THE INTERPLAY OF PATENTABILITY AND MORALITY: A COMPARATIVE STUDY OF US, EU AND INDIA

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ABSTRACT:

Law and morality are always in loggerheads whenever any transmission takes place in the legal system of any orderly civil society. As we are heading into an uncertain technological future, a plethora of inventions are occurring all over the globe. Now, morality comes into the central focus point when an individual invents a product or process relating to biotechnology, AI, neurotech, pleasure patents hinges upon the moral conscience of the people. Recently, the Calcutta high court faced the dilemma of moral aspects of patentability while entertaining a petition regarding the decision of the controller General of patents, Designs, and Trademarks rejecting an application filed by the infamous company ITC limited relating to E-cigarettes. The concepts of morality and public order had been integrated in the article 27 of the TRIPS agreement and under section 3(b) of the Indian patents act,1970 in a very ambiguous manner. It is not the first time that the controller rejected the patent on the grounds of public order and morals. Considering the dynamic nature of morality, the controller has no compass to decide this complex issue rather than his own dimensions of morality. This paper ventures into analyses the legal regime relating to morality as a ground for rejecting the patents and also delves into how the standards of morality have been differing from India and European Union, US when such standards were incorporated into the Patent law landscape.

Keywords: Morality, Patentability, TRIPS, Biotechnology, Ordre Public

Introduction:

Historically, the goal of patent law has been to encourage innovation by granting exclusive rights[1]. A crucial restriction is brought about by the interaction of morality and patentability, though not all technically innovative, creative, and commercially useful ideas should be protected. Agreement on Trade-Related Aspects of Intellectual Property Rights, among other international frameworks, expressly allows member nations to deny patentability to discoveries whose economic use would be against "ordre public" or morals[2]. This clause has generated a great deal of discussion and varying interpretations in different jurisdictions.

Because of its utilitarian philosophy, the US has always downplayed the importance of morality in patent judgments. The European Union, on the other hand, incorporates morality into its legal structure through the European Patent Convention (EPC), namely Article 53(a) and Rule 28, which prohibit inventions like human cloning and germline modification. India expressly bans inventions that are against public order or morals[3], a decision that is informed by both TRIPS requirements and constitutional ideals.

This study compares the use of morality-based exclusions by examining legal precedents and legislative frameworks in the US, EU, and India.

International Legal Regime on Patent and Moral:

The international legal framework governing the intertwining of morality and patentability is characterized by a short but meaningful allocution: states have an obligation to provide patents on an extensive scale, but they may derogate from this where commercial exploitation would offend "ordre public" or morality[4]. At WTO level, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires patents to be made available in "all fields of technology" but explicitly permits Member States to exclude from patentability inventions whose commercial exploitation would have to be barred in order to protect ordre public or morality (including in order to protect health or the environment).

Scholarly literature reiterates that the global texts were designed to be deliberately adaptable;

[1] Katherine C. Mullally, Legal (Un)Certainty, Legal Process, and Patent Law, 43 Loy. L.A. L. Rev. 1109 (2009)
[2] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27.2, Apr. 15, 1994, 1869 U.N.T.S. 299.
[3] Patents Act, 1970,3(b) (India).
[4] TRIPS Agreement art. 27.2

commentators promote principled frameworks to employ morality exclusions consistently especially in biotechnology, gene editing and human-material patents so that ethical protection never turns into arbitrary de facto veto. For a brief summary, the international system sets permissive minima and a moral-exclusion escape hatch; the substantive content of that hatch is delivered by regional rules, case law and domestic statutory practice, forming a multifaceted, jurisdictionally differentiated approach[5].

Locus of US vis-à-vis Morality Exclusion under Patent Law:

The approach of the US in relation to Morality Exclusion of Patenting Inventions can be deciphered by introspecting the relevant statutory Provisions and several Judgements that determined the Jurisprudence of Morality and Patent. Furthermore, the US patent system is architectured by the Utilitarian Philosophy[6]as it will "promote the progress of science and useful arts".

US Patent Law:

It is quite pertinent to note that in US there is no explicit provision that deals with the Inventions are prohibited on the grounds of Morality. The implied inference of Moral exclusion has been shrouded in ***35 U.S.C.101*** which deals with the Inventions that are eligible to be Patented under US Patent law[7] It states that any subject matter can be patentable if it is of any new and useful process, machine, manufacture, or composition of matter which is subject to other Provisions of this title. However, the subject matter of patent was excluded by the Doctrine of "Moral Utility" culminated by Judicial creativity by the vehicle of Judicial Interpretation[8].

The website of United states Patent and Trademark Office (USPTO) made very clear that inventions that goes against the fabric of Public Morality cannot be amenable to patent protection. Nevertheless, the Manual of Patent Examining Procedure (MPEP) prescribed that the patent cannot be rejected on the ground of "frivolous, fraudulent or against public policy"

[5] Nicolas F. Diebold, The Morals and Order Exceptions in WTO Law: Balancing the Toothless Tiger and the Undermining Mole, 11 J. Int'l Econ. L. 43 (2008).
[6] .William Fisher, Theories of Intellectual Property, in *New Essays in the Legal and Political Theory of Property* 168, 173–74 (Stephen R. Munzer ed., Cambridge Univ. Press 2001)
[7] "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 therefor, subject to the conditions and requirements of this title". 35 U.S.C. § 101 (2006)
[8] Margo A. Bagley, Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law, 45 Wm. & Mary L. Rev. 469, 476 (2003).

for lack of utility. Furthermore, the American Invents Act (AIA) apparently restricted on the principles of Morality inventions that related to tax strategies and human organisms[9]

Morality Interpretation by US Courts:

In 1817, Justice Story propounded that the Moral Utility is one of the pre-requisites for the subject matter to be patented placed emphasized that a Patentable invention must be subjected to the "Wellbeing of the human Beings, good policy or morals of the society[10] This case was considered as the origin of the Moral Utility Doctrine and it was again reaffirmed by Justice Joseph story[11]. In 1889, the court was confronted with the invention related to a "Toy Automatic-Race Horse" would be utilized in the gambling establishments and it opined that it was "not a useful device, within the meaning of the statute relating to patent"[12]. In another instance the second circuit court rejected the claim of a patent relating to device that makes the unspotted tobacco plants appear spotted, it remarked that such kind of inventions are designed to deceive the consumers at large[13].

Demise of Moral Utility Doctrine:

The application of Moral utility Doctrine was started diluted in the period of twentieth century which was discernible from the plethora of judgements that is passed by the US courts. In the era of 1920s anti-gambling sentiment was started to influence among the masses, went to the extent of prohibition of gambling activities[14]. Nevertheless, after the Americans began to clasp the gambling activities amidst the great depression, the states passed the laws in support of legalising gambling in order to attain the revenues generated from the gambling to ameliorate the effects of great depression[15]but in 1909 itself Nevada legislature legalised the activity of casinos[16].

[9] .Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33(a), 125 Stat 284, 340 (2011)
[10] *Lowell v. Lewis,*15 F. Cas. 1018 (C.C.D. Mass. 1817) (No. 8,568)
[11] Bedford v. Hunt, 3 F. Cas. 37 (C.C.D. Mass. 1817) (No. 1,217)
[12] *National Automatic Device Co. v. Lloyd*, 40 F. 89 (C.C.N.D. Ill. 1889).
[13] Rickard v. Du Bon, 103 F. 868, 869 (2d Cir. 1900).
[14] Nelson Rose, Gambling and the Law: The Third Wave of Legal Gambling, 17 Vill. Sports & Ent. L.J. 361, 369–73 (2000).
[15] Roger Munting, An Economic and Social History of Gambling in Britain and the USA 28 (Manchester Univ. Press 1996).
[16] Nelson Rose, Gambling and the Law: The Third Wave of Legal Gambling, 17 Vill. Sports & Ent. L.J. 361, 369–73 (2000).

The demise of Moral Utility Doctrine can be sensed when USPTO rejected the application of the patent, known as a Slot machine (One armed bandit) used for the purpose of gambling, on the ground that it abrogated the morals of the public. But the Patent Board of appeals overruled the above decision, held that such invention could be patentable as it is useful[17] and it was rendered as the public opinion vis-à-vis morality on gambling had drastically shifted. The US court of appeals for the federal circuit overturned the US District court of California held that in order to patentable under 35 U.S.C. § 101 the threshold of utility is not that high and if it yields identifiable benefit then it can be sole criterion to hold the invention patentable, the court eschewed the Doctrine of Moral utility and deception recognised the decision in Exparte murphy case, granted the patent to Post-mix beverage dispenser on the ground that it was useful by applying the "principle of Utility"[18].

Contemporary approach to Patentability:

At present, the USPTO's Manual of Patent examining procedure is utterly silent about Morality or ethics but it mentions the Juicy Whip case pointed out "A rejection under 35 U.S.C. 101 for lack of utility should not be based on grounds that the invention is frivolous, fraudulent or against public policy"[19]. After the emergence of biotechnology especially the inventions which hinges upon the Human genetic engineering, CRISPR-Cas 9 or any other inter-alia subject matter questioned the Morality of the Public. But the decision in *Parke Davis* case[20] formed the cornerstone for patenting on genetic materials and subsequently the Supreme court in *Chakraborty* [21]case recognised the intention of the Congress that "anything under the sun that is made by man" can be absolutely eligible for patent which encompassed the living human made organism[22].

In addition to that Inventions that is considered to be taboo among the general masses can also be rendered patentable[23]. After the decision in the case of Juicy whip, the USPTO started to

[17] Ex parte Murphy, 200 U.S.P.Q. (BNA) 801 (B.P.A.I. 1977)
[18] Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364 (Fed. Cir. 1999).
[19] U.S. Patent & Trademark Office, *Manual of Patent Examining Procedure* § 2104, Revision July 2022 (R-07.2022), https://www.uspto.gov/web/offices/pac/mpep/s2104.html (last visited Sept. 26, 2025)
[20] Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95, 99, 102 (S.D.N.Y. 1911). (Judge Learned Hand upheld the patent, finding that the adrenaline claimed in the patent was isolated and purified from its natural surroundings and, thus, it was not a product of nature.)
[21] .Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980)
[22] Crockett, *Morality: An Important Consideration*, 108 Cal. L. Rev. at 288.
[23] A61H19/00 - Massage for the genitals; Devices for improving sexual intercourse" under the Cooperative Patent Classification System".

grant patents under the A61H19/00 classification to sex toys also known as pleasure patents[24].

Locus of European Union vis-à-vis Morality clause:

The exclusions of patents on the grounds of Morality can be witnessed even before the existence of European Union and the foundation had been laid down in 1963 of Strasbourg convention portrayed that invention or publication runs contrary to the *ordre public and Morality* must be excluded, considered to be a minimum requirement for contracting parties[25].

Relevant Legal Regime:

To establish conformity with TRIPS Article 27(2) and Directive Article 6(1), the EPC revision in 2000 replaced "publication or exploitation" with "commercial exploitation" in Article 53(a)[26] of the EPC[27]. It also provides that stipulates that procedures for cloning humans, changing germline genetic identity, industrial or commercial exploitation of human embryos, and genetic alteration of animals inflicting suffering without substantial medical benefit are not patentable[28].The final language of Article 53(a) states that a simple legal prohibition in some Contracting States does not automatically render an invention morally unacceptable for EPC purposes; a broader, substantive assessment of ethical concern is necessary. This avoids simply formalistic denials based only on domestic prohibitions[29].

The Biotechnology Directive (Directive 98/44/EC)[30] adopted in 1998 after a decade of heated

[24] Andrew Gilden & Sarah R. Wasserman Rajec, Pleasure Patents, 63 B.C. L. Rev. 571 (2022)
[25] *Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Invention*, Nov. 27, 1963.
[26] Article 53 defines three exceptions to patentability: (a) inventions the commercial exploitation of which would be contrary to 'ordre public' or morality; (b) plant varieties or animal species or essentially biological processes for the production of plants or animals; this does not apply to microbiological processes or the products thereof; (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this does not apply to products, in particular substances or compositions, for use in any of these methods.
[27] Decision of the Administrative Council of 16 June 1999 Amending the Implementing Regulations of the European Patent Convention, 1999 O.J. E.P.O. 437 (incorporating Articles 5 and 6 of the Biotechnology Directive into the EPC Implementing Regulations, specifically Rules 28 and 29, which were formerly Rules 23b, 23c, 23d, and 23e
[28] Implementing Regulations to the Convention on the Grant of European Patents, r. 28, Oct. 5, 1973, 1065 U.N.T.S. 199, https://www.epo.org/en/legal/epc/2020/r28.html
[29] Convention on the Grant of European Patents art. 53(a), Oct. 5, 1973, 1065 U.N.T.S. 199 ("Under this provision, exploitation shall not be deemed to be contrary to ordre public or morality merely because it is prohibited by law or regulation in some or all of the Contracting States."), https://www.epo.org/en/legal/epc/2020/a53.html
[30] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, 1998 O.J. (L 213) 13

parliamentary debate, was the most significant development for the application of morality in EU patent law. The Directive was intended to increase legal certainty about patent eligibility in the developing biotechnology industry. However, the volatile negotiation process was greatly impacted by ethical considerations, resulting in an increased focus on topics such as the safeguarding of human dignity[31].The Directive's basic morality provisions (Articles 5 and 6) were subsequently merged into the EPC's Implementing Regulations by an EPO Administrative Council decision in 1999. This approach sought to integrate substantive patent law throughout Europe, extending EU-derived standards to all EPC Contracting States, including those outside the EU.

The Biotech Directive's general morality provision, which excludes inventions from patentability if their commercial exploitation would be harmful to public order or Morals[32]. Furthermore, expands on the broad provision by providing particular examples of unpatentable subject matter:

(a) procedures for cloning human beings

(b) techniques for changing the germ line genetic identity of human.

(c)Using human embryos for commercial or industrial reasons,

(d) procedures for altering the genetic identity of animals causing suffering but providing no major medical benefit, as well as animals resulting from such processes[33].

This list conforms to Rule 28 EPC and emphasizes the Directive's role in aligning EU law with the European Patent Convention.

Furthermore, Chapter G of the Guidelines of Examination framed by the European Patent office also critically important as it deals with Patentability inter-alia provides for the Provisions of Ordre Public or Morality. It considers certain subject matter inherently prohibited under Article 53(a) EPC (and Rule 28 for biotech) when commercial exploitation would harm

[31] Duncan Matthews, Timo Minssen & Ana Nordberg, *Balancing Innovation, 'Ordre Public' and Morality in Human Germline Editing: A Call for More Nuanced Approaches in Patent Law*, 29 Eur. J. Health L. 562, 577 (2022

[32] Council Directive 98/44, art. 6(1), 1998 O.J. (L 213) 13 (EC), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0044

[33] Directive 98/44, art. 6(2).

the public order or morality. According to the Guidelines, for the EPO to refuse a grant on moral grounds, the innovation must be such that commercial exploitation is clearly opposed to morality or public order. It is not enough that the invention is subject to legal prohibition someplace; it must also raise significant ethical concerns[34].

The Guidelines distinguish between uses that are intrinsically offensive (morally problematic in themselves) and those where the prospect of a morally problematic use is remote or accidental. If the primary concern is that someone will misuse the invention, that is usually insufficient. The examiner evaluates whether the claimed innovation itself is fundamentally problematic when employed as intended, or unavoidably used in a morally objectionable manner[35].

The Guidelines also agree that solely economic or commercial implications (e.g., inventions that may harm markets, cause unfair advantage, etc.) are insufficient to justify a refusal on moral grounds unless these economic effects are intertwined with moral/public order issues. So moral/public-order concerns take precedence over just commercial harm[36] The Guidelines relate to the list of biotech subject-matter in Rule 28 EPC, stating that it is part of the exclusions list under Article 53(a). If an invention fits into one of the stated biotech areas in Rule 28 (e.g., uses of human embryos for industrial and commercial purposes, changing the germ line, etc.), it is considered a "list exception" and instructs examiners very explicitly[37].

Interpretation of Morality Provisions by CJEU:

The CJEU's primary judgments centre on establishing basic concepts, such as human dignity and applying them to the scope of patent exclusions, particularly those involving human biological materials.

Oliver Brüstle case addressed the patentability of brain precursor cells produced from human embryonic stem cells. The central issue was how to interpret Article 6(2)(c) of the Biotech Directive, which prohibits "uses of human embryos for industrial or commercial purposes,"

[34] European Patent Office, *Guidelines for Examination under the European Patent Convention*, Part G, Chapter II, Section 4.1, *Matter contrary to public order or morality*, EPO (2025), https://www.epo.org/en/legal/guidelines-epc/2025/g_ii_4_1.html.
[35] Id. at (G-II.4.1.2)
[36] Id. at (G-II.4.1.3)
[37] .Id. at (G-II.5.3)

particularly the definition of a "human embryo" and whether the exclusion applied even if embryo destruction was not explicitly claimed. The CJEU ruled that the innovation was not patentable, taking a broad exclusionary attitude motivated by the need to defend "human dignity". The Court concluded that the patent exclusion applies if the technical teaching of the invention entails the prior destruction of human embryos or their use as base material, regardless of whether the method of destruction is included in the claims[38].

In Brüstle, the CJEU construed "commercial exploitation" broadly, confirming that the use of human embryos for scientific research, which is the subject of a patent application, cannot be separated from industrial or commercial usage and is thus precluded from patentability[39].

Interpretation of Morality Provisions by EPO:

The T 356/93 (PGS/Plant cells or Plant cells/PLANT GENETIC SYSTEMS) decision dealing with patents of transgenic plants, plant cells, and production methods of such. It is relevant because it established criteria and concepts used while assessing ordre public and morality under Article 53(a) EPC. It stated that morality "is based upon the sum of the norms accepted which are firmly ingrained in a certain culture". For the purposes of EPC, the relevant culture is the culture ingrained into European civilization and society. It was held by the Board that the ordre public involves the safeguarding of physical integrity of persons and the security of society. It was concluded from the part of the Board that none of the patent claims at issue involved subject-matter the use of which would be against ordre public or morality. The case involved the application of ordre public and the environment and concluded that there was no risk posed from the use of transgenic plant cells. Protection of environmental interest has generally been considered to fall under the principle of ordre public.

For plants, T 356/93 applied an approach of 'unacceptability' of moral norms ingrained in European culture. For this case, the TBA created an avenue for the use of balancing test with regard to plants. The decision highlighted that the specific exclusion provisions (such as Article 53(a) EPC) should be interpreted narrowly. The above decision serves as a guide for the application of the morality provision in the context of plants within the recognized moral hierarchy. Gates remarks in Cold Spring Harbor Perspectives in Medicine that Plant Genetic

[38] Enrico Bonadio, *Biotech Patents and Morality After Brüstle*, 34 Eur. Intell. Prop. Rev. 433, 439 (2012)
[39] Moufang, Rainer, 'Patenting of Human Genes, Cells and Parts of the Body? – The Ethical Dimensions of Patent Law', IIC Vol. 25 No. 4/1994, 487-515 (Moufang 1994)

Systems provided the vision of interpretation with which the EPO could handle contentious moral inventions while not paralysing innovation in the life sciences[40].

T 866/01 (Euthanasia Compositions):

The Decision T 866/01 (Euthanasia compositions) dealt with a traditional pharma patent application of compositions of preparations of medicaments usable in lower mammals.

This decision is characterized by advocating a narrow view of the concept of "commercial exploitation"[41]. It clearly expresses the delimitation of the morality clause's operation in relation to commercial exploitation, excluding developmental aspects from the scope of Article 53(a) EPC[42]. The patent was rejected because the inventor claimed something contrary to morality. Though the composition was designed with euthanasia in mind for "lower mammals," the patent wasn't specifically excluded from use on humans. Exploitation was deemed contrary to morality since it wasn't excluded from use with humans and this undermines the principle of safeguarding human life, particularly because euthanasia of a human being is illegal in the majority of EPC contracting nations[43]

The Patent Office required the patentee to disclaim any human use of the composition, invoking Article 53(a) EPC. The Board referred to PGS (T 356/93), defining morality as principles deeply rooted in European culture and legal traditions. By stressing “legal systems” in plural, the Board acknowledged differing national moral attitudes. Applying the principle of narrow construction to Article 53(a), it concluded that euthanasia in veterinary practice understood as humane killing of animals by trained personnel is an established, morally accepted practice and thus not excluded from patentability. This shows the Board’s balancing act: restricting exclusions under morality to clear, irrefutable evidence of societal unacceptability, while leaving space for differing national sensibilities[44].

[40] Christina Gates, *Patenting the Life Sciences at the European Patent Office*, 4 COLD SPRING HARB. PERSP. MED. a020792 (2014)
[41] Graham Dutfield, *Delivering Drugs to the Poor: Will the TRIPS Amendment Help?* 34 AM. J.L. & MED. 107, 114 (2008)
[42] Jessica L. Greenbaum, Comment, TRIPS and Public Health: Solutions for Ensuring Global Access to Essential AIDS Medication in the Wake of the Paragraph 6 Waiver, 25 J. Contemp. Health L. & Pol’y 142 (2008).
[43] Alexandra G. Watson, Note, *International Intellectual Property Rights: Do TRIPS’ Flexibilities Permit Sufficient Access to Affordable HIV/AIDS Medicines in Developing Countries?* 32 B.C. INT’L & COMP. L. REV. 143, 158–59 (2009)
[44] Euthanasia Compositions (Michigan State Univ.), T 0866/01, Decision of Technical Board of Appeal 3.3.02

T 0315/03 (Oncomouse):

In Oncomouse (T 0315/03), the EPO faced opposition against Harvard's patent of a cancer-prone animal transgenic mouse. Opposers alleged animal distress rendered exploitation unethical. The Board reaffirmed that Article 53(a) directs against exploitation and not against the invention per se[45]. It declined a blanket prohibition of animal patents and asked whether utilization of the Oncomouse with a view to a commercial use would perforce involve acts deemed immoral.

As McMahon and Doyle note, this ruling established the proportionality approach as balancing research benefits against animal welfare[46]. What their analysis makes clear is how Oncomouse shapes consideration of more recent contentious issues like de-extant animals: the crucial question is whether exploitation and not the subject matter violates moral norms. In rejecting blanket exclusion, the Board sent a message of predictability while at the same time leaving leeway for ethical evaluation of specific exploitation scenarios.

T 2510/18 (Simalikalactone E)

The question at issue before the Simalikalactone E case (T 2510/18) was whether charges of biopiracy and misappropriation of traditional knowledge could bar patentability under Article 53(a). Opponents alleged the patent as being tainted with dishonest practices from French Guiana. Even though a bulk of the factual context stood undisturbed before the Board, it held that such-origin issues were ineffective: Article 53(a) applies only where exploitation of the per se invention is against morality or ordre public. Since exploitation of the antimalarial action of Simalikalactone E was not intrinsically immoral per se, the exception did not arise[47].

Matthews criticized this narrow approach, noting that the applied morality clause cannot speak to distributive justice or indigenous rights[48]. He claims T 2510/18 reveals the limitation of EPC morality analysis, it achieves patentees' legal certainty at the expense of broader ethical issues.

(May 11, 2005), ECLI: EP:BA:2005: T086601.20050511, available at European Patent Office, Boards of Appeal —Decision T 0866/01

[45] T 0315/03, Transgenic Animals/Harvard, ECLI: EP:BA:2004: T031503.20040706 (Bd. App. Eur. Pat. Off. 2004).

[46] Aisling McMahon & David M. Doyle, *Patentability and De-extinct Animals in Europe: The Patented Woolly Mammoth?*, 7 J.L. & BIOSCI. lsaa017 (2020).

[47] T 2510/18, Simalikalactone E, (Bd. App. Eur. Pat. Off. 2022).

[48] Duncan Matthews, *Balancing Innovation, "Ordre Public" and Morality in Human Germline Editing: A Call for More Nuanced Approaches in Patent Law*, 29 EUR. J. HEALTH L. 562 (2022)

Gates also remarks that the exploitation-based test ensures consistency while leaving benefit-sharing issues to other laws like the Nagoya Protocol[49]. The case therefore reveals both the stability and the deficiency of the current moral framework of the EPO.

Locus of India in relation to Patentability vis-à-vis Morality:

Indian patent law is principally controlled by the Patents Act of 1970, which has been significantly amended to reflect technological advances and international commitments under the TRIPS Agreement. The goal of the Act is to find a balance between providing inventors with exclusive rights as an incentive for innovation and ensuring that such rights do not jeopardize public health or interest. The Department for Promotion of Industry and Internal Trade administers patent law, issuing regulations and guidance on a regular basis to clarify statutory requirements and solve current concerns[50].

Relevant Statutory Provision:

Indian patent system itself mentions morality as an exception from patentability[51]. It mirrors India's embracing a moral aspect of patentability and joining Article 27(2) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), under which the states are permitted to exclude from patent protection inventions where their exploitation should be prevented as a measure of protecting ordre public (public order) or morality.

Whereas the United States has eschewed the "moral utility doctrine" and adopted a purely utility-based approach, India and the European Patent Convention (EPC) introduce morality as an explicit consideration. Even the EPC excludes from patentability with Article 53(a) inventions "the commercial exploitation of which would be contrary to ordre public or morality. The problem, though, with defining morality is that moral norms are changing with society and what may be considered immoral practice or law at one time or in one territory may or may not be at another[52]. Indian law and Patent Office practice reflect this flexibility.

[49] Gates, supra note 40.
[50] Cybaris, Indian Patent Law, 8 CYBARIS INTELL. PROP. L. REV. 10–20 (2016).
[51] Section 3(b) of the Patents Act, 1970, "invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or could seriously prejudice human, animal or plant life or health or the environment" is not an invention under the Act.
[52] Kartikey Pandey & Alok Kumar Chaurasia, *Morality and Patents: A Reasonable Restriction or a Deterrent to Invention?*10 Indian J. Intell. Prop. L. 48, 50–52 (2019).

II. Judicial Decisions and Practical Applications from the Indian Patent Office:

The Indian Patent Office (IPO) has refused patents under Section 3(b), where inventions were inconsistent with prevailing standards of morality. One notable instance came with the refusal of patentability of a vibrator in 2018. The Controller felt the device's "intended use or commercial exploitation could be contrary to public order or morality" and thus fell under Section 3(b)'s ban[53]. The decision generated publicity with commentators arguing that the practice has the effect of establishing morality as sexual conservatism and could hinder technical innovation in sexual health and related sectors[54].

Earlier, an unreported application in a medicinal powder prepared from exhumed dead bodies was also rejected on the basis of immorality[55]. These rejections are evidence of the IPO's intent to implement exclusions based on morality, regardless of the undeveloped nature of rules of determining immorality in India. The courts in India have not yet developed a robust jurisprudence on morality and patentability, leaving most decisions to the discretion of the IPO. This contrasts with European practice, where courts and the European Patent Office (EPO) have articulated standards such as the utilitarian balancing test (weighing benefits of an invention against moral harms) in the Onco-Mouse case[56], and the abhorrence standard in Relaxin[57],requiring near-universal condemnation for exclusion.

The vibrator denial is one illustration of how moral foundations are able to hold back innovations possessing possible social goods, such as women's reproductive health or sex-positive technologies. Opponents of the law assert that by leaving morality ascriptions in patent officers' hands typically scientists or engineers and hardly ever ethicists or jurists a law runs into inconsistent outcomes[58].This issue has been acknowledged worldwide. In Diamond v. Chakrabarty, the US Supreme Court infamously took a wide approach and ruled that "anything under the sun made by man" could be patented, thus refraining from interference with moral judgments. However, European cases like Brüstle v. Greenpeace restricted patents of human

[53] .Order dated Aug. 7, 2018, Indian Patent Office, Refusal of Application No. 4668/DELNP/2007
[54] Shamnad Basheer, *Sexual Pleasure is Immoral: So Says the Indian Patent Office!*, SpicyIP (Aug. 11, 2018), https://spicyip.com/2018/08/sexual-pleasure-is-immoral-so-says-the-indian-patent-office.html.
[55] Pandey & Chaurasia, supra note 47, at 53
[56] Harvard/Onco-Mouse, Examining Division, O.J. E.P.O. 1989; Bd. App. 1990 EPOR 501.
[57] *Howard Florey/Relaxin*, 1995 E.P.O.R. 541 (T 0272/95).
[58] Pandey & Chaurasia, supra note 47,at 56-57

embryo destruction and demonstrated a greater acceptance of ethical exclusion.

Rejection of Patent on Genetically Modified Mouse :

Regeneron Pharmaceuticals initially filed a patent in India for a mouse, its cells, and their utilization. After the Controller rejected the claims, Regeneron changed the application to seek protection for a process of creating a genetically modified mouse. The Controller denied again, stating that the approach violated morals under Section 3(b) of the Patents Act because genetic modification would inflict suffering to the animal while providing no significant advantage to humans. The Controller also determined that the revisions broadened the invention's scope.

On appeal, the High Court disagreed. It emphasized that Regeneron had specifically claimed a significant medical benefit to humanity in its response which the Controller had disregarded. By discarding this argument without question the Controller failed to apply his thinking objectively. The Court considered the updated claims, which contained a technique for genetically modifying a mouse, an antigen-binding protein, a targeting vector, and a nucleic acid construct. It determined that these were disclosed in the original specification and did not expand the subject matter. The Controller erred by limiting his assessment to the claims alone rather than the entire specification.

The Court cited Allergan Inc v Controller of Patent[59] to underline that changes should be considered in the context of the entire specification, not just the initial claims. It overturned the denial and ordered the Patent Office to evaluate the change objectively under Section 3(b). To avoid unconscious prejudice, a separate officer must make a decision, applying their intellect to the updated allegations and issuing a reasoned, rational order. These ruling underlines that pre-grant changes must be decided comprehensively, focusing on the whole specification[60].

Rejection of Patent on "A Heater Assembly to Generate Aerosol"[61]:

The Controller rejected the innovation, named "A Heater Assembly to Generate Aerosol," under Section 3(b) of the Patents Act because it posed a serious threat to human life, health, public order, and morality. The appellant claimed that, despite proving inventive step and

[59] C.A.(COMM.IPD-PAT) 357/2022
[60] Regeneron Pharms. Inc. v. Controller of Patents & Designs (Madras High Ct. Oct. 22, 2024) (order) (India)
[61] ITC Ltd. v. Controller of Patents, Designs & Trademark, IPDPTA/13/2024 (Calcutta H.C. May 20, 2025)

separating the invention from previous art, the Controller wrongfully dismissed it under Section 3(b) without explanation. The order was challenged for being vague, misinterpreting the innovation, and relying on hidden papers, which violated natural justice. The appellant also claimed that the order incorrectly inferred that the invention was only for use with tobacco substrates, while it could be used with substrates that did not include tobacco.

The Controller had also cited Article 47 of the Constitution and Section 83(e)(a) of the Act to support the rejection. The respondent defended the ruling, claiming it was reasonable and consistent with the Prohibition of Electronic Cigarettes Act of 2019. However, after hearing from both parties, the court considered Section 3(b) in light of the Patents Act's goals stating that the Act aims to foster scientific development in the public interest. It concluded that the Controller fundamentally misunderstood the invention by comparing it primarily with tobacco chemicals[62].

Under Indian law, with no leading precedent, the IPO has broad discretion, and this can produce unpredictability. These sex-related inventions denials demonstrate how an interpretation of "morality" gets applied culturally and further undermine doubts as to whether such exclusions are anything other than a mirror of an inability of society to cope[63]. Meanwhile, morality-based exclusions are still a buffer against harmful technologies that extensively damage the environment, human dignity, or public health. Here lies a problem of preventing this buffer from degenerating into paternalistic censorship of socially desirable technologies.

Conclusion:

The comparative analysis of the United States, European Union and India shows that morality in patent law serves as a reflection of each jurisdiction social compact rather than a consistent legal principle. The United States supports permissive utilitarianism prioritizing innovation and usefulness over moral gatekeeping. The EU incorporates morality into the design of its

[62] The court opined ″The preconceived and subjective notion that all tobacco products cause serious prejudice to human life and health without any reliance on scientific or technical evidence or any other supporting facts is unsustainable. The finding that the subject invention is contrary to public order and morality is unreasoned, cryptic and without any basis. The fact that the Controller was of the view without consideration of any independent scientific or technical evidence that the usage of the invention affects public order and morality cannot be the basis for rejecting the invention."
"The interaction of patent laws and ethics is an uncomfortable relationship and has always produced difficulties. In such circumstance, section 3(b) ought not to be interpreted to deal with all subjective concerns of morality, public order or health regardless of any scientific or technical evidence or any cogent reasoning"
[63] Pandey & Chaurasia, supra note 47, at 58

patent system, prioritizing ethical proportionality and human dignity even at the expense of restricting particular sectors of research. India has statutory morality clauses similar to the EU but lacks consistent jurisprudence, alternating between conservatism and pragmatism depending on the context.

What emerges is that morality in patent law is profoundly influenced by cultural norms and constitutional priorities. It functions as an ethical checkpoint, although its purpose varies permissive silence in US, organized balancing act in EU, or contested discretion in India. The broader consequence is that patent law is not separate from society's moral fabric; rather, it reflects and reinforces the goals of the community it serves. The global discussion on Morality of Patents particularly in fields like biotechnology, Artificial intelligence and reproductive technologies will continue to be shaped not only by technical innovation but also by the varied moral landscapes of various jurisdictions. Unless and until there is a certain objective factors it will be guided by "inarticulate major premise"[64] of the controller of patents and judiciary.

[64] Walter Wheeler Cook, "Due Process," the Inarticulate Major Premise and the Adamson Act, 26 Yale L.J. 519 (1917).