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A Quest to Prohibit Immoral Inventions? An Analysis of Law and Policy in Human Biotechnology

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Abstract: This paper consists of an identification and analysis of the place of, and role of ethics play, in the various patent systems currently in force in Europe. As for the rapid evolution of biotechnology advances, it is significant to observe the response from legislators and the measures put in place to address the further issues. Contemporaneously, this work aims to act as a commentary on the relationship of biotechnology with intellectual property rights, and on the role played in this respect by law.

Keywords: "Order Public" and "Morality" provisions; Human Biotechnology; Role of ethics play

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1. Introduction

Biotechnology is a rapidly developing technology. The question of moral neutrality in granting patents for biotechnological inventions has long been the subject of contradictory debate. At the same time, biotechnology also raised important policy and social issues. Human biotechnology is the most notable discipline of biotechnology and includes many controversial and consequently well publicized, technologies and products, which involve not only legal issues, but also require significant ethical consideration. As a result, disputes concerning these types of patents are far more intense and widely reported than many other technical fields. The existing legislation in the field of biotechnology may well no longer be fit to address the proprietary and ethical questions and problems posed by this progress.

2. "Order Public" and "Morality" Provisions

The European Patent Convention 1973 (as amended) (EPC) is an instrument governing the procedures applicable to the European Patent Office (EPO) and, most notably, providing for a coordinated framework in relation to European patents. This instrument, a foundation in patent law in Europe, contains clauses concerning public order (referred to in the EPC and European patent law at large as order public) and morality.

The principle underlying the exclusion stipulated in Article 53(a) is to clearly distinguish the scope of patentability of inventions, excluding those that are immoral or contravene general interests in public policy, but this has also created significant controversy [1]. Due to the definitions of the terms "order public" and "morality" mentioned in this exclusion are intangible and subjective concepts, significant challenges are faced in their application. The EPO Guidelines for Examination 2019 (EPO Guidelines) clearly state that

the purpose of Article 53(a) is to strictly regulate behaviors that may cause the unrest of society.

In the field of biotechnology, the Implementing Regulations to the Convention on the Grant of European Patents (also 'EPC') stipulates those biotechnological inventions are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used [2]. This specific definition effectively singles out a particular class of invention for special treatment, likely due to the enhanced ethical considerations in this particular field. In this regard, Rule 26(1) EPC also specifically references and links the Biotechnology Directive (1998) on the legal protection of biotechnological inventions with certain provisions of the EPC when the subject of a patent application is biotechnology. More specifically, Rule 26(1) confirms that the Biotechnology Directive will be used a supplement to interpret the EPC. The Implementing Regulations itself also provides some exceptionally helpful guidance on specific categories of biotechnology and how these are to be viewed by the EPO. For example, an absolute prohibition on human cloning.

Article 6 of the Biotechnology Directive excludes the patentability of inventions on the grounds of harming public order or morality, in very similar terms to the EPC. However, Article 6(2) specifically enumerates four types of inventions that violate public order or morality and thus are ineligible for patenting, which differ from the more basic provisions in the EPC.

Following the implementation of the EPC, Article 6(2) of the Biotechnology Directive, the wording of which is incorporated into the Rule 28 EPC, became a significant consideration in the EPO's practices when considering patent applications and Article 53 EPC. Though the aim of associating the Biotechnology Directive, the EPC and the Implementing Regulations of EPC would seem to be harmonization, the differences between EPO guidance and rules and EU directives may cause confusion in the interpretation of European "order public" or "morality" [3].

3. Morality and Inventions Based on Human Biological Materials

Inventions that rely upon the use of human biological materials involve higher-level standards of human and civil rights, such as those guaranteed by international treaties and national constitutions (e.g. the right to life and how this is to be applied to fetuses) [3]. This forms a part of the concept of morality and order public in Article 53(a) EPC. One of the greatest controversies in human biotechnology and patent law is the regulation of research that using human embryo and the patentability of such technologies.

3.1. Human Dignity

The human body that forms the foundation of human dignity [4]. Article 1 of the Charter of Fundamental Rights of the European Union states that, 'Human dignity is inviolable. It must be respected and protected.' This concept is a cornerstone of society and, due to its interrogable nature, is a significant consideration when examining human tissue-based materials. There is, in this respect, a widely accepted school of thought that patenting human biotechnology inventions for commercial purposes is an affront to human dignity. It is therefore clear that there must be a balance between commercial interests and human dignity. The preamble of the Biotechnology Directive stipulates that "Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person [5]," which is an illustration of the acknowledgement by the patent authorities of the paramount importance to be attached to this concept.

Human dignity has become an aspect of the "order public". Advocate General F.G. Jacobs opined that the right to human dignity is a fundamental right that has been recognized by the European Court of Justice('CJEU') and almost all Contracting States and is a foundation of the legislation concerning human materials in biotechnology [6]. Article 6(1) and (2) of the Biotechnology Directive emphasizes that it is necessary to strictly formulate laws and regulations related to patents, to ensure that the human body cannot

be used or a person deprived of their autonomy over their body, thereby safeguarding human dignity. Under the legal framework of current European patent law, the prohibition of patents under Rule 28 EPC emanates from the principles of respect for human dignity and non-commercialization of the human body and its components.

3.2. The Terms "Human Embryo" and "Human Embryonic Stem Cells" (hESC) in European Biotechnology Patenting

The primary focus of much of the dispute concerning hESCs is the fundamental question of at what stage of development the fertilized egg can be considered a human embryo in the context of particular patent applications. This question is of such significance not only because of the broader ethical implications attached to the question by the scientific community, but also because if the human material used to gather hESCs in not classified as a human embryo, then its use will not automatically be prohibited by the morality clause (and the provisions of Rule 28(c) EPC).

What is rather unusual however, given its clear significance, is that neither the Biotechnology Directive, nor the EPC or any related legislation gives a legal definition to the term "human embryo [3]." This problem is them compounded by the international nature of both the issue and the patent legislation in question, as there is a complete lack of consensus on the status of human embryos in European countries.

Having considered some of the national level legislation and cultural difficulties relating to embryonic biotechnology, it is next important to consider the overarching European Legislation. Article 5(1) of the Biotechnology Directive excludes from patentability a "human body, at the various stages of its formation and development." Article 6(2)(c) then provides some further insight relating to the prohibition on using human embryos in certain circumstances. Next considering Rule 28(c) EPC, which is a transposition of Article 6 of the Biotechnology Directive, it can be seen that the legislature has the intention to completely prohibit patenting applications related to human embryos [8]. This increases the necessity to find an accepted definition, in order both to deter unethical innovation, but also to provide certainty and reassurance to scientists operating in this field.

The cases to which the moral protections offered by Rule 28(c) and Article 6 could apply are broad, thus the purpose of this absolute protection is clearly not, in itself to stipulate a specific way of defining embryos. Even were a generally accepted legal definition to materialize, due to the exceptional speed of scientific development in human embryo research, any such definitions could hardly keep pace. Understandably therefore, it is particularly difficult to legislate on these sensitive issues [8]. As a result of this lack of clarity, when interpreting Article 53(a), the undetermined legal term "human embryo" enables the EPO departments and the courts to conduct a subjective "case-by-case analysis" of this term relying on the objectives and purposes of Rule 28(c) and Article 53(a) EPC. This is not to say however that the overall discretion is particularly broad, as the EPO will continue to consider caselaw in this respect (being updated more regularly than statute) and the same will be considered at length later in his work.

3.3. The Meaning of "Ordre Public" and "Morality" In Patent Law for hESC Inventions

As opposed to the generality of the prohibitions in Article 53(a), the patentability of certain human biotechnology inventions is specifically addressed in Rule 28 EPC [9]. Using human embryos for industrial or commercial purpose is considered immoral under Rule 28(c) EPC, given the fact that is directly linked to the morality clause in Article 53(a) EPC. Although the terms contained in Rule 28(c) EPC appear self-evident, they do still merit some explanation. The central issue in this respect is that there are significant biological, ethical and legal differences between blastocysts, embryos, fetuses, and human beings.

In relation to the use of embryos and patentability, it should be noted that the patentability of the invention focuses on the morality of the commercial or industrial exploitation of that invention, and not on

the morality of the invention itself (see for example the wording of Article 6, Biotechnology Directive). Therefore, it is necessary to distinguish between the differing purposes for which human embryos are used, giving rise effectively to the question of whether this is to do scientific research or to be applied in industry or commercial activities. The Court of Justice of the European Union (CJEU) held in the Brüstle case that any use of human embryos is not patentable unless the use of the invention is for therapeutic and diagnostic purposes. Moreover, the CJEU also confirmed that industrial or commercial use of human embryos includes the use of these for the purposes of scientific research [10]. However, the court did not explain in this case what is meant by the term "use." This term is central to accurately interpreting the relevant prohibitions, because it relates to determining whether the invention has a beneficial effect on the embryo, in order to clarify the types of inventions that can be patented, and those that are prohibited. Therefore, the lack of interpretation of the term "use" may cause confusion in terms of practical application.

With respect to the interpretation of "human embryo", the Brüstle case held that fertilization is the beginning of the human development process. As a result, the CJEU applied a fairly wide concept of human embryo in this case. In stark contrast to the Brüstle case, the CJEU interpreted "human embryo" in a far more narrow sense in the International Stem Cell Corporation (ISCO) case [11]. The CJEU in this case followed the basic principles established in the Brüstle case. However, the court emphasized that an unfertilized human ovum must satisfy an additional condition to be considered a "human embryo," that being "having the ability to develop into a human." It was also held that the judging standard for this inherent ability should be connected with the current level of scientific development. This was perhaps a pre-emptive standard applied to address likely future developments in this field.

It is also necessary to emphasize the current scientific level because it has an impact on patent law. When science is in the process of continuous development, legal interpretation will, as is clearly shown in the research discussed in this work, be uncertain, which will further affect the judgment in such cases. Therefore, in the ISCO case, judges of the CJEU held that the Brüstle classification of human embryos was disconnected and out of touch with current scientific knowledge and was effectively in need of modernization. An unfertilized human ovum stimulated by parthenogenesis does not have the inherent ability to grow into a human being [12]. Although the patentability test, predicated on the definition of "human embryo" in the ISCO case is based on whether it has the ability to develop into a human being, it is difficult to apply the same logic to other biotechnology inventions, such as SCNT. This test is only really suitable for parthenogenesis, and lacks further explanation in relation to its other applications. Therefore, whether and how national courts choose to apply this decision in similar but not identical situations, is still an issue requiring further discussion.

In addition to defining the concept of "human embryo," the CJEU has endorsed the reasoning of the EPO's decisions on inventions that use human embryos and the requirement in such cases to meet requirements of morality and "order public [12]." The first important judgment on the patentability of this type of invention was the Wisconsin Alumni Research Institute (WARF) case [13]. The Enlarged Board of Appeal (EBA) in this case refused to adopt the usual moral exclusion methods, and instead interpreted the relevant provisions far more broadly, as they felt that the case concerned the basic supremacy of human dignity. The EBA also emphasized their belief that the purpose of the biotechnology invention patentability exclusions are to maintain the inviolability of human dignity. In particular, for example, Rule 28 EPC specifically confirms the prohibition of the commercialization of embryos. This is a moral leap, which applies to the "human embryo" as defined [14]. Therefore, given the interpretation of the relevant wording, there is little room for further man oeuvre on the application of Article 53(a) and Rule 28 EPC to these specific types of case.

However, the patentability of hESC research is far from being ethically determined, not only because the relevant scientific fields are constantly developing, but also because the relevant judicial interpretations

are influenced by multiple actors. Moreover, different interpretations of public policy terms may also make the public lose faith in the patent system. Therefore, it is necessary to explore ways to increase legal certainty while maintaining this important balance between public policy considerations and a desire for certainty. A further difficulty here is that certainty may be associated with inflexibility, an element that is arguably necessary to meet the rapidly changing field of biotechnology, as we have seen in discussing various aspects of case law.

4. Conclusion

In conclusion, it would be useful to adopt flexible definitions of terms in ethics clauses. However, from a long-term perspective, it may be necessary to adopt a unified understanding of "order public" and "morality" for the global interest in biotechnology innovation, which prohibits inventions that undermine human dignity and put personal welfare above the interests of science or society. As far as the current situation is concerned, however, important restrictions are set on the patentability of hESC inventions by the concept of human dignity, and these restrictions require a unified interpretation. To summarize, the morality provisions of the law and policy in biotechnology must be continuously improved along with the development of science and technology.

Disclosure statement

The author declares no conflict of interest.

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