PATENTABILITY OF HUMAN EMBRYO, GENE AND OTHER LIFE FORMS: A COMPARATIVE STUDY OF MORALITY CLAUSE ON PATENT LAWS IN INDIA, EU AND USA

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ABSTRACT

With the rising technological developments in the field of biotechnology with resulting biotechnology inventions the patentability of these inventions has always been controversial. The inventions in this field often raise ethical and legal questions. This paper encapsulates the concept of biotechnology patents, its patentability and the major hindrance in patenting these inventions, the morality clause. The morality clause, being the result of the Trade-Related aspects of Intellectual Property rights (TRIPS) agreement adopted in 1994, clearly established the principle relating to the inventions against public order, morality, human, animal, plant life or health under Article 27(2) and this has been widely recognised by various countries and the same has been incorporated in their patent laws. This paper specifically addresses the applicability of the morality clause for inventions relating to human embryos, genes and other life forms (genetically modified organisms, micro-organisms and transgenic animals) which often raise ethical and moral questions. It also further covers the views and applicability of the morality clause in different countries, specifically India, European Union and United States of America. This will help in understanding the difference in the patentability of biotechnology patents and the morality clause in India to other countries.

Keywords: Biotechnology patents, patentability, morality clause, TRIPS, human embryos, gene, other life forms.

Research objective

The primary objective of this research is to critically examine the concept of biotechnology patents and the limitations imposed on their patentability by morality clause. It seeks to analyse how inventions involving human embryos, genes, genetically modified organisms, micro-organisms and transgenic animals raise ethical and legal concerns that affect their recognition under patent law by comparing the existing patent laws in European Union, United States of America with India on the light of the Trade Related Aspects of Intellectual Property Rights.

Research Questions:

- How does the TRIPS agreement influence the inclusion and interpretation of the morality clause in domestic patent laws?
- How does section 3(b) and 3(j) of the Indian Patent Act,1970 regulate patentability of biotechnology inventions involving life forms, genes and human embryo?
- Can human embryos and genes be given private ownership through patents?
- Whether section 3(b) and 3(j) of Indian patent act sufficient for biotechnology inventions?

Literature Review:

Priya S. Menon, Morality and Biotechnology Patents in India: A Critical Appraisal, 12 J. Intell. Prop. Rts. 215 (2019) The paper substantiates our claim that the sec 3(b) and 3(j) of the Indian patents act,1970 ensures ethical oversight but hinders the ability to compete effectively internationally.

Thomas Cottier & Marion Panizzon, Legal Perspectives on the Morality Clause in TRIPS Article 27(2), 8 J. World Intell. Prop. 389 (2005) the paper contends that the TRIPS Article 27(2)'s morality clause allows state to preserve ethical integrity without having an effect on innovations by narrowly construing.

Ana Nordberg, The Morality of Biotechnology Patents: Human Dignity and the Brüstle Case, 46 Int'l Rev. Intell. Prop. & Competition L. 485 (2015) the comparative analysis in the paper shows how the European Union incorporated human dignity into the patent law, shaping the global norms on the embryonic research.

Research methodology

This research adopts **doctrinal approach** where it examines various legal statutes, judicial

decisions, international conventions regulating biotechnology patents and morality clause. This study is comparative and qualitative in nature as it involves analysis of legal frameworks in India, United States, and European Union and academic literatures referred in concluding the study respectively.

Scope and limitation

The paper includes a comparative analysis of biotechnology patent laws of India, European Union and United States of America focusing on human embryo, gene and other life forms evaluating the statutes, precedents and moral implications. However, the paper is based only on the secondary sources and dynamic nature of biotech inventions that may outdo existing standards.

1.Prelude

Patents are considered paramount when it comes to new inventions. Patents generally provide a temporary control and exclusivity over a technique, product or process. It protects the interest of the inventor and it immunises those inventions from being misused, sold or any kinds of unauthorised use. Patents are applicable to inventions virtually in all fields of technology including mechanical, electrical, chemical, science and computer related fields. Bio technology inventions are one such subject matter that could be patented. To contend with technological development and its application in the field of biology, numerous inventions and innovations are emerging on a daily basis, thus patenting is indispensable.

The patentability of an invention is determined by novelty, inventive step and industrial applicability.[1] Failing to comply with the criteria jeopardises patentability. However, despite complying with the above mentioned, patents are denied if it contravenes the morality clause. The morality clause plays a decisive role in determining the patentability of an invention. The patentability and morality clause traces back to the mid-19th century. The morality clause was initially referred to as "Generally inconvenient" or "Morally inconvenient".[2] It was only a part of patent texts but was never codified. In the 20th century it was incorporated in various domestic laws. Subsequently, with the view of harmonising the intellectual property laws an international agreement was incorporated which set a minimum standard for various intellectual property known as the Trade related aspects of the intellectual property rights

[1] Understanding Biotechnology patents - IJRPR, https://ijrpr.com/uploads/V5ISSUE9/IJRPR33345.pdf
[2] Fundamental grounds for morality in intellectual property law, https://digilabs.global/wp-content/uploads/2021/07/FundamentalGroundsforMoralityinIntellectualPropertyLaw.pdf

(TRIPs). This agreement acknowledged and included the morality clause thereby granting an international recognition.

The patents and the morality clause are "two sides of the same coin"- While one incentivises the inventors and drives inventions the other curbs and imposes restrictions on those inventions based on the morals and ethics. The biotechnology patents being subject to the morality clause, is being confined to birth inventions on specific areas relating to human embryos, genes and other life organisms. Though there are minimum standards established by the TRIPs agreement, there are differences in patenting of these controversial inventions among various countries. This paper examines the patentability of inventions in biotechnology focusing on the applicability of the morality clause in specific areas analysing the perspectives on patentability of those inventions by India, European Union and United States of America.

2. Understanding Biotechnology

A Hungarian engineer in 1919 named Karl Ereky coined the term "biotechnology" to denote the use of science and techniques to develop products from raw materials with the aid of living organisms. The history of biotechnology and inventions roots back to 6000 years where the biological systems were used to develop products or processes.[3]

Biotechnology is a multidisciplinary field which involves the application of biology and engineering to develop products or methods that help the environment, plants, animals or human society.[4] It usually involves the application or modification of biological systems in the due process.

The concept of biotechnology can be used to explore, invent and innovate in various fields and it is categorized based on those applications and by assigning colours - red (medical processes), White or grey (industrial processes), Green(agriculture), Gold(bioinformatics), Blue (marine and aquatic environment), Yellow (food production), Dark(warfare), violet (governance of ethical considerations). It is important to understand that the field of biotechnology is burgeoning and is being explored all across the world with a plethora of inventions.[5]

[3] Comparison between USA and India, https://ijirl.com/wp-content/uploads/2022/09/BIOTECHNOLOGY-PATENTING-COMPARISON-BETWEEN-USA-AND-INDIA-.pdf
[4] Varsha Gupta et al., An introduction to biotechnology Basic and Applied Aspects of Biotechnology (2016), https://pmc.ncbi.nlm.nih.gov/articles/PMC7119977/
[5] Nick Barney & Sarah Lewis, What is biotechnology? definition, types and applications: TechTarget WhatIs (2022), https://www.techtarget.com/whatis/definition/biotechnology.

The spectrum of biotechnology inventions is huge and some of it ranges from mRNA vaccines under red biotechnology, Golden rice under green biotechnology, Bioplastics under white or grey biotechnology, Genetically modified crops like pest resistant corn under yellow biotechnology, Gene sequence software under gold biotechnology, Algae based cosmetics under blue biotechnology, sophisticated biosensors under dark biotechnology to violet biotechnology analyses and safeguards inventions in the above mentioned.

3. Understanding patents and biotechnology patents

3.1 What is patent?

World intellectual property organization (WIPO) defines Patent as "An exclusive right granted for an invention".[6] The patents grant the inventor legal rights and benefits. It prohibits any person, to make, sell or use an invention for a limited period. In simple, patent provides a monopoly right over a product, process or technique over a time period and also gives a legal protection for those inventions.

The supreme court in *Bishwanath Prasad Radhey Shyam v. Hindustan metal industries*[7] held that it was only optional and not mandatory for the inventor to obtain a patent for their invention. The court further emphasized the significance of patents stating that patents are exclusive rights given to the inventor to possess a temporary statutory monopoly over the invention thus incentivizing innovation, protecting intellectual effort subject to knowledge sharing.

3.2 exceptions

However, there are few anomalies where the patent holder can authorize third parties to make, sell or use the product, process or technique. This includes:

- **Licensing:** It allows a third party to use the patented invention under specific terms like for a specific purpose, duration etc.
- **Assignment:** The inventor legally transfers the patent to another person or a company completely relinquishing the rights. The inventor no longer retains the patent.

[6] Patents, https://www.wipo.int/en/web/patents
[7] Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries on 13 December, 1978, https://indiankanoon.org/doc/1905157/

- **Compulsory licensing:** It is a government authorized exception where the patented invention can be used without the patent holder's consent. For instance, in case of public health, national emergencies.[8]

3.3 Co -relation between time period and types of patents

The TRIPs agreements laid down the minimum standard of time period for the patents to be 20 years. For instance, countries like India, United states of America, European union follows the same as the TRIPs agreement to safeguard these inventions for the period of 20years from the date of filing. However, the time period for the patents varies with the types of patents. The types include

- **Utility patents:** It is the most well-known patent. It protects new products, processes or techniques. It can be patented for a period of 20 years from the date of filing.
- **Plant patents:** It protects the types of plants that are created through artificial means other than the traditional method. It can be patented for a period of 20 years from the date of filing.
- **Design patents:** These patents usually protect the design, shape, pattern and such of the products. It focuses on the looks and appearances of the product. It can be patented for a period of 15 years from the day it is granted.[9]

3.4 Requirements deciding patentability of an invention

There are certain prerequisites that decides the patentability of the invention. It is mandatory for the inventions to meet the prerequisites to be patented under a statute. The TRIPs agreement in Article 27(1) lays down the requirements as[10]

- **Novelty:** The product, process or the technique shall be new and not known, disclosed to the public.
- **Inventive step:** The product, process or technique shall not be obvious and apparent to persons skilled in the same field.
- **Industrial applicability:** The product, process or technique so invented should

[8] Admin, Licensing v. assignment IIPRD (2020), https://www.iiprd.com/licensing-v-assignment/#:~:text=Conclusion,at%20aishani@khuranaandkhurana.com

[9] What are the different types of patents: A complete guide, www.bajajfinserv.in (2025), https://www.bajajfinserv.in/different-types-of-patents.

[10] World Trade Organization, WTO, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm#:~:text=The%20TRIPS%20Agreement%20requires%20Member,novelty%2C%20inventiveness%20and%20industrial%20applicability.

be capable of being applied in any field or an industry.

Failing to meet even one of the criteria impacts patentability of the invention. However, meeting these alone doesn't guarantee the patentability. There are two other factors that determines the patentability given under Article 27(2) of the TRIPs agreement. It is essential for the invention to not fall under those two factors, namely:[11]

- **Public morals:** The invention contrary to public order or morality.
- **Diagnostic, medical and surgical methods:** The inventions related to diagnostic, medicinal and surgical methods for treating humans and animals.

These inventions falling under these categories shall also be excluded from patentability. The patentability of the inventions is always determined by the above-mentioned patents.

3.5 Biotechnology patents

The biotechnology patents are specific type of patents given to the products, processes or techniques involving the modification and manipulation of the biological components like the genetic materials, living organisms (humans, animals, plants, fungi, protists and microorganisms). The US supreme court in the case *Diamond v. Chakrabarty* held that inventions on living organisms could be patented. The court acknowledged the patent system might encourage innovation in biotechnology industry and provides incentives.[12] The biotechnology patent is considered a utility patent as they protect the practical and functional use of an innovation.

The products, processes and techniques shall qualify the above-mentioned key requirements of the patents, failing which affects the patentability. However, specifically for biotechnology patents there always rises concerns relating to the public order and morality aspects. These arise due to various criticisms and contradicting views relating to the inventions in fields relating to human embryos, genes and other life organisms.

4. Understanding morality clause

The general consensus about the morality clause in intellectual property law is that it is a legal principle or a provision prohibit the registration or protection of an intellectual property that is contrary to accepted ethics, public order or religious sentiments. The concept of morality clause

[11] Ibid at 10
[12] Diamond v. Chakrabarty | 447 U.S. 303 (1980) | justia U.S. Supreme Court Center, https://supreme.justia.com/cases/federal/us/447/303/

differs from one intellectual property to other. For instance, in case of copyright, it concerns to the moral rights of the author to integrity and attribution while in trademark and patent law it's a ground for refusing registration or grants considering it might cause harm to the society and environment.[13]

4.1 Evolution of morality clause in patent law

The patentability and morality clause roots back to mid-19th century. It is where the very initial patent texts, documents and patent laws considered rejecting patents for the inventions that were labeled "generally inconvenient" or "morally inconvenient".[14] These expressions reflected that regardless that some inventions passed the test of novelty, inventive step and industrial applicability, it could not be patented as they were against the moral, social and legal norms.

4.1.1 Historical perspective

In the early 19th century, there were explicit references regarding these moral norms in the patent texts

- In 1841 a patent text refers to refusal of inventions "contrary to religion and public morals"
- "Generally inconvenient" and "morally inconvenient" were the primary terms used in texts and documents to refer to such inventions, that refer to the inventions, by its very nature, as detrimental to state, public order.
- From the very beginning, the English law highlighted that patents shall not be granted for inventions that were considered harmful to the "laws of the realm" or "mischievous to the state" thus setting the precedent for excluding inventions by the greater social or ethical firewall.

4.1.2 Legal and philosophical evolution

With the evolution it is possible to understand the idea that patent rights are not conclusive when it is not subject to community welfare. One example was the England Statute of Monopolies (1623) which set the stage for this by stating that

[13] Editorial StaffEditorial Staff at Selvam and Selvam is a team of Lawyers & Editorial Staff at Selvam and Selvam is a team of Lawyers, Morality & IP – How Far Is Too Far? Trademark Patent Attorneys for Registration to Litigation, https://selvams.com/blog/morality-ip-how-far-is-too-far/

[14] Supra at 2

exclusive rights must not come in conflict with public order.[15] However, in the 19th century, the issue of morality as a reason for rejection, by law or judicial doctrine, was more deeply debated in both Europe and the US.

- In 1800s both the civil law and common law countries started denying patents that was against the morals and public order.
- In the United States, the idea of "moral utility" was the basis of denying patents of products that allowed immoral or illegal activities even before the appearance of morality clauses in statutory law.[16]
- Europe had the philosophical and legal discussions, particularly the French and British patent laws, centred on ensuring that inventions did not get monopolies if they were "generally inconvenient"- against the public or moral interest.[17]

4.1.3 Modern context

In the 20th century, the idea of morality clause was incorporated in conventions and various domestic legislations like the European Patent Convention (EPC) and the Indian Patents Act (1970), which assigns the role of morality as one of the criteria for patentability. However, few domestic legislations had their morality clause wider in scope resulting in refusing of patents to many of the inventions which was considered unfair.

There were various negotiations made during “Uruguay round” as a part of trade negotiations in year 1986-1994 and as a result of these negotiations an agreement called the Trade Related aspects of Intellectual Property Rights (TRIPs) was adopted under world trade organisation. Article 27(2) of the agreement sets the standards regarding the patentability and morality. It implies that though the TRIPS Agreement broadly mandates members of the WTO to make patents accessible in every field of technology, there are still some inventions that can be kept out of patentability by those countries provided that a patent grant and commercial exploitation do not pose a threat to ordre public (public order) or morality. Such cases include an invention that may injure the life or health of humans, animals, or plants, or lead to serious pollution of the environment.[18] Nevertheless, TRIPS imposes some restrictions: a nation cannot deny a patent only on the ground that its national

[15] Supra at 2
[16] Critical Analysis of Moral and Public Order Grounds Limiting Patent Protection - IJIRT, https://ijirt.org/publishedpaper/IJIRT172158_PAPER.pdf
[17] Supra at 2
[18] Suma Athreye, Lucia Piscitello & Kenneth C. Shadlen, Twenty-five years since trips: Patent policy and international business Journal of International Business Policy (2020), https://pmc.ncbi.nlm.nih.gov/articles/PMC7549422/

law prohibits the use of the particular invention. Rather, the exclusion has to be supported by the matters of ethics, safety, or public welfare that are dealt with in the morality clauses to ensure that these clauses are not being utilized by any party for the sole purpose of protectionism or arbitrary purposes.[19]

5. Ethical barriers in field of biotechnology

Biotechnology, is majorly one of the most groundbreaking and controversial with respect to ethics, fields of modern science. The possible applications of biotechnology extend to areas like agronomy, medical science, pharmaceuticals, and nature preservation.

Although the use of biotechnology in the production of life-saving drugs, development of genetically modified food crops, and manufacture of sustainable biofuels can tremendously contribute to resolving the most urgent human problems, the field also evokes strong ethical and moral concerns. At the core of these discussions is the problem of whether or not such inventions should be allowed to be patented. Thus, those morality provisions in patent law that operate as the critical safeguard are mingling in the zone where advance technology is balanced against moral and ethical considerations.

Often biotechnology deals with the substantial alteration of living organisms, which is extended to genetic manipulations of sequences, stem cells, embryos, and other life organisms like genetically modified organisms, microorganisms and transgenic animals. These kinds of inventions may be opening those edges and still standing in the middle of the ethical ban on scientific advancement. For instance, in many patent laws, the category of inventions constituting the commercial use of human embryos is totally excluded. Article 53(a) of the European Patent Convention (EPC) states inventions contrary to ordre public or morality shall not be patentable.[20] By the same, Section 3(b) of the Indian Patents Act, 1970 forbids the patenting of such inventions the exploitation of which may be in conflict with public order or morality or may lead to serious injury to human, animal, or plant life or the environment.[21]

Morality clauses can lead to the circumstance of non-inclusion or limitation of patents dealing with the inhumane treatment of animals, the harmful creation of organisms and the manipulation of life forms in such a way that they are considered by the public morality

[19] Ibid at 18
[20] Article 53 – exceptions to patentability, Article 53 – Exceptions to patentability, https://www.epo.org/en/legal/epc/2020/a53.html
[21] Section 3 in the Patents Act, 1970, https://indiankanoon.org/doc/874310/

offensive. These legal provisions foster responsible innovation by cultivating positive features such as openness, accountability, and the ethical forms which in turn may influence the conduct of biotechnology and patent. So these clauses remain as necessary standards of flexibility that could help biotechnology regulations to still be in tune with the intricate and everchanging relationships in nature. Morality clauses in a way function as the moral safety networks in the law of biotechnology patent, which, on the one hand, acknowledges scientific advancement and, on the other, very strictly maintains the fundamental ethical standards related to human life and dignity.

6. Understanding Human embryos, Gene and other life forms

6.1 Human embryos

Morality clauses in patent law are fundamentally important as they essentially figure out the parameters of the patents that deal with human embryos and hence mirror the moral concerns that run deep with such inventions. Normally, these clauses ban patents on inventions that impinge in the disintegration or commercialization of human embryos, as such performances are seen as opposing human dignity and moral principles.

A human embryo is the earliest phase of human growth, which starts with an egg cell and a sperm cell fertilization and goes on with the cell mass differentiation and multiplication until around the eighth week of pregnancy.[22] It thus has moral value, should not be represented as goods or treated with the view to the commercialization of them. In case, processes that involve human embryos are carried out without the exploitation and destruction of the embryos, then the related patents might be allowed. For instance, induced pluripotent stem cells (iPSCs), which are the product of reprogrammed adult cells, are broadly patentable as they do not result in the destruction of the embryo.[23]

However, the rest i.e. patents on embryos or totipotent embryonic stem cells are considered as patent-prohibited immoral ones like neural precursor cells derived from human embryonic stem cells.[24]

[22] PhD Kristin Brogaard, The stages of embryo development Path Fertility (2024), https://pathfertility.com/the-stages-of-embryo-development/

[23] John Lee, Global patent landscape of induced pluripotent stem cells Vanderbilt University (1970), https://wp0.vanderbilt.edu/youngscientistjournal/article/global-patent-landscape-of-induced-pluripotent-stem-cells

[24] David B Resnik, Embryonic stem cell patents and human dignity Health care analysis : HCA : journal of health philosophy and policy (2007), https://pmc.ncbi.nlm.nih.gov/articles/PMC2695597/

The justification from an ethical standpoint is mainly to halt the instrumentalization or commodification of nature and further to reach the goal of showing respect to the inherent dignity of the life forms in question.

6.2 Gene

Morality clauses in patent law are the key elements that dictate the regulation of gene patents, being the main characters in these ethical dilemmas. Genes are part of DNA that give the body instructions or information to make proteins, which are the building and regulating units of living organisms. Genes are the basic units of inheritance and are found in every naturally occurring cell.[25] In patent law, Inventions regarding use or modification of gene includes

- Isolated DNA sequences – the removal and purification of a gene from a body outside.
- Genetic modification – the change of genes to create new traits (for example, pest resistance in crops).
- Gene therapy methods – giving genetic material access to the patients to heal diseases.
- Synthetic DNA (cDNA) – DNA artificially created that resembles natural genes but is not entirely the same.[26]

Such a patent may be opposed from a moral point of view because it converts living things into private property and at the same time, rules human dignity and human integrity may be violated. The moral debate contributes to the idea that genes, particularly those connected to human identity, are not for sale or for being controlled by anybody because they are the common heritage of mankind.[27] Furthermore, gene patenting may result in the unavailability of some necessary medical tests and cures due to the granting of exclusive rights that may be a barrier to research and innovation.

6.3 other life forms

One of the functions of morality clauses in biotechnology patent law is to act as ethical human shields preventing the patenting of ideas that are harmful, unethical, or even contradictory to the public values. Other life forms include

[25] DNA | role, Purpose & production of proteins - lesson | study.com, https://study.com/academy/lesson/what-is-the-role-of-dna-in-protein-synthesis.html
[26] The myriad scare: Isolated DNA molecules remain patent eligible (for now!) | articles | finnegan | leading IP+ law firm, https://www.finnegan.com/en/insights/articles/the-myriad-scare-isolated-dna-molecules-remain-patent-eligible.html
[27] Santa Clara University, Ethics and gene patenting Markkula Center for Applied Ethics, https://www.scu.edu/ethics/focus-areas/bioethics/resources/ethics-and-gene-patenting/

- Microorganisms – bacteria, fungi, yeast, viruses, etc.
- Plants – genetically modified (GM) or hybrid plants.
- Animals – transgenic or genetically engineered animals.

Each one of them leads to a variety of ethical, legal, and commercial issues, especially under questions of morality and biodiversity. With regard to the inventions such as genetically modified animals, genetically modified microorganisms, and transgenic animals, these clauses play a decisive role in taking care of an ethical aspect while letting the scientific progress go further

Genetically modified animals and transgenic animals are organisms whose genomes have been changed by biotechnological methods to get different new features or to secrete valuable proteins. Such changes may be a call for great hopes in the field of medicine and agriculture as well as research but morality clauses are the ones that assure that these inventions will not cause the unnecessary suffering of or oppose the inherent dignity of living things. There is a general atmosphere of concern over the welfare of the animals that accompany the genetic alterations, and ethical issues in that regard are becoming more and more frequent, and they require morality clauses for them to be adequately solved, for instance when animals are genetically altered for experimental purposes or industrial use. Moreover, these clauses enable stopping the process of turning life into a commodity in a way society would find offensive or disrespectful of it.

On the other side, microorganisms, in which the cells have been reprogrammed by the use of biotechnological tools, can still become potential pollutants of the environment or a danger to human health in the simplification of life forms. Morality clauses lead to the assessment of potential adverse effects nerve the release of genetically modified microbes. Such a moral judgement depends not only on the practicality of the invention but also on its extended impact on the biotic and the abiotic components of the environment.[28]

These clauses are rooted in a larger commitment to the ethical treatment of human dignity, animal welfare, the environment, and the prevention of the commodification of life. They first of all acknowledge that social and moral standards should mediate technological innovations. It is important to decide whether the pros that genetic changes bring are worth the cons that

[28]The role of Morality in Biotechnology Patent Law, https://law.bepress.com/cgi/viewcontent.cgi?article=1097&context=uvalwps

they entail like harm, suffering, or ethical breaches.

7. Interpretation by different countries

7.1 India

The Indian Patent Act of 1970, significantly amended in 2005, forms the foundation of the patent system in India. The morality clause in India is implemented through the provisions of "Section 3(b)" of the Indian Patent Act, which lists exclusions from patentable inventions, they are: "primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment." The provision is a general one which sets the boundaries of moral and ethical values as aspects of the law that can prohibit patent rights on certain inventions. The patentability of specific aspects in Indian perspective is as follows

7.1.1 Human Embryos

Human embryos and the commercial use of them are a part of those inventions for which the patent law forbids a patent for ethical reasons. The morality clause contained in Indian patent law is a part of an implicit ban on all those activities that might lead to human cloning and use of embryos in research, or any invention that results in the destruction or exploitation of human embryos. Despite India having no landmark case law in the field, the patent officers take help of such precedents as the decisions of the European Patent Office that grant/reject patents on human embryonic stem cell technologies on morality grounds. Besides, the guidelines of the Indian Council of Medical Research (ICMR) also lay stress on the ethical sourcing and handling of the biological material, which also has an impact on patent decisions. ***Hwang Woo-suk Controversy***[29]**:** Although it is not an Indian case, the scandal caused by the false stem cell research in South Korea is one of the instances that Indian patent officers and scholars often cite when pointing out the need for ethical research and morality provisions. The scandal was regarding forcibly obtained eggs.

7.1.2 Genes

The issue of gene patenting is still a heated ethical debate in India. Section 3(b) forbids patents on inventions that violate the ethical values of the society and among such concerns are commodification of and ownership over human genetic material. Nevertheless, isolated gene

[29] Full article: The Hwang scandal that "Shook the world of science," https://www.tandfonline.com/doi/full/10.1215/s12280-008-9041-x

sequences or genetically modified proteins could be patented when the novelty and inventive step requirements are met, but the morality clause will be there to ensure that no patent protection will be given if the source is unethical and the exploitation of the material occurs. Indian patent officers are less known for their technical approach but rather for carefully scrutinizing the ethical implications, especially when it comes to consent and benefit-sharing of genetic resources and traditional knowledge. This is also supported by the Biological Diversity Act (2002) which is complementary to patent law in preventing the illegal use of native genetic resources.[30] It regulates access to biological resources and traditional knowledge and requires patent applicants who use biological materials indigenous to India to ensure strict compliance. The law prohibits the use of such resources without prior consent, thus imposing ethical restrictions related to the morality clauses.

7.1.3 Other Life Forms (Including Genetically Modified and Transgenic Animals, Microorganisms)

According to section 3(j) of the Indian Patent Act, no patents shall be granted for inventions relating to plants and animals, "whole or any part thereof other than microorganisms."[31] Un-patentability of the invention in the area of life forms is the main aim to ensure the protection of biodiversity and address the socio-ethical concerns of the life forms' ownership. At the same time, it is technically possible to patent microorganisms that have been modified through specific technical processes. This is a reflection of a compromise between the promotion of biotechnology and the moral, environmental, and traditional interests preserving balanced.

Genetically modified and transgenic animals are complex in terms of ethical and moral issues. However, despite the restrictions on direct patenting of these life forms, their genetic components or biotechnological methods are still usually patentable when morality and public order provisions are followed. Indian patent officers remain apprehensive and are still referring to the ethical guidelines and international practices when they examine the application, especially in the area of animal welfare, environmental safety, and welfare concerns.[32]

[30] Raja SelvamFounder & Managing Attorney & Founder & Managing Attorney, Understanding the indian biological diversity law, and its implications for patent applications involving biological resources Trademark Patent Attorneys for Registration to Litigation, https://selvams.com/blog/understanding-the-indian-biological-diversity-law-and-its-implications-for-patent-applications-involving-biological

[31] supra at 21

[32] Patenting life forms in India: Legal & ethical implications, https://www.globalpatentfiling.com/blog/PATENTING-LIFE-FORMS-IN-INDIA

7.1.4 Lack of precedents and regulations

Lack of Landmark Indian Cases: There are not many cases that directly discuss morality clauses in biotechnology patents in India, indicating that there is almost no litigation in this area. The courts extensively rely on international examples and protocols.

Indian Patent Office Guidelines: The procedural guidelines require the disclosure of ethics for biotechnology patents and refuse the patents when the inventions are associated with unethical deeds or exploitation.[33]

Indian patent officers have the power to exercise their discretion under Section 3(b) to make sure that inventions do not violate public morals or legal ethics. Though they are ambiguous in definitions, more often they have to do case-by-case interpretations. Officers talk about the importance of the ethical source of biological materials and the demonstration of respect for the autonomy of the donor, prior consent, and compliance with biodiversity norms. There is a demand in the Indian patent community for more distinct jurisprudence and more clearly defined guidelines that would help to recognize the ethical concerns that come up in an invention as well as the fact that it is simply a new biotechnology innovation. To be guided in the right application of the morality clause in India, officers often consider international best practices that include EPO decisions and TRIPS provisions.[34] This helps India to comply with the global standards and at the same time take into account the local culture and ethical norms.

7.2 European Union

The European Union intimately integrates morality clauses within its patent system, especially through the "EU Biotechnology Directive (Directive 98/44/EC)" and the "European Patent Convention (EPC)" as implemented by the European Patent Office (EPO). The main elements of the morality provisions are:

Article 6 of the EU Biotechnology Directive[35]

This article stipulates that no patents shall be granted if the commercial exploitation of the invention would be contrary to "ordre public" or morality"

- Article 6(1) refers to the general morality exclusion.

[33] Guidelines for examination of biotechnology applications ..., https://ipindia.gov.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf
[34] Helen P Azyu & Avishek Chakraborty, Patentability of Biotechnology Inventions: Indian ethical guidelines Journal of Dharma, https://dvkjournals.in/index.php/jd/article/view/3859
[35] Supra at 21

- Article 6(2) defines recited examples of the kinds of excluded inventions, among these, the use of 'human embryos for industrial or commercial purposes'.

Article 53(a) of the EPC[36]

It prohibits, in very clear terms, that patents should be granted to those inventions, where the commercial exploitation would be contrary to morality or public order. This provision is almost entirely reflected by the Biotech Directive and acts as the legal basis of the morality-bases exclusions.

7.2.1 Human Embryos

The use of human embryos in biotechnology patents is one of the most debated issues under the morality clause. The European Patent Office has in practice and through its jurisprudence consistently applied the refusal of a patent where the invention is the utilization of human embryos for industrial or commercial purposes, basing such decisions on Article 6(2)(c) of the Directive and Article 53(a) EPC.

The *WARF stem cell patent*[37] denial on the basis of morality grounds is one of the most important cases that demonstrate the implementation of the morality clause with respect to human embryos.

On the other hand, various cases depicting inconsistent application and interpretation of Article 6(2) across the Member States have led to legal uncertainty in these jurisdictions. The scholars and policy makers argue whether the morality clause hampers innovation or secures the very same ethical standards that are essential.

In *Brüstle v. Greenpeace (2011)*[38]*,* the Court of Justice of the European Union (CJEU) decided whether the inventions including human embryonic stem cells were patentable under the EU Biotech Directive (Directive 98/44/EC). Dr. Oliver Brüstle reportedly had a German patent on neural precursor cells that were derived from human embryonic stem cells and were used to treat neurological diseases, but Greenpeace filed a complaint, alleging that the patent was immoral. The CJEU held that 'human embryo' must be understood as a concept with very broad definition, embryos after fertilization, and cells that can develop into a human being are

[36] Supra at 20
[37] Schlich, The (European) warf decision Schlich Ltd (2022), https://www.schlich.co.uk/the-european-warf-decision/
[38] CJEU stem cell patents: Brüstle v Greenpeace (C-34/10), D Young & Co, https://www.dyoung.com/en/knowledgebank/articles/brustlestemcells

included and, in addition to that, the court indicated that the invention most probably unpatentable for morality reasons as it leads to human embryo destruction (Article 6(2)(c) of the Directive). With this decisive judgement, the issue of whether in the EU the use of human embryos for commercial purposes constitutes a violation of the fundamental public policy and morality values, thus rendering them non-protectable by patents, was very clearly outlined Nevertheless, there is controversy and legal ambiguity since Article 6(2)(c) came before the isolation of hESCs and does not directly refer to them, hence there are various interpretations among the EU Member States. Though the EPO rules are strict, the actual controlling and interpretation depend largely on individual member states, which reflect the differences not only in their cultures and societies but also in their views on human embryo usage.

7.2.2 Genes

According to EU law, gene patenting is allowed, especially for isolated sequences, but with ethical control. The Biotech Directive, Article 5,[39] permits patenting of the isolated gene sequences, with the emphasis on the technical character that goes beyond their natural state. It should simply be noted that the request for patents on genes may raise some ethical concerns regarding the commodification and ownership of human genetic material. The examination of patent applications in Europe requires that the principle of respect for human dignity and privacy rights is insured.

7.2.3 Other Life Forms

The morality clause in the EU disallows patents on inventions that involve processes or products that are considered repugnant from a moral point of view, including such GMO animals or micro-organisms, which are likely to be the cause of harm to health, environment, or animal welfare. The EPC and the Directive feature ‘ethical evaluation’ as the main issue in the case of animal welfare and environmental impact. By way of example, genetically modified animal patents are evaluated on the issue of achieving a balance between the benefits of innovation and the ethical costs with the patent offices that are taking the action of ‘animal cruelty concerns'.[40]

[39] Directive - 98/44 - en - EUR-lex, EUR, https://eur-lex.europa.eu/eli/dir/1998/44/oj/eng
[40] The European Patent Office outlines a fragile Ethical Frontier, The European Patent Office outlines a fragile ethical frontier – Inf’OGM, https://infogm.org/en/the-european-patent-office-outlines-a-fragile-ethical-frontier/

'*Harvard oncomouse patent' case***[41]** One of the most famous cases that the European Patent Office (EPO) has ever had to deal with is the Harvard Oncomouse case, which is a landmark in the morality clause in biotechnology. Harvard initially filed for a patent for a genetically altered mouse whose cancer was easily treatable, but objections were raised under Article 53(a) EPC, which bans inventions that are contrary to normal social practices or morality.

EPO sympathized with the moral concerns about animal suffering but decided to carry out a balancing test, considering these concerns against the major medical benefits that provided the cancer research. The conclusion was that the patent was maintained but limited only to mice, without granting the invention to all rodents, thus indicating its usefulness while at the same time, the patent and the moral and legal scope were partially receded.

This is a case demonstrating how the ethical concerns are factored in the EU when deciding patentability in the biotech field as opposed to the US which is very liberal and Canada/India which are rather strict.

EPO patent officers rigorously enforce the morality clauses as per the Directive and the EPC. Their approach is a fine balance between ethical barriers and the encouragement of invention. They agree with the dynamic aspect of morality, which means that with every new development in biotechnology, morality has to be reconsidered. European Commission and the EPO are very much in favour of the moral and ethical advisory boards and international bodies playing a role in improving the quality of moral decisions.

7.3 United States of America

In contrast to most other jurisdictions, the U.S. patent system as per the Patent Act of 1952 and run by the United States Patent and Trademark Office (USPTO) does not comprise a non-negotiable statutory morality clause. Morality issues in the U.S. are not a specific ground for refusal of patents. Rather, the eligibility of the patent is determined by the traditional criteria of novelty, non-obviousness, and utility as per 35 of United states code.[42]

The U.S. adopts a method which is sometimes referred to by the academics as a "patent first, ask questions later" approach where it is possible that ethical controversies arise after the

[41] Bioethics and patent law: The case of the Oncomouse, WIPO, https://www.wipo.int/web/wipo-magazine/articles/bioethics-and-patent-law-the-case-of-the-oncomouse-35278
[42] Patent, Legal Information Institute, https://www.law.cornell.edu/wex/patent

granting of the patent of a contentious biotechnological invention.[43] The morality or ethical examination of biotechnological inventions does not usually occur during the patent grant process, but through the intervention of the regulators, public policies, or courts.

The obsolete moral utility doctrine allowed the rejection of patents on inventions that were considered immoral or harmful, but the key court rulings like *Juicy Whip v. Orange Bang (1999)*[44] practically abolished the idea by emphasizing utility and eligibility without considering morality. The USPTO has declared that it does not have the power to refuse a patent if the only grounds for refusal are moral or public policy objections.

7.3.1 Human Embryos

There is no explicit exclusion in the U.S. for patents on inventions involving human embryos, thus a hotly debated area in bioethics.

The *Harvard Oncomouse case*[45] (though the U.S. patent was approved) and the patent applications for human embryonic stem cell technologies have led to protests on ethical grounds but have gone ahead as per the existing laws due to the absence of a clearly defined morality clause.

The issues of ethics concerning patenting human cloning, embryonic manipulation, or germ-line editing have primarily been raised in the forums of public opinion and regulators rather than being a cause for refusal by patent law.

7.3.2 Genes

The series of judicial interpretation helps understand united states approach in gene patenting. The court decision *Diamond v. Chakrabarty (1980*[46] allowed the patenting of a genetically modified bacterium and hence the patenting of isolated genes and genetic sequences was accepted.

The most prominent Supreme Court case in the U.S., *Association for Molecular Pathology v. Myriad Genetics, Inc. (2013)*[47], decided that the naturally occurring DNA sequences cannot be

[43] Patent First, ask questions later: Morality and ..., http://nationalaglawcenter.org/wp-content/uploads/assets/bibarticles/bagley_patent.pdf
[44] Juicy Whip, inc. v. Orange Bang, inc., 185 f.3d 1364 (Fed. cir. 1999) :: Justia, https://law.justia.com/cases/federal/appellate-courts/F3/185/1364/609214/
[45] Supra at 41
[46] supra at 12
[47] Assoc. for Molecular Pathology v. Myriad Genetics, inc. | 569 U.S. 576 (2013) | Justia U.S. Supreme Court Center, https://supreme.justia.com/cases/federal/us/569/576/

patented, however, cDNA (complementary DNA) can be patented. That decision tries to balance the ethical concerns emanating from the ownership of genetic material with incentives for innovation.

The USPTO grants patents on genetically engineered genes and biotechnological processes but is always very careful to follow these rulings.

7.3.3 Other Life Forms

Patents on genetically modified organisms, microorganisms, and transgenic animals are allowed by the U.S. patent system if they meet the patentability criteria. There are ethical issues, but they do not form legal grounds for the refusal of the patent. Patents such as those on the Oncomouse and genetically modified salmon, that arouse the most controversy, have been granted though, frequently, they have been publicly debated and regulated separately. Issues relating to animal welfare or environmental pollution are generally taken care of through other federal regulations rather than within the patent grant system

7.4 Comparing Human embryo, gene and other life forms: EU, USA and India

Aspects	European Union	United States of America	India
Legal Basis	Article 53(a) of EPC explicitly excluded inventions contrary to ordre public or morality. Article 6 of the Biotech directive 98/44 explicitly prohibits patents on human embryo, human cloning and process for modifying human germline.	The U.S patent Act doesn't have an explicit morality clause. U.S follows "patent first, ask questions later" approach.	Sec 3(b) of the Indian Patents Act,1970 explicitly excludes invention contrary to morality or injurious to life or health. Sec 3(j) of the Act excludes plants, animals and essentially biological processes.
Human Embryos	Not patentable In Brustle V. Greenpeace it was held that use of Human embryo for industrial or commercial purposes, even for stem cell extraction	Limited Patentability Stem cells research may be patentable if it doesn't involve the embryos directly	Non patentable Sec 3(b) completely prohibits patents on human embryos

	is contrary to morality.		
Human Gene	Partly patentable The EU directive allows for the patent of isolated gene sequences and not naturally occurring genes	Previously patentable and now restricts gene in natural form. In Association of molecular pathology v. myriad genetics, it was held that only synthetic DNAs such as cDNA shall be patentable	Highly restricted. Gene sequences may be patented only when it is significantly modified and applied in inventive industrial process.
Other life forms	Microorganisms shall be patented. Animals shall be patented if it doesn't fall under "essentially biological processes" (Oncomouse case)	Patentable. In Diamond v. Chakrabarthy it was held that the genetically engineered microorganisms are patentable. It is also extended to Animals (Harvard Oncomouse case)	Sec 3(j) excludes the patentability of Plants, animals or natural biological processes. Microorganisms are patentable.
Underlying ethical basis	Focuses on Human dignity, environment and ordre public.	Focuses on economic aspects and innovations.	Focuses on public morality, environment and safety.

7.5 Advantages and Disadvantages:

Jurisdiction	Advantages	Disadvantages
European Union	Upholds strong ethical standards protecting human dignity Provides clear moral and legal guidance through EU directive Ensures public confidence in biotechnology patents.	Restrictive laws discourage private Research and Development in sensitive Biotechnology fields. Legal uncertainty due to case-by-case interpretation
United States of America	Encourages biotech innovation and investment. Clearer patentability criteria focusing on utility and inventiveness.	Lacks ethical oversight. Risk of commercialisation of human genetic material.

	Strong IP-driven biotech industry growth.	
India	Protects public morality, biodiversity and human rights. Ensures compliance with the socio-cultural and religious sensitivities. Supports access to knowledge and traditional.	Restrictive laws limits biotechnology investments. Lack of judicial precedents leads to uncertainty. Ambiguity in applying morality clause to modern biotechnology such as CRISPR and stem cells.

8. Suggestions for reform and future development

The Section 3(b) that is presently available gives patent examiners a great deal of a choice when it comes to deciding a case, but the problem is that it does not offer a concrete definition of the terms "morality" and "public order." A proper and elaborate legal framework is what India needs to be able to define these terms so that there are fewer ambiguities and inconsistencies in the patent examination process. This will result not only in the promotion of transparency and fairness in decision-making but also in conformity with global best practices.

Just like any other set of guidelines, the patent examination guidelines should be updated regularly and its officers guided specifically on how moral and ethical issues are to be handled when it comes to biotechnologies as well as human embryos, genes, and other life forms. The guidelines should get contributions from:

- Bioethical standards derived from bioethics, human dignity, and the health of the environment.
- Assessment standards of the technological processes involving human embryos and the modifications of the germline.
- The developing of stepwise instructions for genetically modified organisms, transgenic animals, and microorganisms.

The pace of biotechnological changes is speedy; this means that Indian patent laws and rules should be consistently revised and updated to keep up with the new scientific realities especially in areas such as CRISPR gene editing, synthetic biology, and stem cell research. There should be explicit provisions or regulations that directly address these emerging technologies which take into consideration their moral implications.

Without losing sight of India's unique cultural and social aspects, striving for closer alignment with international benchmarks (e.g., TRIPS, EU Biotech Directive) would not only enhance India's strengths in biotech but also facilitate smoother global collaborations. It additionally comprises having the exceptions enumerated in the international patent agreements-based human embryo patenting, germline modifications, morality-keeping areas for India without violating ethical conditions.

A wide variety of opinions from common people, local leaders, and intellectuals while setting morality-related patent policies might boost public faith and democratic merits. To align thoroughly with societal values and norms, India needs to develop wider engagement and increase transparency in the process of patent examination with morality clauses.

Regular training programs need to be made available for patent examiners where they will be sensitized on bioethical principles, ways of interpreting morality and international case law precedents. Such capacity building will facilitate their consistent and knowledgeable handling of ethical dilemmas.

The availability of morality clause-based biotech patent-related judgments' case law in India is very scarce. India should encourage the documentation of case studies and publishing the reasoning and decisions of the examiners will help in building the relevant case law, in guiding the future applications, and in informing the policy debate.

The European Union has explicit definitions for the morality clause with the establishment of formal ethical advisory bodies which offer transparency and balance the advancement of technology with respect for human dignity and scientific progress. while the United States has no explicitly stated morality clauses but depends on the combination of regulatory control and ethical debates that are separate from the patent system, thereby underscoring the need for complementary structures outside the realm of patent law. India may draw advantages from a hybrid framework that melds clear legal norms, the inputs of ethical advisory, and adaptable regulatory supervision to effectively manage the rapid development of biotechnology in a responsible manner.

9. Epilogue

The interdisciplinary of biotechnological inventions and patent laws has always been an area that these two disciplines have fiercely debated the boundaries and impacts not only of technology but also of ethics, the society, and the legal field. Unquestionably, biotechnology

might be dealing with such elements as human embryos, genes, and genetically modified organisms, hence the emergence of questions related to morality and public order. While on one hand, patents aim at fostering innovation and securing the rights of inventors, the morality clause seems to be a balancing actor, providing that it is not at the expense of either fundamental ethical standards or general societal values.

On the other hand, the interpretations of India, the EU, and the USA shows that even though Article 27(2) of the TRIPS Agreement sets up a common framework, there are differences in how the same is interpreted and implemented in each jurisdiction. India is quite stringent with a strong focus on ethical issues hence it prohibits patentability based on such items as human embryos and life forms under Sections 3(b) and 3(j) of the Patents Act, respectively. The European Union, while emphasising morality and public order, opts for a case-by-case analysis and thwarts inventions that exploit human embryos or violate any other ethical principles from patent protection. However, the United States tends to take a more liberal view, whereby scientific progress and industrial application are given more weight than moral objections, thus providing a very limited area of ethical restrictions.

In other words, patents in the field of biotechnology along with the morality clause are from the same basket – one is propelling, and the other is restraining the innovation but within the framework of ethics. Different methods followed by countries worldwide demonstrate that they have not yet found a way to strike a balance between an open innovation environment and keeping issues of human dignity, ethics, and the public interest safe.

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