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COMPARATIVE ANALYSIS OF MICROORGANISM PATENTING: TRIPS AGREEMENT, U.S. AND INDIAN PERSPECTIVES.

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ABSTRACT

Microorganism patentability is a controversial topic at the intersection of bioethics, intellectual property law, and international trade. Although the TRIPS Agreement mandates that member countries utilize patents to protect microorganisms, each country may interpret it differently. As a result, a number of countries have adopted different strategies in line with their own legal, economic, and regulatory frameworks. The United States' liberal worldview is supported by Diamond v. Chakrabarty and other significant judicial decisions. This makes it possible for genetically modified organisms and biotechnological advancements to enjoy widespread patent protection. Several frameworks are examined in this research paper, along with the definitions and restrictions of microbe patenting, the causes of the variations, and the consequences for international trade, public health, and innovation. It argues that national differences highlight the ongoing tension between advancing biotechnological research and safeguarding the public interest, despite the fact that TRIPS harmonization has resulted in some protection.

Keywords: *Microorganism Patents, TRIPS Agreement, Biotechnology and Intellectual Property, Patent Harmonisation, Comparative Patent Law*

1. INTRODUCTION:

Recent advancements in molecular genetics, biotechnology, and cellular engineering have significantly transformed our methods of discovering, manipulating, and using microbes for diverse commercial, agricultural, and medicinal applications. As a result, microorganisms, including genetically modified strains, bacteria, fungus, and viruses, are emerging as significant candidates for patent systems that safeguard intellectual property. The control of patents on microorganisms represents a unique convergence of law, science, and politics,

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whereby lawmakers, judges, and international entities strive to harmonize the promotion of innovation with the assurance of extensive public access to technological advancement.

In the past, patent law didn't protect objects that weren't produced by people. But the fact that germs may be used in so many ways and are so adaptable changed this rule a lot. Frameworks allowing the patenting of microorganisms under specific conditions were created during significant events, notably the 1977 ratification of the Budapest Treaty, the 1980 U.S.

Supreme Court decision in Diamond v. Chakrabarty, and the insertion of Article 27.3(b) in the TRIPS Agreement. TRIPS says that member nations must provide patents to microorganisms, but it's challenging to make things the same all over the globe since each country may understand and apply these laws in a manner that works best for its particular social, economic, and public policy goals.[1]

The two biggest biotechnology economies in the world, India and the United States, have quite different rules concerning patenting microbes. This is because of disagreements within each country about public health, new incentives, and conventional knowledge. The U.S. model includes a lot of qualifying requirements and focuses on new ideas, whereas the Indian model is more constrained and focuses on access and protecting biological resources.

Consequently, a comprehensive understanding of the opportunities and problems in the global regulation of biotechnological innovations may be achieved by examining these countries alongside the fundamental international standards established by TRIPS.[2]

This article looks at US law, Indian law, and the TRIPS Agreement when it comes to patenting microbes. This study contextualizes the intricate domain of law by analysing pertinent legislative measures, judicial rulings, and policy dialogues, highlighting their practical ramifications for innovation and accessibility to biotechnologies in both national and international settings.[3]

[1] Rimpa Pai, *Effects of TRIPS agreement on Indian Pharmaceutical Patenting*, SSRN Electronic Journal (2023).
[2] Harun Rashid A. Kadri & Medha Vivek Saikhedkar, *Post-trips patenting trends in India with special reference to USA: A comparative analysis*, SSRN Electronic Journal (2011).
[3] Michael Blakeney, *A critical analysis of the TRIPS Agreement*, The Intellectual Property Debate (2006).

ISSN: 2582-6433

1.1 Literature Review:

1. **The book "Biotechnology and Patent Law: Patenting Living Beings" by N. S. Sreenivasulu came released in 2008.** Sreenivasulu's research looks at the problems that come up while trying to patent living things, like bacteria, in the realm of biotechnology. The book talks on how the TRIPS Agreement has transformed patent systems in various countries and how patent laws have evolved over time, notably in the US and India. Sreenivasulu talks on the challenges that come up when attempting to find "microorganisms" and the moral problems that come up when trying to patent living things. The author examines methods to foster new ideas while safeguarding public interests. This perspective is essential for the global harmonization of patent rules.
2. ***"Biotechnology and Intellectual Property Rights: Legal and Regulatory Aspects" by K.K. Singh (2015)*** Singh's book talks on the patent rules for biotechnology in Canada, the US, India, and the EU. The author talks about the challenges that come up when attempting to make local laws meet with international standards. They also talk about how the TRIPS Agreement has impacted the way patents work in the US. Singh goes into further depth on what it takes to patent microorganisms, stressing that they must be innovative, not obvious, and helpful for business. The book goes into great detail on how patenting new technological breakthroughs affects society and morality.
3. ***The book "Patenting Microorganisms and Genes" was written by S. K. Agrawal and R. K. Kumar and came published in 2013.***

   Agrawal and Kumar's study give a full look at the laws that regulate patents on microbes and genetic material. The book talks about the TRIPS Agreement's regulations around patenting microorganisms and how the US and India have used these restrictions. The discussion focuses about how hard it is to categorize "microorganisms" and what it means to patent organisms that arise naturally instead of ones that have been genetically changed. The book discusses on moral dilemmas, how new technology might affect public health, and how simple it is for individuals to access it.

1.2 Aims and Objectives:

1. To find out what the TRIPS agreement says regarding microbiological patenting.
2. To examine the current status of microbiological patenting in India
3. To examine the differences between microorganisms that can be patented and those that cannot.

ISSN: 2582-6433

4. To find out whether India's current laws on microbe patents need to be changed.

1.3 Objectives:

- Analyse how the TRIPS Agreement harmonises microbe patenting and how it affects national laws in the US and India, among other member nations.
- Examine the legal systems of the United States and India, paying particular attention to the procedures required to get a patent, the rules that must be followed, and the interpretations of the courts.
- Examine each system's limitations, issues, and potential in terms of striking a balance between innovation, public values, and biodiversity preservation.

1.4 Scope and Limitation:

- The scope of patenting microbes as defined by the Agreement on TRIPS, U.S., and Indian laws, with an emphasis on qualifying subject matter, legal requirements, and deposition procedures.
- Significant limitations, including ambiguous definitions, exclusions, and ethical dilemmas. Animals, plants, and other biotechnological innovations that aren't microorganisms aren't included.
- Without delving further into particular cases or market repercussions, it focusses mostly on statutes, significant court decisions, and current legal practices.

1.5 Hypothesis:

The TRIPS Agreement has brought the U.S. and Indian systems more together when it comes to the fundamental criteria for patenting microorganisms. However, there are still big discrepancies between the two systems when it comes to eligibility, procedure, and policy results.

1.6 Research Questions

1. What are the fundamental patentability requirements for microorganisms under TRIPS, U.S., and Indian law?
2. How has each country interpreted and executed TRIPS responsibilities relating to microorganism patenting?
3. What are the specific obstacle and limitations legal, procedural and ethical faced in the U.S. and Indian contexts?

ISSN: 2582-6433

4. How do disparities in court interpretation and administrative practice influence innovation and public interest in both jurisdictions?

1.7 Research Methodology:

- Basic Legal Evaluations: Examining international agreements (TRIPS), legislative laws (U.S. Patent Act, Indian Patents Act) and policy papers relevant to microbe patenting
- Comparative Method: Contrasting U.S. and Indian law and practice utilising legislative documents, historical cases (Diamond v. Chakrabarty in the U.S., Dimminaco A.G. v. Controller in India) and secondary literature.
- Case Study Method: examining identified patent submissions, registration standards (Budapest Treaty) and court judgements that highlight disparities in the approach to microbe patenting
- Qualitative Analysis: Synthesising academic discourse to capture difficulties and future directions, concentrating on legal, moral, and procedural viewpoints

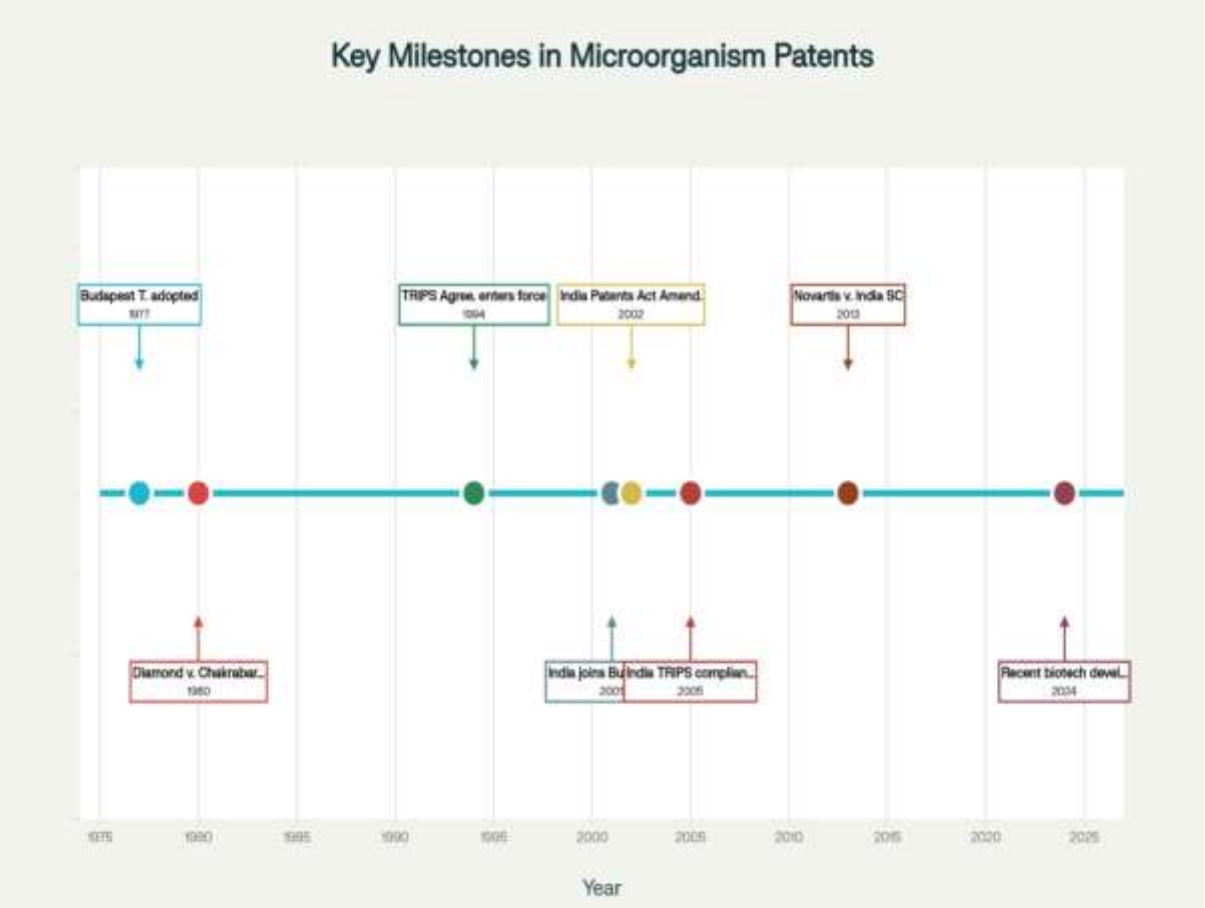
2. THE TRIPS AGREEMENT FRAMEWORK OF INTERNATIONAL MINIMUM STANDARDS

The World Trade Organization's TRIPS Agreement, which entered into force in 1994, established the foundational international framework for microorganism patenting through Article 27. This provision represents a compromise between developed countries seeking broad biotechnology patent protection and developing nations concerned about the implications of patenting life forms. Under Article 27.1, patents must be available for inventions in all fields of technology, provided they meet the standard criteria of novelty, inventive step, and industrial applicability.[4]

The critical provision for biotechnology is found in Article 27.3(b), which permits WTO members to exclude from patentability "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes". This language creates a mandatory obligation for member countries to provide patent protection for microorganisms, while allowing flexibility regarding higher life forms.[5]

[4] Alka Chadha, *Trips and patenting activity: Evidence from the Indian Pharmaceutical Industry*, 26 Economic Modelling 499–505 (2009).
[5] Mir Ahmad Parsa Manush, *A comparative analysis of patent laws in Afghanistan and the TRIPS Agreement*,

ISSN: 2582-6433



Timeline of Key Developments in International Microorganism Patenting Law (1977-2024) Notably, the TRIPS Agreement deliberately leaves the term "microorganism" undefined, providing member countries with considerable interpretive flexibility. Different national approaches have resulted from this definitional divide; some have adopted wide interpretations that embrace a variety of cellular materials, while others have maintained more limited definitions. The Budapest Treaty framework for microbe deposits, which stipulates that a single international deposit is sufficient for patent purposes across all member nations, is also incorporated into the Agreement.[6]

The TRIPS framework reflects several competing policy objectives. Developed countries, particularly the United States, viewed strong intellectual property protection as essential for biotechnology innovation and investment. Conversely, many developing countries expressed concerns about the potential impact on traditional knowledge, biodiversity conservation, and

SSRN Electronic Journal (2024).

[6] Carlos M. Correa, *Patenting human DNA: What flexibilities does the TRIPS agreement allow?* 10 The Journal of World Intellectual Property 419–437 (2007).

ISSN: 2582-6433

access to essential medicines. Through Article 27.2's exclusions for order public and morality, which permit nations to exclude innovations whose commercial use would endanger the health or well-being of people, animals, or plants, the Agreement aims to strike a balance between these interests.[7]

3. UNITED STATES APPROACH: BROAD SCOPE AND INNOVATION FOCUS

According to 35 U.S.C. Section 101, which permits patents for "any new and useful process, machine, manufacture, or composition of matter," the United States has created the most lenient regime for microbe patenting in the world. The seminal 1980 Supreme Court ruling Diamond v. Chakrabarty, which determined that live, artificial microbes qualify as patentable subject matter, encapsulated this broad approach.[8]

3.1 The Chakrabarty Revolution

When General Electric applied for patent protection for a genetically modified Pseudomonas bacteria that could degrade crude oil for environmental remediation, the Chakrabarty lawsuit was born. A slim 5-4 Supreme Court majority finally rejected the Patent Office's initial denial that living things could not be patented. The fundamental tenet that patent law covers "anything under the sun that is made by man," so long as it satisfies legal standards, was established by Chief Justice Burger's judgement. The Court recognised a distinction between man-made creatures that display notably different traits from those found in nature and naturally occurring organisms, which are nevertheless products of nature. In later biotechnology patent law, this distinction has been essential in proving that unpatentable natural events may be turned into patentable inventions by artificial modification and human involvement.[9]

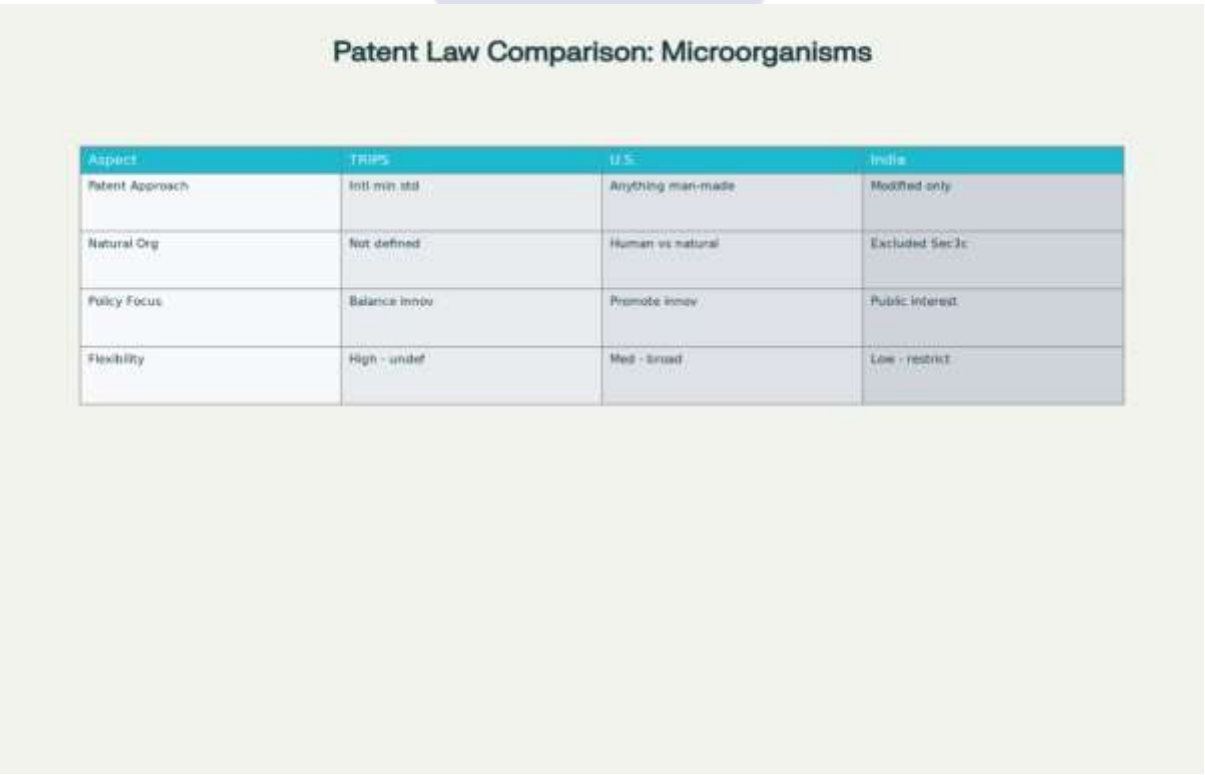
3.2 Implementation and Practice:

In response to Chakrabarty, the USPTO created thorough standards for biotechnology patents under categorisation schemes such as Class 935 (genetic engineering technology) and Class 435 (chemistry: molecular biology and microbiology). Through domestic rules, the USPTO carries out its commitments under the Budapest Treaty by requiring microbial deposits with recognised depositories prior to patent award. As long as the claimed invention proves useful

[7] Implementing the TRIPS agreement, Globalising Intellectual Property Rights 92–121 (2003).
[8] Amendment of the TRIPS agreement, A Handbook on the WTO TRIPS Agreement 405–411 (2020).
[9] Negotiating the TRIPS agreement, Globalising Intellectual Property Rights 43–59 (2003).

ISSN: 2582-6433

and satisfies novelty criteria, American patent doctrine often allows the patenting of isolated and purified microbes, even when the underlying organism is found in nature. This method reflects the wide definition of "manufacture" and "composition of matter" stated in Chakrabarty and is applicable to cellular materials, plasmids, and even some genetic sequences. Only human creatures are not patentable under the U.S. system, which reflects ethical and constitutional concerns. This exclusion is interpreted narrowly, though, permitting patents on human tissues, cells, and genetic materials when properly asserted. The policy justification places a high emphasis on luring investment money, fostering innovation through robust intellectual property protection, and preserving US competitive advantages in biotechnology.[10]



Comparative Analysis of Microorganism Patenting Approaches: TRIPS, U.S., and Indian Legal Frameworks

4. Indian Legal Framework: Balancing Innovation and Access

With a focus on public health, the preservation of traditional knowledge, and fair access to biotechnological advancements, India's approach to microbe patenting reflects a very diverse set of governmental concerns. The TRIPS basic criteria and U.S. practice are less stringent than the Patents Act of 1970, which was modified in 2002 and 2005 to comply with TRIPS.[11]

[10] Content of the TRIPS agreement, Globalising Intellectual Property Rights 60–91 (2003).
[11] Origins of the TRIPS agreement, Globalising Intellectual Property Rights 21–42 (2003).

ISSN: 2582-6433

4.1 Legislative Framework and TRIPS Implementation:

Article 27.3(b) of TRIPS, which is the direct basis for Section 3(j) of the Indian Patents Act, states that "plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties, and species and essentially biological processes for production and propagation of plants and animals" are not patentable. However, the Indian framework imposes additional restrictions through Section 3(c), which excludes "discovery of any living thing or non-living substance occurring in nature

This dual exclusion system creates a clear distinction between naturally occurring and artificially modified microorganisms. Only microorganisms that have been genetically modified through direct human intervention qualify for patent protection, while naturally occurring microorganisms, even when isolated or purified, remain unpatentable. This approach reflects deliberate policy choices prioritizing public domain preservation and traditional knowledge protection

India joined the Budapest Treaty in 2001, establishing three International Depositary Authorities: The Microbial Type Culture Collection (MTCC) in Chandigarh, the Microbial Culture Collection (MCC) in Pune, and the National Bureau of Agriculturally Important Microorganisms (NBAIM) in Mau Nath Bhanjan. Patent applications involving microorganisms must comply with deposit requirements, including submission of viable cultures and detailed characterization data.[12]

4.2 Judicial Interpretation and Enforcement:

Indian courts have not spoken much about whether biotechnology may be patented, particularly when it comes to pharmaceutical cases that include Section 3(d) of the Patents Act. Most of these cases were about chemical compounds, not microbes, but they show that the court is serious about stopping patent "evergreening" and making sure people can get the treatments they need. The important Novartis v. Union of India decision set important rules for biotechnology patents, although it was mostly about pharmaceutical patents. The Supreme Court's support for Section 3(d) being valid and in line with TRIPS shows that the courts back India's strict rules on who may get a patent. Recent decisions, like the 2025 revocation of Novartis's Vymada patent, continue this trend of careful review and arguments after a patent is granted.

The Indian patent system requires evidence of improved efficacy for small biotechnological

[12] Future of the TRIPS agreement, Globalising Intellectual Property Rights 137–153 (2003).

ISSN: 2582-6433

improvements. This may apply to microbe patents that use well-known species. In the pharmaceutical business, it has proven challenging to achieve this need. This restriction is in line with the government's larger goals, which put real innovation ahead of little changes to existing biological materials.[13]

5. Comparative Analysis: Divergent Approaches and Policy Tensions:

The three legal regimes examined exhibit fundamentally distinct methodologies for microbe patenting, resulting from varying legislative objectives, economic motivations, and philosophical viewpoints on intellectual property safeguarding.

5.1 Definitional Approaches and Scope:

This is how the discrepancies manifest in the definitions of microorganisms. The TRIPS Agreement's intended lack of clear definitions gives member countries flexibility, but it also makes it harder to apply for patents and makes it more likely that people would shop about for a forum. The United States has the most general definition, which encompasses normal bacteria, plasmids, genetically modified organisms, and biological components. India is strict since it doesn't allow any wild animals and only allows genetically engineered animals to be patented.

The different definitions have actual impacts on patent strategy and the evolution of biotechnology throughout the world. Because the standards for gaining patent protection are different in each country, multinational corporations may have separate portfolios in each jurisdiction. Because there is no harmonization, enterprises in countries with tight laws may develop competitive goods using naturally occurring microorganisms.[14]

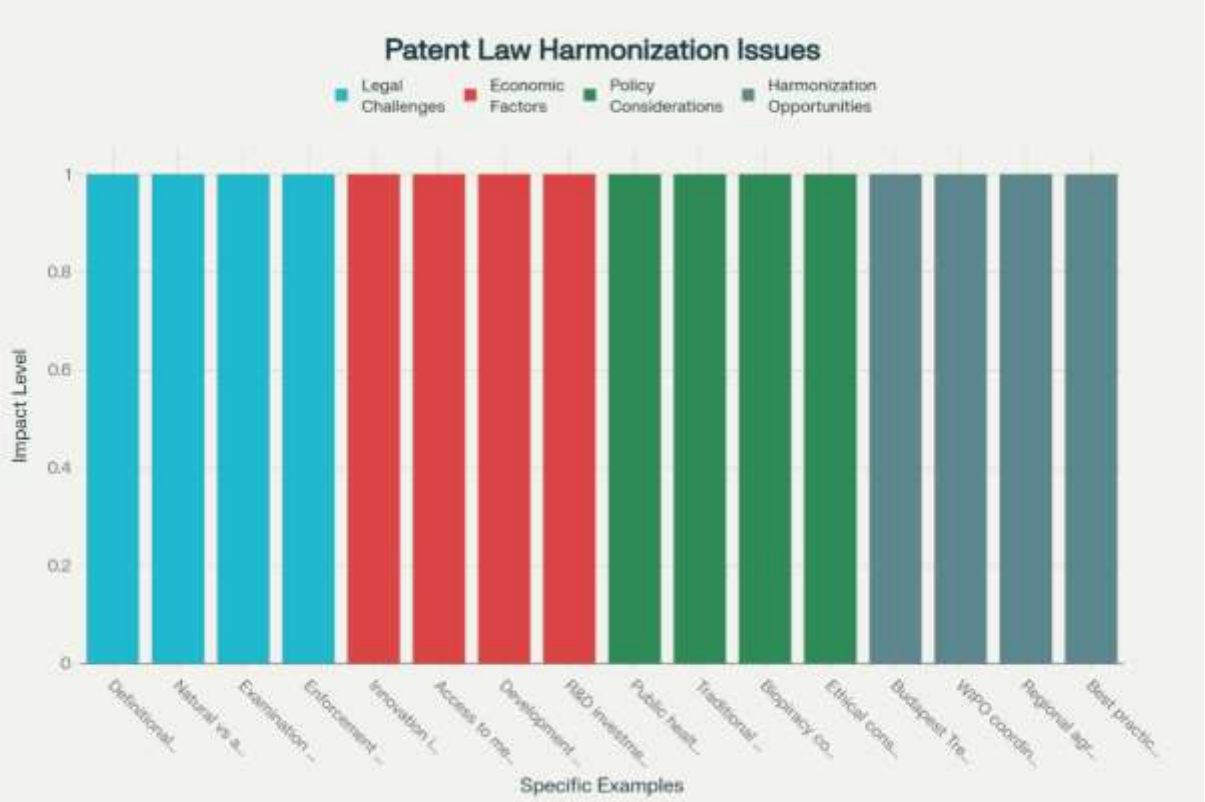
5.2 Policy Objectives and Economic Philosophy:

The three frameworks show different ideas on how to preserve intellectual property in the economy. The U.S. government puts a lot of effort into recruiting investment and giving research incentives because it thinks strong patent protection is important for the growth of biotechnology. This model suggests that strong intellectual property rights will lead to enough new ideas to make up for any access limitations. The TRIPS Agreement aims to strike a balance

[13] Inge Govere & Paul Demaret*, *The TRIPS agreement: A response to Global Regulatory Copetition or an exercise in global regulatory coercion?* Regulatory Competition and Economic Integration 364–381 (2001).
[14] Daniel J. Gervais, *The TRIPS agreement and the changing landscape of International Intellectual Property*, Intellectual Property and TRIPS Compliance in China (2007).

ISSN: 2582-6433

between promoting innovation and meeting developmental needs by setting important standards and enabling countries to implement them in their own way. Still, this balance has been hard to maintain since there are still debates over whether TRIPS regulations are enough to help poor countries deal with their problems. The Patents Act's stated purposes show that India clearly puts the public interest ahead of commercial monopoly rights. This plan puts stopping biopiracy, protecting traditional knowledge, and making sure people can get critical medications at the top of its list. The Indian model says that patents are privileges given to society, not rights that entrepreneurs have by nature.[15]



Challenges and Opportunities in Global Microorganism Patent Law Harmonization

5.3 Enforcement and Practical Implementation

The ways that the three regimes enforced their rules were quite different. The WTO dispute resolution processes, which have been successful yet delayed in resolving disputes, serve as the foundation for the TRIPS Agreement. The United States uses federal court proceedings, which includes substantial damages judgments and robust enforcement measures. In addition to conventional courts, India has a specialized Intellectual Property Appellate Board, and post-grant opposition processes are becoming more and more important. Strategic concerns and

[15] Introduction to the TRIPS agreement, A Handbook on the WTO TRIPS Agreement 1–38 (2020).

ISSN: 2582-6433

patent value are impacted by these enforcement disparities. The rigorous enforcement of U.S. standards makes American patents especially important to biotechnology businesses, even if India's post-grant challenge procedure raises doubts even after a patent is granted. Individual patent holders have limited enforcement possibilities under the TRIPS system, which mostly depends on government-to-government dispute settlement.[16]

6. CHALLENGES AND HARMONIZATION EFFORTS

The different ways that microorganisms are patented provide a number of obstacles to the worldwide development of biotechnology and cast doubt on the viability and appeal of more consistency.

6.1 Legal and Technical Challenges

International patent tactics are complicated by jurisdictional definitional discrepancies, which may cause ambiguity for patent applicants. Because phrases like "microorganism," "essentially biological process," and "human intervention" lack accepted scientific meanings, they may be construed differently, which may have a big impact on the scope of a patent. Additionally, various patent offices have somewhat varied examination criteria, which causes comparable applications to have different results. The USPTO, Japan Patent Office, and European Patent Office did a trilateral study and discovered significant differences in deposit requirements, enablement criteria, and claim interpretation. These differences might make it harder to enforce and license patents since they could be allowed in some places but not others.[17]

6.2 Economic and Development Considerations

The existing lack of clarity in microbial patent law might slow down the growth of biotechnology since it makes transactions more expensive and makes the law less clear. Because each country has its own legal system, businesses that desire protection throughout the globe may need to utilize distinct patent processes and claim forms. The various methodologies also reflect significant variations in political aims and how fast the economy is growing. Stricter patent rules might aid developing nations by providing them access to crucial new technology and pushing them to improve their own expertise. Aligning

[16] Agreement on trade-related aspects of Intellectual Property Rights (Trips Agreement) (as amended on 23 January 2017), A Handbook on the WTO TRIPS Agreement 295–337 (2020).
[17] Talat KAYA, *A comparative analysis of the patentability of computer software under the TRIPS agreement the U.S., the E.U., and Turkey*, Ankara Law Review 043–081 (2007).

ISSN: 2582-6433

with more permissive standards too quickly might put these development objectives at risk.[18]

6.3 Harmonization Initiatives and Prospects

There are a lot of projects throughout the world that are attempting to make it simpler for individuals to work together and coordinate their efforts to fix these issues. The Budapest Treaty is an excellent example of technological collaboration that is targeted. It makes sure that microbiological deposits made in one country are accepted everywhere else in the world. Since 1977, this technique has succeeded, indicating that nations can work together to settle biotechnology patent disputes. The European Patent Convention and the Eurasian Patent Organization are two examples of regional harmonization initiatives. Their purpose is to make the law less divided in certain places. These solutions make it possible to conduct inspections in one place that meet national enforcement criteria. Through a variety of committees and working groups, the World Intellectual Property Organization keeps pushing for talks on how to make biotechnology patents operate better together. But progress has been slowed down by a lack of consensus on the policy's aims and the best way to balance access difficulties with incentives for innovation.[19]

7. Recent Developments and Future Directions:

Recent changes in patent law and biotechnology show that there are both chances and problems for the future of microbe patenting systems.

7.1 Technological Advances:

New categories of inventions are coming up because of advances in synthetic biology, AI-assisted creature design, and gene editing technologies. These new categories don't fit well with current patent systems. Computer-designed microbes bring up new questions about how much people need to be involved and how innovation and discovery are different. Updating patent laws may be necessary to account for technological realities that are now neglected.[20]

7.2 Policy Evolution:

Recent court rulings and patent office guidelines show that the ways to patent biotechnology

[18] Impact of the TRIPS agreement on developing countries, Globalising Intellectual Property Rights 122–136 (2003).
[19] Declaration on the TRIPS agreement and public health, A Handbook on the WTO TRIPS Agreement 397–398 (2020).
[20] Patents: An Indian perspective, The Making of the TRIPS Agreement 295–320 (2015).

ISSN: 2582-6433

are changing.

While upholding wide patentability requirements, the USPTO's 2024 guideline update on patent subject matter eligibility addresses a number of biotechnology-related concerns. Recent revocations of pharmaceutical patents show that careful examination is still highly valued in Indian practice. The COVID-19 epidemic has heightened discussions on patent law and access to scientific breakthroughs, as well as requests for forced licensing and patent waivers. Future methods of microbe patenting may be influenced by these ideas, especially when it comes to public health situations.[21]

7.3 Emerging Challenges:

Climate change and environmental concerns are increasing the need for biotechnological solutions, such as engineered microorganisms for carbon capture, pollution remediation, and sustainable manufacturing. In patent systems, incentives for innovation, environmental protection, and equitable access to climate technologies must all be balanced. The application of AI to biotechnology research also raises questions about inventorship and patentability standards. If AI systems can produce microorganisms with minimal human intervention, then traditional ideas of human creation would need to be rethought.[22]

8. CONCLUSION:

There are significant disparities in microbe patenting under TRIPS, U.S., and Indian legislation, which represent different political goals and economic philosophies. Though their scope, definitional approaches, and enforcement strategies vary, all three systems acknowledge innovation, creative step, and industrial application. While allowing for a variety of approaches and a limited degree of harmonisation, the TRIPS Agreement establishes few worldwide standards. With its emphasis on creative incentives and patenting artificially created microorganisms, the US has the most permissive legislation. India now restricts patentability to really altered microorganisms and places a higher priority on the public interest. These discrepancies reflect actual governmental choices pertaining to intellectual property in the development of biotechnologies. While the Indian framework prioritises fairness while

[21] Martina Schuster, Patenting proteomics: Patentability and scope of protection of three-dimensional protein structure claims under German, European and US law (2010), http://www.jstor.org/stable/10.2307/j.ctv941tv3?refreqid=fastly-default (last visited Oct 11, 2025).

[22] Vartika Prasad, Microorganisms and the Indian Patents scenario Patent - India (2020), https://www.mondaq.com/india/patent/900702/microorganisms-and-the-indian-patents-scenario (last visited Oct 12, 2025).

ISSN: 2582-6433

reducing innovation incentives, the U.S. policy may enhance innovation rewards while restricting access. Although TRIPS aims to balance these variables, it gives nations a lot of leeway. New developments in biotechnology, such as AI-guided design and synthetic biology, will require adaptation from all three systems. Global health concerns and climate change will have an impact on patent scope and access regulations. Instead of rigid harmonisation, the future could call for global dialogue and cooperation. The Budapest Treaty demonstrates that national policy differences may be respected in technical partnership. Comparable approaches might satisfy calls for harmonisation while maintaining policy diversity. Patent regimes for microorganisms that are successful must incorporate access and creative incentives as they adapt to new technologies. The three frameworks for finding this balance reflect a range of interests and values that are still significant in discussions on biotechnology patent policy across the world. Policymakers need to learn from these many approaches and create systems that support innovation and human well-being in a world that is becoming more interconnected by the day.

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