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BIOTECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS IN INDIA: LEGAL FRAMEWORK, CHALLENGES AND EMERGING JURISPRUDENCE

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I. ABSTRACT

This article examines the evolving relationship between biotechnology and intellectual property rights (IPRs) in India, highlighting legal, ethical, and global perspectives. It traces the development of Indian patent law from the exclusion of living organisms to the recognition of biotechnological inventions, shaped significantly by cases like Dimminaco AG v. Controller of Patents and amendments aligning with the TRIPS Agreement. The study explores patent eligibility criteria under the Patents Act, 1970, with emphasis on exclusions under Section 3, and the challenges of proving novelty, inventive step, and industrial applicability in biotechnology. It compares approaches in the United States, European Union, and India, analyzing judicial interpretations and ethical frameworks concerning patents on microorganisms, plants, animals, and human genetic material. While U.S. and European systems adopt broader protection, India maintains stricter exclusions influenced by cultural and moral values. The article also discusses emerging issues such as gene editing, AI-driven biotechnology, green biomanufacturing, and personalized medicine, underlining their legal and ethical implications. It concludes that while biotechnology patents are essential for innovation and societal benefit, they must coexist with ethical safeguards and balanced regulation to ensure progress without compromising human dignity, environmental sustainability, or traditional values.

II. KEY WORDS

Biotechnology, Intellectual Property Rights, Patent Law, TRIPS Agreement, Patentability Criteria, section 3 exclusions, Ethical Issues, Comparative Patent Law, Biotechnology invention, Dimminaco Case.

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III. INTRODUCTION:

Intellectual Property Rights (IPRs) are legal frameworks designed to protect the products of human creativity and intellect. These rights ensure that individuals and organizations receive recognition and control over their innovative work, ranging from technological inventions to artistic and literary creations. IPRs encompass various categories, including patents, copyrights, trademarks, trade secrets, and trade dress. Each of these serves a specific function - for example, patents secure inventions and unique processes, copyrights protect literary and artistic works, and trademarks distinguish commercial identities through unique signs or symbols.

One notable feature of IPRs is their territorial limitation; they are enforceable only within the jurisdiction that grants them. Additionally, they grant exclusive usage rights to the creator or owner, preventing unauthorized use, reproduction, or distribution.

Biotechnology, while often associated with modern scientific advancements, has ancient roots. Humans have long used biological processes - such as fermentation - to produce and preserve food like bread, cheese, and yogurt. The term "biotechnology" was formally coined in 1917 by Hungarian engineer Karl Ereky, who envisioned it as the technological use of biological systems in industrial agriculture.[2]

Modern definitions reflect the evolution of the field. The U.S. Office of Technology Assessment characterizes biotechnology as the use of living organisms or their parts to create or modify products and processes.[3] Similarly, the 1992 Convention on Biological Diversity refers to it as the application of biological systems and organisms in developing or adapting useful goods and technologies.[4]

According to the Food and Agriculture Organization (FAO), biotechnology includes the utilization of biological methods to produce goods and services that benefit human society. This includes improving traits in commercially important plants and animals,

[2]M. G. Fari and Kralovanszky, "The Founding Father of Biotechnology: Károly (Karl) Ereky" (2006) 12 International Journal of Horticultural Science 9-12
[3] P. W Grubb, Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global law, Practice and Strategy 245-246 (Oxford University Press, London, 4th ed., 2006).
[4]Article 2 of the Convention on Biological Diversity, 1992

as well as using genetically engineered microbes for health and environmental purposes.[5]

A. RESEARCH OBJECTIVES:

1. Today, biotechnology plays a vital role in multiple sectors, from healthcare and agriculture to environmental sustainability and industrial manufacturing, including food processing, textiles, and paper industries.
2. To analyze the evolution of Indian patent law in relation to biotechnology, from the exclusion of living organisms to the recognition of biotechnological inventions.
3. To critically examine the provisions of the Patents Act, 1970 (especially Section 3 exclusions) as they apply to biotechnology inventions.
4. To compare the Indian approach to biotechnology patenting with that of the United States and European Union, focusing on judicial interpretation and ethical frameworks.
5. To identify the legal, ethical, and policy challenges in patenting biotechnology inventions in India.
6. To assess the implications of international instruments such as TRIPS and the Budapest Treaty on India's patent regime.
7. To explore the future outlook of biotechnology inventions in light of emerging fields such as AI-driven biotechnology, CRISPR gene editing, green biomanufacturing, and precision medicine.

B. RESEARCH PROBLEM

1. Biotechnology is a rapidly advancing field with transformative potential in healthcare, agriculture, and industry. However, the Indian patent regime struggles to balance innovation with ethical, cultural, and public interest concerns.
2. On one hand, TRIPS compliance and global competition necessitate stronger protection of biotechnological inventions.On the other hand,

[5] A. Zaid, H. G. Hughes, et. al., Glossary of Biotechnology and Genetic Engineering 31 (Food and Agriculture Organization of the United Nations, Rome, 1999).

India's ethical values, biodiversity protection, and farmers' rights demand stricter exclusions and safeguards.

3. This tension creates a research problem: How can Indian patent law provide adequate protection and incentives for biotechnology innovations while ensuring ethical safeguards, cultural integrity, and access to resources?

C. RESEARCH METHODOLOGY

The researcher is primarily relying on doctrinal research for the present research work. Around the world, patent right on biotechnology inventions have recently emerged in the field. Over the past years, the idea of inventions in biotechnology has advanced quickly. Given the enormous development potential of patent on biotechnology inventions as a developing science and creating a major issue in patent eligibility criteria under section 3 of the patent Act,1970.

Thus, the "Doctrinal Research Method" was applied in this thesis.

IV. LEGAL FRAMEWORK GOVERNING IPR IN BIOTECHNOLOGY IN INDIA

A. Evolution Of Patent Law in India: "From Exclusion of Living Organisms to Biotechnology Inventions"

Until 2002, the Indian Patent Office generally did not grant patents for inventions that involved living organisms, whether naturally occurring or artificially created. This also applied to biological materials with replicating abilities, any substances derived from them, and processes involved in producing living entities like nucleic acids. However, patents were allowed for methods involving non-living substances, particularly if they were produced through chemical, bioconversion, or microbiological processes that used micro-organisms or biological components. For example, techniques for producing vaccines, antibodies, or proteins, as long as they were non-living, could be patented.[6]

[6] Guideline for examination of biotechnology application for patent also available at www.ipindia.gov.in

A turning point came with the Calcutta High Court's 2002 ruling in ***Dimminaco AG v. Controller of Patents and Designs***.[7] This case involved a patent application for a process to create a live vaccine for poultry to prevent Bursitis infection. The patent office had rejected the application, arguing that since the vaccine involved microbial processes and gene sequences, it was a natural process rather than a manufacturing activity, and because the final product contained living material, it was not eligible for a patent.

The High Court, however, disagreed. It emphasized that the term "manufacture" was not explicitly defined in the patent law, and thus the interpretation could be guided by its commercial or industrial meaning. If the end product - regardless of its living nature - had commercial value and could be sold or traded, then it fulfilled the test of being a vendible product. The court concluded that a process leading to such a commercially valuable product could be considered an invention under patent law.[8]

Following this, the scope of patentability in biotechnology expanded significantly. The Patents (Amendment) Act, 2002[9] redefined "invention" to mean a new product or process involving an inventive step and having industrial application, removing the older reference to "manner of manufacture". Additionally, biochemical, biotechnological, and microbiological processes were formally brought under the umbrella of chemical processes, making them patentable.

India also became a signatory to the Budapest Treaty in December 2001. As a result, Section 10 of the Patents Act was revised in 2002 to include provisions for the deposition of biological materials with recognized International Depository Authorities[10] (IDAs). This ensured that if a patent application involved a biological material that could not be fully described or was not publicly available, a deposit in an IDA could fulfill the disclosure requirement.

[7] Dimminaco AG v. controller of patents and designs 2002(24) PTC 121(Cal)
[8] *Supra* note 5
[9] The patent (amendment) Act,2002 in INDIA is Act No. 38 of 2002
[10] An International Depository Authority (IDA) is a scientific institution officially recognized under the Budapest Treaty to accept, store, and provide access to microorganisms or biological materials that are deposited as part of the patent application process.

Further, the 2005 Amendment to the Patents Act[11] allowed product patents in all technological domains, including biotechnology, while retaining some exclusions to protect public interest in line with national policies.[12]

D. Provision Regarding Biotechnology Inventions Under the Patents Act,1970

1. Patent Eligibility Criteria:

Under the Patents Act, 1970, any invention seeking patent protection in India must satisfy two fundamental conditions.

- Firstly, it must not fall under any of the exclusions listed in Section 3 of the Act.
- Secondly, it must meet the established criteria of novelty, inventive step, and industrial applicability.

E. Biotechnology- Related Exclusions Under Section 3 Of the Patent Act,1970

1. SECTION 3(b)[13]: Inventions Against Public Morality or Order

Any invention whose use or commercial exploitation is considered immoral, harmful to public order, or detrimental to human, animal, or environmental health is barred from patentability. For instance, genetically engineered animals that suffer without medical or other benefits, or inventions that negatively affect the ecosystem, cannot be patented.

2. SECTION 3(c)[14]: discoveries and natural substances

Biological materials that occur in nature, such as naturally existing DNA, RNA, proteins, and micro-organisms, are not eligible for patents. However, genetically altered micro-organisms and vaccines may qualify, provided other legal criteria are met. The 2002 amendment expanded patentable subject matter to include

[11] The patent (amendment) Act,2005 in INDIA is Act No.15 of 2005
[12] *Supra* note 5
[13] Section 3(b) of patent act,1970 states, "an invention the 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" (w.e.f. 20-5-2003).
[14] Section 3(c) of patent act, 1970 states, "the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature"

biotechnological and microbiological processes. In the Dimminaco case (2002)[15], the court held that the presence of living organisms in a commercially useful product does not bar patentability. While plants, animals, and their biological components are non-patentable, processes involving genetic modification may still be granted protection.

Example:

Claim: A new compound that promotes cardiac development, comprising a peptide with SEQ ID NO: 1, wherein the compound is derived from the perivitelline fluid of the horseshoe crab species Tachypleus gigas.

Analysis: This claim is not eligible for patent protection under Section 3(c) of the Indian Patent Act. The reason is that it pertains to a substance—specifically, a naturally occurring peptide—isolated from the embryo's perivitelline fluid of Tachypleus gigas. Since Section 3(c) excludes naturally occurring non-living substances from patentability, this invention does not meet the required criteria for patent eligibility.

3. SECTION 3(d)[16]: New forms or uses of known substance

A substance that is merely a different form of a known compound is not patentable unless it shows significantly enhanced efficacy. The Novartis v. Union of India (Glivec case, 2013)[17] decision clarified that therapeutic efficacy must be established through substantial data. Enhanced physical or chemical properties alone are insufficient without clear medical benefit. Similarly, identifying a new use or property of a known compound does not qualify for patent protection.

Example:

[15] Dimminaco A.G. v. Controller of Patents and Designs, 2002 (24) PTC 121 (Cal)

[16] Section 3(d) of patent act,1970 states, " the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant" Subs. by Act 15 of 2005, s. 3, for clause *(d)* (w.e.f. 1-1-2005)

[17] Novartis AG v. Union of India & Others, (2013) 6 SCC 1

Claim: Pre-protein A is described as a key regulator of glucose metabolism in mammals, featuring a C-peptide composed of two amino acids selected from XY, YZ, and ZX.

Analysis: The prior art reveals a variant of protein A containing a C-peptide made up of amino acids XX. Since the applicant has not provided evidence showing improved therapeutic efficacy of the claimed invention compared to what is already known, the claim does not meet the requirements of Section 3(d) of the Act and is therefore not patentable.

4. SECTION 3(e): Mere Admixture

The simple combination of known substances without a demonstrable synergistic effect is excluded from patentability. To be eligible, the mixture must produce a result greater than the sum of the individual components, supported by scientific evidence.

Example:

Claim: A formulation comprising a novel combination of dormant spores from the naturally occurring fungi Paecilomyces lilacinus and Arthrobotrys species, along with enzymes, lipids, and plant growth-promoting agents, intended for the management of plant-parasitic nematodes.

Analysis: The claimed invention falls under the purview of Section 3(e) of the Act. Upon detailed review, it is observed that the formulation involves two fungal strains that are already recognized for their efficacy in controlling nematodes. However, the patent specification does not provide any evidence or data demonstrating a synergistic effect arising from the combination of these organisms beyond their individual known effects. Therefore, the claim lacks inventive merit and is considered non-patentable under Section 3(e) of the Act.

5. SECTION 3(i)[18]: Medical and diagnostic methods

[18] Section 3(i) of patent act,1970, "any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products"

While drugs and medical devices can be patented, methods for treating humans or animals-whether surgical, diagnostic, or therapeutic-are not patentable. Nevertheless, compositions, formulations, and instruments used in treatment may be patented. Diagnostic techniques applied to samples taken from the body, rather than on the body itself, may also qualify for protection.

Example:

Claim: A method of monitoring drug response in a cancer patient treated with a combination of Gemcitabine and P1446A, involving detection of a gene signature comprising at least two drug response markers chosen from P21, REV3L, FGF5, PTK7, POLH, P27, and SSTR2.

Analysis: The claimed invention pertains to a diagnostic method applied on humans or animals. As per Section 3(i) of the Patents Act, such subject matter is expressly excluded from patentability. Accordingly, the claim is not allowable

6. SECTION 3(j): Non-Patentability of Plants, Animals, Seeds, and Biological Processes

As per Section 3(j) of the Indian Patents Act, inventions related to plants and animals, either wholly or in part, are not considered patentable, with the exception of microorganisms. This also extends to seeds, species, varieties, and naturally occurring biological processes used in the cultivation or reproduction of plants and animals.

While microorganisms are not excluded from patent eligibility, a combined interpretation with Section 3(c) of the Act suggests that only genetically altered or engineered microorganisms-those that are not merely discoveries of natural organisms-can be considered for patent protection.

Claims involving fundamental biological functions, such as seed germination, plant growth stages, or animal development, are typically rejected under the purview of Section 3(j).

Example:

Claim: A treatment composition intended for immune-related conditions in mammals, which includes ex vivo modified autologous NK T cells that can shift

Th1/Th2 balance toward an anti-inflammatory cytokine profile. The formulation may optionally contain carriers, diluents, or other pharmaceutical additives.

Analysis: This claim falls within the exclusion outlined in Section 3(j) due to the inclusion of ex-vivo educated NK T cells as the key therapeutic agent. Although the claim is framed as a pharmaceutical composition, the optional nature of the additional components (such as carriers or excipients) means the core of the invention is the modified NK T cells themselves. Rephrasing the claim as a composition does not circumvent the prohibition under Section 3(j), as the essential element-the modified cell-remains unpatentable.

7. SECTION 3(h): Agriculture and Horticulture methods

Any method related to conventional farming or gardening practices is not considered patentable. This includes procedures for soil preparation, pest control, irrigation, and harvesting. For example, applications related to crop protection methods or seed treatments conducted during sowing are typically rejected under this clause.

8. SECTION 3(p): Traditional knowledge

Inventions rooted in traditional knowledge or based on the known properties of traditionally used ingredients are not patentable. India's Traditional Knowledge Digital Library (TKDL)[19] supports patent office globally in identifying prior art linked to Indian traditional practices, reducing the chances of unjustified patents being granted in this domain.

Example:

The application of pigeon serum for treating paralysis, due to its anti-paralytic property, falls under traditional knowledge in India and represents a repetition of already known uses of animal-based substances. This is supported by D1 (Mahawar et al., 2006, Journal of Ethnobiology and Ethnomedicine), which documents the use of pigeon blood in managing paralysis.

[19]Traditional Knowledge Digital Library (TKDL) is a pioneering initiative of India to protect Indian traditional medicinal knowledge and prevent its misappropriation at International Patent Offices.

F. Claim in Biotechnological Inventions:

Patent applications in the field of biotechnology generally include a wide range of claims. To understand the issues of novelty and inventive step, it is necessary to first discuss the types of claims usually encountered in this domain.

1. Common Subject Matter in Biotechnology Claims:

- Polynucleotides or gene sequences (both product and process claims),
- Polypeptides or protein sequences (product/process),
- Vectors such as plasmids (product/process),
- Gene constructs, cassettes, and libraries,
- Host cells, microorganisms, stem cells, and transgenic cells (product/process),
- Plant and animal tissue cultures (product/process),
- Pharmaceutical or vaccine compositions involving microorganisms, proteins, or nucleotides (product/process),
- Antibodies or antigen-binding fragments (monoclonal or polyclonal),
- Diagnostic kits and methods, and
- Diagnostic tests for detecting mutations, protein expressions, or diseases.

2. Product-by-Process Claims

A product-by-process claim refers to a product defined in terms of the method by which it is obtained. However, the novelty of such a claim is not recognized merely because the process of production is new. The product itself must be distinguishable from prior art.

Example: A polypeptide/compound produced by the method as claimed in claim X. For such claims to be valid, technical evidence must establish that the altered process results in a product with properties that are different from existing products in prior art.

3. Sequence Claims

When a polynucleotide sequence is already available (for example, as part of a gene library) before the priority date, a claim to that sequence lacks novelty - even if its function or activity was not known earlier. A fragment of a polynucleotide may qualify as novel, provided it meets the requirements of inventive step and is not excluded under Section 3. If the same sequence was disclosed in prior art, it will be treated as anticipated, since the inherent properties are considered already present. If there is a difference between the claimed sequence and prior art sequence, then the novelty may stand, but inventive step and Section 3 exclusions must still be examined.

4. Combination or Composition Claims

Biotechnological inventions often involve combinations or compositions of biological products. While these may overcome novelty challenges, they are usually assessed under inventive step or Section 3 provisions.

Example: A composition effective against diphtheria toxin, comprising anti-diphtheria antibodies with acceptable preservatives and stabilizers, wherein the antibodies are obtained from chicken egg yolk. Already discloses a diphtheria toxin composition containing egg yolk antibodies, carriers, and additives, along with the same preparation process. Hence, such a claim would fail under novelty, as the invention has already been disclosed.

G. Challenges in Patenting Biotechnology Inventions:

1. Strict Patentability Criteria in Biotechnology

Within the sphere of biotechnology patents in developing nations, the conditions of novelty and inventive step are applied with strict rigor. For an application to qualify, the invention must be entirely new meaning it has not been disclosed or used in any form worldwide. This requirement ensures that patents are not granted for knowledge already accessible in the public domain.

The inventive step, also known as non-obviousness, adds another layer of complexity. It requires that the proposed invention must not be something that a person with ordinary expertise in the relevant field could have easily deduced at the time of filing. In biotechnology, proof of this often involves advanced technical documentation and

experimental data. Limited resources and shortage of expert examiners in developing countries make compliance with this requirement particularly challenging. As a result, patent approvals are frequently delayed or refused, creating obstacles for local innovators.

The technical complexity of biotech research adds to the difficulty. Since many biotech inventions emerge through incremental developments, assessing whether they meet novelty and inventive step standards is not straightforward. For this reason, innovators in developing countries often struggle to navigate the system, restricting progress in biotechnology and slowing local development.

H. Complexities In Patent Examination of Biotech Inventions

Determining patentability in biotechnology presents distinctive hurdles that weaken both innovation and enforcement in developing regions. One of the most pressing issues is establishing novelty, especially since biological variations may already exist in nature, making it difficult to distinguish between natural phenomena and genuine inventions.

Evaluating inventive steps adds further complications, as biotechnology frequently advances through small, gradual improvements rather than radical breakthroughs. Different countries apply varying thresholds to define what qualifies as an inventive step, which leads to inconsistencies in granting patents across jurisdictions.

Additionally, proper examination demands in-depth scientific expertise, yet many developing nations face a shortage of trained specialists in biotechnology. This knowledge gap often results in inconsistent evaluations, lengthy examination delays, and backlogs at patent offices.

Taking together, these difficulties highlight the urgent need for specialized examination frameworks and stronger international collaboration. Such measures would enhance the reliability and efficiency of biotech patent assessments, thereby supporting innovation and technological growth in developing economies.

I. Delays And Backlogs in Patent Offices

In many countries with limited resources, patent office struggle with application backlogs and insufficient staffing. These bottlenecks create long waiting periods before innovators obtain legal rights, reducing motivation to invest in costly research and innovation.

J. Stringent And Inconsistent Patent Standards

The strict application of novelty and inventive step criteria adds another layer of difficulty. Many developing countries apply rigorous or uneven standards, which complicates the process of protecting biotechnological inventions. This frequently leads to higher rejection rates or uncertainty regarding patent enforceability.

K. Technical Complexities in Examination

Biotech inventions are often highly technical, requiring examiners to evaluate evolving scientific knowledge. Limited expertise in such areas makes it difficult to assess applications accurately, creating uncertainty about which inventions truly qualify for patent protection.

L. Broader Implications

These challenges collectively restrict the advancement and commercialization of biotechnology. Delays in protection slow down medical and agricultural progress, while uncertainty in patent rights reduces both local innovation and foreign investment. Strengthening examination systems is therefore essential to create a supportive environment for biotech development in emerging economies.

M. Legal And Policy Gaps

In many developing countries, patent systems for biotechnology are underdeveloped due to the absence of specialized legal structures. This creates inconsistencies in the way patent laws are interpreted and enforced, weakening overall protection.

N. Institutional And Administrative Challenges

Patent offices in these regions often face significant limitations in terms of financial and human resources. Shortages of trained personnel, inadequate infrastructure, and

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lengthy application backlogs slow down the examination process, which in turn discourages innovators from seeking patent protection.

O. Technical Complexity of Biotech Patents

Biotechnological inventions must satisfy strict standards of novelty and inventive steps. However, examiners may not always possess the technical knowledge required to assess such complex innovations. This lack of expertise often results in higher rates of rejection or uncertainty over the validity of granted patents.

P. Barriers in Patent Enforcement

Even when patents are granted, enforcing them remains a challenge. Weak judicial mechanisms, the absence of specialized enforcement bodies, and limited awareness of intellectual property rights among local stakeholders make it difficult for patent holders to defend their innovations.

V. RECENT CASES

A. Novozymes v Assistant Controller of Patents and Designs[20]

This was in the Madras High Court. It involved a patent application for phytase variants with enhanced thermostability (a biotech enzyme). The Controller had rejected the application using Section 3(d) (on lack of enhanced efficacy over known substances) and Section 3(e) (mere admixtures) of the Indian Patents Act. The judgment clarifies how those sections should be applied for biochemical inventions, especially enzyme engineering.[21]

B. Chinese University of Hong Kong & Sequenom, Inc. v Assistant Controller of Patents and Designs[22]

The court examined whether a method for determining foetal fraction in maternal blood samples (used in non-invasive prenatal testing) is excluded from patentability under Section 3(i) ("any process for the … diagnostic … treatment … of human

[20] Novozymes v Assistant Controller of Patents and Designs (T) CMA (PT) No. 33 of 2023 (OA/6/2017/PT/CHN)
[21] www.kandspartners.com last accessed on 30th sep,2025
[22] Chinese University of Hong Kong & Sequenom, Inc. v Assistant Controller of Patents and Designs (T) CMA(PT)/117/2023 (OA/21/2018/PT/CH)

beings"). The court held that in-vitro diagnostic processes are not automatically excluded, and that if the method identifies a disease/disorder (even subject to confirmation by definitive tests), it counts as diagnostic. However, if further testing is required to confirm, then it may be allowed.[23]

C. Natco pharma ltd v Novartis AG & anr[24]

This involves Novartis' species patent for eltrombopag ("ELT-O") and the earlier genus patent, vs Natco's generic version. A single judge had refused Natco's invalidity challenge of the species patent, emphasizing that inclusion of a species in a genus (Markush) claim does not automatically disclose that species for patentability purposes. But on appeal, the Division Bench restrained Natco from launching its generic until full hearings; this is evolving jurisprudence about how "genus vs species" coverage/disclosure works in India.[25]

D. R. Squibb & Sons LLC vs Zydus Lifesciences Limited[26]

This is about the patent for Nivolumab (Opdivo), a monoclonal antibody used in cancer therapy. Zydus is developing a biosimilar (ZRC-3276). The issues include structural similarity (including Complementarity Determining Regions) and whether the Bolar exemption (allowing biosimilars/generics to be worked on before patent expiry for regulatory approvals) applies.[27]

VI. COMPARATIVE STUDY

A. UNITED STATE OF AMERICA

1. Eligibility Criteria for Biotech Invention in Usa

Under United States Patent Law, any invention that constitutes a novel and useful process, machine, manufacture, composition of matter, or an improvement thereof can qualify as patentable subject matter.[28] The statute itself does not provide an exhaustive list of what is patentable and what is excluded. Instead, it sets out a broad framework,

[23] www.iam-media.com last accessed on 30th sep,2025
[24] Natco pharma ltd v Novartis AG & anr 2023 /DHC/000113
[25] Ibid
[26] R. Squibb & Sons LLC vs Zydus Lifesciences Limited 2025 DHC 5802
[27] www.singhanilaw.com last accessed on 30th sep,2025
[28] U.S.C Section: 101 Inventions patentable

leaving it to interpret whether an invention falls within this scope. Thus, if a claimed invention can be classified as a process, machine, manufacture, or composition of matter, it is generally considered eligible for patent protection.

2. Judicial Interpretation

Although the statute is silent on biotechnology and life-related inventions, the U.S. judiciary has played a key role in clarifying this issue. In the landmark case of Diamond v. Chakrabarty[29], the Supreme Court was asked whether living organisms could be considered patentable. The case involved a genetically engineered microorganism, and the inventor argued that it fell within the category of "composition of matter." The Court adopted a liberal interpretation, holding that living beings created through human ingenuity and biotechnology qualify as patentable subject matter, since they involve a recombination of physical and chemical properties.

This decision marked a turning point in patent law, as it extended the scope of patentable subject matter to living organisms. Following this precedent, patent offices across the world began granting patents on biotechnological products as "compositions of matter." Subsequently, U.S. courts and the Patent Office recognized plants (Ex Parte Hibberd)[30], genetically engineered animals (Harvard Oncomouse)[31], and even human genetic material (Amgen Inc. v. Chugai Pharmaceutical; In re Bell)[32] as patentable. Methods involving human cloning were also addressed[33], though the cloning of humans is explicitly prohibited under the Human Cloning Prohibition Act,[34] and human beings themselves are excluded from patentability.

From these developments, it is clear that in the U.S., biotechnology inventions-including microorganisms, plants, animals, and human genetic material-are within

[29](1980) USSC 447 at 303
[30]Exparte Hibberd See, Roberts (1996) at Pg. No. 532.
[31] Harvard college v Canada (commissioner of patents) [2002] 4 SCR 45
[32] Amezan Inc. Vs Chugai pharmaceuticals Co. Ltd 927 F.2d 1200.18 USPQ 2d 1016 (Fed.Cir.1991), In re Bell
[33] Pioneer Hi-bred International V. Holden Foundation seeds Inc. 35 F 3d. 1226. 31 USPQ 2d. 1385 (8th Cir. 1994) as cited in Merges et al (1997) Pg. No. 68
[34]The Human Cloning Prohibition Act, 2003

the ambit of patentable subject matter, though complete human beings remain outside its scope.

A. ETHICS IN PATENTING LIFE: A U.S PERSPECTIVE

1. General Ethical Concerns

Moral standards vary across cultures and societies, yet the idea of patenting life forms has often been criticized as immoral. The U.S. Constitution upholds principles of equality, human dignity, and prohibits slavery or commodification of life. Despite this, American society has shown adaptability in embracing new scientific and legal interpretations. Under U.S. patent law, the general rule is that "anything under the sun made by man" can be patented.[35] Since the law itself does not explicitly address morality, courts and the Patent Office have interpreted it broadly to include biotechnological inventions.

2. Patenting Microorganisms

The ethical debate began with Diamond v. Chakrabarty (1980),[36] where the U.S. Supreme Court addressed whether genetically engineered microorganisms could be patented. The invention involved bacteria designed to break down oil spills. Initially rejected as unpatentable, the case reached the Supreme Court, which ruled that such a microorganism was a human-made, non-natural invention and therefore patentable. The judgment shocked many around the world and sparked heated discussions about the morality of treating life forms as patentable subject matter. Critics argued that the law should not ignore ethical considerations. Nevertheless, following this decision, numerous patent applications for engineered life forms were filed, shifting focus more towards utility than ethics.[37]

3. Ethical Issues in Patenting Plants

Concerns deepened when patents were extended to higher life forms. In Ex Parte Hibberd (1985), the U.S. Patent Board recognized a genetically modified plant with

[35] The opinion of judges in Diamond Vs Chakraburty (447 U.S 303 (1980)) while interpreting the patent law of America in order to grant patent on living organis m for the first time in the history. 976 447 U.S 303 (1980)
[36] 447 U.S 303 (1980)
[37] http://hdl.handle.net/10603/73596 last accessed on 27th Aug,2025

enhanced tryptophan levels as patentable.[38] Relying heavily on the Chakrabarty precedent, the Board paid little attention to ethical objections[39]. Critics argued that plants are part of nature's creation and should not be privatized, as doing so undermines natural integrity and "God's wisdom." Despite opposition, the Patent Office continued to issue plant patents. Later, in Pioneer Hi-Bred International v. JEM Ag Supply,[40] the Federal Circuit upheld patents on engineered plants, confirming that ethical considerations would not bar such protection.

4. Ethical Debates in Patenting Animals

Animal patents attracted even stronger ethical objections, since animals, unlike plants, are sentient beings capable of suffering. In Ex Parte Allen,[41] a case involving a genetically engineered oyster, the application was denied on obvious grounds but opened the door for animal patents. Shortly afterward, the U.S. Patent Office announced that non-naturally occurring, non-human multicellular organisms-including animals-were patent-eligible. This moves intensified criticism from animal rights groups, which argued that altering animals for human purposes causes suffering, violates their natural integrity, and undermines morality. The most notable case was the Harvard Onco mouse, a genetically modified mouse prone to cancer, used in cancer research. Despite fierce opposition from animal welfare groups, the patent was granted[42]. Supporters justified the decision by emphasizing the medical benefits for cancer research, outweighing ethical concerns.

5. Patenting Human Genetical Material and Cell Lines

The most controversial debates arose in relation to human genetic material. Biotechnology made it possible to isolate and manipulate human genes, cells, and

[38] K.R.G. NAIR AND ASHOIK KUMAR, INTELLECTUAL PROPERTY RIGHTS, ALLIED PUBLISHERS LIMIKTED, New Delhi, 1994, Pg. No.277
[39] Jas mine Chambers, Patent eligibility of Biotechnological inventions in the U.S Europe and Japan: How much patent policy is public policy? George Washington International Law review, 2002
[40] World Intellectual property Report, Vol. 14, No. 3 dated 15 March 2000
[41] 1987 2 USPQ 2d 1425
[42] Manu Luv Shahalia, Intellectual property rights: Many sides to a coin, Universal law publishing company, New Delhi, 2003 Edition. Pg. No.173

DNA. Critics argued that patenting human cell lines equates to owning parts of the human body, akin to slavery, and violates human dignity.

The landmark Moore v. Regents of the University of California[43] case involved a leukemia patient whose cell line was patented by his physicians. Moore claimed ownership rights, but the California Supreme Court ruled against him, reasoning that patents were not granted on natural cells within the body but on isolated cell lines developed through significant research. Thus, patents on human-derived cell lines were upheld.

Further controversy arose in the early 1990s when the U.S. government sought a patent on cell lines from a woman of the Guayami tribe in Panama for AIDS and cancer research. NGOs and indigenous groups condemned this as exploitation and commodification of human life. Due to international backlash, the government ultimately withdrew its application.[44]

B. EUROPIAN UNION

1. Patent Eligibility Criteria for Biotech Invention

In the European Union (EU), the law draws a distinction between inventions and discoveries-only inventions can be patented, while discoveries fall outside the scope of protection. To be patentable, an invention must be novel, industrially applicable, and innovative.[45]

Under the European Patent Convention (EPC), certain subject matter is excluded from patent protection. This includes plants and animals (other than microorganisms), as well as essentially biological processes such as natural crossing and selection. A "plant variety" is legally defined as a grouping of plants within the same botanical category, characterized by at least one inheritable trait that distinguishes it from other plant groupings, provided it is uniform and stable. Conversely, microbiological processes, which involve technical manipulation of microorganisms or their components to

[43] Supreme Court of California, July 9, 1990
[44] http://hdl.handle.net/10603/73596 last accessed on 28th Aug,2025
[45] EPC: Article: 52

create or modify products, are regarded as patentable exceptions to biological processes.

From this framework, it follows that plants and animals developed through non-biological or microbiological techniques may fall within the definition of patentable subject matter. Over time, the interpretation of the EPC by the European Patent Office (EPO) and courts has played a critical role in extending protection to biotechnology. For example, in the early 1970s-well before the landmark U.S. Supreme Court ruling in Diamond v. Chakrabarty-the German Federal Supreme Court recognized newly developed microorganisms as patentable[46]. Likewise, in Genentech-I/Polypeptide Expression[47], the EPO affirmed that microorganisms qualify as patentable inventions. In Plant Genetic Systems, plant cells and seeds were treated as patentable, being considered analogous to microorganisms.

2. Judicial Interpretation

The EPO further expanded the scope in Harvard Oncomouse[48], where a genetically modified mouse was held patentable despite the EPC's exclusion of "animal varieties". In subsequent decisions such as Relaxin[49] and Biogen v. Medeva[50], even human genetic material was accepted as patentable subject matter, provided it was isolated or produced by technical means. These rulings reveal that although the EPC does not explicitly list microorganisms, plants, animals, or human genetic material as patentable, judicial and administrative interpretation has gradually brought them within its ambit. In this respect, Europe has followed a path similar to the United States, though with notable limitations.

One significant difference lies in the treatment of medical therapies. U.S. law allows patents on therapeutic methods, but the EPC excludes "methods of treatment by therapy or surgery" from patentability. For instance, in Unilever Ltd (Davis's) Application[51], a patent was sought for immunizing poultry against coccidiosis using

[46] Wagner (1976), Pg. No. 335.
[47] (T 292\85) (1989) O.J E.P.O (275)
[48] T 19/90 (1990) O.J. EPO 476, Tech. Bd App; (1991) E.P.O, R.525, Ex. D.
[49] (1995) Official Journal of the European Patent Office 388; (1995) E.P.O R 541
[50] (1997) R.P.C 1, HL
[51] (1983) R.P.C 219

microorganisms as feed additives. The EPO clarified that "therapy" has a broad meaning, encompassing prevention and treatment of diseases. However, since the claimed method was preventive rather than curative, it was not considered therapy and was therefore patentable. A similar approach was followed in Stafford-Miller's Applications[52], where the treatment of lice infestation was not classified as therapy, and thus patentable.

This interpretation has allowed patents on contraceptives (viewed as not treating a disease) and diagnostic methods for detecting disease (seen as identification rather than treatment). In Bruker's Application[53], the EPO confirmed that diagnostic tests constitute patentable subject matter, whereas actual therapeutic procedures remain excluded. The rationale for this prohibition is to ensure medical treatment remains accessible to the public and are not monopolized by private patent holders.

The EU has also enacted a Directive on the Legal Protection of Biotechnological Inventions, which provides further clarity. It prohibits patents on processes such as human cloning, modification of the human germline, use of human embryos for industrial or commercial purposes, and genetic alterations of animals that cause suffering without meaningful medical benefit. Similarly, the human body at any stage of its development, and the mere discovery of its natural elements (including full or partial gene sequences), are excluded. However, if an element is isolated or technically produced, it may still be patentable even if its structure is identical to the natural counterpart.[54]

Thus, the EPC, read in conjunction with the Directive, establishes a framework where biotechnological inventions can be patented, but strict ethical and public interest safeguards limit the scope.[55]

3. Ethical Concern for Biotech Invention in the Eu

[52](1984) FSR 258
[53] (1988) OJ EPO 308FN
[54]European Union Directive on the legal protection of biotechnology invention, 1998
[55] Leslie G. Restaino, Steven E. Halpern and Dr. Eric L. Tang, "patenting DNA related inventions in the European Union, United States and Japan: A trilateral approach or a study in contrast? UCLS Journal of law & technology, J.L & tech.2, 2003.

Although natural law principles are seen as universal, ethics and morality vary across cultures. Unlike the U.S., the European Union (EU) has established a detailed legal structure that integrates ethical considerations into patent law. The European Patent Convention (EPC) expressly excludes certain biotechnological inventions on moral grounds. Inventions that contradict public order or morality are not patentable.[56] For example, patents cannot be granted for plants, animals, or essentially biological processes for their production. Likewise, surgical, therapeutic, and diagnostic methods on humans and animals are excluded to protect public health and dignity. Even naturally occurring living things are considered outside the scope of patentability[57]. Similarly, the TRIPS Agreement echoes these exclusions.[58]

The EU Biotechnology Directive further reinforced these ethical boundaries. The EPO (European Patent Office) first dealt with morality in the Genentech I/Polypeptide Expression case,[59] where a genetically engineered microorganism (plasmid) was involved. The Board ruled that patenting microorganisms did not violate morality, opening the door for wider claims in biotechnology.

4. Ethics in Patenting Animals

After microorganisms, claims for patents extended to animals. Ethical objections were most evident in the Onco mouse case, where a genetically engineered mouse was created for cancer research. Animal welfare groups opposed the patent, arguing that causing suffering to animals for commercial purposes was immoral and contrary to public order. Concerns also included risks of releasing genetically modified organisms into the environment.

Despite these objections, the EPO justified granting the patent by emphasizing the potential benefits of cancer research. It is reasoned that the societal benefits outweighed ethical concerns, balancing public morality with medical progress. However, in a later case involving a genetically modified mouse for hair loss studies, the EPO took the opposite view, holding that the suffering caused to animals could

[56]Article: 53: Exceptions to patentablity
[57] Article: 52: Inventions patentable
[58] TRIPS: Article: 27(2) and (3)
[59](T 292\85) (1989) O.J E.P.O 275)

not be justified for research into baldness. Thus, the invention was denied patent protection on ethical grounds.

5. Ethics in Patenting Plants

The Greenpeace v. Plant Genetic Systems case[60] brought plant patents into focus. Opponents argued that seeds and plants should remain the "common heritage of mankind" and not be commodified. The EPO, however, ruled that genetically engineered plants were not more unethical than traditional breeding practices, since both aimed at improving plant traits.

The Board clarified that "public order" included protection of security, human health, and the environment. Similarly, morality was defined in terms of socially accepted norms within European culture as a whole, rather than regional laws. The EPO was cautious not to consider morality in every case, signaling reluctance to routinely evaluate ethical questions in patent law.

6. Ethics In Patenting Human Genetic Material

A more sensitive issue arose with patents on human genetic material. In the Relaxin case[61], claims were made on a human gene coding for a hormone used during childbirth. Opponents argued that patenting human genes violated dignity and amounted to commodification of the human body.[62] The EPO dismissed these arguments, holding that obtaining human tissue for research was standard medical practice and that gene patents did not equate to ownership of human beings.

Later, in the Novartis decision[63], the EPO classified genetic material (such as cells, genes, and their parts) as patentable in the same way as microorganisms, reinforcing that such claims did not inherently breach morality.

7. Human Dignity and Internation Human Rights

[60] EPO Technical Board decision T 356/93, See also International Review of industrial property and copyright 618, L. Blenty, "Sowing seeds of doubt on oncomouse (1994-95) kings college law journal, 188

[61] (1995) Official Journal of the European Patent Office 388; (1995) E.P.O R 541

[62] Dr. K.V Swaminathan, An introduction to the guiding principles of patent law, Bahri Brother, New Delhi, 2000. Pg. No. 356-357

[63]EPO technical Board of Appeals decision 20th December 1999

Despite the EPO's stance, ethical challenges persisted. The European Convention on Human Rights and Fundamental Freedoms[64] emphasizes respect for human dignity, and this principles places limits on biotechnology patents. Similarly, the UN Declaration on the Human Genome and Human Rights insists that genetic research must respect human rights, dignity, and ethical norms. It also calls for the establishment of ethics committees to oversee biotechnological progress and prevent practices that undermine human values.

The Convention on Human Rights and Biomedicine[65] adopted by the EU further prohibits commercial exploitation of the human body, requires informed consent in biomedical research, and bans the creation of human embryos solely for research. This framework highlights that the interests of individuals must always prevail over the interests of science or society.[66]

C. INDIA

1. Patent Eligibility Criteria for Biotech Invention

In India, only inventions are eligible for patents, not discoveries. The Patents Act draws a strict line between the two, making it clear that only inventions can qualify as patentable subject matter. Section 2(j) of the Act defines an invention as a new product or process that involves an inventive step and is capable of industrial application. Here, an inventive step refers to a feature that makes the invention non-obvious to a person skilled in the field[67].

Indian law also sets out an illustrative list of items that are excluded from patentability. Anything outside this list may be considered patentable, provided it meets the legal requirements. This list has been revised over time to align with the TRIPS Agreement. According to the Act, the following do not qualify as inventions:

- Inventions contrary to the laws of nature.
- Inventions that offend public order or morality.

[64] United Nations Universal convention on Human Genome and Human Rights, 1997
[65] The convention for the protection for the protection of human rights and dignity of the human being with regard to the application of biology and medicine.
[66]http://hdl.handle.net/10603/73596 last accessed on 28th Aug,2025
[67] The patent Act of India (as amended in 2005) Section: 3

- Discoveries of living beings or natural substances.
- Mere duplication of known work.
- Medical or veterinary treatment methods.
- Plants, animals (in whole or in part), and essentially biological processes for their production.[68]

However, microorganisms and living organisms created through microbiological or biotechnological methods are recognized as patentable.[69] This was clarified by the 2002 amendment, which expanded the meaning of "chemical processes" to include biochemical, biotechnological, and microbiological processes. As a result, products and processes arising from biotechnology now clearly fall within patentable subject matter.[70]

At the same time, certain inventions are excluded globally, even if they meet novelty, inventive step, and industrial utility requirements. Examples include:

- Discoveries (as opposed to inventions).
- Human body and its natural elements such as genes (though isolated genes produced by technical means may be patentable).
- Human cloning processes.
- Techniques for altering germ-line genetic identity.
- Use of human embryos for industrial or commercial purposes.
- Genetic modifications of animal's cause suffering without substantial medical benefit.
- Similarly, plants, animals, and pure biological processes are excluded, though microbiological and non-biological processes and their products are patentable.

After the Chakrabarty case in the U.S., living organisms came to be recognized as patentable worldwide. With rapid advances in biotechnology, inventions like genetically engineered plants, novel microbes, synthetic compounds, recombinant

[68]Inserted by amendment in 2002, to comply with the provisions of the TRIPS
[69] section: 3 of Indian patent Act, as amended in 2002.
[70] Indian patents amendments Act 2002.

DNA, and processes for producing proteins or enhancing plant resistance have been brought within the patent system. TRIPS has reinforced this by treating biotechnology as legitimate patentable subject matter, provided that the invention meets the universal requirements of novelty, inventive step, industrial applicability, and adequate disclosure.[71]

2. Ethic And Morality in Indian Patent Law

India is a country where ethical and moral values hold equal importance as law. Traditions play a key role in shaping Indian views-plants and animals such as the cow, tulsi, and neem are treated with reverence. For many, the idea of patenting such living beings is equivalent to owning or commercializing divinity, which makes it ethically unacceptable. Consequently, Indian patent law reflects these sensitivities by excluding plants, animals, and essentially biological processes from patent protection.

3. Ethical Provision Under the Indian Patent Act

The Indian Patents Act incorporates provisions to ensure inventions are not granted protection if they are:

- Against public order or morality
- Harmful to humans, animals, or environmental health

These exclusions reflect India's cultural and ethical stance, even while adhering to international obligations under the TRIPS Agreement. Although TRIPS requires protection for biotechnology inventions, India still maintains restrictions on patenting certain living beings.

4. Biotech Patents and Trips

Following global developments and the TRIPS mandate, inventions such as microorganisms, plants, and animals produced through microbiological, non-biological, or biotechnological processes are now patentable worldwide. India, being a TRIPS member, began granting such patents from January 2005. Yet, this move has

[71] TRIPS agreement aims to make available patents irrespective of the inventions field or place of work

conflicted with traditional ethical values, sparking concerns about how biotechnology intersects with Indian cultural beliefs.

5. Judicial Approach and Ethic Gap

In one significant case, the Calcutta High Court clarified that there is no legal barrier under the Patents Act to granting patents for living processes. However, the court did not consider ethical issues in its decision. Legal scholars have argued that ethical objections must not overshadow the practical benefits of biotechnology. As former Chief Justice of India noted, scientific research with potential benefits should not be stifled by overly restrictive ethical objections.

6. ICMR Guideline in Human Genetics

With the rise of human genetics research in India, the Indian Council of Medical Research (ICMR) issued ethical guidelines to address sensitive issues[72]. These guidelines were necessary given rapid progress in areas like genome mapping, recombinant DNA, assisted reproductive technology, and stem cell research. Key principles include:

- Respect for human dignity and rights
- Informed consent for participants after full disclosure of risks
- Protection from physical and psychological harm
- Oversight by institutional ethics committees, with the establishment of national bioethics bodies

The guidelines also align with international conventions such as the Helsinki Declaration (1964) and CIOMS principles (1993).

ETHICAL BOUNDARIES IN HUMAN GENETICS

The ICMR guidelines clearly distinguish between acceptable and unacceptable practices:

[72] ICMR ethical guidelines, 2000

Permitted: Gene therapy for curing genetic diseases, genetic screening for diagnosis, assisted reproduction (IVF), and use of fetal tissue from a deceased embryo (with ethical approval).

Prohibited: Germline modification, use of embryos for commercial purposes, sex selection, research on embryos beyond 14 days, and enhancement of genetic traits like intelligence or memory.

7. The Challenge of Balancing Ethic and Biotechnology

While biotechnology offers transformative benefits, it also raises serious ethical dilemmas. The Indian Patents Act and TRIPS Agreement acknowledge morality but do not comprehensively address all ethical issues arising from biotechnology research. Unlike the European Union, which explicitly incorporates ethics into patent law, India relies on ICMR guidelines to fill this gap.

The future demands a balanced approach: biotechnology research should continue for the benefit of society, but it must not compromise human dignity or cultural values. A uniform framework is needed to assess and regulate ethical concerns, ranging from microorganism manipulation to embryo research.

8. Comparative Analysis of Biotech Patentability

ASPECT	USA	EUROPEAN UNION	INDIA
PATENT ELIGIBILITY	Very broad: anything under the sun made by man. Including microorganisms, plants, animals, isolated human genes. Human being excluded	Distinction: inventions (yes) vs discoveries (no). EPC excludes plant/animal varieties and biological processes. Microorganisms engineered plants/animals, isolated human genes allowed under interpretation.	Narrow: only inventions (not discoveries). Exclude plants, animals, and biological processes. microorganisms and biotech processes allowed. Human body and natural substances excluded

		Medical/ surgical therapies excluded	
JUDICIAL ROLE	Landmark cases expanded scope: diamond v. chakrabarthy (microorganisms),73 parte hibberd (plants), Harvard oncomouse (animals), Moore (human cell lines)	EPO and court broaden scope: oncomouse74, relaxin75 (human gene patents), biogen v. medeva76. Strong role of judicial interpretation	Limited role: Calcutta high court recognized biotech patentability but avoided ethics. Reliance on statutes and ICMR guidelines
ETHICAL FRAMEWORK	Ethics not in statute. Morality concern debated but court favor utility. Example oncomouse 77justified for cancer research	Ethics intergrated in EPC and biotech directive. Prohibits cloning, germline modification, embryo use. Morality and public order central to exclusions	Ethics tied to cultural/ religious values (sacred animal/plants). Patents excluded if against morality, harmful to life or environment. ICMR guideline regulate ethics
HUMAN GENETIC MATERIAL	Isolated DNA, genes, cell lines patentable (moore case78 upheld research-derived patents). Ban only on human being cloning	Isolated human genes patentable if produced body and natural genetic material excluded. Strong safeguard for dignity	Human body and natural genetic material excluded. Isolated/ engineered products may qualify. ICMR prohibits germline modification, embryo research beyond 14 days, sex selection

[73] Harvard college v Canada (commissioner of patents) [2002] 4 SCR 45
[74] Ibid
[75](1995) Official Journal of the European Patent Office 388; (1995) E.P.O R 541
[76] (1997) R.P.C 1, HL
[77] Supra 64
[78]Supreme Court of California, July 9, 1990

TRIPS INFLUENCE	Already compliant: liberal scope before TRIPS	Harmonized EPC and directive with TRIPS, but retained ethical carve- outs	Significant amendments post-TRIPS (2002,2005). Allowed biotech patents but kept morality- based exclusions
RECENT CASES AND REGULATORY DEVELOPMENT	Amgen Inc. v. Sanofi (2023)[79] — The U.S. Supreme Court clarified that when a patent claim is broad (e.g. to many variants), the enablement requirement under §112(a) demands that the specification enable the full scope claimed. This strengthens the requirement for biotech inventions to provide sufficient disclosure and avoid overly broad claims. It increases uncertainty or risk for very broad biotech patent claims	Refusal by EPO of patents for human-pig chimeras (Sept-2024) on grounds of ethical rules (human dignity) under EPC Article 53(a). Strong reaffirmation that certain biotech inventions that straddle human/non-human boundaries will be scrutinized under morality clauses. Sets precedent for dealing with chimeras, synthetic life, etc. Ethics not just theoretical but having force in decisions. EU proposal to regulate gene-edited plants (NGTs = New Genomic	Patent (Amendment) Rules 2024 — reduced timeline for examination (from 48 to 31 months), simplification of form compliance, introduction of certificate of inventorship, relaxation of working statements frequency, more flexibility with controller to condone delays, discount on renewal fees. Speaks to making the patent system more efficient. For biotech innovators this means speed in obtaining protection. However, the reforms are more procedural than ethical/substantive; do not strongly

[79] amgen Inc. v. Sanofi, 598 U.S. 594, 143 S. Ct. 1243, 215 L. Ed. 2d 537 (2023)

	without corresponding data. Improves enforceability and forces better alignment of what is claimed vs. what is shown experimentally.	Techniques) more strictly. If adopted, this would expand exclusions or impose stricter oversight on biotech innovations in agriculture. Ethical, socio-economic concerns about plant breeding, biodiversity, impact on small breeders are part of the debate. Could make plant biotech patenting more uncertain.	change what biotech inventions are ethical or patentable. But improved procedural efficiency can affect access, cost, etc. "Trailblazing Decisions" in India on claim modification (e.g. Allergan decision80 and Delhi High Court in Honeywell case81) affirming that claim amendments are allowed provided they stay within the core/technical contribution.
IMPLICATIONS FOR BIOTECH & ETHICS	Recent lawsuits over gene-editing / mRNA-based technologies (e.g. AstraZeneca & Cellectis being sued for patent infringement in gene-editing tech). Indicates that the field is full of high-stakes IP battles. These also bring forth ethical issues around monopolization of essential biotech tools, access to health technologies, price, etc.	Ongoing EU study (DG GROW, EU Commission) on the impact of existing regulatory/IP frameworks for NGT plants; looking to possibly adjust or add protections or exclusions. Suggests that policy change is coming: patent/IP policy in biotech will need to keep pace with new methods (CRISPR, gene editing). Ethics (biodiversity, safety, fairness)	Above mentioned cases give more flexibility for biotech applicants to refine claims as experiments/results evolve, which is common in biotech. Can help balance between broad protection and avoiding overly broad/unjustified claims. Also means ethical concerns (e.g. over-claiming or misrepresenting invention) can be somewhat mitigated

[80] Allergan Inc. v. The Controller of Patents 2023 DHC 000515

[81] Honeywell International Inc. v. The Controller of Patents 2024 DHC 4172

		will feature in regulation, not just patents.	
OVERALL APPROACH	Science- driven, broadest scope, utility prioritized	Balanced: allows biotech patents but integrates ethics and human dignity safeguards	Ethics and culture – driven, narrowest scope. TRIPS compliance with strong moral limits

VII. CHALLENGES OF PATENTING BIOTECHNOLOGY INVENTION

A. Difficulties in Reviewing Biotech Innovations

The dynamic and highly technical nature of biotechnology makes the examination process particularly demanding. Since many patent officers may not have deep expertise in specialized biotech areas, assessments can sometimes be delayed or lead to misinterpretations

B. Key Concerns in Assessing Patentability

Patent offices must carefully consider whether the invention meets essential standards such as novelty, inventive contribution, and industrial utility. Because biotech inventions often involve intricate genetic modifications or molecular procedures, proper evaluation requires significant technical understanding.

C. Importance of Detailed Documentation

Applicants can improve their chances of success by submitting thorough applications that clearly describe the unique features of their technology. Providing strong comparisons with existing knowledge and explaining how the invention advances the field can be crucial in demonstrating its patentability.

D. Frequent Obstacles in Biotech Patent Examinations

Some of the most common reasons biotech patents encounter difficulty during review include:

1. Insufficient description – lack of adequate disclosure about the invention.
2. Excessively broad claims – claims drafted too generally without precise technical limitations.
3. Challenges in proving inventive step – especially in complex biotechnological advancements.
4. Eligibility restrictions – limitations on patenting natural substances or biological materials derived from the human body.

E. Hurdles in Proving Inventive Step in Biotechnology

Demonstrating inventive step in biotechnology is particularly challenging due to the subject's complexity. What qualifies as a non-obvious advancement often becomes subjective, making it difficult for patent examiners to assess. Applicants must convincingly show that their work goes beyond simple improvements on prior knowledge. Since many biotech breakthroughs rely on layered scientific principles and incremental progress in fields such as genetics and molecular biology, establishing non-obviousness requires strong technical and legal arguments.

F. Patent Issues in Genetic Resources and Methods

Patenting genetic resources presents unique complications, especially in distinguishing between natural sequences and those altered by human effort. This boundary is critical for patent eligibility but often results in long examination processes or rejections. While artificially engineered sequences may be seen as inventive, naturally occurring DNA generally cannot be monopolized. With advanced

techniques like CRISPR gene editing and synthetic biology, applicants are expected to provide highly detailed disclosures proving novelty and inventive contribution, which increases the legal and scientific burden.

G. Strategies for Managing Biotech Patent Rejections and Disputes

When a biotech patent faces rejection, the applicant must adopt a strategic response. Objections usually involve lack of novelty, inventive step, or eligibility under patent law. Strengthening the application with scientific evidence, technical amendments, and expert declarations can help overcome such challenges. In cases where disputes escalate, appeals and judicial reviews are important tools. Ultimately, effective handling of rejections requires a blend of legal expertise and technical substantiation.

H. Influence of Ethics and Regulation on Biotech Patents

Ethical concerns and legal frameworks heavily shape decisions on biotechnology patents. Innovations involving human genetic material or controversial genetic modification techniques often face stricter scrutiny. International conventions and national laws may limit patentability to prevent exploitation of biodiversity or cultural knowledge. Moreover, societal concerns about monopolizing life forms or potential misuse of biotechnology make ethics an integral factor in examination.

VIII. FUTURE OUTLOOK OF BIOTECHNOLOGY INVENTIONS

A. AI and Machine Learning Transforming Biotechnology

Artificial intelligence and machine learning are reshaping the biotechnology sector, and their influence will deepen further in 2025. These technologies are streamlining drug discovery, diagnostics, and personalized healthcare by enabling the rapid analysis of massive datasets that were once unmanageable.

In drug development, AI models can forecast how chemical compounds might interact with biological systems, significantly accelerating the search for new medicines. Similarly, AI-driven diagnostic tools are making it possible to detect diseases earlier and with higher precision, leading to improved patient care. By 2025, AI will be central to clinical trial optimization, therapy development, and cost reduction across the biotech industry.

B. Next-Generation Gene Editing: CRISPR and Beyond

CRISPR has already set a new benchmark in gene editing, and its potential will expand further in the coming years. By 2025, scientists are expected to use CRISPR and emerging editing tools not only to correct genetic mutations but also to enhance agricultural crops and advance therapeutic innovations. Future improvements will focus on making editing more accurate, efficient, and widely accessible. These breakthroughs will support the treatment of genetic disorders, cancer, and possibly even age-related conditions. However, as gene editing becomes more advanced, ethical debates about its application in humans will become increasingly important, requiring a balance between innovation and responsibility.

C. Rise of Precision Medicine and Tailored Therapies

Personalized medicine, which adapts treatments to an individual's unique genetic and biological makeup, will expand rapidly in 2025. With progress in genomics, diagnostics, and data integration, healthcare providers will be able to pinpoint the genetic roots of diseases and deliver therapies with higher success rates and fewer adverse effects. From targeted cancer treatments to improved therapies for chronic and rare conditions, personalized medicine will become a key pillar of healthcare. The combined use of AI, big data, and genomic sequencing will make these treatments more accurate, accessible, and scalable.

D. Green Biomanufacturing and Sustainable Practices

Sustainability is becoming a cornerstone of biotech innovation. By 2025, companies will invest heavily in eco-friendly biomanufacturing approaches, focusing on renewable raw materials, reduced waste, and environmentally safe production methods. Advances in synthetic biology, metabolic engineering, and bioprocessing will allow microorganisms to produce biofuels, biodegradable plastics, and pharmaceuticals in a more resource-efficient way. Sustainable biomanufacturing will not only lessen environmental damage but also offer long-term cost savings, meeting the growing expectations of both regulators and environmentally conscious consumers.

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E. Expansion of Biotech Startups

The startup ecosystem in biotechnology is thriving and will see continued growth through 2025. Emerging companies are driving innovation in specialized fields such as microbiome research, regenerative therapies, rare disease treatments, and AI-assisted drug discovery. With easier access to venture capital, advanced tools, and collaborations with established pharmaceutical firms, these startups are accelerating the delivery of cutting-edge healthcare solutions. The next wave of biotech startups will likely focus on advanced diagnostics, personalized treatments, and novel therapies, contributing to the sector's rapid evolution.

F. Biotechnology Addressing Global Health Issues

Post-pandemic, biotechnology has proven essential in solving worldwide health problems, and this momentum will continue into 2025. Biotech firms are expected to play a crucial role in developing better vaccines, fighting infectious diseases, and reducing healthcare inequalities across the globe.

Ongoing efforts will target vaccines for malaria, tuberculosis, HIV, and other diseases that have long been overlooked. Additionally, the industry will work on improving vaccine distribution in resource-limited regions. Beyond infectious diseases, biotech innovations will support the management of non-communicable diseases like cancer, cardiovascular conditions, and diabetes through improved diagnostics, preventive strategies, and novel therapies.

IX. CONCLUSION

Biotechnology, with its vast scope and transformative potential, has led to inventions that significantly benefit agriculture, medicine, industry, and the environment. These innovations are the outcome of human ingenuity applied to biological processes, and hence, they deserve legal recognition and protection through patents. However, the journey toward granting patents on living beings has been complex, marked by both legal evolution and ethical debates.

While the law has expanded to accommodate biotechnology patents-from microorganisms to plants, animals, and human genetic materials-it still maintains

limits, particularly in prohibiting patents on transgenic humans and human embryos. This reflects the effort to strike a balance between encouraging innovation and upholding moral and ethical standards.

The benefits of biotechnology-such as higher-yield crops, advanced medical therapies, and tools for environmental protection-often outweigh ethical concerns. Yet, ethics cannot be disregarded entirely. They serve as a necessary check to prevent misuse and ensure that scientific advancement respects human dignity and social order.

In conclusion, patent protection for biotechnology inventions is justified by their immense utility, but it must coexist with ethical safeguards. A balanced approach, where the rewards of innovation are embraced without abandoning moral values, is essential for sustainable progress in this sensitive field.

X. SUGGESTIONS AND RECOMMENDATIONS

A. Strengthen Patent Examination Capacity

1. Train examiners in biotechnology to address technical complexities and reduce backlogs.
2. Establish specialized biotech cells within the Indian Patent Office.

B. Balance Ethics and Innovation

1. Introduce explicit statutory provisions integrating ethical safeguards into biotechnology patenting (similar to the EU model).
2. Strengthening ICMR guidelines into binding legal frameworks for human genetic material and gene-editing technologies.

C. Promote Transparency and Public Participation

1. Enhance public access to patent information, including biotech-related disclosures.
2. Establish consultation mechanisms with farmers, bioethicists, and indigenous communities.

D. Encourage R&D and Indigenous Innovation

1. Provide incentives for Indian startups and universities to engage in biotechnology research.
2. Create funding schemes for innovations in sustainable biotech, including green biomanufacturing.

E. International Harmonization with Safeguards

1. Align more closely with TRIPS while retaining strong exclusions for traditional knowledge, biodiversity, and sacred species.
2. Strengthening collaboration with international patent offices for prior art searches and examination standards.

F. Future-Proofing Patent Law

1. Amend the Patents Act to address emerging issues such as AI-generated biotech inventions, CRISPR-based genetic interventions, and digital sequence information (DSI).
2. Set up a permanent bioethics committee to evaluate patent applications involving human and animal genetic material.

G. Specialized Biotechnology Patent Wing

1. Establish a dedicated "Biotech Patent Wing" in the Indian Patent Office with trained examiners in genetics, molecular biology, and bioinformatics.
2. Introduce continuous training programs with experts from CSIR, DBT, and ICMR to handle highly technical biotech claims.

H. Clearer Statutory Guidance on Section 3 Exclusions

Amend Section 3 of the Patents Act to clarify the scope of exclusions, especially regarding:

1. Genetically modified microorganisms vs. naturally occurring microbes.
2. CRISPR-based genetic interventions.
3. Plant varieties vs. biotechnological plant inventions.

4. Provide illustrative guidelines (like the EU Directive) for consistent interpretation by patent offices and courts.

I. Ethical Oversight Mechanism

1. Make the ICMR Guidelines on Human Genetics legally binding through rules under the Patents Act.
2. Establish a National Bioethics & Patent Review Committee to vet patent applications involving human genetic material, embryos, or higher life forms.

J. Reducing Delays and Backlogs

1. Implement fast-track examination for biotech applications related to public health (vaccines, rare disease therapies, etc.).
2. Use AI-driven prior art search tools (already used by USPTO and EPO) to speed up novelty and inventive step analysis.

XI. REFERENCES

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B. International Instrument

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6. Human Cloning Prohibition Act, 2003 (U.S.)
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