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# Patentability of Biotechnological Inventions should not have to Consider Morality and Ordre Public: A Critical Analysis on the European Patent Laws

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## ABSTRACT

*This paper critically analyses the patentability of biotechnological inventions within the context of European Patent Law, focusing the tension between technological innovation and moral considerations. While biotechnological inventions have led to significant advancements, particularly in healthcare, the legal framework governing these inventions, specifically the European Patent Convention (EPC), incorporates moral and public order exceptions that can limit patentability. The paper examines how these exceptions, particularly under Article 53 of EPC, have been applied to inventions involving genetic modifications, human embryos, and transgenic organisms. It argues that the current interpretation of these exceptions was often guided by ethical concerns rooted in European Cultural values that has led to inconsistencies and a restrictive patent system that could stifle innovation. The paper reviews landmark cases, such as those involving genetically modified organisms and human germline editing, to highlight how the application of morality and public order principles has evolved. The analysis suggests that while moral and public order considerations are crucial in patent law, a more flexible and case-specific approach would better balance ethical concerns with the need for technological progress. Furthermore, the paper critiques the imbalance created by these restrictions, particularly how they may hinder access to life-saving biotechnologies. In conclusion, the paper advocates for a more adaptable legal framework that aligns patentability criteria with the rapid pace of scientific advancement, ensuring that biotechnological inventions can be both ethically developed and widely accessible.*

**Keywords:** *Biotechnological, Innovation, Patentability, Public order, Technology.*

## I. INTRODUCTION

In the current era, the emergence of new technologies has become an irresistible part of human's life. Biotechnological inventions are found to be a prominent one among them. Such inventions

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brought up changes not only to our lives but law and the patent systems. Allowing patentability to new technological inventions can be an encouragement for innovations to make life easier. Perhaps it could turn into a serious threat to the globe. The successful patentability of these inventions indicates that ‘patent might be obtained upon the trees of the forest and the plants of the earth.’<sup>2</sup> For improving the protection of such inventions, patent law shall not be the sole legislative tool. Although inventors aim to claim ownership of patent rights to enjoy monopoly in the market.

European Union Law explicitly enumerate the statutory objection on invention which are against *public ordre* and morality<sup>3</sup>. Various inventions with the involvement of technology in microorganism, plants, animals, and humans has been filed for patent eligibility in the EPO (European Patent Office). The line between an invention with patentable subject matter from a non-patentable subject matter requires clarity. Inventions including transgenic plants, animals and human germline are prominent in the field of patenting biotechnological inventions. Scholars argue that technological inventions should be restricted due to its impact against public order and morality. The need for development of these technological inventions is increasing for achieving proper health care and to discover cure for various diseases in the future.

The statutory exemptions on *ordre public* and the teleological interpretation followed by European Courts in promoting the patentability of biotechnological inventions shall be deeply discussed in this essay. The developments in European Union over patenting biotech inventions starting from transgenic plants, animals, human embryos, human cells, genes & DNA will be discussed by citing the landmark precedents. The application of morality principle is limited by granting patent rights to plants, animals, human tissues and what not. Exceptions mentioned in EPO and EU Directive over biotech inventions will be criticised with reference to relevant cases.

## II. STATUTORY EXCEPTIONS ON *ORDRE PUBLIC* & MORALITY

“The concept of ‘*ordre public*’ covers the protection of public security, the physical integrity of individuals as part of society, and the concept of morality is related to the accepted norms which are deeply rooted in the culture inherent in European society and civilization.”<sup>4</sup> “EPO denies patent for biotechnological inventions which involves (*a*) *processes for cloning human beings*;

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<sup>3</sup> Directive (EC) 44/1998 of the European Parliament and of the Council on the legal protection of biotechnological inventions [1998] OJ L213/13, art 6.2

<sup>4</sup> Duncan Matthews, Timo Minssen, Ana Nordberg, ‘*Balancing Innovation, ‘Ordre Public’ and Morality in Human Germline Editing: A Call for More Nuanced Approaches in Patent Law*’ EJHL 562, 578 (2022).

(b)Processes for modifying the germ line identity of human beings (c) Uses of human embryos for industrial or commercial purposes”.<sup>5</sup> While interpreting the requirements of biotech inventions, EPC must comply with Rule 28 of the Implementing Regulations.<sup>6</sup>

The patent eligibility of every invention is determined with the three tests i.e., novelty, inventive step, and industrial application for all the fields of technology. Development of new technological inventions arises enormous complexity in the interpretation of the patent laws. While granting patent rights to such inventions it is necessary to consider the public policy of that region perhaps such consideration should be in consonance with the patent system’s objectives.<sup>7</sup> Though achieving the objectives of patent law is important, an unethical exploitation of patent rights is deniable.

The exception under Article 53(1) of the EPC denies patentability to the inventions of commercial exploitation which is contrary to the *public ordre* or morality.<sup>8</sup> Since there is no definition for the term ‘public ordre’ in the convention nor any other legal instrument, it must be defined by the court while deciding the cases. The article provides for not granting patents to any plants, animals, or any biological processes. On the other hand, there are inventions patented for discovering new medicines, cures & high nutritional plants by usage of biotechnology which has given a substantial benefit for the world. The court’s findings in one of the first plant biotechnological invention stated that ‘no misuse or destructive exploitation of the procedures followed by the technology for inventing it and the invention benefits the plants and seeds from being protected from weeds and any fungal disease’.<sup>9</sup> There is no threat to public order nor the activities concerned are immoral and therefore, the patent is granted for the transgenic plant. This judgement was a milestone for encouraging biotechnological inventions in EU.

As per Article 6, ‘Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation is not deemed to be so contrary merely because it is prohibited by law or regulation’.<sup>10</sup> Inventions shall be unpatentable if the processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes

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<sup>5</sup> Convention on the Grant of European Patents (European Patent Convention), [1978] OJ L326/255.

<sup>6</sup> Angelica Bonfanti, ‘Environmental Risk in Biotech Patent Disputes: Which Role for *Ordre Public* before the European Patent Office?’ 3 EJRR 47, 50. See, Rule 28 – Exceptions to patentability of EPC (2012).

<sup>7</sup> Duncan, ‘Balancing Innovation’ (n 2) 562.

<sup>8</sup> Convention on the Grant of European Patents (European Patent Convention), [1978] OJ L326/255, art. 53(a).

<sup>9</sup> *Infra*, (n 10), Plant Genetic Systems/Glutamine Synthetase Inhibitors.

<sup>10</sup> Directive (EC) 44/1998 of the European Parliament and of the Council on the legal protection of biotechnological inventions [1998] OJ L213/13, art 6.1

and 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.<sup>11</sup>

“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.”<sup>12</sup> TRIPS flexibilities allow the national legal systems to frame their own mechanism of public governance for the patentability of technological innovation. The EPO and EU directive has incorporated the exceptions in it by considering the ethical concerns of their community. Interestingly, Sweden & Norway has an ethical committee within their patent system which provides opinion on biotech inventions which are immoral<sup>13</sup>.

The inclusion of moral and ethical values in biotechnological inventions is because it involves manipulation or modification in the living matter, i.e., plants, animals, human and their cells, etc. The ECJ has ruled out that ‘it is necessary to leave it up to member states to assess whether a biotechnology invention can be considered valid in the terms of the ethical, sociological, or philosophical context of each country.’<sup>14</sup> Additionally, the Board of Appeal decisions involving the inventions in genome editing do consider ‘ordre public and morality’ exceptions seriously as it would lead to socially undesirable consequences if not considered.

While examining the patent application for biotech inventions, the examiner must consider the provisions of EPC and EU above-mentioned. The law is clear by elucidated what is patentable and what is not. Since this field of technology is dynamic and evolving day to day, it is difficult to follow a uniform law. Currently, the inventions involve transgenic plants & animals, human gene patenting, modification of DNA, human protein, and tissues. We might not know the elements in human body or any other living organisms which would be used for discovering future inventions. Therefore, it is difficult to examine every biotech patent application and like it always said, every case should be decided based on its own merits and drawbacks.

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<sup>11</sup> *Ibid*, (art 6.2)

<sup>12</sup> Decision of the Technical Board of Appeal of 21 February 1995. T356/93 (Plant Genetic Systems/Glutamine Synthetase Inhibitors [opposition by Greenpeace]).

<sup>13</sup> Hellstadius, ‘*A Comparative Analysis of the national implementation of the Directive’s Morality Clause: Embryonic Stem Cells Patents*’, 117 (2009).

<sup>14</sup> Astrid Burhoi & Jonas Ledendal, ‘Moral Exclusions in European Biotechnology Patent Law’, Lund University Publications <https://lup.lub.lu.se/luur/download?func=downloadFile&recordOID=1337961&fileOID=1646263> accessed on 29 December, 2023. *Also See*, Netherlands v Parliament and Council, [2001] 377/98.

### III. WHAT BIOTECHNOLOGICAL INVENTIONS ARE PATENTABLE AND WHAT ARE NOT? JUDICIARY'S RESPONSE

#### 1) *Transgenic Plants & Animals*

The patent application on genetically modified plant & cells to resist glutamine synthetase was one of the landmark decisions of the Technical Board of Appeal (TBA) on biotechnological inventions<sup>15</sup>. Though case has been superseded by many decisions, it was one of the first cases which decided on interpreting public *ordre*. When the opposition division rejected the *Greenpeace's* contention on the derogatory subject matter of the invention, the case was taken to the TBA. The board concluded two significant points (a) public ordre and morality have specific meaning in the EPC irrespective of the legal and regulatory codes of individual contracting states; (b) the meaning must be dependent on the individual institutions of Europe.<sup>16</sup> "Therefore, Article 53(a) should be interpreted at 'crossroads between science and public policy' and thereby entrust it with the conventionally accepted standards of conduct pertaining to the inherent European culture and are to be excluded from patentability."<sup>17</sup>

Two applicability tests which guided the courts to interpret patent applications of biotech inventions related to public order and morale are namely 'the cost-benefit test' and 'the abhorrence standard.' A utilitarian approach has been ruled out in *Harvard Oncomouse case*<sup>18</sup>, which involved genetically modified cancer-promoting gene in the mouse. Primarily animals are being used as a testing material for clinical trials and experiments to invent a new drug or a new product in the field of biotechnology. Such issues deal with various concerns like animal welfare and the suffering which an animal goes through as an outcome of the research. This issue involves high concern on moral and ethical value of the species. There was a paradigm shift from the *Glutamine case* by weighing the balance between suffering of the animal *versus* benefit to the humankind. Court ruled in favour of patentee due to the significant benefits gained by the mankind through the invention. Oncomouse case dealt with 'cost-benefit test.

Another landmark case, *Upjohn mouse* where the patent application proposed a modified transgenic mouse to research on the hair growth. To treat the human baldness and wool

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<sup>15</sup> Decision of the Technical Board of Appeal of 21 February 1995. T356/93 *Transgenic animals/Harvard*. EPO, Decision of the TBA of 6 July 2004, T 0315/03. *See*, Plant Genetic Systems/ Glutamine Synthetase Inhibitors (Opposition by Greenpeace).

<sup>16</sup> *Ibid*

<sup>17</sup> Mhlambululi Mafu, 'Biotechnology patenting: Limits of ordre public and morality provisions' (*Research Square*, 2 May 2023) <https://www.researchsquare.com/article/rs-2868502/v1.pdf> accessed 25 December 2023

<sup>18</sup> Decision of the TBA of 6 July 2004, T 0315/03 (*Transgenic animals/HARVARD*). Oncomouse have a cancer producing gene, a virus used to promote oncogene into an animal's breast tissue. When this virus is injected into the mouse, it develops human breast cancer within a few months.

production, the oncogene (same gene used in oncomouse) is injected to the generation of mice family. The patent office identified the lack of inventive step and pointed out the morality concept. This decision was an improved version of *Oncomouse* case, since it discussed about the differences in ‘acceptable suffering’ and ‘unacceptable suffering’ of the species. The gain earned out the invention does not outweigh the suffering of the animal from the testing process. Therefore, the court considered the absence of nexus between gain of humans and the unacceptable suffering of the mice and rejected the patentability. This case applied abhorrence standard.

The two above-mentioned cases can be the classic example for interpreting similar subject matter of the invention with a different outcome. It can be clearer seen that the ‘concept of morality and public order’ changes from time to time based on the needs of the country or region. Notably, EU wanted to improve its biotechnological research in developing drugs for curing several diseases like cancer and the grant of patent to *Oncomouse* was a milestone for biotechnological inventions.

The two applicability tests guided the courts to interpret patent applications of biotech inventions related to public order and morale are namely ‘the cost-benefit test’ and ‘the abhorrence standard.’ It is pertinent to note that, the ethical dimension is considered by taking a different approach in Canada by granting patent to the *Oncomouse*.<sup>19</sup> They discussed about the importance of advancement of biotechnological inventions and the benefits earned out of research and development and granted patent. The judgement reveals that these inventions are not against public interest and moral concerns of Canada.

Though there are common requirements for a patentable inventions like novelty, inventive step, and industrial application across the globe. There shall be a ‘technical’ requirement which convinces the EPO and the courts for the grant of patent. The invention which provides a technical solution to the already existing work makes the patent application to be stronger. The emergence of new technologies allows good candidates for patent protection.<sup>20</sup> Since an invention which is novel and specific are more likely to satisfy the eligibility criteria for patent. Biotechnological inventions do have the higher probability of discovering novel inventions and

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<sup>19</sup> Harvard college v Canada (Commissioner of Patents) [2002] 4 SCC 76.

See, para 21 of the judgement “Transgenic mice, including the oncomouse, have a role of potential importance, the evidence is that use of transgenic mice improves the effectiveness of the research that can be done, and shortens the time required to produce results. As Dr. Philip Leder, the co-inventor of the oncomouse, told a U.S. Congressional hearing in 1989: “In the past few weeks, the gene for cystic fibrosis has been identified and the ability to replace this gene, for example, in a mouse with defective human cystic fibrosis gene would constitute an extremely powerful model system for the development of an effective treatment and for individuals and families at risk for this and other diseases, this would represent a priceless asset”.

<sup>20</sup> *Ibid* (n 12).

inventions which has strong industrial application.

2) *Inventions involving human's element*

Inventions involving humans namely process of cloning, modifying germ line identity, use of human embryos for industrial/commercial purposes are specifically unpatentable<sup>21</sup>. For instance, the literal interpretation prohibits the subject matter of modifications in human germline by genome editing under the directive. On the other hand, judiciary gives a different interpretation based on the improvements of technology in various cases. Scholars argue that EU law conventionally has teleological interpretation, therefore, the outcome of a case differs based on its purposes rather than following the positive law. Patent claims involving “Inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it are allowed for patentability”<sup>22</sup> So the courts had extended the scope of patent law in biotechnology by allowing germline modification for therapeutic purposes.

In the early 1990s with the absence of any specific references like biotech directive, the courts discussed about the aspect of ‘public order’ in the *Relaxin case*<sup>23</sup>. The patent claim for a DNA fragment encoding human protein from human tissues taken from a pregnant woman is submitted<sup>24</sup>. It is opposed by citing two grounds mentioned in Article 53(a) of EPC; the subject matter is non-patentable and it is against public order and morality. Firstly, it is contended that the fragment is a mere discovery of an element from the female body so it lacks novelty and inventive step. Secondly, taking the relaxin tissue from pregnant woman is immoral on the ground that, it is an offence against human dignity to take advantage of a particular female condition which involves a technical process for profit-oriented commercial purpose<sup>25</sup>. It would involve patenting a human gene or human life, which is violative of human rights.

The opposition division responded to all the contentions and stated, there is no involvement on abuse of woman’s pregnancy. Subsequently, it said that there is no patenting of human life rather it involves patenting a chemical substance called DNA which contains such genetic information which is merely a material from human body. The court also considered the consent given by such pregnant woman for donating tissues and carrying out further research within gynaecological conditions and therefore, granted patent for the claim. This case applied the ‘abhorrence test’ involving patent of a biological material isolated from humans.

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<sup>21</sup> Directive (EC) 44/1998 of the European Parliament and of the Council on the legal protection of biotechnological inventions [1998] OJ L213/13, art 6.2.

<sup>22</sup> Duncan, ‘Balancing Innovation’, 581. (n 2)

<sup>23</sup> Astrid Burhoi & Jonas Ledenda (n 11)

<sup>24</sup> Decision of the Technical Board of Appeal, 23 October 2002, T 0272/95 (Relaxin/Howard Florey Institute)

<sup>25</sup> *Ibid*



Another landmark case related to patenting human germline editing and human embryonic stem cells (hECS) is *Oliver Brustle v Greenpeace* ruling by ECJ<sup>26</sup>. A specified set of isolating & purifying neural precursor cells produced from hECS used for research purposes to treat neurological diseases<sup>27</sup>. Such invention focussed on treating various diseases like dementia, blindness, and Parkinson's disease in humans. This case involved discussion on two issues, the non-patentable subject matter i.e., human embryos which is against public order; the scope of industrial & commercial purpose of such invention. Article 6(2) has been widely interpreted by trying to define the term 'human embryos and commercial use of such inventions'<sup>28</sup>.

The case was filed in Federal Patent Court and Greenpeace has contended that, this invention involves destruction of human embryos which is unethical and should not be granted patent rights. The case was shifted to Court of Justice of EU (CJEU). Article 6(2) read with Article 6(1) specifically states use of human embryos for industrial or commercial purposes is unpatentable and it is against public order and morality. Therefore, the court rejected patentability by citing the morality aspect.

It is pertinent to note that, the primary principles of a patent right involve matters concerning industrial and commercial nature. The law allows for researching human embryos and stem cells but denies patentability. The goal of using the human material for research is to find cures for existing severe diseases and to prevent humans from future diseases. Since patent rights are an acknowledgement for inventors which encourages research and development these restrictions would be a hurdle for biotechnological researchers who would be restricted from enjoying ethical exploitation of patent rights.

#### IV. IMBALANCE BETWEEN EMERGING TECHNOLOGIES & LAW

The recognition of these emerging technologies as a discrete category of technology raises special policy and ethical issues, including for patenting.<sup>29</sup> While granting patents we should guarantee the ethical exploitation of patent rights and must maintain balance between enjoyment of patent rights to rewards innovation and a fair and equitable access to technologies.<sup>30</sup> There is enormous growth in biological sciences which involves introduction of different processes like most-advanced technologies like CRISPR technology for gene editing and patenting. Such

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<sup>26</sup> *Oliver Brustle v Greenpeace*, [2011] 34/10 I-09821 [Judgement of the court (Grand Chamber)].

<sup>27</sup> *Ibid*

<sup>28</sup> *Supra*, (n 14). Biotechnology Patenting, 2023.

<sup>29</sup> J Pila, 'Adapting the ordre public and morality exclusion of European patent law to accommodate emerging technologies', <https://www.nature.com/articles/s41587-020-0504-5> accessed 27 December 2023. *See* page 556, 'The so-called IP% - the world's five largest patent offices, responsible between them for granting approximately 85% of the world's patents are considering how to harmonize their approach to emerging technologies'

<sup>30</sup> Duncan, [2002] EJHL, 566.

scientific improvements are cheap and beneficial for developing new inventions/cures for severe diseases. Though we have specific directive and laws for patenting biotech inventions, the scientific improvements are one step ahead of law. This creates complexities and lack of applicability of law for the unknown new developments in the world.

The moral, ethical and cultural values of the state is not as fast as the technological changes, therefore, legislations and judges find the task patenting which involves moral and ethical aspects to be challenging. The precedents including *Oncomouse* and *Relaxin* had various implication related to bioethics. Though introduction of new technologies were largely opposed by the European people initially, people have started to get adapted to it due to their needs and requirements in the field of health and medicine.

Patenting biotech inventions would limit the accessibility to all the people with an increase in costs, but there shall be improved healthcare on the hand. Scholars argue that inventions which involves advancement in health care should be given protection and encouragement, but patent law is not the only way to protect it. Granting patent rights would stimulate commercialization which would limit the accessibility to all the sections of society. Therefore, there is a need for clarity in law on determining the patentability of biotechnological inventions.

## V. CONCLUSION

Biotechnological inventions have novel subject matters and they provide solutions for various health care challenges. They invent cures for severe life-threatening diseases like cancer, genetic disorders even heart diseases through biotechnology. Some countries do not have any public order and morality provisions which restricts the inventions patentability like United States, Japan, etc. On the other hand, EU puts forth restrictions due to the people's culture and their concern on protecting environment. Having a limitation to these inventions is a good thing because it makes the monopolies to have checks and balances. It will also be a protective shield to the human life or any living organism from being misused for the benefit of commercial activities.

A strict interpretation to the exceptions could be avoided and application of these public order and morality exceptions should be flexible. Although, the public order and social values differ from one country to another. In the *oncomouse* case, the claim fulfilled all the patentable criteria initially and granted patentability in different countries. A complete ban on these inventions would discourage the technological innovations that would foster the society's needs. Overall, the existing laws and exceptions on biotech inventions and its moral exclusions must be in consonance with the emerging technologies. With the outbreak of SARS-COVID and many

other dreadful diseases, we all realised the need for new medicines and cures which would prevent us from death. Improving scientific technologies is both necessary and desirable currently for the mankind. Based on the patent claims, the inventions should be examined case-by-case by looking into the possible outcomes which could be both good and bad. As the saying goes, 'balance is the key to everything.'<sup>31</sup>

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<sup>31</sup> Koi Fresco.