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The European Patent Office outlines a fragile ethical frontier

Par

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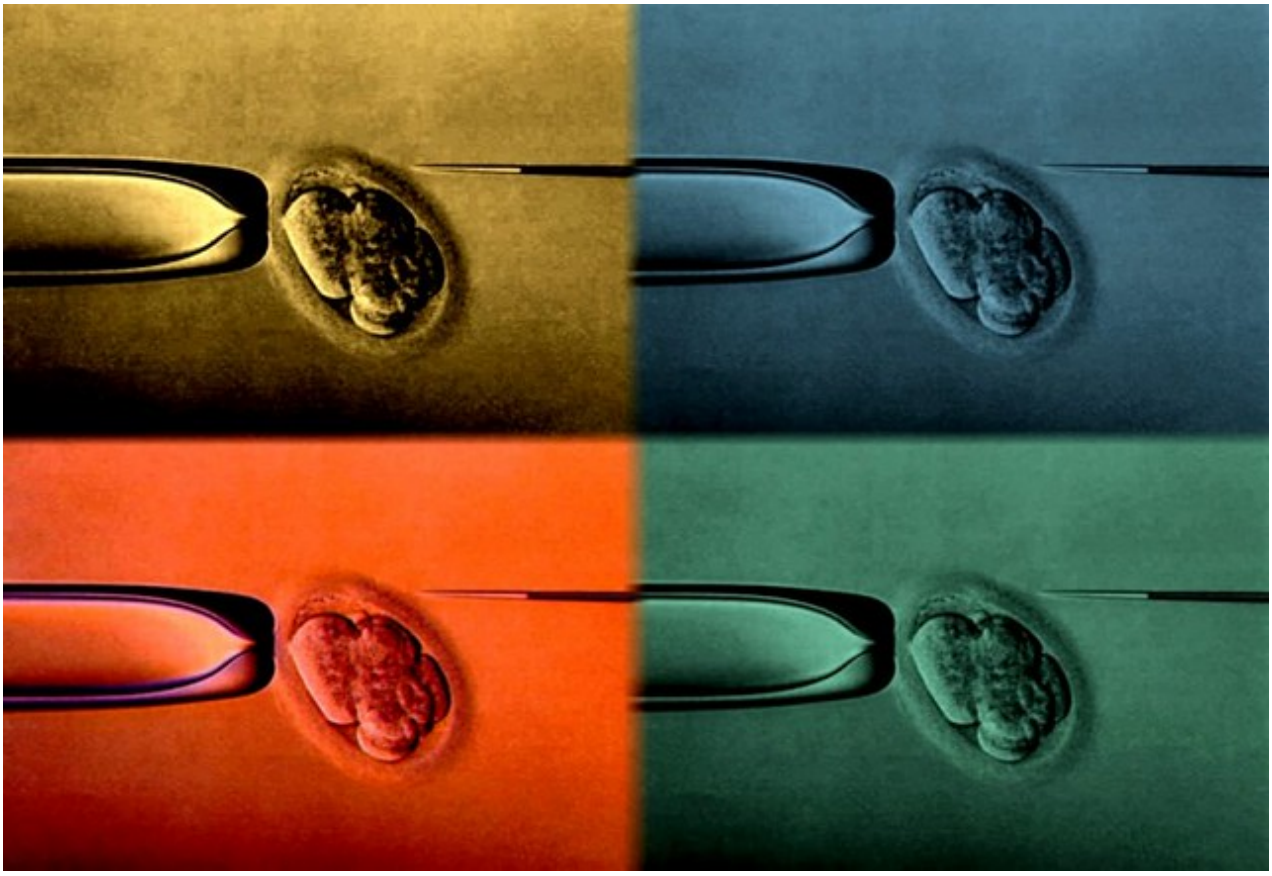
In September 2024, the European Patent Office (EPO) refused a patent for human-pig chimeras on the basis of the ethical rules governing patentability in biotechnology. By invoking the protection of "*human dignity*", the EPO is drawing a sometimes fluctuating line between innovation and respect for fundamental values. This decision sets a - perhaps fragile - precedent for inventions affecting human identity, and highlights the complexity of an ethical framework in the era of unbridled biotechnology.



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In line with ethical considerations that concern only the animal world (including human beings) but not the plant world, Article 53 a) of the European Patent Convention (EPC)[i] excludes from

patentability inventions deemed to be "*contrary to ordre public or morality*", in particular those that offend against human dignity. This provision is intended as an ethical safeguard in the biotechnology sector. This was the case for a patent application from the University of Minnesota, filed in March 2016, concerning the production of a human-pig chimera by integrating human pluripotent stem cells into genetically modified pig embryos. This application was ultimately refused by the European Patent Office (EPO) in September 2024 after a lengthy appeal procedure. EPO decision T1553/22[ii] is a reminder of the limits to the appropriation of living matter when humans are directly concerned.

The EPC aligned with Directive 98/44

Behind the vague and subjective concepts of "*ordre public*" and "*morality*", Article 53 a) seeks to provide a framework for the appropriation of scientific developments, particularly in the field of living organisms, which could compromise fundamental ethical values. In Europe, this article echoes Directive 98/44/EC on the legal protection of biotechnological inventions, which excludes from patentability processes that directly infringe human dignity. Although this Directive is not directly applicable to the EPC, it nevertheless provides, *via* whereas 38, an ethical and legal framework that may influence the EPO's interpretation of Article 53 a). This contributes to a harmonised approach to the patentability of biotechnological inventions in Europe.

Recital 38 of Directive 98/44 provides "*an illustrative list of inventions excluded from patentability so as to provide national courts and patent offices with a general guide to interpreting the reference to ordre public and morality*". This list, which is described as non-exhaustive, cites "*processes, the use of which offend against human dignity, such as processes to produce chimeras from germ cells or totipotent cells of humans and animals*". These are the legal bases on which the EPO based its decision T 1553/22.

A decision that raises ethical issues

The patent application entitled "*ETV2 and uses thereof*"[iii] filed by the University of Minnesota covered a method for producing a human-pig chimera by integrating human pluripotent stem cells into pig embryos genetically modified by deleting the ETV2 gene. This gene enables the pig to produce these cells and blood vessels. This chimera is expected to generate humanised blood vessels and blood cells for therapeutic applications. According to the University of Minnesota, the production of chimeric animals containing a mixture of human and pig cells would also make it possible to harvest organs that are immunologically compatible with human recipients, thereby addressing the critical shortage of organs.

The EPO's Examining Division considered that this technology raised ethical issues, in particular due to the integration of totipotent human stem cells into animal embryos. In application of Article 53 a), the Examining Division therefore refused the patent application in February 2022, a decision which the University of Minnesota has appealed.

The EPO's Board of Appeal therefore followed suit and examined the ethical implications of the University of Minnesota's invention, focusing in particular on issues of human dignity and biological identity. In its brief, the Board of Appeal confirmed the Examining Division's position, finding that the invention "*relates to human-animal chimeras in which human cell participation in the brain or germ cells is a realistic possibility rather than only a hypothetical one*" and that "*the claims [of the patent] are not drafted to exclude embodiments in which human cells are present in the brain and/or germ cells of the chimera*". The Board of Appeal therefore held that, in the light of Article 53(a) of the EPC and Recital 38 of Directive 98/44, the exclusion from patentability could be

justified.

This decision sets a precedent by clarifying the ethical limits for the patentability of human-animal chimeras and emphasising the protection of human dignity in the face of biotechnological advances.

Fluctuating case law

Prior to the chimera case, Article 53 a) was the basis for other EPO decisions, but apart from the specific subject of stem cells (see box), most of these concerned the issue of animal suffering.

In 1992, in decision T 19/90[iv] (the "*Oncomouse/Harvard University"* case), following rejection of the patent application by the Examining Division and an appeal by Harvard University, the EPO Board of Appeal examined the patentability of a genetically modified mouse for cancer research. The Board of Appeal considered that the Examining Division's decision on the exclusion of patentability "*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.*"[v]. On this basis, the Examining Division concluded that the invention was not contrary to morality or public policy. More specifically, it found that the production of an animal suitable for experimentation in cancer research, which makes it possible to reduce the number of tests carried out on animals, while involving fewer risks thanks to the use of qualified personnel, can generally be considered to be beneficial to humanity. This decision laid the foundations for ethical analysis under Article 53 a) EPC.

In 2012, in decision T 1262/04, the Board of Appeal considered the patentability of an invention relating to methods of detecting tumour cells in non-transgenic mice using light-generating proteins to measure the photons emitted. The Board had to decide whether Article 53 a) should be applied with the test of rule 28 d) of the EPC. This rule excludes from patentability "*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*". The Board of Appeal concluded that Rule 28 d) does not apply to non-transgenic animals, but that Article 53 a) still requires an ethical assessment based on a balance between animal suffering and the benefits for humanity. Although the mice received tumour cells, the method was promoted as reducing the total number of animals used and accelerating drug discovery through improved imaging techniques. The Board of Appeal therefore ruled that the medical benefits outweighed the animal suffering, making the invention patentable.

More recently, in September 2020, decision T 1553/15 examined the patentability of a pharmaceutical preparation obtained from rabbits into whose skin the vaccinia virus is injected to create inflammation, the rabbits then being killed to recover the skin. Six to ten rabbits were needed to prepare a single tablet. Given the very low yield and the sacrifice of many rabbits to exploit the invention, the Board considered that "*that the benefit to mankind brought by the present invention is not such as to weigh up against the suffering of animals which is necessary to produce the claimed pharmaceutical composition*". On the basis of Article 53 a), the Board of Appeal established that patentability must be refused if the impact on animal welfare exceeds the expected scientific benefits. It also specified that this case is not comparable to the Oncomouse/Harvard case, "*which opened up new research avenues in the field of oncology at the cost of the suffering of a limited number of animals*". This decision is a reminder of the need for an ethical balance between animal suffering and scientific progress.

Début encadré

Patentability of stem cells

The patentability of stem cells is also governed by Article 53 a) of the EPC. Rule 28 c) of the EPC specifies that, in accordance with Article 53 a), patents shall not be granted for "*uses of human embryos for industrial or commercial purposes*".

European case law has clarified these provisions in a number of key decisions. In case G 2/06[vi] (use of embryo/WARF) of 25 November 2008, the EPO's Enlarged Board of Appeal ruled that any invention requiring the destruction of human embryos is not patentable, even if such destruction is not explicitly mentioned in the patent claim. This position of the EPO was confirmed by the CJEU (Court of Justice of the European Union) in its decision C 34/10 (human embryo - definition - patent) of 18 November 2011.

However, not all stem cells are subject to the same restrictions as human embryonic stem cells. Pluripotent stem cells, which can differentiate into various cell types without being able to develop into a complete individual, are not considered to be embryos. Inventions involving these cells may be patentable, provided they meet the other criteria for patentability, such as novelty, inventive step and industrial application.

Fin encadré

A not necessarily reassuring outlook

This EPO case law shows the importance of interpreting the exclusion of "*morality*" provided for in Article 53 a), over and above the specific cases mentioned in recital 38 of Directive 98/44. It also underlines the need to preserve fundamental ethical guidelines and recalls the persistent tension between scientific innovation and the legal framework. In so doing, it raises questions about the interaction between patentability, regulation and societal acceptability.

Over and above the question of animal suffering, recent biotechnological developments, illustrated by the case of human-pig chimeras, raise fundamental questions about the appropriation and control of living organisms, particularly as regards the ownership of chimeric organisms and patent rights over partially human life forms. The EPO guidelines provide clarification on this point[vii] : "*Although the human body, at the various stages of its formation and development, and the simple discovery of one of its elements [...] cannot constitute patentable inventions, an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application[...] may constitute a patentable invention, even if the structure of that element is identical to that of a natural element*". The EPO guidelines also refer to recital 21 of Directive 98/44/EC, which states that such an element "*is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself*".

Article 53 a) and its notions of "*ordre public*" and "*morality*" are proving to be an uncertain safeguard in the face of biotechnological advances. Biomedical ethics and standards may evolve under the influence of economic and political forces. If respect for "*human dignity*" were to become the last bastion, there is no guarantee that it would be sufficient, especially as it could be argued that it has already been weakened by contemporary society.

i European Patent Convention (EPC), "Article 53, Exceptions to patentability".

[ii] EPO, Technical Board of Appeal, "Decision T 1553/22 (Human-pig chimeras/UNIVERSITY OF MINNESOTA) 04-09-2024", 4 September 2024.

[iii] World Intellectual Property Organization (WIPO), "PCT Patent Application No. WO 2016/141234" , 9 September 2016, from which European application EP3264891 is derived.

[iv] EPO, Technical Board of Appeal, "T 0019/90 (Souris oncogène) 03-10-1990", 3 October 1990.

[v] EPO, Official Journal, "DECISIONS OF THE EXAMINING AND OPPOSITION DIVISIONS - Grant of European patent No. 0 169 672 (Onco-mouse/Harvard)", p. 588-593, 31 October 1992.

[vi] EPO, Enlarged Board of Appeal, "Decision G 0002/06 (Use of embryos/WARF) 25-11-2008", 25 November 2008.

[vii] EPO, Guidelines, "5.2 Patentable biotechnological inventions".
