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**THE SYNERGY OF BIOTECHNOLOGY AND INTELLECTUAL PROPERTY  
RIGHTS IN THE FIELD OF PHARMACEUTICAL MICROBIOLOGY – A REVIEW**

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**ABSTRACT**

Biotechnology and intellectual property rights (IPR) are inseparable subjects crucial to the advancement and preservation of innovations in the pharmaceutical domain. Biotechnology represents the cutting-edge technology of the 21st century, encompassing scientific and engineering methods aimed at altering biological entities or their components for diverse purposes, such as pharmaceutical advancements, agricultural enhancements, and sustainable biofuel production. Concurrently, IPR serves as a fundamental mechanism granting creators exclusive rights and safeguards for their novel technologies, processes, inventions, or designs, thereby facilitating commercial exploitation while deterring unauthorized usage by others. The fusion of biotechnology and IPR has proven instrumental in driving scientific progress and economic growth. By granting innovators the incentive of exclusivity and control over their discoveries, IPR fosters investments in research and development, thereby stimulating further breakthroughs. Striking a balance between encouraging innovation and ensuring broader access to life-saving technologies remains an ongoing challenge. Policymakers and stakeholders need to devise robust frameworks that incentivize biotechnological advancement without compromising public health or limiting the equitable distribution of resources.

In conclusion, the interplay between biotechnology and IPR is pivotal for fostering progress and protecting creators' rights in the life sciences sector. Careful consideration of ethical and social aspects is essential to navigating the complexities and potential implications that arise at this unique intersection, thereby creating a balanced and beneficial biotechnological landscape for all of humanity.

**Keywords: Biotechnology, Intellectual Property Rights, Patent, Trademark, Open-source**

**Biotechnology**

## INTRODUCTION

Biotechnology and intellectual property rights (IPR) are two interrelated topics that are vital to the creation and preservation of novel developments in the field of pharmaceuticals. The concept of "biotechnology" is frequently used to refer to the modern technology of the 21st century. Biotechnology is the use of scientific and engineering methods to change biological things or their constituents for a variety of reasons, such as the development of novel medicines, increasing agricultural output, or producing sustainable biofuels. Intellectual Property Rights provide exclusive rights and protection for the creators of new technologies, processes, inventions, or designs enabling them to commercially exploit their work while preventing unauthorized use by others. However, the intersection of IPR and biotechnology also raises ethical and social considerations.

## INTELLECTUAL PROPERTY AND BIOTECHNOLOGY

### Overview Of Intellectual Property

The conception of "creations of the mind" (frequently ascertained to as "intellectual property, or IP") includes everything from erudite and cultural creations to discoveries in wisdom. These IPRs for an invention are granted to the innovator for a destined quantum of time, during which the innovator can benefit from

their work. Individualities have the right to the protection of both material and moral rights performing from any technological, erudite workshop, or creative work anyhow of whether the author, agrees with The Universal Declaration of Human Rights Section 2 of 27th Article, which serves as the foundation for any IPR. The forms of IP, which are all fairly defended, include patents, imprints, trademarks, trade secrets, and designs. These patents are certain to be the most important kind of intellectual property in the pharmaceutical sector [1, 2].

### Biotechnology in a Rapidly Changing Field

Since the inception of civilization, the biotechnology field has served various purposes and has been categorized into several stages of evolution. The quantity of biotechnology intellectual property is another indicator of its progress. When compared to the patent applications submitted to the European Patent Office (EPO), biotechnology invention has consistently been rated in the leading 10 for several years. He issued 6.8 thousand biotechnological applications for patents in 2012, accounting for 4.8% of all EPO applications [3].

A systematic overview of the growth of biotechnology introduced its three major stages:

- ❖ Ancient biotechnology,
- ❖ Classical biotechnology,
- ❖ Modern biotechnology (circa 1950 to the present).

The "ancient biotechnology stage" is defined as the period before 1800. The majority of development, often known as "discovery," occurs at this stage. The "classical biotechnology" phase of biotechnology's development and evolution started around 1800.

The outbreak of World War II presented numerous challenges for scientific research. However, afterward, World War II, many discoveries in the field of biotechnology greatly influenced the progress and achievements of today's biotechnology. This phase is called Modern biotechnology [4].

## **INTERSECTION OF BIOTECHNOLOGY & INTELLECTUAL PROPERTY**

The interface between biotechnology and intellectual property is a complex and important area due to the need to protect the novelty of biotechnology discoveries through various intellectual property methods.

### **Patent**

A sort of intellectual property known as a patent is one that the government has temporarily awarded to an inventor. 20 years following the submission of an invention application that grants exclusivity. The innovation must satisfy several

requirements, such as novelty, non-obviousness, and industrial benefit, to be given a patent. A patent application, which normally includes a thorough description of the invention and may also include drawings, claims, and an abstract, must be filed by the inventor to reveal the innovation.

Once a patent is granted, the patent holder has the right to enforce the patent and take legal action against anyone who infringes upon their exclusive rights. This can include seeking damages or injunctions to prevent others from using the patented invention without permission.

What is patentable?

As a general rule, only man-made products and processes are patentable, and any innovation that is new, original, and useful in contemporary society is eligible for patent protection. More essential, a person with ordinary expertise in the relevant field should be able to easily understand the idea. And that expert should acknowledge that the description provided in the patent application is adequate for duplicating and using it with her or his expertise in that sector [5, 6].

### **Gene Patent**

A gene patent is a type of patent that grants exclusive rights over a specific DNA sequence or gene, or a fragment of genetic material associated with a particular gene or genetic marker. Gene patents have been the

subject of significant debate and controversy. Patents on human genes are obtained by cloning and describing the sequence of the gene and its role.

Three distinct categories of Gene's inventions are covered by her patents:

- (1) Diagnosis
- (2) Matter composition and
- (3) Use functional [7, 8].

### **Trade mark**

In layman's terms, a trademark is any sign that personalizes a competing product. A mark is used to distinguish one's products from those of other companies. The primary purpose of a trademark is to enable consumers to recognize and associate certain products or services with a particular source or origin.

Benefits of trademark registration include:

**Exclusive Rights:** To prevent others from adopting confusingly similar marks, trademark registration grants the owner the sole right to use the mark in the registered segment of products or services.

**Brand Protection:** Trademarks help build brand identity and protect the reputation and goodwill associated with a particular product or service.

**Market Distinction:** A registered trademark can help distinguish a business from its competitors and create a unique market presence [9, 10]

### **Plant Variety Protection (PVP)**

Plant variety protection is a system that grants breeders exclusive rights over a new plant variety for a certain period, typically 20 to 25 years. The rights conferred under PVP may include the ability to control the production, sale, and distribution of the protected variety. To obtain PVP, breeders must demonstrate that their variety is distinct, uniform, stable, and novel compared to existing varieties [11].

## **CHALLENGES AND CONTROVERSIES OF PATENTS**

### **Patentability Of Biotechnological Invention in India**

Biotechnology-patented inventions are developed in three main areas:

- ❖ Agriculture Patent
- ❖ Industry Patent
- ❖ Pharmaceutical Patent

#### **Agricultural Patent:**

India is conducting ongoing biotechnology research and development (R&D), particularly in the area of agricultural enhancement. The features of genetically modified (GM) plants include input qualities like pest and disease resistance, output traits like delayed fruit ripening and removal of saturated fat, and agronomic traits like tolerance to acidity, salinity, and drought.

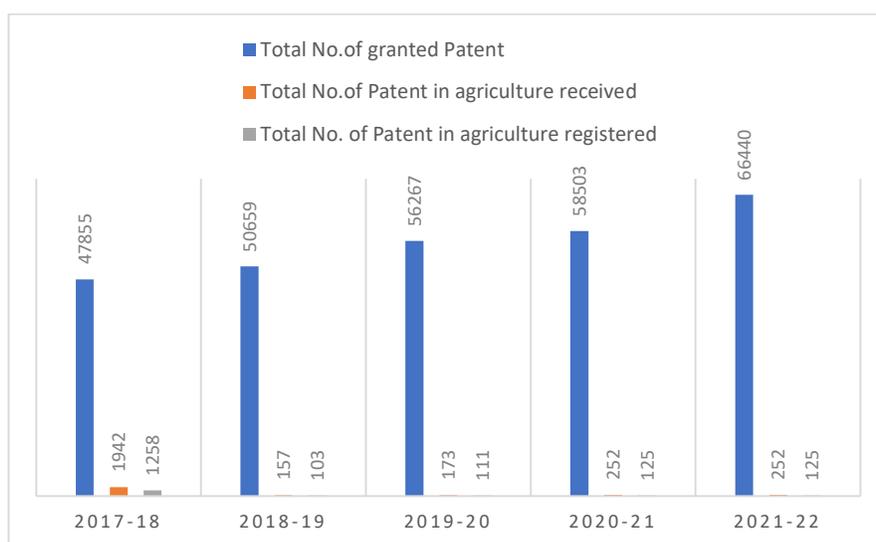
Small agricultural biotech companies need to build strong intellectual property (IP) portfolios. A key step in building an IP

portfolio is licensing third-party patent rights [12].

The **Table 1** shows the gross output value of agricultural and food patents in India.

**Table 1: Compiled from CGPDTM annual reports on agricultural patents,2017 -2022 [13]**

Year	Total number of granted patents	Total number of patents in agriculture received	Total number of patents in agriculture registered
2017-18	47855	1942	1258
2018-19	50659	157	103
2019-20	56267	173	111
2020-21	58503	252	125
2021-22	66440	252	125



**Figure 1**

### Industrial Patent

Encourage the growth of industries that aid in the encouragement of technical innovation, the transfer and dissemination of technology, and the promotion of inventions by encouraging both the protection and use of innovation.

In Biotechnology field is dominated by companies that provide both

pharmaceuticals and biotechnology products. Biotech startup registrations surged nationwide in 2021, with nearly 1,128 established to register, the highest year-long since 2015. The dimensions of India's economy are evaluated at US\$80.12 billion in 2021. This is up 14.13% from \$70.2 billion in 2020.

**Table 2: Compiled from CGPDTM annual reports on Industrial patents,2017 -2022 [13]**

YEAR	Total number of applications received in food	Total number of applications registered in food
2017-18	137	198
2018-19	40	16
2019-20	44	20
2020-21	174	143
2021-22	61	25

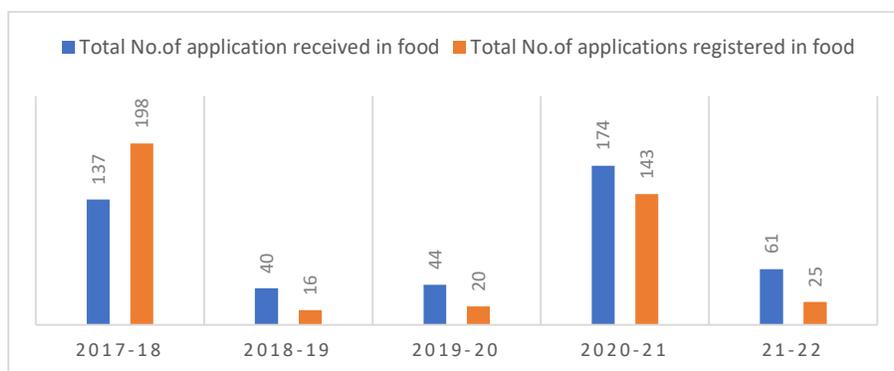


Figure 2

### Pharmaceutical Patent

India is a critical maker of universally perceived high-quality pharmaceutical products & has gotten to be WTO/TRIPs compliant in the post-GATT period.

Biotechnology is utilized for pharmaceutical and drug fabricating through organic forms. The Licenses and Plans Act of 1911 established a uniform administrative framework for all developments in India. However, the government introduced the Patent Act in 1970, which disqualified products containing agrochemicals and prescription medications from being eligible for licensing. The embargo was put up to end India's dependence on imports for large quantities of medications and to promote the development of a self-sufficient indigenous pharmaceutical industry [14].

### BIOPIRACY AND BIOETHICS

#### Biopiracy

Biopiracy and bioethics are two interconnected topics that raise important ethical concerns related to the exploitation

and ownership of biological resources and knowledge.

The Activity Gather on Disintegration, Innovation, and Concentration, a North American promotion group, coined the term "biopiracy" to refer to the unremunerated commercial use of organic assets from developing countries as well as the licensing by organizations of claimed development based on such assets or information. Biopiracy includes the patenting of plant varieties or medicinal knowledge without the informed consent or fair compensation of the communities who have traditionally used or developed them. This can result in the exclusion of those communities from accessing or benefiting from their resources, as well as the potential loss of cultural heritage and biodiversity [15].

To address concerns related to biopiracy, international agreements, and national laws have been established.

For plants from India, a few United States licenses have been granted. Three of the more well-known ones are: [16]

Table 3: Plant from India Patent by Company

COMPANY	PLANT
RiceTec Inc	Basmati (Hindi and English)
W.R. Grace	Neem (Hindi) Margosa Tree (English)
Cromak Research Inc	Jamun (Hindi) Rose Apple Tree (English) Karela (Hindi) Bitter Gourd or Bitter Melon (English) Brinjal (Hindi) Eggplant (English)

### Bioethics

Ethics is the application of moral principles and standards to human activities. A branch of ethics known as "bioethics" provides well-considered and flawless arrangements that combine moral criteria for actual or anticipated ethical dilemmas that practitioners in medicine and research face. Bioethics deals with interactions among professionals and patients, professionals and society, and society and patients, in contrast to professional behavior, which is concerned with managing relationships and intuition amongst professionals [17].

The law has frequently been silent, contradictory, or immorally wrong on issues that are crucial to the biomedical community, which has led to the development of modern bioethics during the past forty years. The emergence of biotechnology at a rapid rate, the inability of the legal system and legislatures to address novel and critical issues, and, in the United States, the growing liability crisis have prompted the medical community to search for ideas for some of the challenging

problems that practitioners have had to deal with daily [18].

### REGULATORY BARRIERS & INDUSTRY INTERESTS:

Regulatory barriers and industry interests are two key factors that influence the dynamics surrounding biopiracy and bioethics. Let's discuss each of these factors:

#### Regulatory Barriers:

Many authors (such as Geroski, 1991; Parker & Stead, 1991; Church & Ware, 2000; European Commission, 2004; OECD, 2005; Bitzenis, 2009) view regulatory obstacles as very significant obstacles to the entry of new rivals, primarily because natural monopolies, monopoly rights, and licenses are produced by governmental action and have legal backing for their use. Regulatory obstacles include laws, rules, and governmental industrial policies.

The following section will list several of the many sources of legal entry barriers [19].

#### Natural monopolies, monopoly rights, and licenses:

Some industries naturally lend themselves to monopolies due to high fixed costs or limited resources. In such cases, a

single company may hold exclusive rights to provide certain goods or services. Licenses can also be granted by the government, allowing limited access to specific industries [20].

**Tariffs:**

Tariffs are taxes applied to imported goods, raising their price in comparison to those made domestically. By increasing the cost of imported goods, tariffs can shield domestic industries from foreign competition.

**Quotas:**

The quantity of particular items that can be imported into a country is restricted by quotas. By restricting the supply of imported goods, quotas protect domestic industries [21].

**Subsidies:**

Government-sponsored financial aid given to domestic companies typically takes the form of grants, tax breaks, or low-interest loans. Subsidies can reduce manufacturing costs and increase domestic firms' competitiveness.

**Government procurement:**

When the government is a major buyer of goods and services, it can establish requirements and specifications that may favor incumbent suppliers, making it challenging for new entrants to compete for government contracts.

**Technical barriers:**

Technical regulations and standards imposed by governments can serve as barriers to entry. Compliance with specific technical requirements may require significant investments in equipment or infrastructure, making it difficult for new entrants to meet these standards.

**Procedures for registering, certifying, granting licenses, and applying for social security:**

Administrative regulations, such as social security compliance, certification, licensing, and registration, can be expensive and burdensome for new enterprises, functioning as entry obstacles [22].

**Industry Interest:**

Industry interface is a fundamental factor in the context of bio-preservation and bio-ethics. Businesses, particularly those in the biotechnological, pharmaceutical, and agri-environmental sectors, have a strong interest in obtaining and exploiting natural resources, genetic material, and traditional data for inquiry, improvement, and commercial exploitation.

To address this, moral rules, codes of conduct, and certification instruments have been created to energize mindful industry hones and guarantee regard for the rights of inborn communities. Collaboration between industry, the scholarly community, government bodies, and innate agents is significant to strike an adjustment between

industry interface and moral contemplations.

It's essential to foster association between industry scholarly community government institutions and innate agents to bridge the gap between the industry interface and moral contemplations [23].

## CASE STUDIES

### Background:

A multinational firm called Monsanto is well-known for creating and marketing genetically modified crops, including soybeans. Roundup Ready soybeans are one of Monsanto's products; these soybeans have been genetically modified to resist the herbicide Roundup. Farmers are compelled to sign a technical agreement before using Monsanto's Roundup Ready seeds, which prohibits them from preserving and replanting harvested seeds.

Vernon One of Monsanto's clients, Indiana farmer Hugh Bowman, bought Roundup Ready seeds for his initial crop. Bowman bought commodity soybeans from a nearby grain elevator, which were meant for consumption rather than planting, to lower his seed expenses in subsequent planting seasons. He found that the Roundup Ready trait was present in a sizable proportion of these commodity soybeans. To effectively develop soybean harvests using patented genetically modified seeds without getting licensing from Monsanto, Bowman started replanting these commodity soybeans.

### Legal Proceedings:

Bowman was sued by Monsanto on accusations of patent infringement and breaking the technology agreement. The Supreme Court issued its majority ruling in Favor of Monsanto in May 2013. The Court decided that Bowman had violated a patent by sowing copyrighted seeds owned by Monsanto without first acquiring a license.

It was found that Monsanto's licensed sale of patented seeds does not give Bowman the right to create a new generation of seeds incorporating the patented technology.

### Implications:

Monsanto v. Bowman has significant implications for agribusiness and intellectual property. The court's decision confirmed the importance of protecting patent rights related to genetically modified seeds and other biotechnology inventions. Revealing that patent depletion does not extend to self-replicating technology, it confirmed Monsanto's ability to control the use and distribution of its patented seeds.

In the case of Monsanto v. Bowman, the United States Supreme Court ruled unanimously in favor of the company's patent rights to genetically modified seeds, as well as the patent exhaustion doctrine. This decision had a major impact on the agricultural industry, as it provided clarity on the safeguarding of intellectual property rights associated with biotechnological innovations [24].

## LEGAL FRAMEWORK AND INTERNATIONAL AGREEMENTS

### Patent laws and regulations

Both international agreements and national lawful systems administer patent law and regulations that furnish a harmonized approach to mental property assurance.

Here are a few imperative lawful systems and universal agreements within the field of patent laws and regulations:

### Paris Convention for the Protection of Industrial Property:

An intergovernmental organization that became one of the specialized agencies of the United Nations system of organization in 1974, the Paris Convention is managed by the World Intellectual Property Organization (WIPO).

Through a system of international intellectual property that is legitimate and efficient, WIPO's purpose is to encourage innovation and creativity for the economic, social, and cultural development of nations worldwide [25].

### Patent Cooperation Treaty (PCT):

By filing an individual global obvious application under the patent participation arrangement (pct), candidates can simultaneously search for patent assurance for their innovations in many different countries. This helps candidates determine patent assurance for their innovations across the globe and encourages public access to a wealth of specialized data relating to those innovations.

The PCT system is a procedure for "filing" patents rather than "granting" rights. A "PCT patent" does not exist [26].

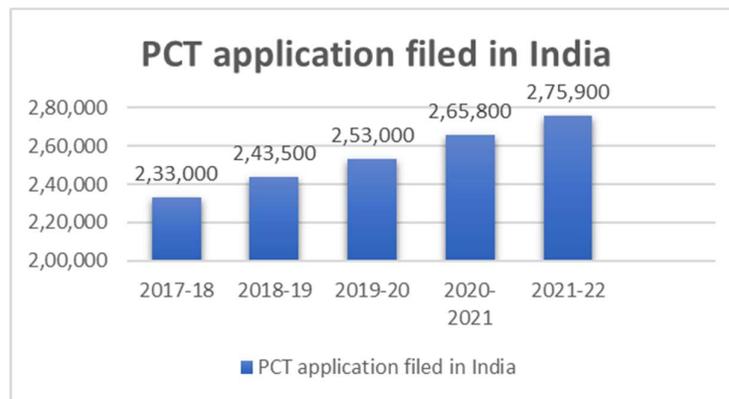


Figure 3: Application Filing a PCT in India from 2017 – 2022

### Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS):

TRIPS, the most significant and comprehensive international agreement on intellectual property rights, was

implemented by the World Trade Organization on January 1, 1995. It establishes minimum requirements for intellectual property protection, including

patents, and establishes enforcement [27, 28].

### **United States Patent and Trademark Office (USPTO):**

The organization in charge of issuing patents in the US is the USPTO. It operates within the parameters of U.S. Patent Laws, that are principally controlled by Title 35 of the United States Code. According to the "first-to-invent" principle, which is followed by the American patent system, the first person to come up with an idea is typically granted patent rights.

It is crucial to keep aware that the legal frameworks and international agreements listed above are not all-inclusive and that other regional and bilateral agreements may have an impact on the rules and laws governing patents for thorough and current information on patent protection it is advised to study the particular laws and agreements of the pertinent jurisdiction.

### **ALTERNATIVE MODELS OF IP PROTECTION**

Alternative techniques for protecting intellectual property can be essential in biological sciences since innovation frequently entails complicated scientific discoveries and innovations. Here are several different strategies that are pertinent to biotechnology [29].

#### **Patent Pools**

Patent pools are created when multiple patent holders who agree to license their IP

work together to reduce transaction costs and avoid patent wars. This approach can help spur innovation by making it easier to access essential technology in areas like gene sequencing and biotech copyright pools are being used to promote collaboration and knowledge sharing.

### **Biotechnology Application of Patent Pools**

In a report published by the United States Patent and Trademark Office (USPTO), the issue of restricted access to genetic resources and data was discussed. It was suggested that patent pooling has four benefits.

- ❖ The use of pooling models may help the biotech sector have fewer blocking and stacking patents.
- ❖ Patent pools can lower the cost of licensing transactions.
- ❖ Businesses in the biotechnology industry should find pooling appealing as a way to offset their high R&D expenses.
- ❖ The final advantage is related to the pool members' increased sharing of confidential technical information [30, 31].

### **OPEN-SOURCE BIOTECHNOLOGY**

The "open-source biotechnology" trend encourages sharing biological products, data, and methods openly. It promotes teamwork and the unrestricted sharing of information and resources. Researchers may

build on one other's work thanks to networks like Bio Bricks Association and Open Plant that make it easier to share genetic resources, instruments, and protocols.

Several organizations and initiatives promote open-source principles in biotechnology. Here are a few prominent ones:

**BioBricks Foundation:**

A nonprofit organization called The BioBricks Foundation promotes open standards and open-source methods in the biotechnology industry. They focus on developing standardized genetic parts, open licensing, and establishing a global common of genetic materials and innovation.

**OpenPlant:**

The collaboration of the Earlham Institute, the John Innes Centre, and the University of Cambridge is called OpenPlant. It aims to promote open-source approaches in plant synthetic biology and genetic engineering. OpenPlant supports the open sharing of research, the development of open technologies, and fostering interdisciplinary collaborations [32].

**DIYbio:**

DIYbio is a global community of amateur biologists, enthusiasts, and professionals interested in biotechnology. While not exclusively focused on open source, DIYbio promotes the open sharing of knowledge, resources, and ideas related to

biotechnology through meetups, workshops, and online platforms.

These organizations, among others, actively promote open-source principles and contribute to the development of open-source biotechnology tools, protocols, and resources [33].

**Data-Sharing Initiatives**

Given the significance of data in biotechnology research, programs that support data sharing can advance innovation and science. Organizations like the European Bioinformatics Institute (EBI) and the Global Alliance for Genomics and Health (GA4GH), which promote data sharing and standardization activities, have made it possible for researchers globally to access and use huge datasets [34].

There are several data-sharing initiatives in the field of biotechnology aimed at promoting the open sharing of scientific data. Here are a few notable examples:

**Protein Data Bank (PDB):**

Protein Data Bank is a global database that offers information on the three-dimensional structures of biological macromolecules including proteins and nucleic acids. It is maintained by the Worldwide Protein Data Bank organization and offers free access to the scientific community. Researchers can deposit and retrieve structural data, supporting a wealth of structural biology research [35].

## FUTURE ASPECTS

It's important to note that the future of IPR and biotechnology will be influenced by the interplay of legal frameworks, ethical considerations, and societal expectations. Balancing the protection of innovation and incentivizing research with considerations of public interest, access to healthcare, and environmental sustainability will be crucial in shaping the future landscape of IPR in biotechnology. Here are some key areas to consider

- ❖ Gene editing technologies
- ❖ Personalized medicine
- ❖ Bioprospecting and Biodiversity
- ❖ Data and Bioinformatics
- ❖ Synthetic Biology
- ❖ Open source and collaboration

The future of IPR and biotechnology lies in finding a delicate balance between promoting innovation and ensuring that new technologies and knowledge are accessible for the broader benefit of society. As the field progresses, it is essential to address emerging challenges such as gene editing, personalized medicine, synthetic biology, and the use of big data and AI in research.

Biotechnology has a very broad application today. Yet the most significant recent research areas and patents have a significant impact on human health. The significant implications for the future aspects are Gene editing and CRISPR, Synthetic biology and bioengineering,

bioprospecting and access to genetic resources, Data, and AI in biotechnology.

Navigating these future aspects of IPR in biotechnology will require ongoing discussions, international cooperation, and the involvement of various stakeholders, including scientists, policymakers, legal experts, and industry representatives. It will be essential to strike a balance between promoting innovation, protecting rights, and ensuring equitable access to biotechnological advancements for the benefit of society as a whole.

## CONCLUSION

In conclusion, the relationship between intellectual property rights (IPR) and biotechnology is a dynamic and evolving field with profound implications for scientific progress, innovation, and societal impact. Effective IPR protection plays a vital role in incentivizing biotechnology research and development by giving inventors and companies exclusive rights to their creations, enabling them to recoup investments and drive further innovation. Patents, copyrights, trade secrets, and trademarks have traditionally been the primary tools for protecting biotechnological inventions, data, and brand identity.

Collaboration with scientists, policymakers, legal professionals, business stakeholders, and the general public is crucial for successfully navigating the

difficulties of IPR and biotechnology. International cooperation and harmonization of IP regulations can facilitate the development of a global framework that fosters innovation, encourages responsible research, and ensures that the benefits of biotechnology are accessible to all while addressing societal challenges and respecting ethical boundaries.

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The authors of this review article declare that they have no conflicts of interest that could influence the objectivity or impartiality of the content presented in this work.

#### REFERENCES

- [1] Raj GM, Priyadarshini R, Mathaiyan J, 2015. Drug patents and intellectual property rights. *Eur J Clin Pharmacol* 71(4), Pages - 403–409.10.1007/s00228-015-1811-5.
- [2] Akers and Co., Grey Friars, Spring Road, *et al*,2003. The future of patent information—a user with a view.*World Patent Information* 25, Pages – 303 – 312.
- [3] Shaklee P,2013. Celebrating 30 years of biotechnology. *Trends in Biotechnology* 31(3), Pages – 117. 10.1016/j.tibtech.2013.01.019
- [4] Sibley KD. The law and strategy of biotechnology patents.biotechnology series. Elsevier: the Netherlands 2013; pp. 262.
- [5] Lin.B.W, Chen.C.J and Wu.H.L,2007. Predicting Citation to Biotechnology Patent based on the Information from the Patent Documents.*International Journal of Technology Management* 40(1), Pages-87-100.10.4236/aasoci.2014.412032.
- [6] Mozafari M, Tariverdian T, Beynaghi A.2019. Trends in Biotechnology at the Turn of the Millennium. *Recent Pat Biotechnol* 14(1), Pages. 78–

- 82.10.2174/1872208313666190924  
162831.
- [7] Stedeford T, 2009. Patents. In: Information Resources in Toxicology, Pages- 711– 716.
- [8] Merz JF, 1999. Disease gene patents: overcoming unethical constraints on clinical laboratory medicine 45, Pages - 324–330.
- [9] Merz JF, Cho MK. 2005. What Are Gene Patents and Why Are People Worried about Them? *Public Health Genomics* 8(4), Pages - 203–208. <https://doi.org/10.1159/000087956>.
- [10] Bently L. 2012. What Is “Intellectual Property”? *Camb Law*. 27 71(3), Pages 501–505.
- [11] WIPO, 2003. Introduction to Plant Variety Protection.
- [12] Gahukar RT, 2003. Issues Relating to the Patentability of Biotechnological Subject Matter in *Indian Agriculture* 8, Pages- 9–22.
- [13] CGPDTM Annual reports. <https://ipiindia.gov.in>.
- [14] Prakash A, Sarma P, Kumar S, et al. 2018. Intellectual property rights and Indian pharmaceutical industry. Present scenario. *Indian J Pharmacol* 50(2), Pages- 57.10.4103/ijp.IJP\_320\_18.
- [15] R. Stone, 1992. A Biopesticidal Tree Begins to Blossom: Neem Seed Oil has Insect Toxicologists Buzzing About its Potential as a Source of Natural Insecticides. *Science*. Pages -1070–1071.
- [16] Hamilton C, 2006. Biodiversity, biopiracy, and benefits: What allegations of biopiracy tell us about intellectual property. *Dev World Bioeth* 6(3), Pages - 158–73.
- [17] Beauchamp TL, Childress JF, 1989. *Principles of Biomedical Ethics*. 3rd edition. New York: Oxford University Press. Pages 6–9.
- [18] Iserson K V, 2006. Ethical Principles-Emergency Medicine. *Emerg Med Clin North Am* 24(3) Pages - 513–45.
- [19] Miguel González-Maestre and Luis M. Granero, 2003. Industrial loans and market structure. *European Economic Review* 47(5). Pages – 841 – 855.
- [20] Mosca, M. (2008). On the Origins of the Concept of Natural Monopoly: Economies of Scale and Competition. *European Journal of the History of Economic Thought* 15(2). Pages - 317 – 353.
- [21] Miljkovic, D. (2005). Sanitary and Phytosanitary Measures in International Trade: Policy Considerations vs. Economic Reasoning. *International Journal of*

- Consumer Studies 29(3). Pages - 283–290.
- [22] Kotsios, 2018. P. Regulatory Barriers to Entry in Industrial Sectors.
- [23] Erickson B, Nelson JE, Winters P, 2012. Perspective on opportunities in industrial biotechnology in renewable chemicals. *Biotechnol J* 7(2), Pages - 176–85.
- [24] Bowman v. Monsanto Co, *et al.* 2013 (Supreme Court of the United States) Prepared by UNCTAD's Intellectual Property Unit 420, Pages 1–3.
- [25] Wipo,OMPI-clear, 1979. WIPO Database of Intellectual Property Legislative Texts. Pages- 1–20.
- [26] Singh A, Hallihosur S, Rangan L, 2009. Changing landscape in biotechnology patenting. *World Pat Inf* 31(3), Pages - 219–225. <http://dx.doi.org/10.1016/j.wpi.2009.03.004>.
- [27] Smith RD, Correa C, Oh C, 2009. Trade, TRIPS, and pharmaceuticals. *Lancet* 373(9664), Pages - 684–691. [https://doi.org/10.1016/S0140-6736\(08\)61779-1](https://doi.org/10.1016/S0140-6736(08)61779-1).
- [28] Chakrabarti S, Amba S, Ramasami T, 2020. Study of the landscape of global leather patents and analysis of technology linkages to trade. *World Patent Inform* 28, Pages - 226–234.
- [29] Osipchuk E, 2018. Working Competition and Biotechnology Patent Pools. *Stock Intellect Prop Law Rev.* 1(1), Pages-28–43.
- [30] Adenle AA, Sowe SK, Parayil G, *et al.*, 2012. Analysis of open-source biotechnology in developing countries. An emerging framework for sustainable agriculture. *Technol Soc.* 34(3), Pages - 256–69. <https://doi.org/10.1016/j.techsoc.2012.07.004>.
- [31] Aoki R, Nagaoka, Sadoa, 2004. The Consortium Standard and Patent Pools. *Economic Review.* 55(4). Pages – 345 – 347.
- [32] Manamley N, Mallett S, Sydes MR, *et al.*, 2016. Data sharing and the evolving role of statisticians. *BMC Med Res Methodol* 16(1), Pages - 37–43. 10.1186/s12874-016-0172-9.
- [33] Vasantha Muthuswamy, 2013. Ethical issues in clinical research. *Perspect Clin Res.* 4(1), Pages – 9- 13. 10.4103/2229-3485.106369.
- [34] Robertson J, Barr R, Shulman LN, *et al.*, 2016. Essential medicines for cancer. WHO recommendations and national priorities. *Bull World*

Healthm Organ. 94, Pages -735–  
742.

- [35] Berman, Helen M, Battistuz, *et al*,  
2002.Biological Crystallography  
the Protein Data Bank.Acta cryst  
.58 Pages – 899 – 907.  
10.1107/S0907444902003451.