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"BIOTECHNOLOGICAL INNOVATIONS: LEGAL ISSUES AND PERSPECTIVES"

AUTHORED BY - RADHIKA DATAR

Abstract:

The purpose of the research article is to study and analyse the various legal issues in the field of biotechnology and specifically in biotechnological innovations. Biotechnological innovations refer to techniques that use living organisms, or parts of them, in order to make or modify products, or to improve or modify certain or all the characteristics of plants, or animals, in order to develop micro-organisms, and organisms intended for specific uses in healthcare, agriculture, pharmaceuticals, and environmental science. The analysis describes the concept and evolution of biotechnology as well as biotechnological innovations in India. It stipulates in short; the various issues in biotechnological innovations which includes environmental, socio-economic, religious and cultural, ethical and legal issues. The study further describes; imbalance between incentivizing of biotechnological innovations and access to its benefits, issue of patentability data ownership and sharing issue, liability of product safety issue as the major legal issues in biotechnological innovations with supporting judicial pronouncements which describes the cause of evolution and amendments in various science and technology laws in India. The study finally suggests some recommendations to combat the ill-effect of legal issues and to enhance the further developments in biotechnological innovations in India.

Keywords: *biotechnology, biotechnological innovations, legal issues, healthcare, agriculture, pharmaceuticals, environmental science*.

INTRODUCTION:

Biotechnology is a rapidly evolving and multifaceted field that encompasses various applications in healthcare, agriculture, pharmaceuticals, and environmental science. The biotechnology sector in India as well as in various other countries has grown significantly over the years and plays a crucial role in driving innovation, research, and economic development. Biotechnology exists since ancient times and its progress has been witnessed through many centuries. It is the field that exploits living organisms to make technological advances in various fields for the sustainable

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development of mankind. The term "biotechnology" broadly includes not only the old biotechnology such as the traditional method of manufacturing fermented products but also the new biotechnology represented by genetic engineering and recombinant technology. The biotechnological research, application and innovations can be traced back decades ago with the agricultural revolution. The biological processes of living organisms have also been used for more than 6000 years to make essential products such as bread, cheese, alcohol, etc. In 19th century after the establishment of Department of Biotechnology (DBT) in 1986[1]; India saw the rapid emergence and development of the biotechnology industry in agriculture, healthcare, and pharmaceuticals attracting investments from both domestic and international sources. India became a hub for clinical trials, biopharmaceutical manufacturing, and research and development. A biotechnological innovation has been one of the greatest scientific achievements in the history of mankind. Biotechnological inventions refer to techniques that use living organisms, or parts of them, in order to make or modify products, or to improve or modify certain or all the characteristics of plants, or animals, in order to develop micro-organisms, and organisms intended for specific uses. However beside all its applications some social, environmental, legal, ethical, moral and religious issues are also coexist within the fields of Biotechnology. These issues includes many defects and side effects of products, tools and techniques along with economic, environmental loss and other negative impacts. Legal and policy issue is one of such key issue in biotech innovations. This may involve issues like intellectual property rights and patentability issues, biosafety regulations, clinical trial and drug approvals issues and data ownership and sharing relating to the innovation issues.[2]

Earlier nobody thought that biotechnology could manipulate either plants, animals or human beings and therefore no one thought about the need for evolving a comprehensive law on biotechnology for regulation. However, as biotechnology has progressed in various generations at different times and and due to the plenty of legal concerns and issues which emerged in biotech innovations; this field mandated a comprehensive legal framework for proper regulation, TRIPS agreement provided protection and regulation of various biotechnology inventions. Indian government have also developed comprehensive laws such as The Patents act, 1970, New drugs and clinical trial rules 2019 etc. to ensure safety and protection of biotech innovations.

[1] Department of Biotechnology (DBT), Ministry of science and technology, Government of India https://dbtindia.gov.in/
[2] Knowledge, Technology and Law (Law, Science and Society) Hardcover; Illustrated, 16 September 2014 by Emilie Cloatre (Editor), Martyn Pickersgill (Editor)

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CONCEPT OF BIOTECHNOLOGY:

Biotechnology is a rapidly evolving and multifaceted field that encompasses various applications in healthcare, agriculture, pharmaceuticals, and environmental science. The term biotechnology was used for the first time by Karl Erkey, a Hungarian Engineer, in 1919. The term biotechnology is derived from the Greek root i.e. 'bios', which means life, and 'techne' meaning craft or skill. Biotechnology is a culmination of human intervention and natural processes. It is the field that exploits living organisms to make technological advances in various fields for the sustainable development of mankind. It is the use of biology to develop new products, methods and organisms intended to improve human health and society. The term "biotechnology" broadly includes not only the old biotechnology such as the traditional method of manufacturing fermented products but also the new biotechnology represented by genetic engineering and recombinant technology.
Definition: Biotechnology consists of "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services.

Karl Erkey: Biotechnology is "The process of using technology to convert raw, biological material into a useful product".[3]

EVOLUTION AND DEVELOPMNT OF BITECHNOLOGY:

Biotechnology began nearly 6,000 years ago with the agricultural revolution. During this era; agricultural productivity increased dramatically through the development of new technologies and land management practices. This early era was also characterized by exploiting living organisms in their natural forms or modifying their genetic makeup through selective breeding. Around the same time, humans learned to harness the biological process of fermentation to produce bread, alcohol and cheese. Biotechnology remained limited to these selective breeding, agricultural methods until the 19th century when biologist Gregor Mendel discovered the basic principles of heredity and genetics. During that era, scientists Louis Pasteur and Joseph Lister discovered the microbiological processes of fermentation. This laid the foundation for biotechnology industries where scientists can interact directly with the genetic and molecular processes of organisms. Based on the work of these various scientists, genetic engineering developed in 1973. This method of genetic engineering is the foundation of modern biotechnology and recent advancements. It enabled the first direct manipulation of genomes of

[3] https://brainly.ph/question/10095973#:~:text=Answer%3A-,1.,material%20into%20a%20useful%20product.

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various plants and animals.

The history of biotechnology in India can be traced back several decades, and it has evolved significantly over the years. India has a rich history of using biotechnology in the form of traditional medicine systems like Ayurveda, which date back thousands of years. In the 1960s and 1970s, India underwent a Green Revolution, which involved the development and adoption of high-yielding crop varieties and modern agricultural practices. This marked an important application of biotechnology in Indian agriculture. Then in 19th century, The National Biotechnology Board was established in 1982, which later evolved into the Department of Biotechnology (DBT) in 1986 under the Ministry of Science and Technology. [4]Therefore, 1990s saw the emergence of the biotechnology industry in India, with the formation of biotech companies engaged in agriculture, healthcare, and pharmaceuticals. Then after the 2000 till present India's biotechnology sector continued to grow, attracting investments from both domestic and international sources. India became a hub for clinical trials, biopharmaceutical manufacturing, and research and development.[5]

CONCEPT OF BIOTECHNOLOGICAL INNOVATIONS:

A biotechnological innovation has been one of the greatest scientific achievements in the history of mankind. Biotechnological inventions are nothing but the techniques that use living organisms, parts of living organisms in order to make or modify various products, or to improve or modify specific or all the characteristics of that plants, or animals, in order to develop micro-organisms. Biotechnological inventions are applied in a wide range of fields including agriculture, agro-industry, fertilizers, the food industry, diagnostics, zoo-techniques, semi-conductors, pharmaceuticals, the refuse industry, fuels, chemistry, etc.

Biotechnology innovation is “The technology that utilises biological systems, and living organisms to develop or create different products”.

[4] Department of Biotechnology (DBT), Ministry of science and technology, Government of India https://dbtindia.gov.in/

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DEVELOPMENT OF BIOTECHNOLOGICAL INNOVATIONS IN INDIA:

India has made significant progress in the development of biotechnological innovations over the years. The growth of the biotechnology sector in India can be attributed to several factors, including a strong research and development ecosystem, government support, a skilled workforce, and a growing market for biotech products. The roots of biotechnological innovations in India can be traced back to ancient practices like fermentation and the use of traditional medicines. India has a rich tradition of herbal and medicinal knowledge, which has contributed to biotechnological advancements.

During early 1950s to 1970s period, India laid the foundation for biotechnological research. Research institutions and universities initiated studies in microbiology, biochemistry, and genetic engineering. This era saw the establishment of organizations such as the Indian Council of Agricultural Research (ICAR) and the Indian Council of Medical Research (ICMR).[6] The Department of Biotechnology (DBT) was established within the Ministry of Science and Technology in 1986. [7] The DBT's mandate was to promote, coordinate, and fund biotechnology research and development. 19th century witnessed significant progress in agricultural biotechnology. India developed and adopted genetically modified (GM) crops and also emerged as a key player in the global biopharmaceutical industry, producing affordable generic medicines and vaccines. Ever since a GMO was granted patent, the field of biotechnology gained enormous significance and patents have been granted to genetically engineered plant and human genetic material.

The India launched the NBDS in 2002 [8]to provide a strategic framework for the development of biotechnology in India. It aimed to strengthen research and innovation, promote entrepreneurship, and address societal and environmental challenges. During this period, biotechnology parks and incubators were established in various regions of India to provide infrastructure and support to biotech start-ups and innovators. These facilities fostered innovation and entrepreneurship. India developed a regulatory framework for biotechnology to ensure biosafety and ethical practices in

[6] https://icar.org.in/
[7] Department of Biotechnology (DBT), Ministry of science and technology, Government of India https://dbtindia.gov.in/
[8] ***National Biotechnology Development Strategy*** (NBDS)

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research and development. This included guidelines for genetically modified organisms (GMOs) and clinical trials. In late 20th century Indian biotech institutions and companies entered into international collaborations and partnerships, enhancing their global footprint and contributing to collaborative research projects. The government introduced various policies and initiatives to boost the biotech sector. These included grants, subsidies, and support for research and development. India experienced a surge in biotech start-ups, particularly in the fields of health-tech, agribusiness, diagnostics, and bioinformatics. These start-ups played a significant role in driving innovation and attracting investment. India became a global leader in the production of affordable healthcare solutions, including generic drugs and biopharmaceuticals. It contributed to addressing global health challenges through the export of quality medicines and vaccines.

ISSUES IN BIOTECNOLOGICAL INNOVATIONS:

Biotechnological innovations have the potential to bring about significant advancements in various fields including healthcare, pharmaceutical, agriculture and environmental conservation. Biotechnology had improved the way of living in many aspects including the industrial, agricultural production, Fight against diseases etc. and it can ensure sustainable development by improving agricultural productivity. [9]However beside all these applications some issues also coexist within the fields of Biotechnology. These issues includes many defects and side effects of products, tools and techniques along with economic, environmental loss and other negative impacts.

Following are the key issues in biotech innovations: -

1) **Environmental issues:** Biotech innovations such as genetically modified organisms etc. may result into some unintended environmental consequences. These innovations may result into biodiversity loss, contamination of non-target organisms, west generation and also can sometimes lead to the harm to aquaculture.
2) **Legal issues:** Intellectual property plays vital role in biotech innovations. Researchers generally seek for the patents to protect their innovations but this can create imbalance between incentivizing biotech innovation and ensuring access to innovation. Biotech innovations also leads to the pivotal problems such as patentability of innovations. [10]

[9] https://www.journalijar.com/article/31470/challenges-in-biotechnological-product-innovations-patent:-a-review/
[10] https://blog.ipleaders.in/issues-faced-while-patenting-biotechnology-inventions/

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3) **Socio-economic issues:** Biotech innovations such as genetically modified organisms etc. can have great impact on traditional farming industries and rural livelihood. It can also create disparities in access to its benefits since many innovations bears high costs which is only affordable to rich people and wealthier nation.
4) **Religious and cultural issues:** Reproductive technological innovations such as IVF, surrogate mother can clash with religious and cultural beliefs about sanctity of family, status of children born out of this issue.
5) **Ethical Issues:** Biotech innovations such as gene editing, germ line modification can have some consequences such as permanent genetic change, creation of designer babies which can create ethical issues. [11]

LEGAL ISSUS AND PERSPECTIVES IN BIOTECHNOLOGICAL INNOVATIONS:

Earlier nobody thought that biotechnology could manipulate either plants, animals or human beings and therefore no one thought about the need for evolving a comprehensive law on biotechnology for regulation. However, due to various developments and advancements; this field mandated a comprehensive legal framework for proper regulation

Following are the key legal issues in biotechnological innovations:-

1) **Imbalance between incentivizing of biotechnological innovations and access to its benefits:**

The imbalance between incentivizing biotechnological innovations and ensuring access to their benefits is a complex challenge in India, as it is in many countries. While incentivizing innovation in biotechnology is crucial for scientific progress and economic growth, it must be balanced with the need to make biotech products, especially in the healthcare sector, accessible and affordable to the broader population. Here are some factors contributing to this imbalance:

Intellectual Property Rights (IPR): Strong IPR protection, including patents, can incentivize innovation by granting exclusivity to developers. However, it can also lead to high prices and limited access to biotech products. Balancing IPR with provisions for compulsory licensing or

[11] Knowledge, Technology and Law (Law, Science and Society) Hardcover; Illustrated, 16 September 2014 by Emilie Cloatre (Editor), Martyn Pickersgill (Editor)

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limitations on patents for essential medicines can ensure that access is not hindered.[12]

High development costs: Biotechnological innovations often involve substantial research and development costs. These costs are often recovered through high prices for new biotech products. Governments and organizations can provide funding or incentives for research in critical areas, like neglected diseases, to reduce the burden of high development costs.

Regulatory Hurdles: Stringent regulatory processes can delay market entry for biotech products, increasing costs and affecting accessibility. Streamlining and expediting regulatory processes while maintaining safety standards can make biotech products available sooner and at a lower cost.

Public private collaboration: Private companies or private companies in collaboration with public companies often drive biotech innovation, and their profit motives may hinder affordable access. Encouraging public-private partnerships and ensuring that collaboration agreements prioritize affordable access can help address this challenge.

Balancing incentives for biotechnological innovations with access to their benefits is an ongoing policy challenge that requires careful calibration to address the specific needs of the population. Collaboration between government, industry, civil society, and healthcare providers is essential to strike the right balance between innovation and accessibility in the biotech sector in India.

In the case of ***Novartis AG v. Union of India*** (2013) [13]often referred to as **"Gleevec Case"** the Indian Supreme Court issued a landmark judgment in 2013 that had significant implications for access to biotech innovations. Novartis, a multinational pharmaceutical company, developed the drug Gleevec (generic name: Imatinib Mesylate), which is used in the treatment of chronic myeloid leukemia (CML) and other cancers. The drug was considered a significant medical breakthrough. Novartis sought to patent an improved crystalline form of Imatinib Mesylate in India. The patent application was filed in 1998 under the Indian Patents Act, 1970. In 2005, the Indian government amended the Indian Patents Act to strengthen provisions related to intellectual

[12] Singh R. Vol. 1. New Delhi: Universal Law Publishing Co. Pvt. Ltd; 2004. Law relating to intellectual property (A complete comprehensive material on intellectual property covering acts, rules, conventions, treaties, agreements, case-Law and much more)
[13] Novartis AG v. Union of India,1 April, 2013

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property and patents. One crucial amendment was the introduction of Section 3(d), which aimed to prevent the grant of patents for minor modifications of known substances. The Indian Patent Office rejected Novartis's patent application for the newer form of Gleevec. The rejection was based on the interpretation of Section 3(d)[14], which prohibited the grant of patents for incremental or minor modifications of known substances unless they demonstrated significantly enhanced therapeutic efficacy. Novartis challenged the rejection of its patent application in various legal forums, arguing that the rejection violated international trade agreements and intellectual property rights. The case garnered widespread attention due to concerns about access to affordable medicines in India. India has a large population with a significant burden of diseases like CML, and access to affordable treatment was a public health concern. The Indian Supreme Court ruled against Novartis in a historic judgment in April 2013. The Court held that the amended Indian Patents Act, particularly Section 3(d), was consistent with India's obligations under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. The Court emphasized that the patent application did not meet the requirement of significantly enhanced therapeutic efficacy. The key outcome of the Novartis AG v. Union of India case was the refusal to grant a patent for the improved crystalline form of Gleevec. This judgment reaffirmed India's commitment to balancing the need to protect intellectual property rights with the imperative of ensuring access to essential medicines. It had a significant impact on pharmaceutical and patent law in India, as well as international discussions about access to medicines and intellectual property. The case emphasized that in certain situations, public health considerations and affordable access to medicines could override the exclusive rights of patent holders, especially when it came to life-saving drugs. It set a precedent for the use of flexibilities within the TRIPS Agreement to address health and access concerns in the context of patents on pharmaceuticals.[15]

2) Patentability of biotechnological innovations:

Intellectual property rights plays vital role in biotechnological innovations. Companies and researchers who has invented particular innovation generally seek for the patents to protect their innovations. A patent is an exclusive right granted to the person who has invented an innovation. It is a government grant to an inventor assuring him or her the right to stop others making, using, and selling the invention for a limited period. In India, all the patents are governed by the Patents

[14] The Patents Act,1970, section 3(d)
[15] Knowledge, Technology and Law (Law, Science and Society) Hardcover; Illustrated, 16 September 2014 by Emilie Cloatre (Editor), Martyn Pickersgill (Editor)

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Act, 1970. [16]However, the law has been subject to various amendments and interpretations, particularly concerning what is eligible for patent protection.

During the pre-independence era India had a patent system under British colonial rule, primarily governed by the Indian Patents and Designs Act, 1911. [17]This system allowed for the grant of patents, but it was largely influenced by colonial interests. After gaining independence in 1947, India continued with the existing patent law. However, concerns were raised about the impact of patents on industrial and technological development, and the government introduced a modified patent regime under the Indian Patents Act, 1970. This Act aimed to balance the need for patents with the need to ensure accessibility to essential medicines and technology. This legislation marked a significant change in India's patent system. It limited the patenting of certain subject matters and established criteria for patentability. Importantly, it allowed for the pre-grant opposition and compulsory licensing, ensuring that patents did not hinder public access to essential products, especially pharmaceuticals.

One of the most substantial changes in India's patent regime occurred in 2005, driven by India's obligations under the (TRIPS) Agreement which required member countries to grant product patents for all fields of technology.[18] Prior to the amendment, India had a process patent regime for pharmaceuticals, which allowed the manufacturing process to be patented, but not the product itself. The amendment introduced Exclusive Marketing Rights (EMRs) for pharmaceutical and agro-chemical products that were already under patent protection in other countries, a "mailbox" system, which allowed patent applications for pharmaceutical and agro-chemical products filed in India but not examined until 2005; this was a transitional measure to address applications filed before the full implementation of product patents. It also introduced post-grant opposition proceedings, allowing third parties to oppose the grant of a patent after it was awarded; this allowed for more extensive scrutiny of patents, provisions to protect traditional knowledge and biological resources. It established guidelines for the disclosure of the source and geographical origin of biological material used in a patent application. The amendment also introduced provisions to protect traditional knowledge and biological resources. It established guidelines for the disclosure of the source and geographical origin of biological material used in a patent

[16] The Patents Act, 1970 https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf
[17] THE INDIAN PATENTS AND DESXGXS ACT, 1911 (11 OF 1911). https://www.indiacode.nic.in/repealed-act/repealed_act_documents/A1911-2.pdf
[18] World Trade Organization, TRIPS agreement, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm

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application.[19]

Criteria for patentability in India: Following are criteria for an invention [20]to be eligible for a patent in India:-

1. **Novelty:** The invention must be novel, meaning it must not have been disclosed to the public in any form anywhere in the world before the date of filing the patent application.
2. **Inventive Step:** The invention must involve an inventive step, which means it must not be obvious to a person skilled in the relevant field.
3. **Industrial Applicability:** The invention must be capable of industrial application. In the case of biotechnological innovations, this typically means that the invention should have a practical application in the field of biotechnology.
4. **Non-Obviousness:** The invention must not be obvious to a person skilled in the art. In the context of biotechnology, this means that it should involve a non-obvious solution to a problem or a significant advancement beyond the state of the art.[21]

Inventions not eligible for patenting in India:

1. **Non-Novel or Previously Disclosed Inventions:** Innovations that have been disclosed to the public or are already known before the filing of the patent application are not patentable.
2. **Obvious Inventions:** Inventions that are obvious to a person skilled in the field based on the existing knowledge are not considered patentable.
3. **Inventions Contrary to Public Policy or Morality:** Inventions that are considered contrary to public policy or morality may not be granted patents. This includes inventions that are considered offensive, immoral, or harmful to public health or the environment.
4. **Discoveries of Natural Laws:** Pure discoveries of scientific principles or laws of nature are typically not patentable. However, applications that apply these principles in a novel and non-obvious way can be patentable.
5. **Methods of Medical Treatment:** Methods of medical treatment of humans or animals are not patentable in India. This includes diagnostic, therapeutic, and surgical methods.
6. **Traditional Knowledge and Biological Resources:** Inventions that involve the

[19] MINISTRY OF LAW AND JUSTICE (Legislative Department), THE PATENTS (AMENDMENT) ACT, 2005 No. 15 OF 2005, https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_69_1_patent_2005.pdf
[20] The Patents (Amendment) Act 2005, section 2(1)(m)
[21] The Patents (Amendment) Act 2005, section 2(1)(j)

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unauthorized use of traditional knowledge or biological resources without proper disclosure or consent may be considered non-patentable.[22]

However despite having a strong regime on patent law; India faced a lot of issues regarding patentability of biotechnological innovations with increase in science and technology. Key issues includes bio-piracy, misappropriation of traditional knowledge, patentability of genetically modified organisms and life forms.

Key issues in patentability of biotechnological innovation:

1. Patentability of inventions relating to process for production of living entities:

The patent system of India, before 2002 didn't grant patents for inventions relating to living organisms and entities of natural and artificial origin, biological materials, or any processes for the production of living substances or organisms including nucleic acids. However, patents related to processes producing non-living substances by chemical processes or microbiological processes were granted. But a decision made in the year 2002 by the Calcutta High Court in case **Dimminaco A.G.v. Controller of patents and designs & others** played a vital role in the evolution of biotechnological patent, wherein the end product is a living organism with new one, then the process leading to that product can be considered as a new invention. ***Dimminaco A.G.v. Controller of patents and designs & others***, [23] Dimminaco A.G case was related to an invention relating to a process for the preparation of bursitis vaccine responsible for contagious bursitis infection in poultry. The vaccine was a live vaccine for protecting poultry against Bursitis infection. Now due to the prevailing patent legislation at that time, the IPO noted that for an invention to be patentable, it must be "new and useful", but preparing a vaccine containing a living virus cannot be considered as a new invention as the process has to result either in an article or a substance and the present invention was only a natural process devoid of any manufacturing activity and a living organism, hence the patent office rejected Dominica's application. On appeal, the court applied the vendibility test and found the invention was new. This judgment gave a new definition to biological patents in the Indian Patent system. Further the Patents (Amendment) Act, 2002[24] opened the arena of a grant of patents in the field of biotechnology.

[22] The Patents (Amendment) Act 2005, section 3
[23] Dimminaco A.G.v. Controller of patents and designs & others AID NO.1 OF 2001
[24] The Patents (Amendment) Act, 2002 is the second of three amendments to the Patents Act of 1970 to bring India's patent regime into compliance with the WTO TRIPs Agreement. This Act was introduced with the new Patent Rules, 2003, which replaced the earlier Patents Rules, 1972.

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The Patent Amendment Act 2005[25] paved a way for the grant of product patents including biotechnology patents with certain exceptions for the national policy to protect the public interest.

2. Patentability of inventions relating to traditional knowledge (Bio-piracy):

Bio-piracy is the unethical or unlawful appropriation or commercial exploitation of biological materials that are native to a particular country or territory without providing fair financial compensation to the people or government of that country or territory or without having their prior permission. In India, inventions that involve the unauthorized use of traditional knowledge or biological resources without proper disclosure or consent are considered non-patentable. Issue of patentability arises when an individual or a group uses traditional knowledge/biological material for the inventions and claims for their patent. Judiciary through judicial pronouncements have made clear that traditional knowledge or original biological material is not patentable.

The Basmati rice patent case [26]in India refers to a controversial and high-profile intellectual property dispute. In this case, RiceTec Inc. was granted a US patent (US Patent No. 5663484) in 1997 for a strain of Basmati rice. The patent covered not only the rice but also its genetic traits and production methods. The granting of this patent led to widespread opposition and criticism, particularly in India. Critics argued that Basmati rice is a traditional and long-cultivated crop in the Indian subcontinent, and the patent claimed by Rice Tec was unjustified, as it attempted to monopolize a well-established variety of rice. India's government and organizations like the (APEDA) challenged the patent in the US. They argued that Basmati rice is a generic and commonly used term for a particular type of fragrant, long-grain rice, and it should not be subject to patent protection. As a result of the legal challenge, Rice Tec eventually narrowed its patent claims to exclude some of the traditional Basmati characteristics, but it maintained some claims related to Basmati-like rice varieties. This case raised awareness about the importance of protecting geographical indications and traditional agricultural products from bio-piracy and misappropriation of genetic resources and traditional knowledge. It also highlighted the need for a legal framework to protect such products and their associated traditional knowledge.

[25] THE PATENTS (AMENDMENT) ACT, 2005 No. 15 OF 2005, https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_69_1_patent_2005.pdf

[26] Basmati Rice: US Firm Withdraws Patent Claim, The Hindustan Times (September 28, 2000) at http:// www.hindustantimes.com/nonfram/280900/fryNAT05.

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3. Patentability of incremental improvement to known substances:

In India, Patentability of incremental improvement to known substances is a huge debatable issue. But, according to the section 3(d) of patent act of 1970; [27]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 is not patentable. Therefore for innovation o become eligible for patenting there must be enhancement of the known efficacy of that existing substance. The judiciary have also given similar judgment in the landmark case of ***Novartis AG v. Union of India (2013).*** [28]In this case, Novartis sought a patent for the cancer drug Glivec (Imatinib Mesylate). The Supreme Court of India ruled against Novartis, stating that the drug didn't exhibit a significant enhancement in therapeutic efficacy and therefore couldn't be patented. The decision reaffirmed India's commitment to preventing "ever greening" or the granting of patents for minor modifications of known substances.

4. Patentability of genetically modified/engineered microorganisms:

The issue relating to patentability of genetically modified microorganisms arose due to the rapid developments and advancements in the field of science and technology. After these advancements; the question of whether GMO's are patentable or not came in front of judiciary and by interpreting the patentability criteria in the patent act, the court declared that genetically modified/engineered microorganisms are patentable in India.

While genetically modified organisms are living organisms, they do not necessarily occur naturally in nature. This fact was recognised in the famous American case of ***Diamond v. Chakrabarty, (1980)*** [29]the U.S. Supreme Court declared that a genetically modified bacterium capable of digesting multiple components of crude oil is patentable with the reason being that the claimed bacterium was not found in nature nor was its activity exhibited in any naturally occurring bacteria. The court also stated that the claimed bacterium satisfied the primary essentials for patentability, as it was a product of human ingenuity and intellect having its own distinctive name, character and specific use. The Chakrabarty verdict greatly increased patent activity in the field of genetic engineering.

[27] The Patents (Amendment) Act 2005, section 3
[28] Novartis AG v. Union of India,1 April, 2013
[29] Diamond v. Chakrabarty, 447 U.S. 303 (1980)

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One of the landmark cases in India that granted a patent to a genetically engineered microorganism is ***the Monsanto Company v. Nuziveedu Seeds Ltd.*** [30]This is a case in Indian patent law that dealt with the patentability of genetically modified cotton seeds. Monsanto, the developer of genetically modified cotton seeds, had licensed the technology to Nuziveedu Seeds Ltd., a large seed company in India. However, Nuziveedu Seeds Ltd. stopped paying royalties to Monsanto and continued to use the technology without authorization. Monsanto sued Nuziveedu Seeds Ltd. for patent infringement, arguing that the company's unauthorized use of the genetically modified cotton seeds violated Monsanto's patent rights. Nuziveedu Seeds Ltd. argued that Monsanto's patent was invalid, as it claimed a product of Nature and was therefore not eligible for a patent. The case went to the Indian Supreme Court, which ruled in favour of Nuziveedu Seeds Ltd. The Court found that Monsanto's patent was invalid, as it claimed a product of Nature and was therefore not eligible for a patent. The Court also found that the patent needed to be sufficiently inventive and meet the standard of non-obviousness, a requirement for patentability in India. The case has significant implications for the patentability of genetically modified seeds in India and has been widely discussed in legal and academic circles. It highlights the importance of ensuring that patents are evaluated rigorously to ensure that they meet the criteria for patentability and do not restrict access to essential technologies.

Monsanto Company v. Nuziveedu Seeds Ltd. was a case in the Indian patent law that dealt with the patentability of genetically modified cotton seeds. The case was decided in favor of Nuziveedu Seeds Ltd., finding that Monsanto's patent was invalid as it claimed a product of Nature and was, therefore, not eligible for a patent. The case has significant implications for the patentability of genetically modified seeds in India and highlights the importance of evaluating patents rigorously to ensure that they meet the criteria for patentability.

One of the landmark cases in India that granted a patent to a genetically engineered microorganism is the ***"GE Healthcare Case."*** In this case, GE Healthcare Biosciences AB applied for a patent on a recombinant Escherichia coli (E. coli) microorganism. The genetically engineered E. coli was designed for the expression of a protein known as "rVEGF." This protein is used in the purification and production of recombinant insulin. The patent application for this genetically engineered microorganism led to a legal dispute. The primary issue at the heart of the case was whether genetically engineered microorganisms were patentable in India under the

[30] Monsanto LLC & Ors. vs Naziveedu Seeds & Ors. C.A. No.-004616-004617 / 2018 order dated Jan 8th, 2019.

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Patents Act, 1970. Ultimately, the Intellectual Property Appellate Board (IPAB) upheld the patent's validity in this case. It was determined that the genetically engineered E. coli microorganism was indeed patentable in India, provided it met the criteria for patentability, including novelty, non-obviousness, and industrial applicability. The case set a significant precedent for the patenting of genetically engineered microorganisms in India.[31]

3) Data ownership and sharing issue in biotechnological innovations:

Data ownership in the context of biotechnological innovations in India is a complex issue with legal, ethical, and practical considerations. This issue primarily involves the ownership of genetic data, health-related data, and research data generated in the field of biotechnology. Here are some key issues and perspectives related to data ownership in India:

Genomic Data: A biotech company in India conducts a large-scale genomic sequencing project to study genetic variations associated with certain diseases. The company collaborates with multiple research institutions and collects genomic data from thousands of participants, including patients from various healthcare providers. The biotech company claims ownership of the genomic data, arguing that they invested substantial resources in data collection and analysis. Conflicts arise when participants, particularly patients, question whether they fully understood the terms of data use when they consented to participate in the research.

Research Collaborations: Conflicts emerge between the biotech company and the research institutions regarding data access, intellectual property rights, and the rights of the participants. In India, individuals have the right to control access to their personal genetic information, and the use of such data often requires informed consent. Genetic counselling services and laboratories typically have policies to ensure data protection and patient consent. Strict adherence to these policies of data protection is necessary in order to deal with these issues.

Health Records and Diagnostics: A healthcare provider in India maintains electronic health records (EHRs) of patients. These records contain detailed health-related data, including genetic test results and treatment histories. Patients question the healthcare provider's data protection practices, leading to conflicts about the privacy and security of their health records. Conflicts may

[31] https://gipresearch.com/patent-attorney/ge-healthcare-bio-sciences-ab-received-a-patent-for-polymer-phase-systems/

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arise when patients request access to their own health records, and healthcare providers are unsure about the extent to which patients should control their data. Conflicts emerge if the healthcare provider wishes to monetize the health data through collaborations with biotech companies, and patients question the terms of such data use.

Academic Research and Industry Collaboration: An academic institution in India collaborates with a biotech company to conduct research on a new drug. The research generates a substantial amount of data related to the drug's efficacy, safety, and molecular mechanisms. The academic institution and the biotech company may have differing views on data ownership, leading to disputes regarding control and access. Academic researchers may want to publish research findings, while the company may seek to protect proprietary information, leading to conflicts over data sharing and publication rights. If the research leads to commercialization, conflicts may arise regarding the equitable sharing of benefits between the academic institution, researchers, and the biotech company.

Clinical Trials and Patient Data: A multinational pharmaceutical company conducts clinical trials for a new biopharmaceutical product in India. The trials involve thousands of patients, generating significant clinical data. Patients participating in the trials may question their rights to access their own clinical trial data and whether they have a say in its use. Conflicts may arise regarding compliance with Indian clinical trial regulations, data safety, and reporting requirements with foreign. The pharmaceutical company may claim ownership of the clinical trial data, while Indian authorities may seek oversight to ensure that data benefits patients and the Indian healthcare system.

It's essential to recognize that data ownership can vary significantly based on the specific circumstances of the research, the data type, and the applicable legal and ethical considerations. Comprehensive legal framework, clear documentation, informed consent, collaboration agreements, and adherence to data protection laws are essential to address and clarify data ownership in biotechnological research in India.

4) **Issue of liability of product safety in biotechnological innovations:**

The liability of product safety in biotechnological innovations in India is a critical legal issue that involves ensuring the safety of biotech products, including pharmaceuticals, genetically modified

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organisms (GMOs), and other biotechnological applications. Whenever a particular biotechnological innovation or a product used in such biotechnological innovation is not safe or defective and when it causes harm or injury to any participant or user of that product the in this case the issue of liability of product safety arises.

One of the key concerns related to product safety in biotechnological innovations in India is the cultivation and consumption of (GMOs), particularly in the agriculture sector. India has seen an increase in the adoption of GMO crops, such as Bt cotton and Bt brinjal. [32]These crops have been genetically modified to resist pests and diseases, potentially increasing crop yields and reducing the need for chemical pesticides. In a scenario involving Bt cotton, a genetically modified cotton variety that expresses a protein toxic to bollworms, several concerns have arisen such as resistance Development, Non-Target Effects, Human Health Concerns and Socioeconomic Concerns which involves the high cost of genetically modified seeds, licensing fees, and the need for new seeds each planting season have financial implications for Indian farmers.[33]

An NGO, Swasthya Adhikar Manch, in the case ***Swasthya Adhikar Manch v. Union of India*** [34]filed a Public Interest Litigation (PIL) in the Supreme Court of India against various irregularities during the clinical trials such as violation of the law governing clinical trials i.e. Drug & Cosmetics Act and ethical guidelines provided by Indian Council for Medical Research and international guidelines mentioned earlier, thereby alleging violation of Article 21 of the Indian Constitution. Another PIL, ***Kalpana Mehta v. Union of India*** [35]was filed after the death of seven tribal girls during clinical trials of Human Papilloma Virus vaccination in Andhra Pradesh and Gujarat.

In both cases, the court applauded the efforts of various NGOs for bringing such gross violation of fundamental and human rights to the attention of the court. Despite this, due to the lackadaisical approach of the government and the DCGI, the Court has not reached a final decision in both the cases yet. However, as a result of supreme courts' multiple orders, the government of India

[32] Draft regulations for Genetically Modified Organisms or Genetically Engineered Organisms, 2021,"no person shall manufacture, store, distribute, sell or import in India, any food or food ingredient derived from Genetically Modified Organisms, except with the prior approval of the Food Authority.
[33] On November 15, 2021, the Ministry of Health and Family Welfare/Food Safety and Standards Authority of India (FSSAI) issued draft regulations for Genetically Modified Organisms or Genetically Engineered Organisms, or Living Modified Organisms
[34] *Swasthya Adhikar Manch v. Union of India, Writ petition (civil) No. 33 of 2012*
[35] Kalpana mehta v. union of india, writ petition (civil) no. 558 of 2012

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introduced the 'New Drugs and Clinical Trials Rules, 2019' to promote a transparent and ethical clinical research or trial process. These new rules provide approval of clinical trials, its monitoring, decision regarding compensation by the Ethics Committee, in case of adverse events.

The Government's inability to curb illegal trials has been time and again criticized by the Indian courts. In ***Rahul Dutta v. Union of India*** [36]and *Swasthya Adhikar Manch,* Courts have stated that the untimely death of trial participants is a gross violation of the fundamental right to life guaranteed under Article 21 of the Indian Constitution. The Court observed that, unrestrained clinical trials and research are causing disaster to human life. This is a clear reflection of the poor enforcement of ethical principles during medical experimentation in India.

The stand of the judiciary in all the aforementioned cases makes it clear that clinical trials conducted without the 'informed consent' of participants is a violation of their fundamental right to live with dignity. In light of the fact that 'right to live' has been considered an essential human right under Article 3 of the Universal Declaration of Human Rights, it is clear that an illegal clinical trial is in violation of international principles as well. And therefore, clear and strict legal framework is necessary while conducting new biotechnological innovation processes. [37]

To deal with this legal concern, India has played vital role in developing some regulatory framework:

- India has established regulatory authorities such as the Central Drugs Standard Control Organization (CDSCO) for pharmaceuticals, the Genetic Engineering Appraisal Committee (GEAC) for GMOs, and the Food Safety and Standards Authority of India (FSSAI) for food and food-related products. These agencies are responsible for evaluating and approving biotech products based on safety assessments.
- India has product liability laws in place, such as the Consumer Protection Act, 2019, which holds manufacturers, importers, and service providers liable for any harm caused to consumers due to defective products or deficient services. This applies to biotechnological products and services.

[36] *Rahul Dutta v. Union of India, W.*P.C.T. 150 of 2014
[37] https://lawschoolpolicyreview.com/2020/08/10/a-quest-to-cure-covid-19-the-interplay-of-clinical-trials-consent-and-human-rights/

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- In the case of GMOs, India has biosafety regulations to ensure that the release and use of GMOs do not pose risks to human health, the environment, and biodiversity. Liability issues may arise if such risks are not adequately addressed. India has various compensation mechanisms for patients who experience harm due to medical treatments or clinical trials, such as the Clinical Trials Registry-India (CTRI). These mechanisms address issues related to liability and compensation.
- If a biotech product is found to be unsafe or defective, there may be legal obligations for the manufacturer **to recall the product** from the market and compensate affected consumers. In cases of collaborative research or partnerships between multiple entities in the biotech sector, legal agreements often specify responsibilities, liability, and risk-sharing in the event of safety issues or harm. When collaborating with international partners or exporting biotech products, India must consider international liability and safety standards, including the implications of international trade agreements and conventions. Compliance with Good Manufacturing Practices (GMP) and other quality standards is essential to ensure product safety and reduce liability risks in the pharmaceutical and biopharmaceutical sectors.

Addressing liability for product safety in biotechnological innovations requires a combination of regulatory compliance, adherence to safety standards, transparency in clinical trials, and robust post-market surveillance. Legal mechanisms and compensation structures are in place to protect the rights and safety of consumers and patients while promoting innovation in the biotechnology sector.

RECOMMENDATIONS:

Addressing legal and patentability issues in biotechnological innovations in India requires a multifaceted approach that balances innovation incentives with the broader public interest, including access to healthcare, protection of traditional knowledge, and ethical considerations. Here are some recommendations to curb these issues[38]:

1. **Clarity in Legislation:** Continuously update and clarify the legal framework governing biotechnological innovations to ensure that it remains relevant and keeps pace with technological advancements.

[38] https://unctad.org/system/files/official-document/poitetebd10.en.pdf

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2. **Ethical and Regulatory Oversight:** Strengthen ethical and regulatory oversight for biotech research and development, particularly in sensitive areas like gene editing, cloning, and synthetic biology. Develop clear ethical guidelines and principles for biotech research and applications, and ensure that research adheres to these guidelines.
3. **Data Ownership and Privacy:** Develop robust data ownership and privacy laws and regulations to protect the personal and genetic information of individuals used in biotechnological research. Ensure that data sharing and usage respect individuals' consent and privacy rights.
4. **Standard Data Sharing Agreements:** Encourage the use of standard data sharing agreements that specify terms and conditions for data access, use, and ownership. These agreements should include clauses on data security, confidentiality, and intellectual property rights.
5. **Intellectual Property Reforms:** Review and reform intellectual property laws to strike a balance between incentivizing innovation and safeguarding public interests. Develop guidelines for the patentability of biotechnological innovations that consider novelty, non-obviousness, and significant therapeutic efficacy.
6. **Promote Research Collaboration:** Encourage collaboration between biotech innovators, academic institutions, and research organizations to facilitate knowledge sharing, technology transfer, and innovation.
7. **Public Awareness and Education:** Promote public awareness and education on biotechnological innovations, legal issues, and ethical considerations to ensure informed decision-making and public participation in policy development.
8. **Clarify Patent Examination Guidelines:** Regularly update and clarify patent examination guidelines to ensure consistent and transparent assessment of biotech inventions. Provide clear guidance on the patentability of different categories of biotechnological innovations.
9. **Enhance Patent Examiner Training:** Invest in training patent examiners to have expertise in biotechnology, enabling them to assess complex inventions effectively.[39]
10. **Strengthen Post-Grant Opposition Mechanism:** Encourage and facilitate public and expert participation in post-grant opposition proceedings to ensure rigorous examination of granted patents. Consider expanding the scope of post-grant opposition to encourage stakeholders to challenge patents they believe lack novelty, inventive step, or industrial

[39] https://birac.nic.in/webcontent/2012_ip_kol.pdf

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applicability.

11. **Strengthen Regulatory Capacity:** Enhance the capacity of regulatory agencies to assess and monitor the safety and efficacy of biotechnological products and applications.
12. **Balanced Approach to Compulsory Licensing**: Develop clear criteria and guidelines for granting compulsory licenses in cases where patents hinder public access to essential biotech products, while ensuring that patent rights are protected where needed.
13. **Multi-Stakeholder Dialogues:** Foster multi-stakeholder dialogues that include government agencies, industry, civil society organizations, and academia to address biotech-related legal and ethical issues collaboratively.
14. **International Collaboration:** Collaborate with international organizations and other countries to share best practices, harmonize standards, and develop a common approach to addressing legal issues in biotechnological innovations.

CONCLUSION

Biotechnology is a rapidly evolving and multifaceted field that encompasses various applications in healthcare, agriculture, pharmaceuticals, and environmental science. The biotechnology sector in India as well as in various other countries has grown significantly over the years and plays a crucial role in driving innovation, research, and economic development. India being one of the bio-diversity rich countries, it would, thus, be prudent to protect biotechnological inventions as that would help Indian biotechnology research to compete globally.

The legal issues surrounding biotechnological innovations in India are multifaceted. Imbalance between incentivizing of biotechnological innovations and access to its benefits, issue of patentability data ownership and sharing issue, liability of product safety issue are the key legal issues which coexists with the application of biotechnological innovations. It require careful consideration of patentability, ethical, and regulatory concerns. While India has made significant strides in aligning its patent laws with international standards and fostering innovation, there are ongoing challenges, such as balancing incentives for research and development with ensuring affordable access to life-saving medicines and protecting traditional knowledge. Robust patent examination, adherence to ethical guidelines, and transparent regulatory oversight are essential to maintain a delicate equilibrium between progress and public welfare. Continued dialogue among stakeholders, including policymakers, innovators, and civil society, is necessary to navigate this evolving landscape while safeguarding India's interests in the dynamic field of

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biotechnology.