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Interface between Legal and Moral Implications on Patenting Biotechnological Inventions: A Comparative Analysis of the Patents Law of India, the US and the EU

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The biotechnology industry has seen one of the most significant expansions in the Patent Laws. It is challenging for a law to link with protecting the intangible property vested in biotechnology patents, as the biotechnology resources come from living organisms. Patenting biotechnological inventions raises legal, ethical and moral concerns. In the light of the current context, this paper examines patents law of Section 3(b) of the Indian Patents Act, 35 U.S.C Section 101 of the U.S. Patent Law, Article 53(a) of the European Patent Convention and Article 6 of the EU Biotech Directive. The paper compares the legal structure of these three countries, illuminating the similarities and differences in interpreting morality provisions by referring to various case precedents, statutes, and legal references within the patent laws of the United States and the European Union as a benchmark for evaluating India's patent system. The paper proposes and suggests clarifying morality clauses of the Indian Patents Act to keep up with the advancements in Biotechnology inventions by providing a clear definition of morality and contrary to public order instead of patent controllers exercising their discretionary power unguided. The paper highlights that it is vital to consider moral and ethical implications as biotechnology evolves, ensuring that law and morality should foster a holistic and informed approach to shaping the future of biotechnological inventions in a global context.

Keywords: Biotechnology Inventions, Morality, Ethics, Public order, Patents Law, India, European Union, United States

The biotechnology sector has raised various ethical questions about the patenting of biotechnological ideas, owing to the challenges of scientific progress and commercial potential. The creation of innovative public goods is one of the critical reasons for awarding exclusive patent rights. For nearly two decades, patents have provided holders exclusive rights from others, exploiting and promoting their inventions.[1] These rights can be highly profitable, giving enormous incentives for inventors to generate patented discoveries and stakeholders to promote the research that would harvest proprietary outcomes.

The issue of patenting biotechnology inventions presents an intriguing opportunity to explore the relationship between ethics and morality. The concepts are closely intertwined and play a crucial role in shaping the legal framework of a given jurisdiction. Morality relates to ethics, as ethics encompasses the study of morality and the spectrum of principles and standard of behaviour within specific age and environment. In this context, ethics is applied to the principles and logic used to determine whether an inventions breach the accepted system of moral judgment and standard in law and society thereby establishing what we deem appropriate and inappropriate. Generally, ethics is considered to have an ideological objective in the form of the search for the well-being of individuals and humankind. In that case, the law may be thought of as having a quest for the ideal, i.e. the pursuit of societal stability.[2] There are several perspectives on law and ethics, ranging from the legal positivism that separates law from morality to calling for unity between the two normative frameworks.[3]

A key consideration in determining the patentability in Biotechnological invention is whether legal principles should reflect morality or can it be kept separated. The positive school of law argues that law should be founded on logic and reason rather than morality. On the other hand, the school of natural law claims that the law reflects societal morality and cannot be purely based on rules on logic and reason.[4] While discussing the terms ethics and morality concerning patent law, the terms ethics and morality

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are seldom defined and often used identically.[5] Morality and public order are quasi-legal concepts since they are used for exclusionary reasons in various international, regional, and national legal contexts. Their interpretation and function necessitate recourse to non-legal sources regarding their function in a societal context.[6]

The moral dilemmas surrounding the patentability of biotechnology inventions are not limited to India, the United States and the European Union. They provide a framework for analysing the broader relationship between ethics, law and society across different jurisdictions. Many countries have initiated investigations and generated reports addressing the moral aspects of patenting definite biotechnological innovations.[7] Regional cultures, religious beliefs, and governmental institutions influence the methods various nations and areas use to address these issues.[8] The EU, the US, and India are notable instances of how patenting morally dubious biotechnology topics are handled.

Innovations in biotechnology have a massive impact on the future. Modern molecular biology has opened up new views and given rise to optimism for innovative solutions, especially in agricultural and medical technology.[9] The rapid advancement in this field and the granting of patents for discoveries like DNA sequences, protein sequences, stem cells, genetic engineering, etc., have generated severe ethical questions that affect all living things.[10] The ethical issues raised by biological research and its applications in biology and medicine are debated in the field of ethics.[11] It encompasses a variety of topics, such as discussions about human dignity, issues surrounding the beginning and end of life, consent for medical treatment, research freedom, donor consent for human genetic material, access to healthcare, the sources of healthcare, equitable access to the findings of biological research, animal welfare, and environmental ethics.[12]

Biotechnology is a notorious area that generates ethically or morally questionable inventions.[13] Genetically modified transgenic animals, extracted sequenced DNA, medicinal treatments, somatic stem cells, and techniques for animal cloning are all included in the uncertainties surrounding patented biotechnological innovations.[14] Biotechnology inventions create several moral conundrums, including worries about the hybridization of living things, the potential degradation of human decency, the elimination of possible human existence, and the concept of owning individuals.[15] Patenting biotechnological innovations creates a challenging ethical situation where societal values, intellectual property rights, and scientific advancement coexist. Questions concerning the ethics of giving exclusive ownership of life-changing technologies arise as biotechnology develops. It is imperative to make sure that patent rules are align with current technology developments, providing adequate protection without excluding or rejecting them based on morality, as certain discoveries may have potential benefit for millions of people.

With this regard, this paper aims to deliver a comparative study of the existing challenges between legal and moral in India, the US and the EU. The paper draws various case law and legislative advancements of these three jurisdictions to measure the effects of the transformations on the protection and enforcement of biotechnology inventions, as well as assess the dilutions and limitations of the current patent systems in India, the US and the EU with regards to the challenges of biotechnology inventions.

Finally, the paper delivers valuable perspectives on the future of biotechnology-related patent laws in these jurisdictions. The article urges the development of a refined legal framework that fosters innovation while addressing the moral, ethical, and sociological implications of biotechnology inventions to balance the interests of creators, investors, and society. This will aid the continuous ambiguity surrounding biotechnology inventions, patent laws, and ethics and provide decision-makers and innovators with possible future directions for this quickly developing industry.

Principles behind Morality on Patenting of Biotechnology Inventions

Before embarking on morality and patenting of biotechnology inventions, it is significant to analyse the meaning of morality, which is linked to the expression ethics, as ethics is the study of morality and the entirety of principles and standards of action chosen in a particular decade and context. "*Morality is an informal public system applying to all rational persons, governing behaviour that affects others, and includes what is commonly known as the moral rules, ideas, and virtues and had the lessening of evil or harm as its goal*".[16] Ethics seeks to determine whether an action is right or wrong, what moral standards should guide the behaviour, whether moral principles can be justified, what moral virtues are worth cultivating and why, what ultimate goals people

should pursue in life, whether there are good reasons to accept a particular moral theory, and what the meaning of terms such as right, wrong, good and bad.[17] In this context, ethics indicates to the practical application of principles and reasoning while determining if an invention violates the established moral decisions and principles of law and society, so establishing what is considered appropriate and inappropriate is significantly essential.[18]

The fundamental tenet of the benefit claimed for patents is that paying an inventor fosters advancement in research that benefits society, which aligns with the moral guidelines of beneficence.[19] In contrast to the economic well-being of an individual or nation, universal medical or agricultural growth is covered by the principle of beneficence in patent law. However, some contend that encouraging the patenting of biotechnology inventions will advance scientific understanding. Rewarding innovations allows innovators to focus their time and effort on invention. The patent itself is not necessary for commercial usage of inventions. It is susceptible to social pressures. Furthermore, it is argued that if patenting is not allowed, valuable information will turn into trade secrets. For other researchers to apply the prior knowledge for the innovation, granting a patent may make an invention publicly known.

Furthermore, a person's personal dignity and moral values are intrinsically linked to their autonomy. The capacity to make judgements independently of external pressure or coercion is known as autonomy, and it is seen as a crucial component of the dignity of human beings.[20] The patent method is constructed on the notion of autonomy, which makes sure that creators get compensated for their innovations while still having ownership over them. The argument is that autonomy can impede scientific investigation because investigators could be hesitant to conduct experiments in fields where important technology are already protected by patents.

The nonmaleficence principle highlights the moral obligation to act with no malice in the context of the patentability of biotechnology. This principle encourages authorities and patent applicants to thoroughly evaluate the risks and potential consequences connected to a biotechnology invention before issuing a patent.[21] While the goal of non-maleficence is to avoid harm, this goal may not always be achieved. Consider how patients who would otherwise benefit from these medicines could be harmed by delaying the grant of patents on specific biotechnological advances, such as life-saving medications.

The justice principle strives to provide fairness and equitable access to biotechnological breakthroughs when applied to biotechnology's patentability. By encouraging the accessibility and affordability of necessary biotechnological products, such as medications and medical treatments, to a wider variety of people, regardless of their socioeconomic situation, justice-oriented patent policies can assist alleviate health inequities.[22] Meanwhile, applying the justice concept to patentability decisions might be complicated. It might be challenging to define a just distribution of benefits and access because it depends on the situation.

Indian Approach - Patentability of Biotechnology Inventions

The most significant intellectual property in the scientific community is a patent. Suppose an invention satisfies the requirements of novelty, non-obviousness, and industrial application.[23] In that case, the patent office grants the inventor a patent, giving them exclusive rights to make, sell, and utilise their innovation for a predetermined tenure. The first Indian Patent Act was enacted in 1856 during the British colonial era, and by 1911,[24] Indian Patent legislation complied with international standards.[25] However, patent regulations were loosened in 1970 to promote economic growth through reverse engineering Western inventions under the industrial import substitution policy.[26] India's 1995 admission into the WTO and adoption of TRIPS led to quick changes in IP legislation. To comply with TRIPS standards, patent laws were reinforced in 1999 and updated in 2002.[27] In contrast to the 1970 law that restricted patents to pharmaceutical manufacturing techniques, the 2005 legislation resumed patenting pharmaceutical substances.[28] This modification increased the patent protection from 5–14 to 20 years and added full product patents for pharmaceutical discoveries.

In contrast to other domains, the issue of patenting in biotechnology carries significant importance due to its involvement with living organisms. A biological patent pertains to a patent for an innovation within the field of biology. Biotechnology encompasses various technologies that utilize living entities, specifically animals, plants, or microorganisms.

Section 3(b) of Indian Patents Act, 1970: Morality

Under the Indian Patent Act, any product or process can be considered patentable. Nevertheless, Section 3(b) of the Act provides that "*inventions contrary to public order, morality or those causing significant harm to human, animal, or plant life, health, or the environment are not eligible for patents*".[29] For instance, inventions involving (a) the commercial exploitation of human embryos, (b) human or animal cloning, (c) the alteration of the human germ line, (d) the alteration of the hereditary makeup of animals in ways that trigger needless stress without substantially improving their health or other conditions, including the animals that result from such processes, and (e) methods for formulating seeds or genetic materials that contain elements that leads to disease.[30]

One instance featured the patent controller initially rejecting a patent application for a vaccine against the infectious bursa virus since it involved a living thing. The Calcutta High Court reversed the controller's ruling, claiming that a residing microorganism meets the standards for patentable subject matter in a manner similar to that of a manufactured good.[31] Therefore, it can be said that under both statutory provisions and well-established case law, genetically modified microorganisms in India are eligible for patent protection. According to the Manual of Patent Practice and Procedure, biological products, viz. Plasmids and recombinant DNA, as well as the processes used to develop them, may be patentable if they are the consequence of significant human involvement.[32]

In the *Dimminaco AG* v *Controller General of Patents, Designs and Trademarks case*, the controller of patents rejected a patent application over a vaccine for the infectious bursitis virus on the ground that it is a living organism.[31] The Calcutta High Court overruled the controller's decision, which decided that a living microorganism meets the requirements to be a manufacturer of patentable subject matter.[31] Based on this decision, it may be said that genetically modified microorganisms are patentable in India in conformity with the legislation and case law. Recombinant DNA, plasmids, and manufacturing methods are examples of patentable biological products created with significant human participation, according to the Manual of Patent Practice and Procedure.[33]

Table 1 shows the patentability of gene-related subject matter in India, the USA and the EU to show where India stands in gene-related inventions.

Section 3(b) of the Act provides that an innovation is not eligible for patent protection if it is regarded immoral, against the law, dangerous to people, animals, or plant life, or destructive to the environment. [35] According to the Manual of Patent Practice and Procedure, biological materials and the methods used to make them, such as terminator gene technology, have the potential to seriously harm human, animal, plant, or human health or the environment and also violate public order and morality are not eligible for patenting.[36] The guideline also emphasizes that procedures that violate public morals or order, such as cloning people or animals, altering their germ lines, changing their genetic makeup, or exploiting human or animal embryos for any reason, cannot be patented.[37] Gene patenting and gene-based invention patenting are strictly forbidden under Indian patent law for morality and public order reasons.

According to the Manual handbook as of 2005, genetically altered animals employed in studies on cancer or other serious illnesses would not be eligible for patents because doing so would endanger the health of the animals. Additionally, genetic engineering of plants that could endanger species, like terminator technology, is deemed immoral and against the law and is not protected under patent system. This

Table 1 — The comparative analysis of patentability of gene-related subject matter in India, the USA and the European Union

Subject Matter	India	USA	EU
Genes	Patentable	Patentable	Patentable
Genetically modified Unicellular Organisms	Patentable	Patentable	Patentable
Genetically modified Multicellular Organisms	Not Patentable	Patentable	Patentable
Genetically modified Animals (excluding humans)	Not Patentable	Patentable	Not Patentable (except mammals)
Genetically modified Plants	Not Patentable	Patentable	Patentable
Genetically Modified Humans	Not Patentable	Not Patentable	Not Patentable
Gene therapy	Not Patentable	Patentable	Not Patentable but not enforceable

Source: Kankanala KC. Genetic patent law and strategy, 2007[34]

includes intrinsically evil practice of genetically altering humans through gene therapy or germline modification.[37]

Social values, public order, and the ethical considerations surrounding certain biotechnological inventions determine the morality of patentability. Morality refers to the accepted clause in the law for assessing the patentability of biotechnological inventions. Additionally, the following are the activities of patent application and award on biotechnology inventions in India.

Table 2 shows that a certain entity's patent activity across five consecutive fiscal years. 992 patent applications were submitted for the fiscal year 2017–2018, of which 546 were approved and 446 were denied. The following year, 2018-2019, saw the filing of 882 patent applications, of which 457 were approved and 425 were dismissed. In 2019 and 2020, the organization submitted 1065 patent applications, of which 357 were approved, and a higher number of 708 were denied. Notably, in the fiscal year 2020–2021, there was a considerable increase in the number of patent application filings, reaching 3368. Of these, 574 were awarded, and 2794 were denied. During 2021–2022, 3530 applications were submitted, 611 were approved, while 2919 were dismissed. This information shows fluctuations in the success of the entity's patent applications.

Judicial and IPO Decision

Apart from *Dimminaco A.G.* v *Controller of Patents and Design in 2002*,[31] no case law was determined despite India ranking among the top twelve nations in the biotechnology industry. The Calcutta High Court upheld the Indian Patent Examiner's ruling. The Court states that patent application successfully satisfied the standards for both novelty and usefulness. The vaccine to prevent Bursitis disease in chicken was produced using a specific procedure submitted to precise conditions.[31]

Table 2 — Patent activity across five consecutive fiscal years

Financial Year	Patent Application on Biotechnology	Patent Grant on Biotechnology Invention
2017-2018	992	546
2018-2019	882	457
2019-2020	1065	357
2020-2021	3368	574
2021-2022	3530	611

Source: Annual Report of Financial Year 2021- 2022 of Indian Patent Office[38]

The Indian Patent Office (IPO) denied two patent claim applications submitted by the cigarette corporation Phillip Morris Products S.A. regarding two nicotine delivery devices based on Section 3(b) of the Indian Patents Act, 1970.[39] The claim that the invention is subject to Section 2(i)(j) and Section 3(b) of the Patent Act was rejected. Concerning Section 3(b), the controller pointed out that the applicant neglected to describe how the nicotine delivery system avoids nicotine's addictive properties, which creates a health risk. ITC Limited submitted another application, which was denied under Clause 3(b). Like the Philip Morris application, it was turned down because the device's tobacco use was deemed vital. The rejection notes that the harm caused by tobacco to human health and life is because of carcinogens, respiratory toxicants, cardiovascular toxicants, reproductive/development toxicants and addiction.[40] The denials listed under Section 3(b) are said to be related to whether the patent applications were equally harmful to health as tobacco products. It is believed that Section 3(b) is ambiguously worded since it allows for many different interpretations of what "public order", "morality," and "serious prejudice" mean. Although tobacco toxicity is previously established, it is unclear how a tobacco-based invention might seriously impair health without compelling justification.[41]

Indian viewpoint on the EPO303033 case: Molecular cloning and characterization of a second human relaxin-encoding gene sequence,[42,43] patents are granted by the USPTO and EPO. They drew support from data showing that the genomic DNA encoding for H2-preprorelaxin had introns that might result in the synthesis of extra amino acids not present in the known amino acid sequences. Following EPO regulations that permit novelty recognition when existence is not demonstrated, this evidence revealed that the particular kind of relaxin stated in the patent claim was previously unknown.

However, the gene was naturally present in the female human body; the innovation concept is different under the Indian Patent Act. While extracting tissue from a pregnant woman is vital, the Indian Patent Office may contend that doing so is unethical and violates human dignity, especially when the goal is financial gain. Patenting a human gene is equivalent to patenting human life, which is intrinsically unethical. On the other hand, the USPTO and EPO emphasize that there was nothing immoral

as this is a common practice in medical operations as long as the patient from whom human tissue was removed agreed to take that tissue. It can also be argued that all of the justifications for refusing patents and grants are the following: no loss of human dignity because the tissue was taken with informed consent; no slavery because the patenting gene did not give the patentee any control over any individual; and no solid moral majority.

The United States Approach- Patentability of Biotechnology Inventions

The US has led its way in advancing Patent Law and biotechnology. Previously, it embraced a reasonably permissive method to patent biotechnology inventions. In both biotechnology and patent law, the USA has taken the lead in developing patent laws to safeguard biotechnology applications and products.[44] The US Constitution gives Congress the ability to empower patents in order to advance science and useful arts by providing writers and inventors exclusive rights to their particular works for a finite amount of time.[45] Sections 101, 102, 103, and 112 of the Patent Act of 1952 describe the fundamental requirements for getting a patent; however, this paper only discusses section 101 of the US Patent Act.

Section 101 of the US Patent Act

Section 101 of the US Patent Act provides the standard for patentable subject matter "*Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title*". [46] Although the term "art" was altered to "process" in 1952, the text continued enormously intact from the time when the first Patent Act of 1793[47] was introduced. In 2010, the Supreme Court reaffirmed Chakraborty's decision in *Bilski* v *Kappos*[48] emphasizing that the inclusion of the word "any" immediately preceding the four categories, i.e., process, machine, manufacture and composition of matter and concluded that "*Congress contemplated that the patent laws would be given wide scope*".[49] The Court upholds these inclusive but limited classifications. According to Justice Breyer's statement in the Mayo case, natural occurrences and abstract conceptions are not eligible for patents.[50] This emphasizes a significant implicit exclusion to Section 101 of the US Patent Act.

To qualify for patent protection, a biotechnological invention should fall within four categories of subject matter, i.e., process, machine, manufacture, or composition of matter.[51] According to the United States Supreme Court, this means laws of nature, natural events, and abstract ideas are three types of subject matter that are not qualified for patent protection under 35 U.S.C. Sec. 101.[52] However, an inventive "*process, machine, manufacture, or composition of matter employing a law of nature, natural phenomenon, or abstract idea would not, by itself, be entitled to such protection*" as long as the use of the invention results in *"a useful, concrete and tangible result*".[53]

Life forms were not eligible for patent protection in the US until 1980.[54] Products and procedures used in biotechnology were not patentable and were instead regarded as natural occurrences. According to the "product of nature doctrine", living things or natural substances cannot be considered innovations and are therefore not subject to patent protection.[55] On "mixtures or compounds that included microorganisms in modified form", very few patents have been granted.[56] However, when it granted Louis Pasteur a patent 1873 for yeast devoid of organic disease-causing chemicals, the USPTO affirmed the product of nature argument.[57] "*In the USA, despite the Pasteur precedent, it has become a practice of the Patent Office to reject claims to the living system as not being patentable subject matter*", said the patent attorney Grubb.[58]

The US Supreme Court's ruling in *Diamond* v *Chakraborty* emerged in the 1980s[59] as a paradigm shift for USPTO. The USPTO previously tended to prohibit the patenting of living beings as a natural product before the Supreme Court's judgement in Diamond v. Chakraborty. Under the US patent law, "*anything under the sun that man makes*" is eligible for patenting.[60] The processes for creating genetically modified plants and animals, as well as human gene therapy, all fall under the ambit of patent-eligible subject matter as a result of biotechnology breakthroughs in the US.

Moreover, the USPTO added a moral qualification to the subject matter doctrine in 1987, stating, "*A claim directed to or including a human being within its scope will not be considered the patentable subject matter*".[61] This assertion was irrelevant to creations made entirely of human materials, such as DNA. Around 1,500 patent applications for genetic material

were approved by the USPTO between 1890 and 1996, with 30% of those pertaining to human DNA.[62] The USPTO vehemently defended patents for human genetic material in utility guidelines published in 2001, arguing that the inventions are chemical molecules and not anything human.[63]

Morality and Patent Law

The US patent law regulating the ethical dimension of the patentability of biotechnology does not provide explicit provisions regarding the determination of the morality of biotechnology inventions. Since morality is not a factor in patentability requirements, analyzing an invention's patentability in the USA does not include making moral judgments. A determination cannot be made per the subject matter requirement because the US Supreme Court rejected claims that hereditary/genetic research would increase disease and pollution, which could lead to a decline in genetic diversity. It is not within its purview to consider morality-laden high-policy arguments.[64] The Court continued by stating that it is impossible to implement any restrictions on topic matters or other requirements and that Congress must do so. The Court made it abundantly plain by declaring that morality analysis does not belong in the subject matter.

The USPTO stated in the guidelines for patent examiners that patent protection will not be granted for subject matter concerning humans because doing so would violate the 13th Amendment of the US Constitution, which forbids slavery.[65] This is true even though morality does not come under that factor in determining patentability evaluation. The USPTO introduced morality into the subject by providing these guidelines, which may or may not be accepted by a court of law. The rules were put to the test when Jeremy Rifkin submitted a patent application for an animal-human hybrid; however, the United States Patent and Trademark Office (USPTO) dismissed the claim because the invention contravened the 13th Amendment's ban on slavery and was irreconcilable with the constitutionally protected right to privacy.[66] Based on the Constitution, it is unclear whether the Patent Office has authority to reject. The Patent Examiner takes morality into account while reviewing human-related patent applications.

Judicial and USPTO Decision

In *Diamond* v *Chakraborty*, the court determined a genetically engineered oil-digesting microbe was not exempt from the patent protection provided by Section 101 of the 35 U.S.C.[67] The Court claims whether an invention and not only an invention holds living organisms as a criterion for biotechnology patent-eligible subject matter.[60] Despite Chakraborty's vociferous defense of the patentability of single-celled bacteria, it remained unclear if the USPTO and courts would approve the addition of patent protection to include complex multicellular living creatures like plants and animals. *Pioneer HI-Bred International, Inc.* v *J.E.M. AG Supply, Inc.*, *DBA Farm Advantage, Inc.*, *et al.*, on appeal to the Board of USPTO and Interferences, produced the first text in 1985.[68] Hibberd discussed the patentability of a corn plant modified to have excessive amino acid tryptophan.[69] The Board found that 35 U.S.D. Sec. 101 of the Act permitted patenting of plant subject matter even though it could be protected under the Plant Patent Act[70] or the Plant Variety Protection Act.[71]

In *Animal Legal Defense Fund* v *Quigg*[72], several farmers' and animal welfare organizations contested the USPTO's legitimacy in issuing the 21st April 1987 notification. The Animal Legal Defense Fund, the appellant, was found to lack standing to bring the lawsuit, and the Court of Appeal rejected the case for the Federal Circuit.[73] With this decision, the court disregarded the complainant's claim that the public general was interested in statutory patentability restrictions and sidestepped addressing societal objections to granting animal patents.[74]

The Board expanded its categories of patentability of living beings in Ex parte Allen to include multicellular organisms. In this case, it was determined that "non-naturally occurring non-human multicellular living organisms, including animals, are patentable subject-matter within the meaning of 35 U.S.C. Section 101".[75] However, according to the USPTO, any claims relating to people will not be regarded as patent subject matter under Section 101 of the 35 U.S.C: "*The Constitution prohibits granting a limited but exclusive property right to a human being. Accordingly, it is suggested that any claim directed to a non-plant multicellular organisms which would include a human being within its scope include the limitation 'non-human' to avoid this ground of rejection"*.[76]

Moreover, the requirement for a utility under 35 U.S.C. Section 101 is significantly essential in *Brenner* v *Manson*,[77] the Supreme Court ruled that

something cannot be patented if it has no recognized uses and is only known to be useful for scientific research. This calls into question some biotechnology-related inventions' patentability, primarily those involving sequenced DNA and lacking any proven commercial applications yet having great scientific promise: "*A patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion*".[78] Hence, inventions without a defined purpose or function might not be patentable due to their lack of utility.

Additionally, the University of California received the first gene patent in 1982 after applying in 1977 for a synthetic hormone linked to breast growth in pregnant women.[79] Since then, DNA taken from the human body has frequently been subject to patents, raising questions about who should own and regulate genetic data. However, in a landmark case, *Association for Molecular Pathology* v *Myriad Genetic* (2013) 79, the Supreme Court held that inherently existing DNA sequences are not eligible for patent protection.[80] The decision significantly impacted the landscape of gene patenting and addressed some ethical concerns associated with owning human genetic material, which is unethical.

Table 3 shows that from 2017 to 2020, 2,610,336 patent applications were filed, with 1,471,398 patents granted. The yearly data shows distinctions in the number of applications filed and patents granted, with the highest number of applications filed in 2019 (669,434) and the lowest in 2018 (643,303). Similarly, the highest number of patents granted occurred in 2019 (391,103), while the lowest was in 2018 (339,992). This data reflects the level of innovative activity in the United States. However, 2021-2022 data is not available on the USPTO website.

European Union Approach – Patentability of Biotechnology Inventions

Any innovation is eligible for patentable subject matter under the EPC, barring any exclusionary inventions listed in Article 52 of the EPC.[82] Although biotechnology inventions are included in the list, the Biotech Directive 99/44/EC 1998 clarified the range and extent of patentability of biotechnology and genetic inventions. On June 16, 1999, the European Patent Organization's Administrative Council updated Rule 23 of the instigating regulations of the EPC to conform to the Biotechnology Directive.[83] According to Rule 23(b),[84] the applicable requirements of the Convention will be construed in harmony with principles outlined in Chapter VI of the implementing regulations for European patent applications and patents relating to biotechnological inventions. It further states that to evaluate how biotechnological inventions are protected legally, the European Biotechnology Directive will be considered as an additional interpretation.

Table 3 — U.S. Patent grants on biotechnology inventions from 2017-2020

Calendar year	No. of patent application filed	No. of patent grant
2017	651,355	351,403
2018	643,303	339,992
2019	669,434	391,103
2020	646,244	388,900
Total	2,610,336	1,471,398

Sources: U.S. Patent Statistics Chart Calendar Years 2017-2020[81]

Article 53(a) of the EPC: Morality

In contrast with US patent law, the EPC contains clauses that consider morality when issuing patents. Under Article 53 of EPC," *the European patent cannot be granted for inventions whose disclosure or use could compromise morality or public order*". It is important to note that inventions should not be contrary to ordre public or morality because it is prohibited by law or regulations in some or all contracting states.[85] Article 53(a) of the EPC further stated that patents cannot be granted if " *inventions the commercial exploitation of which would be contrary to 'ordre public' or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting states*".[86] Biotechnological inventions are expressly prohibited from receiving a European patent under this clause: methods for cloning humans, methods for altering a human germs line, methods for using human embryos for industrial or commercial exploitation, and techniques for altering the genetic makeup of animals that are likely to suffer without providing the animal with any appreciable medical benefit.[87]

The abovementioned reflect EPO's commitment to upholding fundamental ethical considerations and preventing the misuse of patent rights in areas fraught with moral implications.[88] The morality clause of the EPC in Article 53(a) emphasized striking a balance between innovation and societal ethics. It shows that the patent system is motivated not just by financial concerns but also by a desire to uphold the more significant benefit for humanity. The execution of this

clause is not without challenges. The complex task of determining ethical rights in today's diverse cultural and social environment may call for continuing changes to the patent assessment process.

Genetic engineering and pharmaceuticals using recombinant DNA technology, two critical fields of biotechnology patenting, have seen several trends in the EU.[89] The EPO released the Patent Index 2022 on 28 June 2023. Figure 1 represents patent applications and patent grants in the field of biotechnology sector from the year 2017-2022.

The cumulative data include a thorough summary of the European Union's patent operations over the previous six years. In 2017, 3119 claims were submitted, and 1535 patents were issued. The overall number of patent applications filed in 2018 climbed to 3356, but the number of patents issued decreased to 1501. The number of patent applications filed in 2019 declined significantly to 3279, while 1442 patents were awarded. In 2020, there were 3446 more applications submitted overall, but only 1320 were approved. A total of 3190 applications were submitted, and 1050 were approved in 2021. Only 605 patents were awarded in 2022 out of 3402 submitted applications. This demonstrates that yearly biotechnology invention patent applications for biotechnology inventions were fluctuating. However, the patent grant for biotechnology inventions drastically decreased from 2020-2022.

Article 6 of the EU Biotech Directive (98/44/EC)

The Directive emphasizes that innovations should not be patentable if commercial exploitation violates public policy or morality.[91] It calls for establishing a list of instances that would be viewed as immoral. Under Article 6 of the Directive, any invention whose economic exploitation goes against the "ordre public" or morality cannot be patented. According to Clause 2 of Article 6, "*procedures for cloning humans, changing the genetic makeup of human germ lines, using human embryos for industrial or commercial purposes, and procedures that change an animal's genetic makeup in a way that causes it pain without significantly benefiting humans or other animals medically are not patentable*".[92] This is because the procedures violate morals or public order.

Fig. 1 — EP-Biotech, Patent Index 2020 by European Patent Office
Source: *European Patent Office, Patent Index 2022*[90]

The Directive also specifies procedures that violate human dignity by employing biological material from humans or animals, such as producing chimaeras through germ cells or totipotent cells, shall not regarded as Patent.[93] Suppose an invention comes from biological material of human origin or uses such material. In that case, the Directive mandates that the person from whom the bio-material is removed must give their voluntary consent. These concepts are crucial in biotechnology because of the various technologies and their inherent connection to living beings.[94] It is also provided that the standards under the patent law, as stated in 39 Recital of the European Parliament and the Council, should be supplemented by legal and ethical considerations.

Judicial and EPO Decisions

The case of Harvard Mouse is associated with genetically altered mice. A transgenic non-human mammalian animal with a higher propensity to develop neoplasms (an oncogenic test animal)[96] was created by introducing an activated oncogene sequence at a stage later than the eight-cell stage. The resulting animals were the subject of Claim 17, while Claim 18 focused on the case where the animal was a rodent.[95]

According to Article 53(a) of the EPC, the division of examination took into account moral concerns about the patenting of animals. Patents cannot be awarded for invention if commercialization is against morality or contrary to public order. It is noted that the public has vehemently opposed the idea of patenting higher creatures for ethical and financial reasons.[96] The board emphasized that under Article 53(a) of EPC, any invention that leads to riots, public disturbances, or other generally illegal acts is intended to be excluded from protection.[97]

The Technical Board had previously stated that the determination of whether Article 53(a) EPC impeded patenting any inventions whose foundation primarily depends on the suffering of the animal and could have any potential risk for the environment is not patentable; however, if the invention has potential usefulness to humanity and other living organisms will grant patent after carefully reviewing the examination.[98] The division concluded, however, after

carefully reviewing the investigation, that the invention was neither immoral nor contrary to public order.

The concern of the patentability of biotechnology invention concerning embryonic stem cells raised in the Brustle v. Greenpeace case,[99] human blastocyst stage are not patentable if their extraction necessitates embryo destruction, according to the ECJ (European Court of Justice). The case clarified the scope of patentability for inventions involving human embryos. *Oliver Brustle* v *Greenpeace* eV(C-364/13) 43 followed the previous Brustle case and focused on whether Induced Pluripotent Stem Cells (IPS cells) are patentable.[100] The ECJ ruled a method requiring the prior eradication of human embryos cannot be used in a patentable invention.

The EPO Technical Board of Appeal debated how to interpret the "contrary to public ordre and morality" rule on the patentability of particular plant methods in the Daisy Decision case.[101] The Board clarified that the provision covers choosing plants based on specific features and manufacturing processes. It emphasized the significance of moral issues while determining whether to stipulate the safeguard of biotechnology inventions under the Patent Law. In the *Epogen case*, the EPO's Technical Board of Appeal measured the patentability of a directed claim on a technique to produce Erythropoietin (EPO) using transgenic animals.[102] The Board observed that the claimed process involved introducing DNA sequences into animals to produce EPO and did not violate public ordre and morality.[103] It highlighted the difference between the claimed method's morality and the probable uses of the generated product. The ECJ (European Court of Justice) consulted about the patentability of isolated DNA sequences in the Myriad Genetics dispute.[104] A naturally existing DNA sequence obtained from the human is not patentable, according to the ECJ. The selection serves as an example of how social and moral considerations were considered when determining patent eligibility.

Relaxin Case: In this instance, the patentee created a method for procurement of H2-relaxin and DNA encoding.[105] The innovation was criticized for being unpatentable under EPC Article 53(a), among other things. It argued that because it involved utilizing a feminine condition (pregnancy) in a scientific procedure focused on professional advancement.

Conclusion

Compared to the US, the EU and India have more solid foundations for the law governing morality. When determining whether biotechnological advances are eligible for patenting, the European Union and Indian patent laws specifically address morality and public order. In contrast, there are none in U.S. Patent Law. As a result, India and the European Union are much more likely than the USA to reject biotechnology inventions due to moral and ethical concerns. For instance, a genetically altered animal employed in research on baldness that caused animal pain would be rejected in the EU and India since the potential human benefits exceed the animal's suffering. In contrast, the moral aspect would not pose any hindrance in the USA. In the United States, morality do not play a role in shaping patent protection, whereas in India and the European Union, they play a pivotal role.

It is pertinent to understand that there is still a requirement for comprehensive legislation on patenting various forms of innovations. As stated in section 3(b) of the Indian Patents Act of 1970 and Article 53(a) of the EPC, the patent law should be clear and devoid of any ambiguities, particularly when it comes to terms like "morality" or "contrary to public order". Rather than leaving these definitions open to the discretion of the patent controller, the provision should clearly articulate the meaning of "morality" or "public order" concerning inventions that may fall under these categories. Similarly to the EU Biotech Directive (98/44/EC), India needs to set up distinct guidelines specifically addressing the patentability of biotechnological inventions. This is particularly crucial given the rapid growth of the biotechnology sector, with India emerging as one of the top global destinations for biotechnology and the third-largest destination for biotechnology in the Asia Pacific in 2023.

Moral considerations are evident in overarching patent principles across all nations. In this framework, it means the applied principles and rationale when verifying whether an invention violates the accepted system of moral judgement and norms in law and society, determining what is considered acceptable and unseemly. In the case of Indian Patent Law, it forbids patenting animals, deeming it immoral and contrary to societal values. Similarly, granting patents to human beings is universally prohibited due to the prevailing belief that it goes against moral, ethical,

and social norms. However, the United States has positioned itself as a global leader in biotechnological research and development by leveraging its biotechnology research resources and establishing broad standards for patent-eligible subject matter. The EU and India, on the other hand, have lagged behind the US and implemented more stringent patent protection in some biotechnological fields.

Furthermore, principles like utility guidelines in the USA and the EU Biotech Directive have resulted from public dissent against patenting biotechnology inventions. The general public plays a significant role in shaping patent principles, particularly concerning genetic-based inventions, constructed on their perception of morality regarding the issuance of such patents. In addition, a careful analysis of the moral worth of the technology is required to establish whether it protects human rights and dignity. In this regard, it is necessary to ensure that the consent stakeholders share the risk and reward evenly so that it helps in serving the common good.

To conclude, the European Union and India explicitly banned the patenting of inventions that violate morals or public order, likely to stimulate participation by private persons in the patent-granting process. The European Union and India have fewer patent applicants and grants than the United States, according to Tables 2 & 3, and Fig. 1. This demonstrates that what may be patentable in the United States may not be patentable in the EU and India. It is evident that if the patent claim were rejected in India or the EU, the same patent claim could still be patented in the United States.

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