

INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS



Open Access, Refereed Journal Multi Disciplinary
Peer Reviewed Edition :

www.ijlra.com

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ISSN

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BIOTECHNOLOGY PATENTING, DIFFERENCE BETWEEN USA AND INDIAN PERSPECTIVE

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Abstract

The paper explores the complexities of biotechnology patents, focusing on the differences between the United States and India. It addresses the legal, economic, and societal implications of patenting in these jurisdictions, offering valuable insights for international collaboration and investment strategies. The study emphasizes the need for a comprehensive understanding of the global landscape of biotechnology patenting. The impact of court decisions on biotech patent interpretation is illustrated through landmark cases in both countries. The Monsanto case in India addressed patent eligibility for creating transgenic plants, highlighting disagreements on human intervention. In the US, the Association of Molecular Pathology v Myriad Genetics Inc decision differentiated between naturally occurring DNA and engineered elements, influencing patent eligibility.

Keywords

Biotechnology patents, Intellectual Property Rights, Comparative Analysis, Legal Frameworks, Global Implications

Introduction

One of the most intriguing and difficult problems facing the patent system is biotechnology. Biotechnology is the technical application of biological materials, including cells or enzymes, to produce pharmaceuticals, among other things. Beyond the patent system, biotechnology unites industry, law, and technology. Legislation is also greatly influenced by ethics and morality.

Biotechnology items that are eligible for patents include sequences of nucleotides and amino acids, microbes, procedures, or techniques for altering these products, applications in the

production of pharmaceuticals, etc. Inventions can be protected in a variety of ways, as long as they meet the three primary criteria for patentability: industrial applicability, inventive step, and novelty. A product or procedure for a particular purpose can be made by biotechnology by using an organism, or a part of an organism or other biological system.

Relevance of the study

The United States and India possess distinct legal frameworks and regulatory landscapes for biotechnology patents. A comprehensive study of these differences enables professionals to navigate the complexities of international collaboration, technology transfer, and investment strategies.

Objectives of the study

A comparative analysis of the USA and Indian Perspective is to provide a comprehensive examination of the legal, economic, and societal implications of biotechnology patents in these two significant jurisdictions. By achieving these objectives, the research paper aims to contribute valuable insights to academia, and the broader public, fostering a deeper understanding of the global implications of biotechnology patenting and guiding future developments in this critical field.

Research Methodology

This research employs an empirical methodology to investigate biotechnology patenting, specifically comparing the perspectives in the USA and India. The study relies on survey conducted, articles, and books to analyse the practical implications of patent laws. Through this empirical approach, the research aims to provide a data-driven understanding of how biotechnology patenting differs between the two jurisdictions and their tangible effects on legal, economic, and societal aspects.

Literature Review

K. Jeyaprakash (2016) elucidates the pivotal role of Intellectual Property Rights in the realm of biotechnology. The author offers an insightful exploration of the legal framework's impact on innovation, providing a comprehensive overview of patent laws and their application within the biotech domain. The article "Biotechnology Patenting" by Jidesh Kumar (2004) deals with the

latest technology to create major intellectual property problems for courts and legislatures, viz., biotechnology.

Problem statement

The increasing significance of biotechnology in addressing global challenge prompts a critical examination of the Intellectual Property Rights landscape. Despite its acknowledged importance, a gap exists in understanding how IPR, particularly patents, functions in biotechnology across diverse jurisdictions such as the United States and India.

Hypothesis

Distinct legal and regulatory environments in USA & India influence innovation incentives, industry dynamics, and societal implications differently which ultimately makes the biotechnology patent differ in two countries.

Research Questions

- A. How do the patent laws and regulatory frameworks in the united states and india differ concerning biotechnology?
- B. How do differences in patent examination processes and criteria contribute to the disparities in the scope and nature of biotechnology patents granted in the united states and india?
- C. How do legal precedents and court decisions in the united states and india shape the interpretation and enforcement of biotechnology patents?

Regulatory Frameworks for Biotechnology Patents in US and India

The law which governs patents in India is Patents Act, 1970 and the Patents Rules, 2003, which includes grant of patents to biotechnology inventions. As per the Patents Act, 1970, in India not everything created or invented under the Sun is patented or patentable.

The way the laws are worded determines the main distinction between the legal systems of the two nations. The US defines what CAN be patented in a more demonstrative manner. Conversely, India's patent regulations specify what is NOT eligible for patent protection.

Minor modifications or extensions to awarded patents are prohibited by Indian Patent Law. That flexibility is, however, granted by US patent laws.

The Utility patent is a legal concept in the United States. This permits the patenting of a machine or process discovery as long as it is new, practical, and obscure. In India, this is not the case. India's patent rules prohibit patenting the act of discovering a machine, technique, or product.

The United States permits patents for the discovery or invention of novel plants under the Plant Patent Act. There is no similar provision in India. In the United States, new and inventive business models are patentable. India also prohibits this. It is clear from the comparison above that US patent laws are more flexible than those in India. This results from the limitations imposed by the nations on WHAT is patentable. This depends in part on how "non-obviousness" is defined. In essence, non-obviousness indicates that no other person with the same competence is aware of the invention.

Naturally, as people's perceptions can differ, the definition of such a term needs to adhere to clear guidelines.¹

Challenges and Opportunities in Biotech Patent Examination

For patent practitioners, the United States Patent and Trademark Office (USPTO) offers examination guidelines and training materials. The papers offer subject matter eligibility instructions, examples, training, and guidelines for treating related concerns in patent applications and for assessing compliance with 35 U.S.C. 112.²

Additionally, the USPTO offers a two-part test for patent practitioners that consists of 100 multiple-choice questions spread over two three-hour sessions. The exam measures candidates' familiarity of patent laws, regulations, and procedures as well as their capacity to apply that information to particular situations.³

¹ Rahul Dev, "Comparative Study between Indian & U.S Patent Laws", available at <https://patentbusinesslawyer.com/comparative-study-between-indian-us-patent-laws/>

² Examination Guidance and Training Materials, USPTO, available at <https://www.uspto.gov/patents/laws/examination-policy/examination-guidance-and-training-materials>

³ Application and Registration process, USPTO, available at <https://www.uspto.gov/learning-and-resources/patent-and-trademark-practitioners/becoming-patent-practitioner>

The MPEP (Manual of Patent Examining procedure) offers comprehensive information about the review of biotechnology patent applications, including the conditions that must be met in order for a patent to be eligible, the kinds of claims that can be made, and the review processes.⁴

The guidelines for the review of biotechnology patent applications have been released by the Indian Patent Office. The purpose of the guidelines is to create standardised and consistent procedures for the Patents Act of 1970's examination of biotechnology and related subject patent applications. The instructions offer comprehensive details about the review process for biotechnology patent applications, including the kinds of claims that can be made, the conditions that must be met for patentability, and the methods for examination.⁵

Impact of Court Decisions on Biotech Patent Interpretation

The legal framework in the field of biotechnology has come across many challenges which has led to certain amendments done in the Patents Act, 1970 and the Patents Rules, 2003, time to time. *Diamond v. Chakrabarty*⁶ is a landmark case in the United States that expanded the application of the U.S. Patent Act, which had an impact on the biotechnology industry.

In the *Monsanto Technology LLC v. Controller of Patents and Designs*⁷ case, the Intellectual Property Appellate Board (IPAB) addressed a patent application related to creating transgenic plants resistant to environmental challenges. The disagreement centered on whether the process involved significant human intervention, as claimed by Monsanto, or if it constituted a non-patentable biological regeneration and selection process, as argued by the Indian Patent Office (IPO). While the IPAB disagreed with the IPO regarding the application of Section 3(j) of the Patents Act, it upheld the IPO's decision on lack of inventive step and ineligibility under Section 3(d). The IPAB determined that the claimed method involved human intervention on a plant cell, making it exempt from Section 3(j).

Additionally, the evolution of biotech patent doctrine in India was influenced by a 2002 ruling in

⁴ Manual of Patent Examining Procedure (MPEP), Ninth Edition, Revision 07.2022, Published February 2023, available at <https://www.uspto.gov/web/offices/pac/mpep/index.html>

⁵ "Guidelines for Examination of Biotechnology Applications for Patent", Office of the Controller General of Patents, Designs and Trademarks, March 2013

⁶ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)

⁷ *Monsanto Technology LLC v. Controller of Patents and Designs* (2022)

Dimminaco AG v. Controller of Patents,⁸ Designs, and Trademarks. In this case, Dimminaco AG sought to patent a method for producing an infectious bursitis vaccine for poultry. However, the IPO rejected the application, arguing that creating a vaccination containing a living virus did not qualify as a manufacturing method under the existing patent laws, which required inventions to be related to a "new and useful" method of manufacture. This ruling significantly impacted the interpretation of patent eligibility in the biotechnology sector.

Regarding living organisms and patentability, certain provisions exclude the patenting of sequences directly isolated from nature, unless obtained through substantial human intervention. A pivotal 2013 US Supreme Court decision, *Association of Molecular Pathology v Myriad Genetics Inc.*,⁹ declared that isolated, naturally occurring full-length DNA molecules or gene fragments are not patent-eligible, being deemed "products of nature." However, complementary DNAs (cDNAs), lacking naturally occurring non-coding regions (introns), were deemed patent-eligible. The court reasoned that cDNAs, synthesized in the laboratory from RNA, are not naturally occurring, affirming the patent eligibility of engineered/recombinant DNAs.¹⁰

Conclusion

In summary, the regulatory frameworks for biotechnology patents differ significantly between the United States and India. The U.S. defines what can be patented more explicitly, while India specifies what is not eligible for patent protection. The flexibility of U.S. patent laws contrasts with more restrictive regulations in India. Challenges and opportunities in biotech patent examination reflect these disparities. Furthermore, court decisions, such as the Monsanto case, shape patent interpretation, demonstrating the ongoing evolution of biotech patent doctrine. Notably, the 2013 U.S. Supreme Court decision on DNA molecules underscores distinctions in patent eligibility between natural and engineered elements.

⁸ *Dimminaco A.G. v. Controller of Patents and Designs*, (2002) I.P.L.R. 255 (Cal)

⁹ *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013)

¹⁰ Debashish Banerjee and Pankaj Musyuni, "Biotechnological inventions in India: law, practice and challenges", Published on 23 October 2015, IAM, available at <https://www.iam-media.com/global-guide/iam-yearbook/2016/article/biotechnological-inventions-in-india-law-practice-and-challenges>

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Diamond v. Chakrabarty, 447 U.S. 303 (1980)

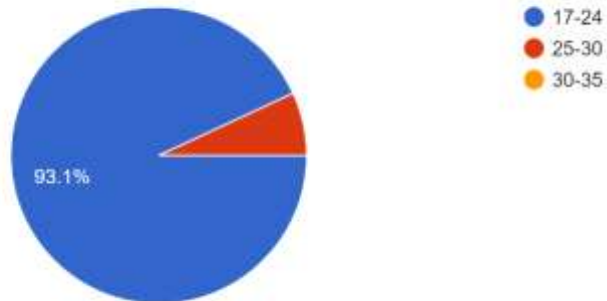
Dimminaco A.G. v. Controller of Patents and Designs, (2002) I.P.L.R. 255 (Cal)

Monsanto Technology LLC v. Controller of Patents and Designs (2022)

Empirical research report

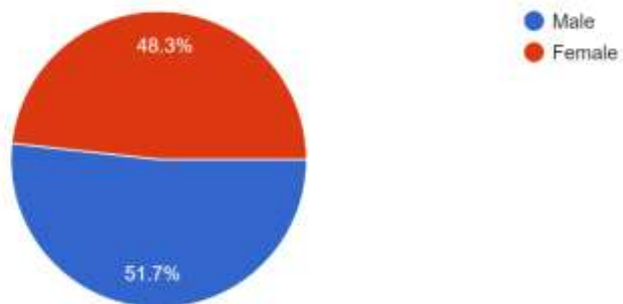
Age:

29 responses



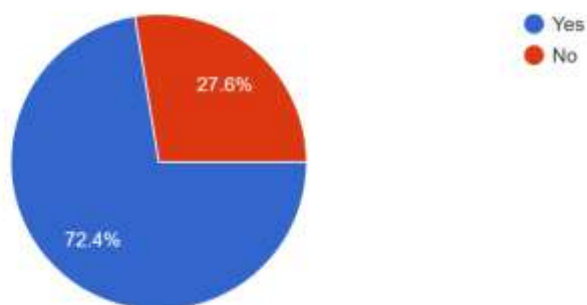
Gender:

29 responses



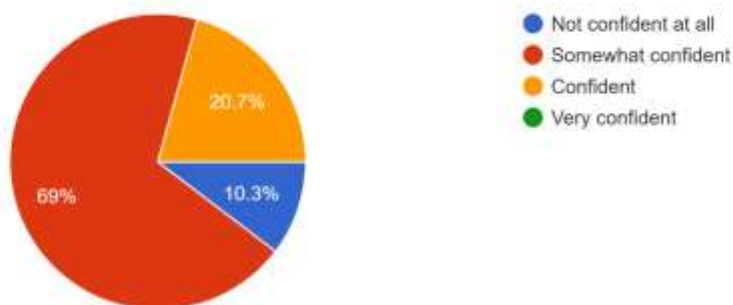
Were you aware that patents exist for inventions in the field of biotechnology? (through articles or any discussions or news)

29 responses



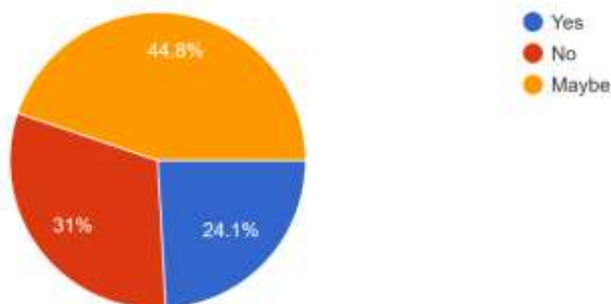
How confident do you feel about your understanding of what a biotechnology patent is?

29 responses



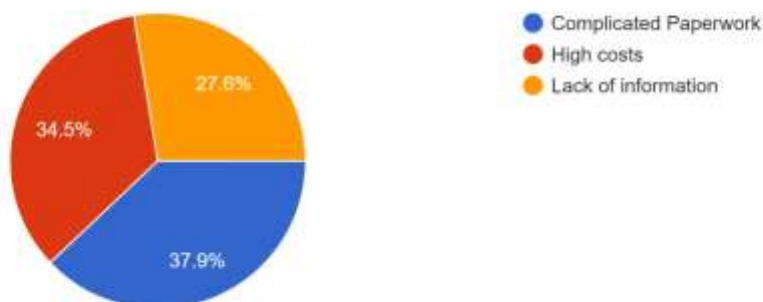
In your opinion, do you think it's easy for biotechnological inventors to get a patent in India?

29 responses



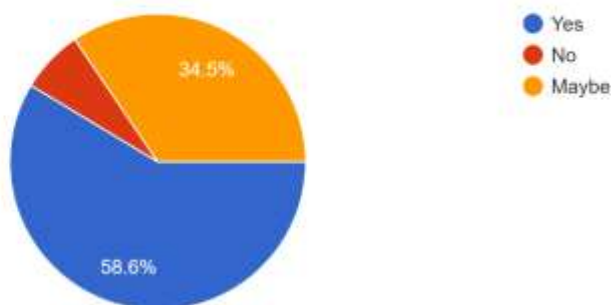
What challenges, if any, do you think inventors face when trying to patent biotechnological innovations in India?

29 responses



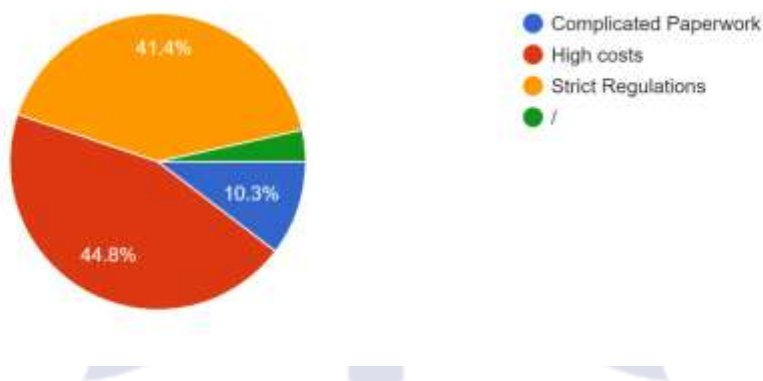
In your opinion, do you think it's easy for biotechnological inventors to get a patent in the USA?

29 responses



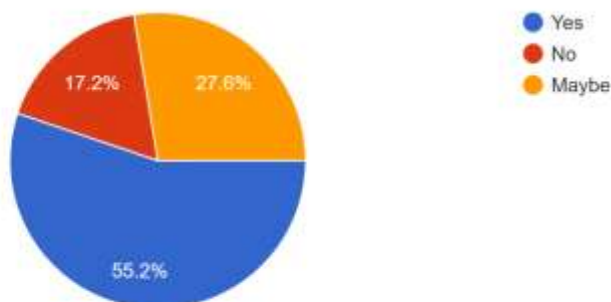
What challenges, if any, do you think inventors face when trying to patent biotechnological innovations in the USA?

29 responses



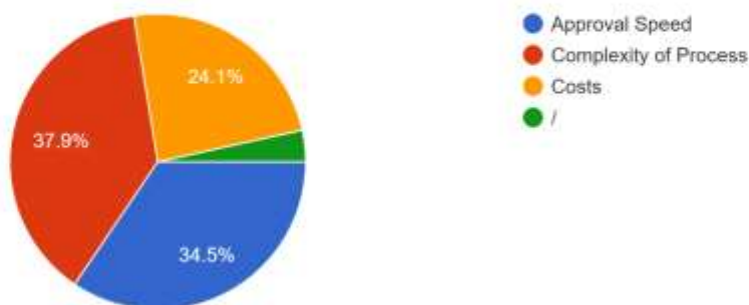
Do you think there are significant differences in how biotechnology patents are granted in India compared to the USA?

29 responses



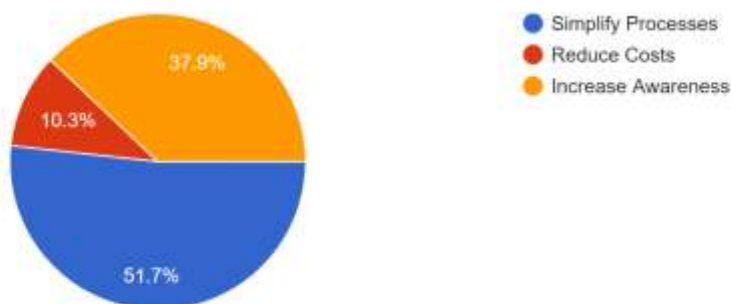
If yes, what do you think could be the main differences?

29 responses



What do you think could be done to make it easier for inventors to obtain biotechnology patents in India?

29 responses



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