earlier version of this paper was presented at the "Regulating the Tyrell Corporation: Company Law and the Emergence of Novel Beings" workshop in 2018 and the author is very grateful to the attendees and organisers for their comments, and to the anonymous reviewers and editor for their very helpful comments.

Notes

1. For example, see Boseley S. Calls for action on patients denied £100,000 cystic fibrosis drug. *The Guardian* 2019 Feb 3; available at https://www.theguardian.com/science/2019/feb/03/nhs-cystic-fibrosis-drug-orkambi-vertex (last accessed 30 Nov 2020).
2. Lawrence DR, Morley S. Regulating the Tyrell Corporation: The emergence of novel beings. *Cambridge Quarterly of Healthcare Ethics* 2021;**30**(3):421–34; available at 10.1017/S0963180120000973. See also: Lawrence DR, Brazier M. Legally human? The status and challenge of novel consciousness in law. *Medical Law Review* 2018;**26**(2):309–27.
3. Lander ES, Baylis F, Zhang F, Charpentier E, Berg P, Bourgain C, et al. Adopt a moratorium on heritable genome editing; 2019. Nature Comment 2019 Mar 13; available at https://www.nature.com/articles/d41586-019-00726-5 (last accessed 8 May 2020) where the authors call for a global moratorium on clinical uses of human germline editing in the reproductive context.
4. See discussion in: Parthasarathy S. Use the patent system to regulate gene editing. *Nature* 2018;**562**:486–8.

5. See: McMahon A. Biotechnology patents as private governance tools: The good, the bad and the ugly. *Intellectual Property Quarterly* 2020;**3**: 161–179.
6. In the context of patentability of de-extinction in the animal context see: McMahon A, Doyle DM. Patentability and de-extinct animals in Europe: The patented woolly mammoth. *Journal of Law and the Biosciences* 2020;forthcoming, advance access: https://doi.org/10.1093/jlb/lsaa017.
7. There are provisions which explicitly exclude patents on the human body within European patent law (Art 5 Biotechnology Directive) and on humans *per se.* However, given that it would be highly ethically contentious and therefore arguably unlikely someone would seek to claim patents on any former human species if developed, it is nonetheless, plausible. In such contexts, it is likely existing exclusions on patents related to humans within European patent law may be interpreted or extended to apply to, for example, any potential patent claim related to a de-extinct human species, or something resembling this, but questions and uncertainty arguably may still arise in this context.
8. Art 27(1) TRIPS Agreement; these requirements are also evident in regional patent treaties, for example, Art 52(2) European Patent Convention 1973.
9. For a discussion see Pila J. *The Requirement for an Invention in Patent Law*. Oxford University Press; United Kingdom, 2010.
10. European Patent Office. *Guidelines for Examination Part 3.1 Discoveries*; available at https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_3_1.htm (last accessed 8 May 2020).
11. This is the case in Europe—(Art 5(2) Biotechnology Directive).
12. See note 5, McMahon 2020.
13. Currently, there are 164 State Parties to the WTO—see available at https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last accessed 8 May 2020).
14. In the past, countries such as Brazil and India abolished patents on pharmaceuticals which allowed less restrictive development of these areas, and of generic medicines. This is not now possible for WTO State Parties.
15. Case T0149/11 of 24 Jan 2013: Method and device for processing a slaughtered animal or part thereof in a slaughterhouse; available at http://www.epo.org/law-practice/case-law-appeals/pdf/t110149eu1.pdf (last accessed 8 May 2020).
16. See note 15. The EPO's Technical Board of Appeal stated patents could not be applied for involving human beings as this could amount to potential for slavery. It stated: "[s]ince 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 commercialized, however far-fetched such an interpretation may seem."
17. Case T 0272/95 (Relaxin/Howard Florey Institute) of 23 Oct 2002.
18. There are likely to be significant broader ethical objections to any de-extinction attempts in the context of former human species (aside from questions of patentability); such questions are beyond the scope of this current article, but for a discussion see: Hank Greely, On Not De-Extincting Homo Neanderthalensis; available at https://law.stanford.edu/2013/02/18/lawandbiosciences-2013-02-18-on-not-de-extincting-homo-neanderthalensis/ (last accessed 26 Feb 2020); see also: Cottrell S, Jensen JL, Peck SL. Resuscitation and resurrection: The ethics of cloning cheetahs, mammoths, and Neanderthals, **10**(3) LSSP 1–17; 2014. On patents and de-extinction in the animal context, see note 6, McMahon, Doyle 2020.
19. See also: Laurie G. Fore-warned is fore-armed: Is intellectual property a suitable case for foresight? *International Review of Intellectual Property and Competition Law* 2008;**29**:507–10, 39 pp.
20. Art 52(2) EPC.
21. There remains uncertainty in relation to the patentability of algorithmic inventions; patents tend to be granted for applications of algorithms to solve technical problems but not for algorithms *per se*: see Strange H, Barnfather K. Patentability of artificial intelligence and machine learning inventions in Europe (Withers and Rogers, 2018); available at https://www.withersrogers.com/news/ip-case-law/

patentability-of-artificial-intelligence-and-machine-learning-inventions-in-europe/ (last accessed 8 May 2020).

22. Art 6(1) Directive 98/44EC.
23. For a discussion of the relationship between the EPC and Biotechnology Directive, see Bakardjieva-Engelbrekt A. Institutional and jurisdictional aspects of stem cell patenting in Europe (EC and EPO): Tensions and prospects. In: Plomer A, Torremans P, eds. *Embryonic Stem Cell Patents in Europe: European Law and Ethics*. OUP; United Kingdom; 2009; McMahon A. An institutional examination of the implications of the unitary patent package for the morality provisions: A fragmented future too far? *International Review of Intellectual Property and Competition Law* 2017;**48**:42.
24. Art 6(2) excludes patents on: (1) processes for cloning human beings; (2) processes for modifying the germ line genetic identity of human beings; (3) uses of human embryos for industrial or commercial purposes; (4) 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.
25. The Directive took over 10 years to adopt and questions arose around ethics of patenting technologies, which some may be reluctant to reopen. See: Porter G. The drafting history of the European biotechnology directive. In: Plomer A, Torremans P, eds. *Embryonic Stem Cell Patents. European Law and Ethics*. Oxford University Press; United Kingdom, 2009.
26. European Patent Office, Guidelines for Examination (Section 4.1); available at https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_1.htm (last accessed 8 May 2020).
27. See note 26.
28. For further discussion of the morality provisions see: Warren-Jones A. Vital parameters for patent morality—a question of form. *Journal of Intellectual Property Law and Practice*2007; **2**(12):832; Warren-Jones A. Finding a "common morality codex" for biotech—a question of substance. *International Review of Intellectual Property and Competition Law* 2008;**39**(6):638–61; Warren-Jones A. Morally regulating innovation: What is "Commercial Exploitation"? *Intellectual Property Quarterly* 2008; **2**: 193; Drahos P. Biotechnology patents, markets and morality. *European Intellectual Property Review* 1999;**21**(9):441; Mills O. *Biotechnological Inventions, Moral Restraints and Patent Law*. Revised ed. Ashgate; 2010.
29. Such cases to date in Europe have arisen primarily in the context of biotechnology.
30. EPO, Opposition Division, *Leland Stanford,* 16 Aug 2001 (2002) E.P.O.R. 2, para 44.
31. (2002) E.P.O.R. 2, para 51.
32. McMahon A. An institutional examination of the morality provisions in the "European" patent system for biotechnological inventions [PhD Thesis]. University of Edinburgh; United Kingdom 2016.
33. [1995] E.P.O.R. 357. For an analysis, see Bently, Sherman. The ethics of patenting: Towards a transgenic patent system. *Medical Law Review* 1995;**275**:280.
34. Decision of the Board of Appeal of the European Patent Office, *Greenpeace Ltd. v. Plant Genetic Systems*, decision of 21 Feb 1995, T 356/93, p. 17, Reasons for the decision, point 8.
35. [2000] E.P.O.R. 303.
36. Case T 0866/01 Decision of the Technical Board of Appeal 3.3.02 of 11 May 2005.
37. See note 36, para 5.2.
38. See note 36, para 5.4.
39. See note 36, para 6.12.
40. See discussion in: Beyleveld D, Brownsword R. *Mice, Morality and Patents: The Onco-Mouse Application and Article 53(a) of the European Patent Convention*. Intellectual Property Institute; 1993.
41. Indeed, the Art 6(2)(d) exclusion states the following is unpatentable: "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."
42. [1991] EPOR 525 and Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03.
43. See note 42, para 5.

44. There have been discussions on the appropriateness of "patents on life" but such discussions often fall short of nuanced engagement with potential ethical issues at stake. The focus is often, for example, in the biotechnological context, on the extent to which the person whose bodily material was used gave informed consent to this use. However, there is limited engagement within patent law, of the implications for other living bodies of having a patent on, for example, isolated genes. For example, see: Case T 0272/95 (Relaxin/Howard Florey Institute) of 23 Oct 2002.
45. McMahon A. Gene patents and the marginalisation of ethical issues. *European Intellectual Property Review* 2019;**41**(10):608–20.
46. See note 32, McMahon 2016. See also: Bently L, Sherman B. The ethics of patenting: Towards a transgenic patent system. *Medical Law Review* 1995;**3**:275–91. Furthermore, Bagley M. Patent first, ask questions later: Morality and biotechnology in patent law. *William and Mary Law Review* 2003–2004;**45**:469–547.
47. 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."
48. Armitage E, Davies I. *Patent and Morality in Perspective*. Intellectual Property Institute; 1994, at **16**.
49. See note 48, Armitage, Davies 1994, at 20. This analysis was based on their reflections on the drafting of the Strasbourg Convention which they had been involved in and on reports of the committee meetings which they had inspected but which had since been destroyed.
50. See note 48, Armitage, Davies 1994, at 24.
51. See note 48, Armitage, Davies 1994, at 44–5.
52. See note 32, McMahon 2016.
53. Recital 38 also refers to exclusion of uses which offend against "human dignity."
54. See discussion in McMahon A. An institutional examination of the morality provisions in the "European" patent system for biotechnological inventions [PhD Thesis]. University of Edinburgh; 2016. For a discussion of dignity in the context of patent law, see: Plomer A. Human dignity and patents. In: Geiger C, ed. *Research Handbook of Human Rights and IP Rights*. Edward Elgar; 2014.
55. Patents were recently rejected on isolated genes in the USA and Australia in: *Association for Molecular Pathology v. Myriad Genetics Inc.* (2013) 569 U.S. 576, and *D'Arcy v Myriad Genetics Inc.* [2015] HCA 35, respectively. However, the decisions were not based on ethical issues related to the patents but rather based on whether genes were seen as discoveries instead of inventions for patent law.
56. McMahon A. Gene patents and the marginalisation of ethical issues. *European Intellectual Property Review* 2019;**41**(10):608–20.
57. See Recital 43, Article 16. See also discussion: Plomer A. Human dignity, human rights and article 6 (1) of the EU directive on biotechnological inventions. In Plomer A, Torremans P, eds. *Embryonic Stem Cell Patents: European Patent Law and Ethics*. Oxford University Press; 2009; European Plomer A. Towards systemic legal conflict: Article 6(2) (c) of the EU directive on biotechnological inventions. In: Plomer A, Torremans P, eds. *Embryonic Stem Cell Patents: European Law and Ethics*. Oxford University Press; 2009; Arvind TT and McMahon A, Commodification, control and the contractualisation of the human body, In: Bertrand E, Catto Marie-Xavière, Mornington A (eds) The limits of the market: commodification of nature and body, Paris: Mare & Martin; 2020.

Cite this article: McMahon, A. 2021. Patents, Governance and Control: Ethics and the Patentability of Novel Beings and Advanced Biotechnologies in Europe. *Cambridge Quarterly of Healthcare Ethics* 30: 529–542, doi:10.1017/S0963180120001073