On value-laden patents: a call for moral limits

Benedicto Acosta

Instituto de Estudios de la Ciencia y la Tecnología, Universidad de Salamanca, Salamanca, Spain

Abstract

Purpose – The main purpose of this paper is to discuss the suitability of moral and ordre public clauses, and to advance the view that ethical reflection within patent systems is valuable.

Design/methodology/approach – This is a conceptual paper that draws upon the present situation in Europe to illuminate a discussion of the different views about the morality patents, with particular emphasis on criticism of authors who have espoused a narrow interpretation of moral clauses, such as that adopted by the European Patent Office.

Findings – This research found that the claim that patent systems are not appropriate places in which to evaluate moral matters and, therefore, they cannot inform us about morality is false. This is because inventors do not need to wait for authorizing legislation prior to making use of their technology. Hence, moral implications can be evaluated.

Research limitations/implications – These ideas also lead to important theoretical consequences, especially regarding the debate on value-laden science and technology. However, further efforts are needed to address other patent regimes, such as the non-European.

Practical implications – It is shown how the bioethicist community can be incorporated into patent offices. The responsibilities of examiners and businesses in the process are also discussed.

Originality/value – There have been a limited number of studies that examine the value of ethical considerations within the patent system. This paper provides a thought-provoking discussion of moral clauses in Europe. The author also suggests new ways of incorporating ethical scrutiny into patent systems.

Keywords Ethics, Ordre public, Society, Ethics committee, Technology

Paper type Conceptual paper

1. Introduction

Most patent codes recognize cases in which patentability is not possible, not as a result of the invention's "internal" characteristics (e.g. lack of inventive step or novelty), but due to "external" – typically, moral and social – characteristics.

There are usually two types of external limits in patent codes: exclusions for inventions that violate *ordre public* [1], and those that are contrary to morality. The main difficulty highlighted by scholars who have studied them is that, apart from their rarity, it can be difficult to distinguish the morality clause from the *ordre public* clause in patents (Schneider, 2014). One reason could be the heavily interdependent nature of what is immoral for a society and what represents a violation of *ordre public* for that society.

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Value-laden patents



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Some authors consider these limitations imposed by individual States as "reactive" (Ribeiro and Shapira, 2020), because they only prevent certain technologies from being marketed, but do not necessarily generate social value. To do so would require an active approach. Examples include technologies designed to be greener, less opaque or more accessible.

Although cases involving the creation of social value in patents have been increasingly studied in recent literature (cf. Aiello *et al.*, 2021; European Commision, 2021), studies pertaining to external limitations are relatively few, as such cases are rare. However, while it is true that few patent applications are denied for moral or political reasons, those cases exemplify the way in which technologized societies attempt to regulate science and technology.

Some such cases have been discussed – especially in patents concerning health issues (McMahon and Richardson, 2022; Forsberg *et al.*, 2017), and almost always from a legal perspective (Sterckx and Cockbain, 2012; Hawkins, 2022; Ghidini and Falce, 2022). Much less is known about the status and justification of external limits as such, when not limited to health or biotech. General reflections on patent systems focus on the lawfulness of patents (cf. Merges, 2011), but not on external restrictions. This study aims to fill these gaps, while simultaneously contributing to the existing body of work relating to values in science and technology (cf. Kitcher, 2001). The main objective is to discuss the suitability of these moral and *ordre public* clauses and to advance the idea that ethical reflections within the patent system are valuable, arguing against the restrictive or narrow interpretation of external clauses, focusing on the situation as it currently stands in the European Patent Office (EPO).

2. Methodology

As a philosophical paper, the research is conducted by observing, analyzing and criticizing already present information on the topic of morality in patents. The method used in this paper is to criticize the narrow interpretation of ethical preclusion from patentability, by showing that patent systems are relevant arenas in which to evaluate moral [2] issues.

I begin by analyzing the limitations of patentability on the grounds of public policy and immorality in Europe. The main aim of this section is to show that the EPO's interpretation of these two limitations is highly restrictive. Second, I review the academic literature in which such a narrow interpretation is advocated. Then, in the discussion section, I explicitly argue that such moral and *ordre public* limitations are entirely appropriate. Here, I use a twostep strategy. First, to criticize the idea that patent systems are not relevant places in which to evaluate ethical issues, I develop an argument concerning the use of the inventions, highlighting the relationship between such use and societal impacts. Second, to show effective ways of conducting such ethical reflection, I outline a proposal concerning the inclusion of the bioethicist community in patent systems.

While my initial interest was in the analysis and ethical reflection on external clauses in general, I believe it is appropriate to focus on one of these regimes: the European. In the case of a patent system, patent prosecution and granting organizations (such as the EPO) have a particularly significant impact on the effects of patents because, together with the courts, they are responsible for interpreting and enforcing intellectual-property law. Emerging and more controversial technologies need a new stance in the application of patent law, and often, patent offices serve as the point of first contact. The EPO exercises both international and regional influence in this regard. Within Europe, national patent offices also examine patents, but their practices are largely in line with those of the EPO. Therefore, the EPO is a key institution when discussing patents and external clauses.

3. External clauses at the European Patent Office

The European Patent Convention (EPC) regulates the granting of European patents, by means of a single procedure that allows a person in any signatory country to apply for a patent with validity in the number of countries they designate. The EPC currently comprises 178 articles; they state how inventions can qualify to be patentable, for how long, the effects of such patents at territorial level, and how they should be granted, opposed or appealed.

Among the articles that focus on which inventions are patentable, we find the following words: "European patents shall be granted for *any* inventions, in *all* fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application" (art. 52; italics are mine). However, the Convention also recognizes which patents shall not be granted In this article, I will focus on "inventions the commercial exploitation of which would be contrary to 'ordre public' or morality" (art. 53a). Although some authors highlight the vagueness of the terms "morality" and "*ordre public*" at a European level (Prifti, 2019, p. 5), the fact is that a distinction is drawn between these two concepts.

The EPO defines the idea of morality as follows (Board of Appeal of the EPO, 1995):

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

As for the idea of "ordre public," the EPO establishes the following (Board of Appeal of the EPO, 1995):

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

Sterckx and Cockbain (2012) – two of the most prominent commentators on this subject – have been critical of these definitions. The idea of morality that the EPO supports, they argue, reduces ethics to mere sociology, to the perception of correctness for a population, but they do not determine what is in fact right or wrong, according to well-developed arguments, based on deep knowledge of a situation (a "leap" which, using G. E. Moore's term, is often referred to in philosophical literature as the "naturalistic fallacy").

For example, as Shobita Parthasarathy has shown (2011), in the famous case of the oncomouse in 1993, opponents to patents on genetically modified animals had to point the EPO to the *Eurobarometer* as proof that Europeans, deeply concerned about animal suffering, would be against the genetic modification of animals for the purpose of developing cancers. There is a danger of committing the naturalistic fallacy when ethical examinations are performed at European level.

Regarding the definition of public policy, Sterckx and Cockbain argue that, although the EPO clearly states that it is not limited to the illegal ("contrary to ordre public" may not be limited to what is illegal in view of the second half-sentence of art. 53(a) EPC), such a notion seems to *de facto* reduce public policy clause to what is illegal or criminal, because to "breach public peace or social order (for example, through acts of terrorism) or to seriously

prejudice the environment," as the definition says, often means the same as prohibiting acts that are not legal.

The most important thing to note is that, in any case, beyond the invocations made by the EPC and these definitions given by the EPO, the interpretation made by the EPO itself, which can be found in the EPO guidelines, establishes very restrictive requirements for allowing external exclusions to patentability in practice:

The purpose of this is to deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour (see also F–II, 7.2) [...]. This provision is likely to be invoked only in *rare* and *extreme* cases. 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* (European Patent Office, 2022, Part G, Chapter II, 4.1; italics are mine) [3].

This consideration is even more limited if one examines which types of acts related to an invention are covered by morality and public policy clauses. For example, continuing with the case of animal suffering, the EPO decides to take account only of the damage that is induced by the exploitation of a patent, and not the harm that is somehow an indirect consequence of it: "experiments [that] were carried out during the making or development of the invention [...] as such do not fulfil the condition of being part of the exploitation of the present invention" (Board of Appeal of the EPO, 2005, para. 6.8; in Sterckx and Cockbain, 2012, p. 269). In other words, they would not be subject to moral or *ordre public* exclusions.

However, even in the rare case in which a situation of animal suffering meets the criteria of exploitation used to trigger both *ordre public* and moral clauses in Europe, the assessment of how much suffering is sufficient to deny a patent is still very narrow. The decisions of the Boards of Appeal of the EPO are in line with the requirements of Rule 28 (d), whereby the EPO requires *substantial documentation* of suffering to deny a patent (cf. T1199/08). Some authors have responded by saying that such substantial documentation would certainly be difficult to obtain for early stages in animal biotechnology applications (Forsberg *et al.*, 2017).

It should be recognized that historical experiences or cases evaluated by courts or boards of appeal have helped establishing a body of explicit moral limits to patents (see Salter and Salter, 2013, explaining the case of stem cells, for example). For this reason, codes and regulations are sometimes quite concrete in specifying some of these external limits (though as previously highlighted, the application or interpretation of such limits may vary). The EPO (European Patent Office, 2022, Part G. 4.1) calls them "practical examples" [4]. Among these common limitations we find surgical procedures and medical treatments, for example.

The EPO policy has, in any case, been so restrictive that some external limitations have exceeded the content of legislation. It is important to mention the case of the internal programs that certain offices have implemented (such as SAWS in the USA and SeCa at the EPO) to detect "sensitive" patents, which prescribe specific actions for these controversial patents, from granting or denial to possible subsequent dissemination in the media. This course of action seems to go beyond the institutional channel, giving rise to external limitations (Parthasarathy, 2017, pp. 95–98).

Finally, it is appropriate to briefly review a controversial case, at this point, that exemplifies how a patent can be obtained in Europe without an examination of these ethical reservations, plainly demonstrating the limitations of the current European framework.

A good example in this regard was obtained in the interviews I conducted with Spanish patent examiners as part of another research project (Acosta, 2023). At a certain point in the process, two examiners revealed the case of an invention that caused them moral objections, but in the end, they had no choice but to grant it a patent. The invention in question was a

IJOES

train derailment system. It was claimed, euphemistically, to be "a security system for train stations"; in the case of a terrorist attack or an uncontrolled train with no way of braking, the system would cause the train to derail, thus supposedly causing less damage than were it allowed to crash into a station.

The moral force of this case is so outstanding that, if we look closely, we see that it coincides with one of the best-known examples of a moral dilemma, "the trolley problem," in which we are encouraged to discuss two morally debatable choices: either let a tram continue on its way and kill a group of people, or actively divert it onto a track on which there is a single person, who will also die. In any case, as intimated above, it seems that European patent systems are not willing to stop in cases of dilemma such as these, simply preferring (to continue with the example) the runaway tram of innovation to continue unimpeded.

I believe this example and the analysis illustrate that the clauses relating to *ordre public* and morality are usually interpreted and applied on the basis of highly restrictive criteria, at least at a European level.

4. Literature review

Whereas this paper criticizes the restrictive interpretation of moral and *ordre public* exclusions, it must be acknowledged that a case has been made for this initiative. The situation described above is defended by some arguments. A group of scholars argue that patent systems (specifically, patent offices) are not the right places in which to evaluate ethical issues, because the patent systems are simply not designed to do such thing (Beyleveld, 2000; Crespi, 2005; Johnston and Wasunna, 2007). According to this point of view, moral or social concerns about patents should be limited to extreme cases at best.

An argument frequently used to defend a narrow interpretation of the ethical exclusion from patentability – like the one followed by the EPO – is that patent law would only protect the ownership of the invention (Witek, 2005). An assumption here is that a patent does not confer a positive right to implement the invention in practice, but rather a negative right, which simply prevents others from using or commercializing the invention (Forsberg *et al.*, 2017, p. 12). This is because there may be other legislation prohibiting the use of the invention, such in the case of patented drugs, which would need the approval given by regulatory agencies.

From this standpoint, any concern about the moral impacts of patented inventions should be limited, for example, to cases that are *abhorrent* (to use the term used by the EPO), and, in any event, regulated by other laws or regulatory agencies.

There have also been attempts to follow this path in the case of explicit limitations. Concerning surgical procedures, Jones, McCullough and Richman (2003) comment that it may be unfair to freely share the invention while getting nothing in return, whereas Tołłoczko (2005) disputes the difference between surgical procedures which cannot be patented and medicines or biotechnologies, which can. Regarding medical treatments, Mitnovetski and Nicol (2004) make a similar claim.

Some others add that even if the patent system had a responsibility in some cases, it would not be staffed of well-equipped to carry out these tasks. This is the main argument developed by Raymond Spier, who says that it seems "unusual for a secular component of the administrative machinery of the society to make determinations about the morality of issues" (Spier, 2005, p. 156).

One of the most relevant current debates on the role of morality and values in technology and science is the so-called "New Demarcation Problem" (Holman and Wilholt, 2022; Resnik and Elliott, 2023), namely, the discussion about the (legitimate or not) role played by

epistemic and non-epistemic values in science and technology. Faced with the traditional conception that only the former played a role, multiple studies have revealed the relevance that non-epistemic values, such as economic, moral and even aesthetic values (Douglas, 2009), have for the choice of scientific theories and models. Focused on technology, there are scholars who have argued that the traditional position on artifacts and techniques has also been axiological neutrality (Miller, 2021). This implies defending, from a moral perspective, that technologies are not good or bad *per se*, because they only become appropriate or not when they are used, applied, by an agent.

We can frame the position which argues for a restrictive interpretation of moral and *ordre public* exclusions within this conception: precisely because the patent would solely be a negative right, telling us nothing about the specific application of the protected technology, then moral considerations should be limited. A clear example which shows that the argument for neutrality in technology is present in this literature can be found in the work of R. S. Crespi, who recognizes that "the exercise of such a right (the patent) might be immoral if it entailed an immoral act" (Crespi, 2000, p. 175). We will begin the discussion section just from this point.

5. Discussion

5.1 Ethics and patents

As previously said, one of the main arguments in favor of a narrow interpretation of the ethical exclusion from patentability is that a patent grants not a positive right to use the invention, but a negative right, which only prevents others from commercializing it.

Momentarily sidelining the discussion on whether technologies in general are axiologically neutral – something that seems to be presupposed here – I shall begin by asking whether the use given to an invention, at least in patents, is not already determined, in some way. In the coming paragraphs, I argue that this is indeed the case, for several reasons.

The first point has to do with a conceptual error. Those who claim patent "neutrality" by arguing that patents confer a negative right usually base their position on an exceptional feature of the use of a patented invention – namely, the prohibition of such use by other legislation or a regulatory agency. However, the nature of patents cannot be determined on the basis of an exceptional characteristic, but rather on the basis of the rule. W. A. Adams has brilliantly pointed it out: "that the default position, however, is entitlement and not constraint is significant" (2003, p. 209), because the patent holder does not need to wait for authorizing legislation before making use of the intellectual property, as the aim of industrial commercialization is stated from the beginning.

Another argument in this regard would have to do to these aims or tendencies. Specifically in patents it does not seem possible to completely separate the ethical dilemma from the praxeological or informational consideration, which is a common requisite to support the idea that technology is neutral (cf. Hare, 2022). Here, they seem to overlap, as the invention disclosed by the patent is always strategic and oriented, as can be seen in the claims section [5]. In patents, it cannot be argued that the knowledge contained in the document is independent from its potential use. At least some uses of a technology, or parts of an artifact, are claimed (whether such claims relate to *process* or *product*), and the protection of the IP is, at least *ideally*, only limited to that use.

Thus, patents do not only imply the right to exclude third parties from using them, but also the possibility of commercial exploitation by their holder. Solid evidence of this can be found in the fact that "a claimed invention is expressed in affirmative terms" (Adams, 2003, p. 195). In this regard, most patent regulations state that the person submitting the patent

application must sufficiently demonstrate the industrial application of a product or technology; in other words, its usefulness must be clearly defined and fully stated (Romeo Casabona, 2014, p. 176). This is so to such a degree that the following words appear in the EPO's Guidelines for Examination:

It is to be expected that, in most cases, the way in which the invention can be exploited in industry will be self-evident, so that no more explicit description on this point will be required (European Patent Office, 2022, Part F, Chapter II, 4.9).

To this could be added Siva Thambisetty's point that:

The argument that there is no link between the grant of a patent and exploitation of an invention if accepted, subverts the very existence of Article 53(a) in the European Patent Convention (and correspondingly of Article 6 of the Directive). This provision clearly establishes a link between the exploitation of an invention and the grant of a patent for that invention (Thambisetty, 2002).

Moreover, the interpretation the EPO established in its guidelines about limitations on the grounds of Article 53 suggests a limitation to the patentability of inventions, in the case an invention would be "inconceivable" for a population, as previously stated. This clearly assumes that certain uses are foreseen.

These technical and legal provisions imply not just certain uses, but also certain values. When something is said to be "inconceivable" or "abhorrent," certain values are also presupposed. Numerous studies demonstrate that, even if a certain technical design may not, in itself, be intended to have a political consequence, that design can clearly make it possible (see Winner, 1980). We shall come to this topic later on, when discussing those uses or exploitations that are beyond the moral consideration of the patent (those that preceded its exploitation – i.e. the development of an invention).

Some inventions protected by a patent may also have unintended consequences – not only in society, but also in the innovation market. It has yet to be explored how the narrow application of ethical considerations and public policy in patents can contribute not just to creating unfair or unethical technologies, for example; but also how could the encourage the development of future technologies built on that precedent. This issue can also be related to the difference highlighted in the introduction, about reactive limitations and positive value generation (cf. Ribeiro and Shapira, 2020).

Undoubtedly, these moral, legal, and technical considerations are problematic when they come together. Laws created in democratic parliamentary systems have an internal dispute-resolution mechanism, but morality is a different matter. However, it is not sufficient "to leave the issue without consideration or resolution" (Townend, 2014, p. 91). Patents bring different values and uses into play, which could have an impact on society, on the one hand, and on other innovations, on the other. Let us take a closer look at this in the next chapter.

5.2 Patents and society

Having said all this, it is not yet clear whether these external constraints should be affected by the context or the society "served" by each patent regime, as harmonization of patent systems – though imperfect – is a real trend in some regions of the world, such as Europe (De Lange, 2021). Nor is it clear how they can influence patent systems, and to what extent. This is why, to answer all these queries, it is important, first, to discuss whether the harmonization of patent systems should be an irreversible trend.

An argument that is commonly used in response to the call to exclude social influences is that, unless we want to subsume or reduce the external limitations and the social value of

patents to purely economic value, cases where there is a strong social influence should be considered on their own merits and demerits (Maskus and Reichman, 2004).

As is well known, the presumption that the market, rather than the regulator, is the appropriate place in a democracy to assess the moral or social validity of a product or process protected by a patent is questionable. Some scholars have noted that there is an inconsistency in our treatment of the concept of property:

As a concept it is a social construction that is changeable because of moral or social pressure, but it is treated as absolute and unchangeable (arguably because of economic pressure) (Townend, 2014, p. 95).

These arguments could ultimately base their claims on social contract schemes – at least on a version that do not limit them to a deal struck between an established patent office and inventors, whereby inventors obtain exclusivity (which, more often than not, turns into a monopoly) in return for the disclosure of certain information. Rather, the claims should be based on a pre-existing pact between society as a whole and inventors; in other words, between inventors and the possible beneficiaries of the technologies they invent.

There have been several attempts in the specialized literature to outline the benefits of keeping the economic and social spheres separate. Karen Walsh perfectly summarizes this endeavor:

When it comes [to] issues concerning, for example, morality, human dignity, and *ordre public*, this scope for divergence needs to exist. Judges in all jurisdictions ought to be able to go against the majority if there is such a reason to do so. It is important that these types of issues remain open to debate and that national diversity remains, given the importance of these topics, the different views involved, and the changing nature of technology (Walsh, 2019, p. 425).

One of the most widely highlighted problems in this regard is that patent law-making processes, by which some external limitations still exist:

[...] often happen [in] the international or regional arena. Less frequently, law-making is happening at the national law-making level. This means that the regular democratic process is altered as in these international arenas states are represented by the executive body of government rather than elected representatives (Tvedt and Forsberg, 2017, p. 168).

This situation clashes with a common intuition among contemporary political philosophers: the idea that political organizations are responsible for justifying their institutions according to the good generated in their society, because only then do they become legitimate institutions, and that such "good" can only be established through participatory procedures (see Rawls, 1995, pp. 165–170).

Treaties like the TRIPS Agreement, which bind many nations in the interest of reducing "distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights," already incorporate and recognize "the special needs of the least-developed country Members" (Preamble). Hence, it does not seem difficult to make the case that countries – especially the least developed ones – should have their own voice even within the current status quo, different from the prevailing one or from the majority, especially when they are seeking to serve their society, in accordance with the idea of a social bargain.

In conclusion, there is reason to think that moral and social issues raised by patent applications – especially those arising from modern biotech industries – ought to be considered *before* the patent is granted, rather than relying on the idea that moral acceptability will come later, on the part of consumers who buy or use the technology, or those who oppose its granting through the painstaking process of challenging a patent. As

IJOES

stated earlier, claims that are immoral or contrary to *ordre public* are normally allowed to be challenged within the opposition periods, after the patent has been granted. Yet in order for this to be an effective safeguard, we must trust that non-profit organizations, which often have very specific aims (activists concerned with human health or animal welfare, for example) will be sufficiently attentive to the technology information bulletins.

Still, this would not be enough; as Pila (2020) says:

Opponents of a patent bear a heavy burden of demonstrating that the patent would offend morality or public policy, including by presenting "conclusive evidence" that its risks to public policy outweigh its benefits.

Furthermore, this scheme takes no account of the cost of litigation, which is prohibitively expensive, making this path to moral reflection unrealistic (Townend, 2014, p. 89).

One possible solution could be the inclusion, within the system, of individuals who are *familiar* with the mechanisms to make moral and ethical judgments. I will now respond to those who say that patent systems are not equipped to deal with ethical issues, and propose ways of incorporating such *familiarity* into patent systems, mainly by means of ethics committees.

5.3 Ethics committees and patent system

Having established that patents ought to be subject to moral consideration, like any other human enterprise, and that third parties or societal influences on that consideration are valuable, another question opens up: How can patent regimes be influenced by ethical reflections? There follow some suggestions to confront the idea that patent systems are not sufficiently equipped to address moral issues. In making these suggestions, I will not elaborate a detailed proposal, but rather respond to the idea that it is not possible to introduce moral reflection mechanisms into patent systems.

I believe there are several proposals to be made regarding ethical demands on the patent system, in relation to various actors. These actors have not necessarily been entirely forgotten, although they have been treated unequally (for example, activists account for the most important discussion in this literature; see Geiger, 2021).

For this reason, I am particularly interested in those who have argued for the inclusion of the bioethicist community within patent systems (perhaps only Salter and Salter, 2013; Jiang, 2019, indirectly). One promising way forward would be an ethics committee that could, at least to a minimal extent, provide indications for the action protocol of the office, the code of conduct or co-examine inventions that might have negative social consequences. In fact, this is already the procedure used in hospitals, universities, and many other scientific or technical institutions.

The general role of bioethicists is "to clarify, systematize, and extend one's moral thinking, surveying all the relevant considerations, explicating the concepts, detecting the theoretical commitments and practical implications" (Varelius, 2008, p. 129). This means that an advisory body could "provide positive input to the current patent system and help control and reduce the possibility of granting patents with negative socioeconomic consequences" (Jiang, 2019, p. 805).

Precisely the case-by-case approach which the EPO currently uses allows certain actors within the office to play a decisive role – one that they would not have in an *ex-ante* highly regulated system, full of explicit moral limits (without prejudice to broader proposals in terms of revisiting these "practical examples").

In view of the EPO's current restrictive moral and case-by-case approach when examining, for example, different uses that can be claimed for or assigned to an invention,

bioethicists could offer alternative interpretations. It should be remembered that, in the words of an EPO examiner, "the refusal of an application under Art 53(a) on the basis of this possible offensive use would be unjustified as long as there are acceptable purposes for which the invention can be used" (Fernandez y Brañas, 2014, p. 194). This means that "to reject patentability, an invention must not be capable of being used in a socially fruitful manner" (Schneider, 2014, p. 151). It goes without saying how controversial this could be, and how bioethicists could contribute to criticism and review.

We could link this with the EPO's doctrine whereby animal suffering in the development of the invention, or at any stage other than the direct consequence of its exploitation, cannot give rise to exclusions on the grounds of public policy or morality. The first question to be asked here is this: why do science and technology disclosed through patents have fewer ethical requirements than science published through other means? It should be remembered how it is normally assumed that any scientific paper that involves animal experimentation, or that has obtained data from human beings, will be published *only* if it includes the permissions granted by bioethics committees. If we recognize that patents determine certain uses of technologies, *a fortiori*, they should be candidate points at which to incorporate this scrutiny.

The possible inclusion of bioethicists in patent offices does not imply – and nor does any of the above – that such deontology would necessarily be applied according to the criteria of specific philosophical traditions or certain religions; nor that it should be restricted to the doctrine of certain national schools of bioethics. The fact that patent regimes have to consider societal influences on morality and public policy does not mean that such ethical tools would always be self-serving or nationalistic. As Salter and Salter (2013, p. 291) rightly point out, "there is a common utilitarian emphasis on identifying ethical procedures that can be used to address conflicting moral positions," as the oncomouse case has demonstrated.

The objective of this article is not, in any case, to argue in favor of prohibiting certain specific inventions – for instance, by their inclusion in the limits to patentability detailed in art. 53 – but rather, to propose a "playing field" that would allow specialists, in a similar way to what is already happening in other institutions, including scientific ones, to determine the degree to which morality and public order are affected by specific inventions. To use a very common metaphor in political theory, my goal here is not to indicate what the move on the board should be, but rather to discuss the rules of the game.

For all this to be possible, it would also be necessary to rely on the examiners themselves, who sometimes find it difficult to make use of the available tools (see Drahos, 1999, p. 440). I have been able to detect this in the interviews conducted for another contribution (cf. Acosta, 2023). The programs for sensitive patents also show that the legislation does not provide them with tools, and that regulations, codes and even internal protocols are not specific enough with regard to how they should act in the event of conflict or possible dispute. Bioethicists may be a useful resource in this regard.

The inclusion of both bioethicists and examiners, compared to aprioristic approaches, such as those that list all specific immoral cases, allows for evaluation of those types of patent applications that, to avoid falling foul of some pre-established external limitation, use ambiguous language, to hide the true intent behind their technology. Bioethicists, with the help of examiners, can more accurately interpret the authentic intentions and the genuine uses behind elaborate patent language.

With examiners and bioethicists together, it would become possible to review the explicit external limitations as well, such as surgical procedures or medical treatments, mentioned above [6]. This is so, in particular, because the intrinsically historical nature of technology

changes the perception we have, not only of disruptive technologies, but even of those that are well established [7].

Sterckx and Cockbain have developed a framework to apply in these cases. They believed that any review should be conducted at two levels. First, with respect to situations in which, although commercial execution of the invention contravenes "public policy" and/or morality, non-commercial execution may not. The example they choose is organ donation, which is considered morally acceptable, compared with organ sale (i.e. when the transfer of organs takes place for financial gain), which is considered morally unacceptable. The second level refers to cases in which exploitation (both commercial and non-commercial) of the invention may be acceptable, but monopolization of the invention would be contrary to "public order" and/or morality, "for example if the invention concerns parts of the human body" (Sterckx and Cockbain, 2012, p. 301).

5.4 Final reflections: the private and the public

It seems compatible with the ideas discussed above to demand supererogatory responsibility from businesses as well; and above all, from universities and public research institutes. Note that I am not limiting this demand to the requirement for inventors not to apply for patents on inventions that they believe violate public order or morality, but instead wondering about the infiltration of deeper ethical reflection.

Some historical cases, such as Marie Curie's refusal to seek a patent on radium (Hemmungs Wirtén, 2015, pp. 15–37), and many others, show that when (mainly public) institutions and individuals act for the public interest, efforts can be made not only to expand access to technologies, but also to make fairer and more socially beneficial technology, without having to reach the potential extreme of restrictions based on morality/ *ordre public*.

The well-known case of the insulin patent is interesting in this regard. In 1922, researchers at the University of Toronto discovered that the symptoms of diabetes could be reversed with insulin – a substance obtained from the cow's pancreas. They developed a manufacturing method and decided, against the medical *ethos* of the time, to patent it. However, they did not intend to use the intellectual property to make a profit, but to "defend the interests of patients" (Cassier and Sinding, 2008, p. 155). How did they do it? They applied for a patent very quickly, so pharmaceutical companies could not get ahead of the registration and make a business opportunity out of it. The University controlled industrial production by deciding on the companies to which the manufacturing could be assigned, looking at the quality of the resulting substance rather than the potential profit. Thus, their intention when patenting was to prevent the creation of monopolies and thus to guarantee not only access, but quality as well. Such an apparent "break" with the logic of patents led to certainly paradoxical circumstances, such as the intention to patent to prevent a monopoly, but it is a real example which illustrates that such a case has been possible, and could be again.

In this sense, I would also like to return to the "contract" that serves to justify the emergence of patents. Why not call upon the "signatory" society to play a decisive role in it? Perhaps we should also consider including citizen participation in innovation within patent offices, similarly to the way we discuss public participation in science. Well-known scholars like Justine Pila have advocated raising this social representation to a more decisive role: "the opportunity for public representation in the process of negotiating them should be increased beyond its currently limited degree, and assessments of the moral and public policy implications of patenting inventions be expanded accordingly" (Pila, 2020).

Internal committees in patent offices (such as ethics committees) could be the perfect platform for integrating citizen participation, bringing together both expert and lay members. According to Philip Kitcher in his very well-known model (2001), with this type of citizen participation in science, technical experts – in this case, examiners – would act as "tutors," certifying that the information available to citizens reflects the technical reality as such, avoiding "false beliefs about the natural world" and ensuring that the needs of minorities are given voice. From there, citizens would take the floor. The primary objective of the emerging discussion is to generate a decision arrived at by genuine consensus, rather than merely by vote. To this end, both citizens and experts must be honest, and not make risky bets from the outset. Finally, they must be obliged to explicitly incorporate into the agreement not only the interests of possible minorities, but also those of future generations.

Many other models could be proposed, or even applied, for patent systems. Indeed, some authors have even distinguished between these wide ranges of models in "citizen science," such as Kitcher's, and other forms of "community-based participatory research," "community science" or "user-centered design research" (Vaughn and Jacquez, 2020), depending on the degree of inclusion of non-scientists. However, when taking this into account as an inspiration for patent systems and offices, differences between scientific research and the assessment of patent applications should also be noted.

6. Implications

While it is true that few patent applications are denied for moral reasons, those cases are representative of the way in which societies attempt to regulate scientific institutions. This study helps advancing the discussion about morality in patent systems and, by extension, it brings a case for the wider debate regarding the role that moral limits should play in science and technology. The theoretical discoveries of the study facilitates the comprehension of patens as value-laden human creations, contrary to the dominant view, according to which patents are mere negative rights with no moral force. To show this dominant view, the position of the EPO and several scholars who have defended a restrictive interpretation of the moral limits to patentability have been reconstructed.

The research is also a practical attempt that can bring many insightful points to the practice of patent. It has been shown a way in which the bioethicist community could be incorporated into patent offices and co-examine inventions that might have negative social impact. The discussion about the responsibilities of examiners and businesses in all these processes can also be effective.

Notwithstanding the implications of this study, I believe there are some potential limitations. For instance, with respect to the scope, because I focus on the European context. The literature that argues for the narrow interpretations of moral and *ordre public* clauses is also limited. Further discussions about ethics committees, supererogatory responsibility and public representation are needed as well, especially if we want to enable a genuine debate about a patent's target public and public interest.

7. Conclusion

What is clear is that, precisely because society matters, as it can be affected by what patents do and do not protect, ethical debates must be heard. It was not my intention, in this article, to elaborate a detailed proposal, but rather to respond to the idea that it is not possible to introduce mechanisms of moral reflection into patent systems.

It has been shown throughout this article that the interpretation made by the EPO regarding the exclusions to patentability for moral and public policy reasons is restrictive, and some arguments defending this type of interpretation have been outlined.

Several criticisms to the restrictive interpretation of moral and ordre public clauses have been advanced. The aim was to promote the idea that, first, some uses are foreseen in patents, so that their moral implications can be evaluated. Second, that societal influences are valuable in evaluating the morality of patents, precisely because inventions protected by patents can affect the interests of the citizenry. Proposals concerning the inclusion of the bioethicist community, and the responsibility of examiners and companies, have been discussed.

This research has shown that it is possible to discuss the whole question about morality and patents beyond biotechnologies or case studies, using a broader approach, capable of responding to the arguments against the inclusion of ethics, but without falling into too many legalisms. In this paper, I have tried to exemplify this, but much more needs to be done in the future. The EPO's Board of Appeal has argued that *ordre public* and morality clauses are a question of principle to safeguard the public trust in the patent system (see Prifti, 2019, p. 3).

Notes

- 1. This French expression is usually translated as "public policy."
- 2. I will use the terms "morality," "moral" and "ethics" interchangeably.
- 3. It should be noted here that the EPO is even more sensitive to these external constraints than other offices like the USPTO, as shown by Parthasarathy (2011).
- 4. Some scholars call them "exceptions," in contrast to the more general morality and *ordre public* clauses, which would be "exclusions" (Bently, 2011). However, for the purpose of this article, I will unite them under the umbrella term "external limits." Where distinctions are necessary, I use the terms "practical examples" and "*ordre public* and moral clauses."
- 5. If the patent were to be subjected to ethical scrutiny, orientations toward certain uses would also be detected in the descriptions, in sections such as the "background" of the invention.
- 6. In this sense, some have also called for the revision of technological families and technical standardization, as "the apparently neutral processes of standardization are inextricably entwined with issues of cultural value, particularly around the ethical status of the embryo" (Waldby and Salter, 2008).
- There are authors who have recently called for an expansion of immoral cases in the codes for example, asking to avoid publishing certain results, even in scientific articles, when they could potentially be exploited by terrorists (Resnik, 2006, p. 144).

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Further reading

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Corresponding author

Benedicto Acosta can be contacted at: bneacosta@usal.es

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