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INTELLECTUAL PROPERTY RIGHTS AND PATENTS IN BIOTECHNOLOGY

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Intellectual Property Rights and Patents in Biotechnology

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PREFACE

The 21st century emerges as a sentinel of progress, fostering innovation, knowledge, and intellectual growth. In modern globalized and technology-driven world, the prosperity of nations is judged by their ability to change knowledge into tangible innovations. Intellectual property accelerates economic development, enhances competitiveness, and fosters sustainable development. Intellectual Property Rights (IPRs) grant creators and inventors exclusive legal rights over their inventions, artistic expressions, symbols, designs, trademarks, and business models. In developing countries like India, IPRs hold transformative potential to unleash new routes of development and technological advancement. However, the success of this potential depends on the establishment of a balanced, accessible, and transparent intellectual property framework that fosters both innovation and public interest.

Biotechnology represents one of the most transformative fields of science and innovation in the modern era, offering advancements in medicine, agriculture, and environmental sustainability. At the heart of this dynamic sector lies the intricate framework of Intellectual Property Rights and patents, which serve as both a shield and a catalyst for innovation. This book, Intellectual Property Rights and Patents in Biotechnology, explores the critical intersection between legal protections and scientific ingenuity, aiming to provide readers with a comprehensive understanding of how intellectual property shapes the future of biotechnology. The field of biotechnology thrives on creativity and substantial investment in research and development. From patented genetic sequences to genetically modified organisms, and from proprietary drug delivery systems to bioinformatics processes, intellectual property law provides a structured mechanism to protect and commercialize these innovations. The aim of this book is to explore the practical implications IPRs for researchers, entrepreneurs, policymakers, and society at large. It highlights how a robust intellectual property protection enhances innovations. Let us embark on this journey into the fascinating world of biotechnology and its intellectual property regime—a realm where science meets law to shape the future.

- Editors

ACKNOWLEDGEMENT

This edited book on Intellectual Property Rights and Patents in Biotechnology has been a truly collaborative effort, and I am deeply grateful to all who have contributed to its compilation. The interdisciplinary nature of this field—where law, science, and ethics converge—made the work particularly challenging, yet immensely rewarding.

First and foremost, I would like to express my sincere gratitude to Almighty for providing me this opportunity and being a constant source of guidance and inspiration from compiling information and editing to bring the book in its final form.

I wish to express my sincere thanks to the esteemed contributors whose expertise in intellectual property law, biotechnology, and related fields has brought invaluable depth and perspective to the chapters.

I am particularly grateful to my co-editors, for their dedication, collaboration, and academic insight throughout the editorial process.

A special thanks to the various legal practitioners, biotechnologists, and researchers whose pioneering work in IP and patents continues to shape the landscape of biotechnology.

Finally, I would like to express my sincere thanks to the readers of this book with the hope that the information and perspectives presented in the book may further enhance their knowledge and inspire them to learn more about the topics.

- Editors

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Chapter 1

TYPES OF INTELLECTUAL PROPERTY RIGHTS, PATENT, COPYRIGHT, TRADEMARK AND DESIGN

Sagaldeep Kaur
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Abstract:

Intellectual property rights (IPR) are described as concepts, inventions, and artistic expressions that the public is ready to grant property status. A basic intellectual property right is an intangible product of human imagination. Authors and inventors are granted special exclusive rights under IPR, allowing them to make money out of their reputation or creative achievements. Works of literature, art, inventions, designs, and names, symbols, and images used in trade are all considered forms of intellectual property (IP). Property protection comes in a variety of forms, including trademark, copyright, patent and design. An invention may be granted a patent if it satisfies the criteria of worldwide novelty, non-obviousness, and industrial use. IPR is essential for better invention or creativity identification, planning, marketing, rendering, and, eventually, protection. A patent is a form of intellectual property that, in exchange for publishing an enabling disclosure of the invention, grants its owner the legal authority to prevent others from creating, utilizing, or selling it for a set amount of time. This chapter will present overview and explains the fundamental idea of intellectual property rights (IPR), their goals, and the types of IPR (industrial designs, patents, trademarks, copyrights, and related rights).

Keywords: Patent, Copyright, Trademarks, Inventions, Intangible and Novelty.

Introduction to IPR:

The renowned jurist Salmond once said, "*A man's immaterial brain product may be as valuable as his lands or his goods." As a result, he has an exclusive right in the law*.[1]

Inventions, ideas, and creative expressions that the general public is willing to recognize as property are referred to as intellectual property rights (IPR). IPR is a phrase used to describe a variety of legal rights that are attached to specific kinds of ideas, information, or other intangibles in their expressed form. Regarding the intellectual property's subject matter, the holder of this legal entitlement typically has the ability to exercise a number of exclusive rights. Typically, they grant the inventor the only authority to utilize their creations for a specific amount of time.[2]

An intangible attribute of the person who put effort into the invention or production is the final concept that led to it. Accordingly, the creator or innovator is granted legal rights or

monopoly rights to profit from their innovation or invention. Like physical property, the owner can sell, purchase, or grant a license for his intellectual property (IP) through the territorial rights that is IPR. However, in order to profit from IPR, one must register it with the appropriate legal authorities in a presentable or tangible form. Every form of IPR grants its author or inventor unique rights to maintain and reap financial rewards, which further encourages scientific and social advancements.[3]

Since India gained its independence in 1947, the government has taken a number of steps to protect Indian individual's intellectual property rights and encourage domestic creation. A big step in this direction was taken in 1957 with the passage of the Indian Patent Act, which gave indigenous inventors and business owners easier access to a more economical and easily navigable system for their patent registration and protection. Since then, India has periodically amended its intellectual property laws to comply with TRIPS obligations and other international accords, all the while trying to balance the needs of domestic innovators and consumers with those of global firms. Important reforms include the 2005 introduction of pharmaceutical product patents and the 2016 revisions to the National IPR policy, which aims to encourage entrepreneurship, innovation, and knowledge access.[4]

Patents, trademarks, industrial designs, copyright, and related rights (such as literary and artistic works, musical works, artistic works, photographic works, motion pictures, computer programs, and performing arts and broadcasting works) are the categories of intellectual property rights based on the types of inventions and creations of the human mind and their applications.

The Importance of Intellectual Property Rights

As the centre of every production, IPRs play a crucial role in individual and group production. Awareness is now a crucial factor in setting businesses apart from competitors. Some people consider the twenty-first century the century of understanding. In today's society, a man's information base is his sole real safety protection, as Henry Ford rightly said. The protection of this reservoir under various assets, constitutional rights, and the safety of human intelligence, however, is extremely important. Exclusive rights to innovative, distinctive, or creative products, designs, and brands should be awarded to businesses with intellectual property rights. Their level of exclusivity makes it worthwhile to invest in increasing their competitiveness. A company gains a great deal of goodwill from its customers by using its trademark. In addition to being the source of some really valuable goods and services, the brand is proof of greatness. Consumers or clients consider a brand or trademark to be an instantaneous reflection of the owner. It is often known that intellectual property provides a solid position for breaking into new markets. Businesses make money from the asset class of intellectual property through the selling, licensing, and franchising of legally protected goods and services. In the event of a purchase or

merger, a company's worth is significantly increased by protected intellectual property assets. It is important to keep in mind that Apple, Microsoft, and Blackberry—the biggest corporations in the world—have developed robust revenue streams as a result of their extensive intellectual property holdings. As a result of rapid development, globalization, technological advancement, an increase in commercial activities, the growth of global big business, and, last but not least, improved understanding, business entities now recognize the importance of intellectual property assets and its requirements in the development of business As a fitting way to wrap up this article, the well-known American businessman Mark Getty asserts that intellectual property is crucial to the development of any corporate entity: "Intellectual property is the oil of the 21st century." Natural resource extraction or transportation employed the wealthiest individuals a century ago. For the wealthiest people of today, intellectual property has been their primary source of income.[5]

Types of IPR

- Patents
- Trademarks
- Copyrights and related rights
- Industrial designs
- Geographical indications

1. Patents:

A patent is a kind of exclusive right awarded for an invention, which could be a new method of doing something or a product or process that offers a technical solution to an issue. The invention is protected for the patent holder by the document. The protection is only available for a 20-year term.[6] Companies benefit greatly from patents since they grant them exclusive commercial rights for their inventions and shield them from competition, which is one of the primary reasons why hundreds of new patents are given each year.[7] Without the patent owner's permission, an innovation protected by a patent cannot be produced, used, distributed, or sold on a commercial basis. When an invention is covered by a patent, the patent holder has the power to decide who can and cannot use it. Third parties may be granted permission or a license by the patent owner to exploit the innovation on mutually accepted terms. Another option is for the owner to sell the patent to a third party, who would then acquire the innovation's rights. When a patent expires and an invention enters the public domain, its owner no longer has the sole right to utilize it for profit, its protection comes to an end.[8]

Patentable Subject Matter

Before submitting a patent application, inventors take into account a number of important factors, including whether or not their invention is patentable. Patentable inventions are those that satisfy certain requirements outlined in patent legislation. A patentable invention typically needs to be new, non-obvious, and practical. New tools, processes, or materials compositions that exhibit a definite creative step and provide a measurable advantage are examples. Many requirements are placed on individuals who want to get a patent for their innovation by patent systems. Most patent systems use three standards to determine if the government should patent an invention: I.) novelty of the invention, ii.) inventive steps and, iii.) industrial application.[9]

- Novelty - According to the novelty criteria, the invention must not be revealed in the "prior art"—that is, all of the publicly available information that existed before to the inventor's filing of the patent application.[10] This criterion usually indicates that the data must not have been publicly accessible before the first application date.[11]
- Inventive Step - The creator of the innovation must have contributed some originality to it. It should be an unexpected thing for someone with artistic talent. In the event that an inventor creates a solution to a technical problem and another expert in the same field uses his knowledge or receives instruction, advice, or encouragement to provide the same solution, the inventor's technical solution will not be regarded as innovative.[12]
- Industrial applicability - The invention must be applicable to all industries, including agriculture. Any technological physical action is considered industry in this context.[13] An invention only needs to be operable and capable of satisfying some function of benefit to humanity.

The Indian government has not established a definitive, all-inclusive list of inventions that are eligible for patent protection. A subject matter is eligible to seek patent protection if it meets the three requirements of patentability outlined in section 2(1)(j). For the ultimate registration, however, the conditions of the territory's governing laws apply.[14]

Non-Patentable Subject matter:

On the other hand, inventions that were not patentable were not covered by patent protection. Natural phenomena, rules of nature, and abstract concepts are frequently among them. Additionally, inventions that are judged to be unoriginal or that are clear from the body of existing knowledge cannot be patented. Additionally, an innovation must be related to the patentable subject matter. Each nation has its own standards for determining what types of subjects are patentable. It particularly mentions the list of non-patentable subject subjects in India.

The following would not qualify as patents:

- An invention that deviates from established natural law, is pointless, or makes any clear claims. The primary or intended use of an invention that would violate morality, the law, or public health
- A mathematical technique, scientific hypothesis, or discovery
- Simple application of a known machine, technique, or procedure; or, unless the known process yields a new product or uses at least one new reactant, the discovery of any new property or use for a known substance.
- A material produced by a simple mixing that just causes the characteristics of its constituent parts to aggregate, or a method for creating such a material
- A method of agriculture or horticulture
- A simple configuration, reorganization, or replication of a well-known gadget that each operates independently in a unique manner
- Any procedure used to treat humans medically, surgically, curatively, prophylactically, diagnostically, therapeutically, or in any other way, or any procedure used to treat animals in a similar manner in order to cure them of disease or raise the value of their products or themselves economically
- An invention relating to atomic energy
- Traditional wisdom is actually an invention.[15]

Types of Patent Application under The Patent Act, 1970

i. Provisional Application

The patent office receives a preliminary application to establish priority. This kind of application is essentially submitted when an innovator needs more time to refine their creation. The Indian Patent Office uses the "First to File system," which makes this application advantageous. The inventor keeps any comparable inventions from becoming prior art to their application by filing early. For this kind of application, the application will be canceled if a complete specification is not submitted within 12 months of the date the provisional application was filed.

ii. Ordinary or Non-Provisional Application

The applicant files a non-Provisional Application with the patent office if they have no priority to make a claim. A comprehensive specification that thoroughly explains the invention must be submitted with this application.

iii. Conventional Application

Submitted to the Patent Office, a convention application is a patent application that claims a priority date based on an application that is identical or substantially similar and submitted in one or more of the convention countries. For an applicant to be granted convention status, their application must be submitted to the Indian Patent Office within a year after the date on which a similar application was initially filed in the convention nation.

iv. PCT International Application

It is a simplified method of applying for patents in numerous nations simultaneously. Valid in up to 142 countries, it is regulated under the Patent Corporation Treaty. This sort of application has the benefit of requiring only one international patent application, which can be submitted to seek protection for an invention in up to 142 countries worldwide.

v. PCT National Phase Application

The inventor submits this kind of application in each nation where they wish to obtain protection. This application must be submitted 30 or 31 months after the international filing date or the priority date, whichever occurs first.

vi. Application for Patent of Addition

When an applicant improves or modifies the invention that was described or disclosed in the primary application for which they have already applied for or received a patent, they file this kind of application. Because an addition patent can only be acquired subsequent to the parent patent's grant, there is no need to pay a separate renewal fee for the addition patent throughout the main patent's lifetime.

vii. Divisional Application

When an applicant's application asserts many innovations, the applicant may, on his own initiative or in response to an official objection, split the application and submit two or more applications, one for each invention. Divisional applications are those that are separated from their parent applications. Each and every divisional application will have the same priority date (ante-dating) as the parent application. A divisional application's patent will be valid for 20 years after the main application's filing date.

Procedure for Grant of Patent

After submitting an application for patent issuance, a request for review of the application must be submitted to the Indian Patent Office within 48 months after the application's priority date or the date of first filing. The applicant is given a chance to address the concerns expressed in the first examination report, which is issued following the completion of the application examination. The applicant must fulfill all requirements within six months of the first examination report's issuance; this period may be extended for an additional three months only

upon the applicant's request. If the applicant fails to fulfill all requirements within the allotted nine months, the application is considered abandoned. The patent is issued and published in the Patent Office Journal when the objections have been addressed and all requirements have been met.[16]

Patent specifications can be divided into two categories: (i) Provisional specifications and (ii) Complete specifications. In situations where the disclosed invention is still in its early stages and a delay in giving it its final form is anticipated; a provisional specification is typically filed to prove priority of the invention. Even though a provisional specification included with a patent application does not grant the petitioner any actual patent rights, it is a crucial document for determining who owns an invention first. There is no way to change the tentative specification since it is a permanent, independent scientific and legal document. No provisional specification is used to grant a patent. Complete Specification Submission of the complete specification is required to obtain a patent. After the provisional specification is filed, the full specification must be submitted within 12 months; this deadline cannot be extended. An application with the complete specification can be filed immediately after the provisional specification.[17]

In exchange for patent protection, all inventors are required to make information about their invention publicly available in order to contribute to the global body of technical knowledge. Others are encouraged to be more creative and innovative by this growing corpus of public /information. In this sense, patents not only offer the owner security but also important knowledge and motivation for upcoming generations of scientists and creators.

2. Copyright

The legal term "copyright" refers to the rights granted to authors and artists for their creative works. Literary works like novels, poems, plays, reference books, newspapers, and computer programs; databases; movies, music, and dance; artistic works like paintings, drawings, photographs, and sculptures; architecture; and commercials, maps, and technical drawings are among the types of works that are protected by copyright. Since copyright exists in a work simply by virtue of its creation, registration is not required. Nonetheless, registering a copyright proves that the work is owned by the inventor and that copyright exists in it. In exchange for money, creators frequently sell the rights to their creations to people or businesses who can best promote them.These payments, which are known as royalties, are frequently contingent on the work's actual usage. With the exception of photographs, these commercial rights are only valid for the lifetime of the creator plus sixty years following their passing.[18]

Copyright protects the following literary and artistic works:

- Musical compositions, including bands, orchestras, solos, choruses, and songs.
- Creative works, such as paintings, drawings, sculptures, ads, and architecture.

- Photographic work, including portraits, fashion or event shots, and landscapes.
- Motion pictures: movies, dramas, documentaries, TV shows, video recordings, and DVDs.
- Computer programs: software, computer programs, databases associated with them, etc.

India's intellectual property laws include the Patent Act of 1970, the Trademarks Act of 1999, the Copyright Act of 1957, the Designs Act of 2001, and others.[19]

The following rights belong to the copyright owner:

- Right of Reproduction- A copyright holder is able to have his work reproduced. Without the copyright owner's consent, no one other than the author may make copies of the work or any portion of it in any format.
- Right of Communication- Public communication refers to releasing any work that is protected by the author's copyright. If a work, like a movie, is registered under the copyright statute, it cannot be released to the public without the author's consent.
- Right of Adaption- The process of creating new work in a different way based on existing work is known as adaptation, change, or alteration. The ability to transform a dramatic work into a non-dramatic work, transform a literary or artistic work into a dramatic work, rearrange a literary or dramatic work, transcribe a musical work, or carry out any other act that entails altering or rearranging an already-existing work is known as the right of adaptation, according to the Copyright Act. This permission merely allows for the concept to be taken, after which it is modified in accordance with the specifications. For instance, movies were made based on Chetan Bhagat's Five Point Someone or Half Girlfriend. Here, the book's idea is borrowed rather than the entire expression.
- Right of Translation- Translating his work into another language is entirely within the owner's rights. Any other individual who does so without the owner's consent is violating their rights. Before translating a copyrighted work, the individual interested in doing so should obtain the owner's consent.
- Moral Rights- Individual authors are the only ones who are granted moral rights, which are often linked to economic rights in many nations. Moral rights encompassed both the right to assert authorship and the right to protest any alterations or distortions made to a work. Even after the copyright is assigned, he remains the owner of the moral rights.
- Rights in dramatic and artistic work- A dramatic or artistic work's copyright grants the sole authority to reproduce it, distribute copies to the general public, convey it to the public or perform it in public, incorporate it into a cinematograph picture, or adapt it in any way.
- Rights in musical works- The exclusive right to duplicate a musical work, distribute copies to the general public, incorporate the work into a cinematograph film or sound recording, and translate and modify the work are all known as copyright.

- Rights in sound recording- Copyright protection for sound recordings includes the ability to create other sound recordings that incorporate them, sell or rent copies of the recordings, and share the recordings with the general public.
- Rights for computer programmes- Computer programs are covered by all literary rights since they are considered literary works. The owner of the copyright has the authority to sell, donate, or rent a computer program. Making copies of software without the owner's permission is against the law.[20]

Copyright protects original "Works of Authorship" that are fixed in any tangible medium of expression, whether now known or subsequently invented, and that can be viewed, copied, or conveyed in any other way, either directly or via the use of a computer or other mechanism. A work is considered to be protected by copyright as soon as it is created. The work is regarded as copyrighted if it has been recorded or written down in a definite form. However, it is not required to register. Copyright protection for works produced after 1978 typically lasts for the lifetime of the author plus an additional 70 years. Works created for hire are protected for 95 years from the date of publication or 120 years from the date of creation, whichever is shorter. This is a technical definition that does not always encompass independent contractors. The author can use a copyright notice, such the © sign or the term "Copyright," to inform users that a work has been copyrighted (i.e., created and fixed in a tangible medium of expression). The year of creation and the name of the copyright owner should be used with these symbols.[21]

3. Trademark

Businesses use trademarks to distinguish products as belonging to them. A name, phrase, symbol, design, or a mix of these that distinguishes and identifies one party's goods from another's is regarded as a trademark. They could include illustrations, symbols, threedimensional indicators like the form and packaging of products, voices or music, scents, or colors that serve as identifying characteristics.[22] They are valuable because they identify the source and caliber of the goods they are associated with. With the exception of identifying and differentiating the provider of a service as opposed to a product, a service mark is identical to a trademark. Trademarks are essentially acquired in two ways (aside from purchasing rights in a mark from a rightful owner). First, acquisition may be accomplished through use of the mark in commerce. Acquiring a trademark through use alone limits the mark owner to protection of the mark in the geographic area in which it is used. However, in certain situations, the mark owner may have the exclusive right to use the mark across the country if it is utilized in connection with products or services that are sold online. However, in certain situations, the mark owner may have the exclusive right to use the mark across the country if it is utilized in connection with products or services that are sold online. Second, applicants are permitted to reserve, or "register," a

trademark under federal law (as well as specific state regulations). Names, titles, or specific groups of related phrases cannot be used as trade or service marks, nor can they be generic terms. A trademark cannot be confusingly similar to or identical to one that is currently in use. This will require a search of the federal registrations, and ideally state registrations as well as other databases that contain brand names for products and services, including Internet domain names. The trademark must be used on products sold as part of a business in order to be registered. The trademark legislation of the state in which the products are sold will take effect. Federal law will be applicable if the sale is made as part of interstate commerce. Files attesting to use of the mark must be made eight and fifteen years after the mark is registered, however protection lasts for ten years before it needs to be renewed. Both late renewal penalties and renewal fees apply. Think about companies such as Apple, a wellknown TATA is used for branding by the Tata group of companies. Like the swoosh logos from
Nike and Mercedes.[23]

There are several different kinds of marks, including:

- Trademarks (marks that identify certain products as being made by a particular company),
- Service marks (marks that identify certain services as being offered by a particular company),
- Collective marks (marks that identify the goods or services of an individual or group of individuals who own them from those of others),
- Certification marks (marks that identify goods or services that meet a set of standards and have been certified by a certified authority), and
- Well-known marks (marks that are regarded as being well-known in the market and, therefore, benefit from stronger protection).[24]

4. Industrial Design

Design rights refer to a new or unique design that is granted to the owner of a legitimately registered design, whereas industrial designs are creative endeavours that give a product an ornamental or formal aspect. In the realm of intellectual property, industrial designs are one element. Minimum requirements for industrial design protection have been established under the TRIPS Agreement. India, a developing nation, has already made these minimal standards a part of its national legislation. Design law is primarily concerned with promoting and protecting the design element of industrial production. It also aims to encourage creative activities in the industrial sector. The New Designs Act, 2000, which contains India's current industrial design laws, will be a useful tool given the swift advancements in technology and global trends.[25] Generally speaking, when someone makes, imports, or sells products that are basically replicas of a registered industrial design or design patent for profit, the owner of the

patent has the power to stop them.[26] The current legislation is in line with the evolving technical and commercial landscape and has been crafted to adhere to worldwide trends in design administration, since India has also attained a mature position in the field of industrial designs in light of economic globalization. In addition to addressing the development of designrelated activities across other fields, this replacement Act aims to adopt a more thorough classification of design in order to comply with the worldwide system.[27]

5. Geographical Indicators (GI)

Products with a particular geographic origin are identified by marks known as geographic indicators. A geographical indication (GI) designates a product's place of origin, which could be a town, village, region, or nation, and confers unique characteristics on the product. As a result, all community members profit from its registration, which is a unique right granted to that community. It can be used by any manufacturer or merchant whose goods are from that location and have similar features. Famous GIs include Tuscany (olive oil), Bordeaux (wine), Darjeeling (tea), Chander (sarees), and Kulle shawls.[28]

Conclusion:

Creativity and innovation are encouraged when the rights of artists and inventors are protected by intellectual property laws. IPRs ensure the availability of genuine and original items. These rights safeguard creators of intellectual property by allowing them to control how it is used for a set amount of time. To protect their investments in invention, businesses use intellectual property rights, such as patents, copyrights, trademarks, and designs. One important element in safeguarding intellectual property rights in India is the careful registration of patents. From performing patent searches to assessing the invention's novelty to creating and submitting the patent application, each stage of the patent registration procedure in India is essential. IPRs are essential for fostering economic expansion.

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Chapter 2

EMERGING TRENDS IN INTELLECTUAL PROPERTY AND BIOTECHNOLOGY

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Introduction:

The Intellectual Property, and Biotechnology has made great progress, with greater development of technologies such as artificial intelligence and CRISPR gene editing, and has converged great between these two areas. The process of developing, practising, and providing the solutions to healthcare, agriculture and environment sustainability have constantly and recently been changing due to the constant emerging new innovations in biotechnology; IP legal complexities are also changing at the same pace with biotechnology development.

Building on this introduction, this paper provides a broad exploration of emerging trends, challenges, and opportunities in this intermingling space of IP and biotechnology, based on recent scholarly research. The implications of AI-driven innovations on inventorship and patent protection as well as the potential for increasing debate about antibody-drug conjugate therapies and changing IP frameworks for agricultural biotechnology represent key areas of investigation. Moreover, the mRNA vaccine patent landscape, the roiling issues of the patentability of genetic material, and the patent peculiarities of bioprinting will be considered. The impact of emerging technologies on the traditional IP rights will also be discussed to highlight the necessity for current development of global IP harmonization, and future directions for IP law in the digital age will be also presented.

This paper hopes to shed light on this innovation/legal framework dynamic and to show that adapting to the dynamic will be integral in ensuring sustainable growth in biotechnology while not closing off innovation possibilities through a proscriptive legal framing.

AI-Driven Innovations in Biotechnology and IP Challenges

It has revolutionized biotechnology with artificial intelligence that has been used in drug discovery, personalized medicine and diagnostics. AI enabled improvements in the efficiency of drug research by analyzing enormous datasets and predicting possible drug candidates (Poddar & Rao, 2024). Though these developments have also brought along many complex IP challenges as to how are you assigning the inventorship when the work is made by an AI and how do you

provide adequate patent or copyright protection for AI works (Bharati, 2024) (Poddar & Rao, 2024).

For instance, AI algorithms can be used to generate new biological sequences or novel drug compounds, and there are issues with regard to ownership and authorship. The IP frameworks in force until now were not built to address these concerns, thus stirring up voices for harmonization and collaboration between policymakers, researchers and different stakeholders of the industry (Poddar & Rao, 2024; Bharati, 2024).

Antibody–Drug Conjugate (ADC) Therapy and IP Trends

In the last two decades, Antibody–Drug Conjugate (ADC) therapy has emerged as a promising therapeutic approach in cancer treatment; where the fundamental components are antibodies, linkers, and cytotoxic payloads. Global ADC market displays rapid increase, including 14 approved treatments through 2022 and many candidates in clinical trials (Choi *et al.,* 2024). There has been a burst in patent applications by major pharmaceutical companies such as Pfizer and AbbVie, who have been stepping up the R&D efforts in this field (Choi *et al.,* 2024).

However, the potential of ADC therapy is challenged by such as the premature release of the payload or immune related side effects. Currently, efforts are ongoing to develop new ways to conjugate Gd and stable linker designs and also to utilize it in conjunction with (e.g. nanotechnology) (Choi *et al.,* 2024).

Evolving IP Frameworks in Agricultural Biotechnology

There would be quite a few advances in agricultural biotechnology change in IP frameworks on genetic material as well as plant varieties. The purpose of these changes is to have a better innovation and access balance particularly in developing countries (Jefferson & Padmanabhan, 2016). The nature of plant transformation research has become shifting from basic to applied and this emphasis increased with patenting as the dissemination of knowledge (Michiels & Koo, 2008).

The increase of stronger IP rights has provided farmers a choice to pursue genetic research that forgoes private sector assurances of IP protection, while leaving behind the public sector. The trend of this type causes the need for equitable access to genetic resources and technologies (Michiels & Koo, 2008).

mRNA Vaccine Patent Landscape

mRNA vaccines have revolutionized the vaccine industry in the applications of infectious diseases, cancer immunotherapy, and allergy treatments (Li et al.). mRNA patent landscape for

vaccine is very competitive and BioNtech and Moderna are leading the innovation (Li *et al.,* 2022).

Lipid nanoparticles have been a focal point of patent activity due to the technical and commercial importance of this technology (Li *et al.,* 2022). For these researchers and industry leaders, understanding the patent landscape is of primary importance for controlling such a fast-developing field.

Biotechnological Inventions and Patentability Limits

Biotechnological inventions are patentable, though the question continues to be controversial in the U.S. and in the EU. It is set in accordance with recent case law as it established precedents for determining the limits of patent protection for genetic material (Stazi, 2014); for example, Myriad and Mayo decisions in the U.S. According to the European approach, fundamental rights are also given, trying to accommodate private interests with public access to genetic information (Stazi, 2014).

Value based choices are being routinely regulated in the Western countries via a case by case examination guided by the principle of proportionality (Stazi, 2014). Given its especially relevant content for transatlantic cooperation on IP issues, this approach constitutes a valuable addition to the edTPA.

Genomics and Patenting of Genetic Material

Genomics has paved the way for patenting of genes, gene fragments, and single nucleotide polymorphisms (SNPs). These applications of these patents serve in agriculture, medicine, and industry and have ethical and legal concern (Yadav *et al.,* 2012). With the advancement of sequencing projects, a large amount of genetic data is being accumulated, there is need forclarity on patenting of genes and sequences (Yadav *et al.,* 2012).

The area of genomics and patents on biomarkers for cancer diagnosis and treatment is a fast growing area as these biomarkers have the potential to revolutionize healthcare (Yadav *et al.,* 2012).

Bioprinting and IP Challenges

Formed by the fusion of biotechnology and additive manufacturing, bioprinting has the ability to manufacture tissues, organs and implants. However, it presents novel IP issues, like IP protection of the bioprinting hardware, bioinks and digital files based on biological data (Kantaros *et al.,* 2025). However, these complexities are not covered by current IP frameworks and how such frameworks can deal with these described complexities remains a challenge (Kantaros *et al.,* 2025).

Commercialization of bioprinted tissues and organs brings back the discussion of ownership and commodification of biological innovations. However, there is a need for adaptive legal and ethical frameworks that manage innovation with fair access (Kantaros *et al.,* 2025).

Global IP Harmonization in Biotechnology

Global biotechnology innovation is challenged by the fragmented global patent landscape. Progress is inhibited and access to therapies is limited because patent regulations differ among jurisdictions (Tjandrawinata and Budi 2024. The harmonization efforts are necessary to facilitate global access and sustainable innovation (Tjandrawinata & Budi, 2024).

Tjandrawinata and Budi (2024) suggest possible strategies for addressing ethical dilemmas and cross border enforcement issues involve regional agreements, international dialogue, and open model of innovation. Finally, the analysis of CRISPR gene editing and CAR-T therapy case studies confirms that effective IP regulation should be coordinated.

AI And IP: Legal Frameworks and Future Directions

The fast cultural adoption of AI technologies has resulted in a worldwide discussion on IP law. AI generated works challenge the traditional IP concepts like authorship and inventorship (Bharati, 2024; Samuel, 2024). Legal frameworks regarding AI IP rights are developing with a view to the balance of incentives for innovation and public interest (Bharati, 2024).

Issues of liability are emerging, and there is a need to create new types of categories for AI generated works (Marchenko *et al.,* 2024). Under discussions of legal reforms, the EU has begun, while other countries are using existing frameworks (Marchenko *et al.,* 2024).

Generative AI and IPR Challenges

But while democratic content creation is in its potential, it also ruins the traditional notions of intellectual property rights (IPR) (Samuel, 2024). Given AI's capacity to generate original works, the legal frameworks are found wanting in protecting the idea of authorship and originality (Samuel, 2024).

AI in IPR presents ethical and economic challenges, which necessitate a multifaceted approach that evaluates the state of the art in the context of legal, technology and ethics studies (Samuel, 2024). It is necessary for the future to have a revised model of IPR, which can encompass AI while still protecting human creative work.

Emerging Technologies and IPR Protection

Blockchain and AI are emerging technologies where both opportunities and challenges exist for IPR protection. The benefits of Blockchain on IP transactions include higher transparency and security, and AI facilitates monitoring and identifying infringements (Qianlan

et al., 2024). Nevertheless, these technologies create new issues, like ownership of AI created works and management difficulties of blockchain (Qianlan *et al.,* 2024).

To overcome these, all stakeholders such as policymakers, practitioners, and users need to work together to reform legal frameworks as well as increase awareness of IPR (Qianlan *et al.,* 2024).

Table 1: Key Technologies and Their Application in Biotechnology

Technology	Application	Citation
AI in Drug Discovery	Efficiency in the research of drugs and personalized medicine.	Poddar & Rao, 2024
ADC Therapy	Targeted cancer treatment with antibodies, linkers, and cytotoxic payloads.	Choi *et al.,* 2024
mRNA Vaccines	Rapid development of vaccines for infectious diseases and cancer	Li *et al.,* 2022
CRISPR Gene	Results applicable to precise genome editing for therapeutic applications.	Geissler *et al.,* 2024
Bioprinting	Fabrication of tissues, organs, and patient-specific implants	Kantaros *et al.,* 2025

Patent Data-Driven Analysis of Innovation Trends

The analysis of innovation trends in biotechnology can be analyzed by patent data. For example, biology statistical methods such as time-series analysis can be used to discover major trends and correlations between patents and other scholarly works (Geissler *et al.,* 2024). For instance, in CRISPR-based gene editing, cyanobacterial biotechnology, it saw drastic growth in patent activity (Geissler *et al.,* 2024).

However, this approach allows researchers to assess how relevant the publications are from something that goes beyond just citation counts, to elucidate the technical needs needed for innovations (Geissler *et al.,* 2024).

Biotechnology and Security

Therefore, biotechnology has emerged as a vital component of a nation's security due to its applications to bio-agriculture, genomics, and bio-manufacturing (Biotechnology; an Evolving Dimension of Security, 2023).

Biotechnology has great opportunities but also carries the risks associated with bio weapons (Biotechnology; an Evolving Dimension of Security, 2023). However, with the free

availability of biological data on the internet, there is the fear of creation of novel pathogens (Biotechnology; an Evolving Dimension of Security, 2023).

To counter bioweapon threats and strengthen national security (Biotechnology; an Evolving Dimension of Security, 2023), collaboration and observance of legal regimes are necessary.

IPR in the Digital Age

Emerging technologies have brought new challenges for IPR protection in the digital age. Blockchain and AI as rise have determined the landscape of IPR (Qianlan *et al.,* 2024), which is both challenges and opportunities. Although these technologies increase traceability and are more efficient, they bring in issues regarding ownership and enforcement (Qianlan *et al.,* 2024).

The protection of IPR by the emerged technologies involves them to act as double roles, and for a balance take, legal and regulatory standardization (Qianlan *et al.,* 2024).

The Future of IP in Biotechnology

This paper examines how emerging technologies, the increasing trend of international collaboration, and the desire to harmonize available legal frameworks are shaping the future of IP in biotechnology. With the growing field of biotechnology, the IP landscape also changes to deal with the emerging issues and opportunities (Wandhe, 2024). This includes the making of new IP strategies, cooperating on international level, and ethical considerations (Wandhe, 2024).

An effective protection and commercialization of innovations shall have a crucial impact on proceed of such areas as medicine, agriculture and engineering (Wandhe, 2024).

Conclusion:

In conclusion, the underlying technological progress and the appearance of new therapeutic approaches are progressing very fast, the overlap of the intellectual property (IP) and the biotech is evolving at an equally fast pace. As artificial intelligence, CRISPR gene editing and bioprinting are changing the fabrics of healthcare and agriculture, the IP challenges tied to them demand a careful consideration and adaption of existing legal frameworks. Important aspects of this research include the impact of AI on inventorship, changes in the patenting landscape for the mRNA vaccines, and ongoing debates about patentability of genetic material. Moreover, it highlights the need for global harmonization to combat IP fragmentation and thereby, to guarantee fair access to bio technological innovations and to promote sustainable biotechnology innovation. Based on this, collaborative strategies are needed to determine the future of IP in the biotechnology, while balancing the interests of innovators alongside principles of public access and ethics to help further the field’s progress.

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Chapter 3

TYPES OF INTELLECTUAL PROPERTY RIGHTS: PATENT, COPYRIGHT, TRADEMARK AND DESIGN

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Abstract:

Intellectual Property Rights are crucial for protecting innovative ideas, distinct brand identities and creative expressions. Patent safeguard novel inventions and grants exclusive right to creator. Trademark gives protection against various designs, symbols, logos for business purpose and customer satisfaction. Copyright shields artistry, literary and cinematic work to avoid unauthorized distribution. Designs being the subset of copyright aims to protect design of the product. All the four aspects aim to manage legal frameworks, enforcement mechanism and registration processes while considering a new invention. The present study aims to depict significance of each IP with its exemplary analysis.

Keywords: Novel, Innovation, Protection, Legal

Introduction:

Intellectual Property Right is the exclusive right of the inventor to protect its invention from any misuse. Better invention or creativity identification, planning, commercialization, and rendering are all made possible by IPR. Depending on its area of expertise, each industry should have its own IPR policies, management style, plans, etc. Additionally, it has been proved beyond dispute that the innovation's intellectual effort should be accorded the weight it deserves in order for the public benefit to result. Research and development (R&D) expenses have skyrocketed, and with it, so have the capital needed to get new technologies to the market (Anonymous, 2002). Europe is the birthplace of IPR legislation and administrative practices. The fourteenth century saw the beginning of the patent-granting trend. In certain ways, England was more technologically accomplished than other European nations, and it used to draw artisans from other regions on favorable terms (Singh R, 2004). Every form of IPR grants its author or innovator unique rights to maintain and reap financial rewards, which further spurs advancements in society and expertise (WIPO, 2020). Because intellectual property rules vary from one jurisdiction to another, it is important to individually seek out or obtain IP rights in each place of interest in order to register, acquire, or protect them. A variety of legal rights pertaining to specific categories of information, concepts, or other intangible assets that are

expressed in their expressive form are encompassed under the term "intellectual property right" (IPR) (Tamboli, F. A. *et al.,* 2023). The categories of intellectual property rights are as follows: Patent, Trademark, Copyright, Industrial Designs, Geographic Indications. The following Paper highlights the impact of each IP and its significance in research and development.

Patent

A patent is a set of temporary, exclusive rights that a sovereign state grants to an inventor or assignee in return for thorough public disclosure of an invention. An invention is a technical solution to a particular issue. A product, such a chemical compound, or a method for creating a particular chemical compound can both be considered inventions. The World Intellectual Property Organization (WIPO) defines it as an exclusive right granted for an invention, which is a technique or product that gives a new technical solution to an issue or a new way of doing something. Technical details of the invention must be made public in a patent application in order to receive one (IPOI, 2015). According to national laws and international agreements, the process for awarding patents, the conditions imposed on the patentee, and the scope of the exclusive rights differ significantly between nations. A complete "Request for the Grant of a Patent" application form, found in Schedule II of the Patents (Amendment) Rules 2009 (Form No.1), and a specification make up a patent application. Form No. 1 is incorporated into the online patent e-filing system. The Patent Application Guide offers instructions on how to fill out a paper Patent Application Form No. 1 and draft specifications, claims, drawings, and abstracts for applicants who want to submit a patent application directly to the Intellectual Property Office of Ireland via postal mail. The specification must be typed or printed on single-sided A4 sheets with margins of two to three centimeters and adhere to the provisions of the Patents Act 1992 and the Patents Rules 1992 (Tietze, F., 2023) Every page should have a number, and these margins should be empty. The specification needs to be turned in in two copies. The specification gives the invention's technical details as well as its legal definition.

Its four parts are listed in the order that they ought to appear in an application:

The title, claims, drawings, and an explanation of the invention, if applicable, are included. Three basic and general factors that patent office usually utilize to establish patentability are at the basis of the progressive harmonization of patent laws across nations over the past few decades. "Novelty," is the first requirement. This implies that before submitting an application to a patent office, your innovation must not have been made public in any way. Any invention for which a patent applicant applies must be inventive, according to the second criterion, which is "inventiveness" (non-obviousness). Most patents tend to represent incremental improvements, though some inventions may be considered breakthroughs, i.e., having a high

inventive step. The United States Patent and Trademark Office receives patents applications, examines and grants patent. Patent Trial and Appeal Board (PTAB), guaranteeing that the patent system provides chances for reexamination and equitable decision-making in patent appeals. Inventors must apply for patents in each nation or through international agreements such as the Patent Cooperation Treaty in order to obtain patent protection in other nations (Deel., L.G, 2024). The scientific community was going through a lot of introspection when Stanford University submitted the first patent application in November 1974. At first, Stanley Cohen was reluctant to file the patent, as was Herbert

Boyer, who co-developed the method at Stanford and the University of California, San Francisco (UCSF) (Beardsley 1994). This was followed by years of debate between Congress and the National Institutes of Health (NIH). By 1978, NIH had made the decision to allow universities to protect their recombinant DNA breakthroughs, and the process patent for creating molecular chimeras was granted in December 1980. In 1984, the prokaryotic DNA product patent was granted. Stanford and UCSF received joint patent awards. On December 15, 1981, the first licensee signed contracts with Stanford. Royalties from licensing agreements have increased exponentially since their inception, totaling $139 million as of February 13, 1995. The licensing fees brought in $102 million in 1990–1995 alone. (Fore, J., *et al.,* 2006).

Trademark

A trademark is an identifiable term, phrase, symbol, or insignia that designates a particular product and legally sets it apart from all others of its sort. A trademark acknowledges the company's ownership of the brand and uniquely identifies a product as belonging to that company (Mendonça, S. *et al.,* 2004). The goal of using a trademark is to stop third parties from using a business's or an individual's goods or services without that person's consent. Additionally, marks that are likely to be confused with an existing mark are prohibited by trademark regulations. This implies that a company cannot use a sign or brand name that sounds or looks like one that already exists on the books, or that has a similar meaning, particularly if the goods or services are related.[10] For example, it is illegal for a soft drink company to use a name that sounds like Coke or a symbol that resembles Coca-Cola. Trademark act was started in 1999 (Bhalawe, S., 2023). A registered trademark is crucial for using products by owner. Trademark is given for 10years.Trademark is applied by particular agent. Trademark has to be applied differently for particular country. A number of international treaties have been developed in an effort to streamline the application process for applicants wishing to register in many countries and to standardize the varied TM registration procedures across nations. The Madrid Protocol, which allows trademark owners to apply for protection in many countries with a single

application, is the most important international agreement for trademarks, aside from the Paris Convention and TRIPS, which standardize trademark procedures across states. Nevertheless, it is impossible to register a single trademark that would be instantly applicable everywhere in the world (Batar, S., 2012). One of the most significant trademark infringement lawsuits in India is Coca-Cola vs. Bisleri. While the defendant is a well-known Indian business known for its bottled water, the plaintiff is the biggest soft drink brand in the world, having a presence in 200 countries. The plaintiff purchased the rights to the soft drink MAAZA from the defendant in September 1993. The complainant filed a trademark application for the name "MAAZA" in Turkey in March 2008. The defendant announced its intention to start using the trademark in India and revoked the licensing agreement in a legal notification filed to the plaintiff in September 2008. The defendant was directly and indirectly involved in the production, distribution, and exportation of goods bearing the MAAZA brand (Appalla Vinay., 2022).

Copyright

The legal ownership of intellectual property, including unique works of fiction and nonfiction, is known as copyright, and it confers the authority to regulate its dissemination and reproduction. A unique or original product that took a lot of mental effort to produce is considered intellectual property. To prevent abuse or unapproved distribution, intellectual property might be copyrighted.

Unique creations include, for example Novels, Poetry and Art, Compositions and lyrics for music, Software for computers Graphic designs Movies, Designs for architecture, Content for websitesTitle 17 of the U.S. Copyright Act codifies U.S. Code. Although more changes have been made since the Act's adoption, the Copyright Act of 1976 offered the most substantial recent updates to U.S. law. As per the legislation as it stands, Unless the work is created for hire, the original copyright owner is the creator. The employer or contracting organization is the owner of the copyright if the work was produced by an employee while she was working for the company or under a special contract that specifically states it was done for hire.

Through a specific written and signed contract, any copyright owner can "assign" or transfer their copyright to another party. The work is usually reproduced, marketed, and sold by a publisher after the author sells the copyright to them (or offers them an exclusive license). Beginning in January 1958, the Copyright Act, 1957 (the "Act") became operative. Since then, the Act has undergone five amendments: in 1983, 1984, 1992, 1994, 1999, and 2012. The most significant is the Copyright (Amendment) Act of 2012. The primary goals of the 1957 Copyright Act amendments were to protect the music and film industries and address their concerns, as well as to bring the Act into compliance with two WIPO internet treaties that were concluded in 1996:

the WIPO Copyright Treaty ("WCT") and the WIPO Performances and Phonograms Treaty ("WPPT").Shortly after Windows 2.0, a major update to the original version, was released in 1988 (Kenton,W., 2024,) Apple filed a lawsuit against Microsoft. A famous case study of copyright states that Apple claimed at the time that Microsoft had stolen the Macintosh system's graphical user interface without authorization or a license.

The matter gets intriguing at this point since Apple did allow Microsoft to incorporate Macintosh design aspects into Windows. The puzzle here is that, when Windows 2.0 was released, the memo was somehow not sent to Apple's legal department. Apple did not convey any kind of advance warning or threat since it was so surprised by how abrupt the legal proceedings were. Because of this misinterpretation, the court decided in favor of Microsoft in 1989. Despite Apple's repeated attempts to appeal the ruling, none of them were successful (Copyright., 2025).

Design

A product's look is protected by a design right, and the drawings or photos in registered documents establish the extent of protection (WIPO, 2004, p. 375). A design right holder has the authority to bar others from using their creation for profit. A design right is deemed violated in the majority of jurisdictions if an alleged infringing party's design and the protected design are indistinguishable to a hypothetical informed user, or "ordinary observer" in the United States (Heikkilä, J. *et al.,* 2019). The owner of a registered design has the only right to use it for ten years, with the possibility of an extra five-year extension. Because of its exclusivity, rivals are unable to use or copy the design without authorization. The Designs Act of 2000 provides protection for the registered design. The product's shape, configuration, pattern, and decoration are all covered under the protection.

Unless the design is registered in another country, protection is territorial and only applies within India. We will prepare the full application for your design registration once you are happy with the design patentability search findings, or if you choose to skip this step. The application includes:

A design registration request in Form-1

1. Four copies of the article's depiction that display several design perspectives
2. A description of the design's uniqueness and any applicable disclaimers
3. A proof of ownership or authorization to apply for the design
4. A power of attorney in Form-21 (if the application is filed by an agent) (Patent Attorney Worldwide India., 2024)

In a case concerning a registered design for steel rods with a double rib pattern, the Delhi High Court summarily revoked the registration, ruling that a full trial was not necessary. The design that was included in the registration was published as part of British, ISO, and other standards prior to the design application filing date, which was the main basis for the Court's judgment. The Delhi High Court decided that a full trial was not required and immediately withdrew the registration of a registered design for steel rods with a double rib pattern. The Court's decision was primarily based on the fact that the design included in the registration had already been published as part of British, ISO, and other standards before the design application filing date (latest Design cases, 2021).

Geographical Indications

Products with a specified geographical origin and attributes or a reputation attributed to that origin are designated with a geographical indication (GI). A sign must identify a product as coming from a specific location in order to serve as a GI. Those who possess the right to use a geographical indication can stop a third party from using it if their product does not meet the relevant standards (Geographical-indications., 2025.) For instance, producers of Darjeeling tea may not use the term "Darjeeling" for tea that is not grown in their tea gardens or that is not made in accordance with the guidelines outlined in the code of practice for the geographical indication in jurisdictions where the Darjeeling geographical indication is protected. Geographical indications are typically used for agricultural products, foodstuffs, wine and spirit drinks, handicrafts, and industrial products. For agricultural products, foodstuffs, wine and spirit beverages, handicrafts, and industrial goods, geographic indications are commonly utilized. GI act was first implemented with TRIPS incorporation in India in 1999 (Rai, D., 2023) The local and international protection of Darjeeling tea under the Geographical Indication (GI) Act. Darjeeling tea's GI protection has been essential to preserving its quality and standing both nationally and globally. In order to avoid theft and preserve customer confidence, the 2004 GI status guarantees that only tea grown in the Darjeeling region under particular circumstances may be sold as Darjeeling tea (Kundu. D., 2024).

Conclusion:

In order to safeguard distinct facets of creativity and invention, intellectual property rights (IPR) come in a variety of forms, such as patents, copyrights, trademarks, designs, and geographical indications. It is crucial to comprehend these kinds in order to protect intellectual property and promote economic expansion. There re many systems of intellectual property protection and their importance in preserving innovation and creativity across a range of industries are demonstrated by the case studies on patents, copyright, trademarks, designs, and

geographical indications. Effectively managing the complexity of intellectual property laws requires an understanding of these ideas.

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Chapter 4

COMPREHENSIVE DESCRIPTION OF PATENT WRITING AND ITS SPECIFICATIONS

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Abstract:

Patent writing is a fundamental aspect of intellectual property protection, requiring a precise combination of legal and technical expertise. This chapter provides a comprehensive overview of the patent writing process, including the essential components of a patent document such as the title, abstract, background, summary, detailed description, claims, and drawings. It delves into critical elements like enablement, the best mode requirement, and the role of claims in defining the legal boundaries of an invention. Additionally, the chapter explores common pitfalls in patent drafting, legal considerations, and best practices to ensure a robust and enforceable patent. By following structured guidelines and legal frameworks, inventors can create well-drafted patent applications that effectively safeguard their innovations against infringement and maximize commercial potential.

Keywords: Patent Writing, Intellectual Property, Claims Drafting, Patent Specification, Patent Drawings, Enablement, Legal Protection, Novelty, Non-Obviousness, Prior Art.

Introduction:

Patent writing is a crucial step in the process of securing intellectual property rights for inventions. It serves as a legal document that grants the inventor exclusive rights to their innovation while preventing unauthorized use, production, or distribution by others. A welldrafted patent not only protects the inventor's interests but also enhances the commercial value of the invention by establishing clear ownership and enforceability.

Crafting a patent application requires meticulous attention to detail, as it must adhere to stringent legal and technical standards. It involves articulating the invention's uniqueness, functionality, and applicability while ensuring compliance with the guidelines set forth by patent offices. A poorly written or vague application can result in rejection, limiting the scope of protection or rendering the patent unenforceable in cases of infringement disputes.

The patent document is typically divided into several key sections, including the title, abstract, background, detailed description, claims, and drawings (if applicable). Each of these

components plays a vital role in defining the scope and essence of the invention. The claims section, in particular, is critical, as it establishes the legal boundaries of protection.

In this chapter, we will explore the essential elements of patent writing, the best practices for drafting a strong and defensible patent application, and the common pitfalls to avoid. By understanding the intricacies of patent documentation, inventors and legal professionals can ensure that their intellectual property is adequately protected, thereby maximizing the invention's potential impact and commercial viability.

Structure of a Patent Document

A patent document is a legally binding technical disclosure that follows a standardized format to ensure clarity, enforceability, and compliance with patent laws. It serves as both a technical manual for those skilled in the field and a legal instrument defining the inventor's rights. Patent offices worldwide, including the United States Patent and Trademark Office (USPTO, 2023) and the World Intellectual Property Organization (WIPO, 2022), adhere to a structured format to maintain consistency and ensure that inventions are adequately described and protected.

A complete patent document typically consists of the following sections:

1. Title

The title of the patent should be concise yet sufficiently descriptive to reflect the purpose and function of the invention. It should clearly convey the essence of the innovation without being overly broad or vague. A well-crafted title helps patent examiners and the public quickly grasp the subject matter of the invention.

Example:

- *"Adjustable Ergonomic Office Chair with Lumbar Support Mechanism"* instead of *"Office Chair"*

2. Abstract

The abstract provides a brief yet comprehensive summary of the invention, typically within 150-250 words. It outlines the technical field, primary objective, and key features of the invention, giving readers a snapshot of its purpose and functionality (European Patent Office [EPO], 2021). The abstract is crucial for patent searches, as it helps examiners and researchers determine the relevance of the patent without delving into the full document.

Best Practices:

- Avoid unnecessary technical jargon and keep the language clear and precise.
- Summarize the core inventive concept without including claims or legal disclaimers.
- Maintain a neutral, informative tone to facilitate easy comprehension.

3. Background of the Invention

This section provides contextual information about the invention, including prior art, industry challenges, and the specific problem the invention seeks to address (Burk & Lemley, 2009). It explains existing solutions, their limitations, and why a new invention is necessary. By illustrating the shortcomings of prior approaches, this section establishes the need for the proposed invention.

Key Components:

- Description of the technical field of the invention.
- Discussion of related technologies and previously patented solutions.
- Identification of unresolved issues or inefficiencies in existing designs.

4. Summary of the Invention

The summary presents a high-level explanation of how the invention solves the problem identified in the background section. It highlights the novelty, benefits, and core functional aspects of the invention. This section should be clear and compelling, ensuring that the reader understands the significance of the invention before diving into the detailed description.

Purpose:

- Provide an overview of the invention's core principles.
- Emphasize key advantages over prior art.
- Offer a transition between the problem statement and the technical details.

5. Detailed Description

The detailed description is the most technical and comprehensive part of the patent document. It provides an in-depth explanation of the invention's construction, function, and implementation, ensuring that a person skilled in the field can replicate the invention (Merges & Duffy, 2019). This section often includes references to figures and embodiments to illustrate various configurations and use cases.

Key Elements:

- A step-by-step explanation of how the invention works.
- Description of various embodiments and potential modifications.
- References to accompanying drawings and figures.
- Explanation of materials, dimensions, and manufacturing processes (if applicable).

6. Claims

The claims section is the most critical part of the patent, as it defines the legal boundaries of the invention's protection. Claims establish what is covered by the patent and determine its

enforceability. Each claim must be written precisely to avoid ambiguity while ensuring comprehensive protection.

Types of Claims:

- **Independent Claims:** Standalone claims that define the broadest aspect of the invention.
- **Dependent Claims:** Additional claims that provide further details and specify limitations or enhancements of the independent claim.

Example:

- **Independent Claim:** *"A chair comprising a height-adjustable base, a backrest with integrated lumbar support, and an adjustable armrest."*
- **Dependent Claim:** *"The chair of claim 1, wherein the lumbar support is dynamically adjustable based on user weight distribution."*

7. Drawings and Figures

Illustrations play a vital role in clarifying the invention's structure and function. Drawings help patent examiners and potential users understand the technical details that may be difficult to describe in words. These visual aids should be labeled clearly and referenced throughout the detailed description.

Guidelines for Patent Drawings:

- Must be professionally rendered and follow the patent office's requirements.
- Should include multiple views (e.g., front, side, perspective, exploded).
- Should be referenced in the written description to enhance clarity.

Writing the Patent Specifications

The **patent specification** forms the foundation of the patent document. It serves as the technical disclosure that enables a person skilled in the relevant field to understand and reproduce the invention (WIPO, 2022). A well-drafted specification must be **clear, complete, and legally precise** to ensure strong intellectual property protection. In addition to defining the technical aspects of the invention, it plays a crucial role in determining the enforceability and scope of the patent rights.

The key components of the **patent specification** include the **detailed description, claims, enablement, and best mode requirement**. Each of these sections must be carefully written to meet legal requirements and prevent potential challenges during patent examination or litigation.

1. Detailed Description

The **detailed description** is the most comprehensive section of the patent specification, providing an in-depth explanation of the invention (Thompson & Kuhn, 2020). The primary

purpose of this section is to **fully disclose** how the invention works so that a person skilled in the field can reproduce and apply it without undue experimentation.

Key Elements of the Detailed Description:

- **Use of Clear, Precise, and Consistent Terminology**: The description should be free of vague language and ensure that terms are used consistently throughout the document.
- **Inclusion of Multiple Embodiments**: Various embodiments of the invention should be described to showcase possible variations, making the patent more robust against challenges.
- **References to Technical Illustrations**: Drawings and figures should be integrated into the description to enhance clarity, especially when explaining complex mechanical, electrical, or chemical structures.
- **Step-by-Step Explanation of Implementation**: Each component, process, or element of the invention must be explained in detail to ensure a complete understanding.
- **Potential Modifications and Improvements**: Discussing possible variations or enhancements ensures that the invention is adaptable for future developments while strengthening its legal enforceability.

Example:

If the invention is a **new type of surgical instrument**, the detailed description should:

- Explain the materials used in its construction.
- Describe its function and how it improves upon existing designs.
- Include alternative configurations to broaden protection.

2. Claims

The **claims** define the **boundaries of legal protection** granted by the patent. They are the most critical part of the patent document because they specify what is legally protected and enforceable. Claims must be drafted with **utmost precision**, as any ambiguity can lead to legal disputes or limit the enforceability of the patent (USPTO, 2023).

Types of Claims:

Independent Claims:

- Broadly describe the invention without reliance on other claims.
- Must be self-contained and define the core inventive concept.
- Example:

"A method for filtering water comprising the steps of passing water through a multi-layer filtration membrane, wherein the membrane consists of activated carbon and silver nanoparticles."

Dependent Claims:

- Provide additional details and refinements based on an independent claim.
- Narrow the scope by adding specific limitations or features.
- Example:

"The method of claim 1, wherein the filtration membrane further includes a UV sterilization layer."

Types of Patent Claims by Subject Matter:

- **Method Claims**: Protect processes or steps in performing an invention.
- **Apparatus Claims**: Cover physical devices, machines, or structures.
- **Composition Claims**: Define chemical or material compositions, such as pharmaceutical formulations.

A well-drafted claim **avoids ambiguity**, **ensures broad protection**, and **anticipates potential workarounds** that competitors might use to design around the patent.

3. Enablement and Best Mode Requirement

The **enablement requirement** ensures that the patent provides enough technical information for a person skilled in the field to **replicate and use the invention** without excessive experimentation (35 U.S.C. §112). Failure to meet this requirement can lead to rejection or invalidation of the patent.

The **best mode requirement** mandates that the inventor discloses the best-known way to implement the invention at the time of filing. Omitting the best mode can result in legal challenges and possible patent invalidation (Merges & Duffy, 2021).

Key Considerations:

- **Detailed operational instructions** should be included.
- **Working examples** demonstrating the invention's real-world application strengthen the patent.
- **Any known superior method or configuration** must be disclosed to avoid accusations of withholding critical information.

Importance of Patent Drawings and Figures

Patent drawings **complement** the written description by visually representing the invention. In some cases, **well-prepared drawings can clarify complex technical details that may be difficult to express in words.**

Functions of Patent Drawings:

- Provide **multiple perspectives** (e.g., front, top, sectional views).
- Highlight **critical components and their spatial relationships**.

- Improve clarity in **process-based inventions** by using flowcharts and diagrams.
- Aid in legal interpretation by offering a visual reference for claims.

Patent Office Formatting Rules for Drawings:

- Must be **black-and-white line art** with consistent shading.
- Proper labeling of **components with reference numbers**.
- Figures must be **numbered and referenced in the description**.

Drawings **increase the enforceability** of the patent by providing **unambiguous visual proof** of the invention's structure and function.

Legal Considerations in Patent Writing

Patent applications must comply with legal frameworks established by governing bodies such as the USPTO, WIPO, and EPO.

Key Legal Requirements:

1. **Patent Eligibility**: The invention must fall under **patentable subject matter** (e.g., processes, machines, compositions).
2. **Novelty Requirement**: The invention must be **new** and not disclosed in prior art (Burk & Lemley, 2009).
3. **Non-Obviousness**: The invention must not be an **obvious improvement** over existing technology.
4. **Utility Requirement**: The invention must have **specific, substantial, and credible utility**.

Patent attorneys and agents play a crucial role in ensuring applications meet all **legal standards** and **avoid potential pitfalls**.

Common Pitfalls in Patent Writing

1. **Lack of Clarity**: Ambiguous wording can lead to rejection or litigation.
2. **Inadequate Scope**: Claims should be broad enough to **prevent design-arounds**, yet not overly broad to avoid rejection.
3. **Failure to Distinguish from Prior Art**: The invention's **novelty** must be clearly demonstrated.
4. **Omitting Essential Details**: Missing key technical aspects can **invalidate the patent**.
5. **Ignoring Best Practices in Claim Drafting**: Poorly structured claims can lead to **unintended interpretations**.

Best Practices for Effective Patent Writing

To improve the quality and success of a patent application, inventors and patent professionals should:

- **Conduct a thorough prior art search** before drafting the application.

- **Use clear, precise language** to avoid misinterpretation.
- **Follow the structured format** required by patent offices.
- **Include alternative embodiments** to enhance patent robustness.
- **Work with experienced patent attorneys** for legal validation.
- **Stay updated with changes in patent laws** and regulations.

Conclusion:

Effective patent writing is a blend of legal acumen, technical expertise, and strategic foresight. A well-drafted patent provides strong protection for innovations and increases the likelihood of successful commercialization. By adhering to established guidelines and best practices, inventors can secure robust patent protection that withstands legal scrutiny.

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Chapter 5

BIOTECHNOLOGY PATENTS AND ITS ETHICAL AND DEPOSITORY CONSIDERATIONS

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Abstract:

Biotechnology patents play a critical role in fostering innovation and investment in research and development, particularly in fields such as genetic engineering, pharmaceuticals, and bioinformatics. This chapter explores the historical evolution, legal framework, and ethical considerations of biotechnology patents, with a focus on Indian regulations. The study examines the fundamental requirements for obtaining a biotechnology patent, including novelty, non-obviousness, and industrial applicability. Additionally, it highlights the ethical dilemmas surrounding patenting life forms, gene-editing technologies, and essential pharmaceuticals. The chapter also discusses the significance of depository considerations in ensuring the accessibility and sustainability of patented biological materials. By addressing these aspects, this research aims to provide a comprehensive understanding of the intersection between biotechnology, intellectual property rights, and ethical responsibility.

Introduction and Historical Background

Karl Ereky, a Hungarian engineer, created the word "biotechnology" in 1919 to describe the science and procedures that allow goods to be manufactured from raw materials using living organisms. Biotechnology goal is to harness and shape the nature to improve our lives. Its tools are crucial for addressing serious global concerns like food scarcity, climate change, and healthcare disasters (Sinhmar *et al.* 2025). Genetic engineering, gene editing, and bioinformatics are the emerging trends of biotechnology. Intellectual property rights (IPRs), particularly patents are mainly responsible for latest innovations in these sectors.

A ‘biological patent’ is a patent on a biological innovation that gives the patent holder the legal right to exclude others from creating, using, selling, or importing the protected invention for a certain time. This exclusivity encourages the investment in risky and costly Research & development activities, potentially leading to great life changing invention. Between 2001 and 2020, biotechnology patents accounted for around 5% of all patents filed. Over 96% of biotechnology patents focus on industrial and medical uses. The United States is in the forefront

of biotechnology patent creation, accounting for 39% of overall patents in 2020 followed by the European Union, and then China (Grassano *et al.* 2024).

The first biotechnology patent registered in the United States with the case of Diamond vs. Anand Chakrabarty (1980), a biochemist who created a genetically engineered bacterium (*Pseudomonas putida*) capable of decomposing crude oil in oil spills. The Indian Patent Act was enacted in 1970. However, there was no special provision for the biotechnology sector because at that time biotechnology was not developed in India. India became a member of WTO in the TRIPS Agreement (1994). TRIPS approval encourages India to update its intellectual property laws, particularly patent law, to allow for the patenting of biotechnology inventions. The patent laws were amended in 2002 to specifically incorporate biochemical, microbiological, and biotechnological processes in the definition of potentially patentable methods (Deshpande, 2021).

Fundamental Requirements for Acquiring Biotechnology Patents in India

1. Patentable Subject Matter

The range of qualifying topic matters in India is extensive. In India, any process or product, irrespective of the technology employed, qualifies as patentable subject matter. The Patents Act of 1970 delineates an extensive enumeration of inventions that are excluded from patentable subject matter, including several categories of biotechnology inventions.

The excluded topics are as follows:

- Identification of organisms present in nature
- The entirety of plants and animals, including seeds, varieties, and species, as well as the biological processes involved in the development or propagation of these organisms; Genetically engineered multicellular creatures, encompassing plants, humans, animals, and their components
- Human beings and embryonic stem cells; medical treatment methodologies. Conversely, microbiological and microorganism techniques qualify as patentable subject matter under Biotechnology Patents in India. In India, DNA sequences and gene sequences with specified functions are regarded as patentable subject matter.

2. Novelty

Novelty is the primary criterion that must be satisfied. Section 2(1)(j) of the Indian Patent Act stipulates that an invention must be novel and distinct from the 'prior art.' Inventions that have been previously disclosed in any format prior to the submission of a patent application will no longer be considered novel.

The Manual of Patent Office Practice and Procedure is utilised to assess the novelty of biotechnology inventions. The Patent Office in India grants numerous patents for isolated gene sequences, which are deemed innovative in consideration of their natural counterparts.

3. Non-Obviousness

Section 2(ja) of the Patent Act addresses non-obviousness. It describes an innovation that demonstrates a technological advancement over current knowledge, possesses economic significance, or both, rendering the invention non-obvious to an expert in the field (Deshpande, 2021).

4. Utility in Industry

For an invention to be considered industrially applicable in India, it must be proven that it can be implemented, used in at least one field, and consistently reproduced with the same characteristics as needed. Since the Patent Act of 1970 does not explicitly define the industrial applicability of biotechnology patents, the general principles of industrial applicability are applied to inventions in this domain.

Biotechnology-related innovations that can be developed and utilized in an industrial setting, and can be reproduced as required, meet the Industrial Applicability criteria in India. The Manual of Patent Practice and Procedure provides guidelines for assessing biotechnology patents. In particular, it specifies that gene and DNA sequences must have clearly identified functions; otherwise, they do not satisfy the Industrial Applicability requirement for biotechnology patents in India. (Biotechnology patents in India: A complete outlook (2024) Corpbiz. Available at: https://corpbiz.io/learning/biotechnology-patents-in-india/)

Ethical Considerations

The combination of biotechnology and patent law creates a complicated ethical framework, causing significant concerns over the ownership, regulation, and moral use of revolutionary innovations. In India, ethics and morality hold significant importance, as they are regarded and followed with the same respect as the law. Morality is the belief that one conduct is right and another wrong. The ethical issues related to biotechnology patents are as follows:

1. Patenting of Life forms

Many people view the patenting of life forms as ethically problematic. In India, the concept of owning living organisms has long been discouraged due to a deep-rooted tradition against private ownership of natural and biological entities. However, as a signatory to the TRIPS agreement, India is required to adhere to its provisions, which allow for the patenting of inventions, including microorganisms and innovations resulting from microbiological, nonbiological, or biotechnological processes.

The legal framework specifies that any invention deemed contrary to public order or morality, or one that poses substantial risks to human or animal health or the environment, cannot be granted a patent. Additionally, it explicitly states that plants, animals, and the essential biological processes involved in their production are not patentable due to ethical concerns (Deshpande, 2021).

2. Patenting of Gene editing technology

Furthermore, the competition for patents in biotechnology generates issues regarding the ethical application of gene editing technologies. Example- CRISPR-Cas9 gene-editing technique has great potential for treating genetic illnesses, improving crop yields, and potentially modifying the human germline.

But concerns regarding the potential misuse of such potent technology are prevalent. Ethical considerations cover not only the act of patenting but also the proper development and deployment of biotechnological innovations. Responsible use of patentable technologies requires strong ethical frameworks to prevent unexpected effects such as off-target genetic modifications or the development of genetically modified species with unpredictable ecological impacts (Prasanna *et al.* 2023)

3. Patenting of gene or genetic material

Patenting the genetic material turns nature into a proprietary product, violating ethical rules. Example-The Myriad Genetics patent claims on the BRCA1 and BRCA2 genes, linked to breast and ovarian cancer risk, illustrates the ethical dilemma. Although the patent was initially awarded, legal challenges raised questions about the morality of patenting genes with inherent health concerns. The discussion highlights the conflict between promoting innovation and upholding ethical norms relating to life. Myriad Genetics, the company that held patents on BRCA1 and BRCA2, had exclusive rights to conduct genetic testing for these genes, meant that other researchers and laboratories needed permission or had to pay licensing fees to study these genes. This restricted independent research, slowing down advancements in cancer diagnostics and treatments. The U.S. Supreme Court rejected Myriad Genetics' patents in 2013 saying naturally existing genes cannot be patented. This judgement allowed genetic testing and research for patients and scientists worldwide (Sinhmar *et al.* 2025)

4. Patenting of Biopharmaceuticals & Life-saving drugs

Patented pharmaceuticals have long been expensive, especially in developing nations where access to crucial drugs is limited. Patents encourage pharmaceutical companies to engage in new drug development, but they also create monopolies that make these drugs costly and sometimes unavailable in underdeveloped nations. 50 Patented HIV/AIDS medications were a

major barrier to treatment in developing countries before cheaper alternatives were available due to patent issues.

The conflict between therapeutic availability and patent protection is particularly evident in Novartis' cancer treatment Gleevec. Novartis wanted to renew its medication patent in India to prevent generic versions from being released. It claimed its invention had saved lives. The Supreme Court of India ruled against extending the Gleevec patent, recognised as a public health success. This case emphasises the need to balance inexpensive medicine availability and rights protection, particularly for life-saving drugs (Sinhmar *et al.* 2025).

The growing link between research, innovation, and intellectual property calls for ethical biotechnology patenting. Ownership, access, and appropriate use of life-altering technologies are all included in the ethical dimensions. Innovative biotechnology demands a proactive and inclusive approach to ethical concerns. Achieving equilibrium between promoting innovation and maintaining ethical standards guarantees that the potential of biotechnology serves humanity while honouring the values that are the foundation of our comprehension of life and advancement (Prasanna *et al.* 2023)

Depository Considerations

In 1949, the Patent and Trademark Office (PTO) started recommending that inventors submit a deposit of the pertinent microorganism with a culture collection as part of patent applications for inventions that used microbes. Although not required, patent examiners recommended that such deposits might make an invention clearer when a written description by itself was inadequate.

On July 8, 1949, a sample of Streptomyces venezuelae was deposited with the American Type Culture Collection (ATCC) by Parke Davis Co., where it became ATCC 10712. This strain had been linked with U.S. Patent 2,483,892, awarded on October 4, 1949, for the fermentation of chloramphenicol. Also in August of 1949, American Cyanamid Company deposited Streptomyces aureofaciens at the Northern Regional Research Laboratory (NRRL), where it was assigned NRRL 2209. This culture was cited in U.S. Patent 2,482,055, issued on
September 13, 1949, for the production of aureomycin.

These initial patent deposits are considered to be pioneering cases in the area. Patent applications involving biological materials—microorganisms, plasmids, vectors, cells, plant tissues, and seeds—are now required to have a deposit in an accepted patent depository. This has become a standard requirement for reproducibility and availability in biotechnology patents.

According to the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO), biological material encompasses any substance capable of selfreplication or

propagation within a biological system. Such materials are frequently challenging to convey verbally. To meet the statutory criteria for patentability, specifically enablement of the claimed invention and adequacy of the written description, an invention must be articulated in a manner that allows a skilled individual to construct and utilise the claimed invention. For numerous biological inventions, these criteria cannot be adequately fulfilled without a biological deposit.

Consequently, instead of necessitating biological deposits in each jurisdiction where patent protection is pursued, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure ("Budapest Treaty"), established in 1977, acknowledges biological deposits with any "international depository authority," irrespective of jurisdiction. The Budapest Treaty reduces costs for applicants by permitting a single deposit to fulfil the obligations of each participating state, while instituting standardised biological deposit protocols to guarantee the accurate submission and validation of samples.

Important considerations during deposit are as follow:

1. Time of Deposit

According to USPTO, a deposit can be submitted at any point throughout the application, but not after paying the issue fee or a time period designated by the examiner at the time of the notice of approval. If the applicant deposits material after the effective filing date, they must submit a declaration from someone who can verify it is the item included in the application. Since the US does not require actual reduction to practise before submitting a patent application, a post-filed deposit may occur even if the material did not exist at the time. When filing in both the United States and international jurisdictions, it is imperative to make a biological deposit before the application or priority application filing date.

2. Public availability of deposit

To completely fulfil the legal criteria for patentability, the invention must be publicly accessible, enabling a person proficient in the art to create and utilise the invention.

3. Complexities of deposit

According the Budapest Treaty, a deposit shall be preserved for a minimum duration of 30 years and for at least five years following the latest sample request received by the repository

- Viability - A deposit must be viable at deposit and during its tenure. Depository must verify deposit is sustainable, or reproducible. The application is examined as if no deposit was made if the deposit is not viable or the Examiner cannot accept the assertion of viability.
- Cost- As of September 2024, the fee for a patent deposit with the American Type Culture Collection (ATCC) may amount to $2,500 per deposit.

- Survivability - A deposit must stay as described in the application specification during the application or patent term. The depository may not be able to provide samples if biological material becomes polluted or ineffective. If you notice an issue, you must promptly replace the deposit and get a certificate of correction or the application will be handled as if no deposit was made. Avoid losing rights by properly submitting a replacement or supplemental deposit.

Before submitting an application or priority document, it is essential to ascertain:

- Are you submitting filings solely within the United States or on an international scale?
- Is a patent submission mandatory?

Conclusion:

The expansion of biotechnology patents has significantly contributed to advancements in healthcare, agriculture, and industrial processes. However, the ethical implications and legal complexities associated with patenting life forms and genetic material necessitate a balanced approach. While intellectual property rights incentivize innovation, excessive patent control can hinder access to essential medicines and research. The Indian legal framework, shaped by international agreements such as TRIPS, seeks to align patent protection with public welfare. Ethical challenges, including the morality of gene patents and the affordability of biopharmaceuticals, remain at the forefront of debates in this field. Furthermore, depository requirements under the Budapest Treaty ensure that biological materials remain available for scientific research and development. A comprehensive and ethically guided approach to biotechnology patenting is essential to ensure that innovation benefits society while respecting fundamental ethical principles.

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Chapter 6

PARIS CONVENTION, CBD, UPOV, AND PGRFA: LEGAL FRAMEWORKS FOR GENETIC RESOURCE MANAGEMENT

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Abstract:

The management and conservation of genetic resources are fundamental to global food security, biodiversity protection, and agricultural sustainability. The present chapter examines the Paris Convention for the Protection of Industrial Property (1883), the Convention on Biological Diversity (CBD), the International Union for the Protection of New Varieties of Plants (UPOV), and the Plant Genetic Resources for Food and Agriculture (PGRFA) as key international legal frameworks governing genetic resource management. Each of these frameworks plays a distinct role in balancing intellectual property rights, biodiversity conservation, and equitable access to genetic resources.

The Paris Convention, administered by the World Intellectual Property Organization (WIPO), harmonizes industrial property rights, ensuring national treatment and priority rights for plant innovations. The CBD, established in 1992, focuses on the sustainable use of biodiversity and the fair distribution of benefits arising from genetic resources. The Cartagena Protocol on Biosafety further regulates the transboundary movement of Living Modified Organisms (LMOs). The UPOV Convention (1961) provides plant breeders' rights (PBRs), fostering innovation in agriculture but also raising concerns about smallholder farmer rights and genetic diversity loss. Additionally, PGRFA conservation initiatives, including ex-situ gene banks and the Svalbard Global Seed Vault, safeguard crop diversity against climate change and genetic erosion.

Despite these legal frameworks, challenges remain, including equity in access, enforcement issues, and conflicts between intellectual property regimes and traditional farming practices. This paper emphasizes the need for stronger legal enforcement, enhanced international cooperation, and sustainable innovation policies to ensure that genetic resource management supports both economic growth and environmental sustainability.

Keywords: Genetic Resources, Paris Convention, CBD, UPOV, PGRFA, Biodiversity, Intellectual Property Rights, Plant Breeders' Rights, Biosafety, Sustainable Agriculture.

Introduction:

Intellectual Property Intellectual property refers to the creations of the mind which include inventions; literary and artistic works; and symbols, names, and images used in commerce. Multilateral international conventions are legally binding agreements negotiated and signed by multiple states, typically under the auspices of international organizations such as the United Nations (UN), the World Trade Organization (WTO), or regional bodies like the European Union (EU) or the African Union (AU). These conventions are essential tools for fostering global cooperation, addressing transnational challenges, and establishing common legal standards across various domains, including human rights, trade, environmental protection, and security.

This chapter explores the nature, significance, negotiation process, implementation, and challenges of multilateral international conventions.

Paris Convention, 1883

The **Paris Convention** is an international treaty aimed at fostering trade among member nations by enabling the protection of **industrial property rights** across multiple countries while maintaining the **priority date**. Member states are required to extend **national treatment**, ensuring that applicants from other contracting countries receive the same legal protections as domestic applicants.

Initially signed in **1883**, the Convention has been revised multiple times, including in **Brussels (1900), Washington (1911), The Hague (1925), London (1934), Lisbon (1958), and Stockholm (1967)**, with the latest amendment occurring in **1979**.

Scope of the Paris Convention

The treaty protects various forms of **industrial property**, including:

- **Patents** and **utility models** (a smaller-scale patent recognized in certain jurisdictions)
- **Industrial designs**
- **Trademarks**, **service marks**, and **trade names**
- **Geographical indications**, including designations of origin
- **Measures against unfair competition**

The **World Intellectual Property Organization (WIPO)** administers the Paris Convention as part of its **Intellectual Property Treaties** framework.

Key Provisions of the Convention

The substantive rules within the Convention can be categorized into three main principles:

1. National Treatment

- Contracting States must provide the same industrial property protection to nationals of other member states as they do to their own citizens.
- Nationals of non-member states can also claim national treatment if they are domiciled in or operate a significant commercial establishment in a member country.

2. Right of Priority

- Applicants who file for patents, trademarks, or industrial designs in one member country can claim priority when filing in other member states. o The priority period is **12 months** for patents and utility models and **6 months** for industrial designs and trademarks.
- This system allows applicants time to strategize on international protection without risking loss of rights due to subsequent filings by third parties.

3. Common Rules and Additional Protections

- **Patents**: Each country grants patents independently, meaning a patent refusal or annulment in one country does not affect its status in others. The inventor must be credited in the patent, and compulsory licenses to prevent patent abuse must meet specific conditions. o **Trademarks**: Member states maintain their own filing and registration conditions. Trademark registrations are independent across countries, and wellknown marks receive special protection against unauthorized use.
- **Industrial Designs**: Must be protected in each member state, and protection cannot be forfeited due to non-manufacturing in that country.
- **Trade Names**: Protection is granted without the need for filing or registration.
- **Indications of Source**: Measures must be implemented to prevent false indications of a product's origin or its producer. o **Unfair Competition**: Member states must provide legal safeguards against deceptive trade practices.

Administrative Framework

The **Paris Union**, established under the Convention, is governed by an **Assembly** and an **Executive Committee**. Countries that have ratified at least the administrative and final provisions of the **Stockholm Act (1967)** are members of the Assembly, while the Executive Committee members are elected from among Union members. The **WIPO Secretariat** oversees the Convention's budget and administration.

Membership and Ratification

The Convention is open to all nations, and ratification instruments must be submitted to the **Director General of WIPO**. Over time, its membership has expanded significantly, making it a cornerstone of international **intellectual property law**.

Revisions and Amendments

The Paris Convention has undergone multiple **revisions** to modernize its provisions:

- **Rome (1886)**
- **Madrid (1890 and 1891)**
- **Brussels (1897 and 1900)**
- **Washington (1911)**
- **The Hague (1925)**
- **London (1934)**
- **Lisbon (1958)**
- **Stockholm (1967) – Most widely adhered version today**
  - **Amendment (1979)**

These revisions, particularly those addressing **unfair competition**, have strengthened the treaty over time.

Role of WIPO

The World Intellectual Property Organization (WIPO) was established in 1967, coinciding with the Stockholm revision of the Paris Convention. As a United Nations specialized agency, WIPO oversees global intellectual property policies, ensuring that innovators and creators receive fair recognition and protection. The organization also manages global trademark, industrial design, and patent registration systems, including the Patent Cooperation Treaty (PCT) and the Madrid System for trademarks.

Relationship with TRIPS and WTO

Countries that are not part of the Paris Convention but are members of the World Trade Organization (WTO) must still comply with many of its principles. This requirement stems from the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which was finalized during the Uruguay Round (1989–1990) of the General Agreement on Tariffs and Trade (GATT).

- Article 2 of the TRIPS Agreement mandates that all WTO members follow Articles 1 to 12 and Article 19 of the Paris Convention.
- TRIPS further outlines enforcement mechanisms, legal remedies, and dispute resolution procedures for handling intellectual property disputes.

Thus, the Paris Convention remains a foundational treaty in global intellectual property law, shaping modern frameworks such as TRIPS and influencing IP regulations worldwide.

CBD for Genetic Resources Management

The Convention on Biological Diversity (CBD) was established in 1992 in response to the growing recognition that isolated conservation efforts focusing on individual species or

ecosystems were inadequate in halting the rapid depletion of natural resources. This depletion threatened the foundation of human societies and sustainable development. The CBD is a comprehensive and ambitious agreement, requiring extensive efforts by the Conference of the Parties to translate its broad commitments into concrete actions.

A key principle of the Convention is the need for global and national action to prevent biodiversity loss. It emphasizes international cooperation, particularly by ensuring financial and technological support from developed to developing nations. This support is crucial, as many developing countries hold the majority of the world's biodiversity. The CBD aims to conserve biodiversity at all levels—genetic, population, species, habitat, and ecosystem— ensuring that ecosystems continue to sustain life on Earth. Furthermore, the Convention acknowledges that sustainable development depends on balancing social and economic goals with biodiversity conservation.

Key Strategies for Implementing the CBD:

- Strengthening policies, legislation, and financial measures to regulate biodiversity use
- Encouraging incentives that promote sustainable biodiversity use
- Establishing trade regulations that support biodiversity conservation
- Enhancing coordination between governments and stakeholders
- Securing adequate financial resources for conservation and sustainable use
- Leveraging advanced technology for biodiversity protection
- Raising political commitment for biodiversity conservation
- Increasing education and public awareness on biodiversity's value

The Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety, a supplementary agreement to the CBD, was adopted in 2003 following ratification by 50 countries. Its primary objective is to protect biodiversity from potential risks associated with living modified organisms (LMOs)—commonly known as genetically modified organisms (GMOs)—that result from modern biotechnology.

The Protocol mandates transparency and an Advance Informed Agreement (AIA) procedure to ensure that countries importing LMOs receive prior written notification. This enables them to make informed decisions regarding the first-time importation of such organisms into their environment. LMOs intended for food, feed, or processing must also be identified in documentation with the label "may contain LMOs" and a declaration that they are not meant for environmental introduction.

This agreement primarily governs the intentional introduction of GMOs—such as genetically engineered crops, trees, and fish—while also addressing trade regulations for GM agricultural commodities, including corn and soybeans.

Criticism of the Cartagena Protocol

- The Protocol does not replace national biosafety laws, requiring countries to establish their own regulations.
- Many nations have not ratified the agreement, and some—such as the United States—oppose it, favoring free trade in biotechnology.
- The Protocol primarily addresses **intentional** GMO introduction, leaving room for **unintentional** GMO contamination.
- Once GMOs are introduced into an environment, their effects can be unpredictable and difficult to reverse.

Suggested Solutions for Strengthening the Cartagena Protocol

- Reconciling economic growth with biodiversity conservation, prioritizing ecological protection
- Expanding global support and ratification of the Protocol
- Strengthening legal enforcement and monitoring mechanisms
- Establishing clear legal supremacy for biodiversity treaties when conflicts arise
- Promoting scientific research on the impact of biodiversity and ecosystem services

Convention on International Trade in Endangered Species (CITES)

Enacted in 1975, the Convention on International Trade in Endangered Species (CITES) regulates global trade in approximately 30,000 species to prevent overexploitation. It has received widespread international support, with many national governments implementing domestic laws to protect species within their borders. So far, no species listed under CITES has gone extinct.

However, the Convention's scope is mostly limited to species with commercial value. The challenge remains in extending protections to lesser-known species that provide essential ecological functions.

Convention on Migratory Species (CMS)

The Convention on Migratory Species (CMS), established under the United Nations Environment Programme (UNEP), provides a global framework for protecting migratory animals and their habitats. The CMS unites nations along migration routes—known as Range States—and sets legal standards for coordinated conservation efforts.

Species at risk of extinction are listed under Appendix I, requiring strict protection measures, habitat conservation, and mitigation of migration obstacles. CMS encourages cooperative conservation action among countries that share migratory species.

Recommended Actions for CMS:

- Strengthen cross-border cooperation to ensure safe migration routes for animals.

- Establish an international task force to combat wildlife crime and illegal activities.
- Encourage stronger intergovernmental resolutions to enhance wildlife law enforcement.
- Utilize platforms like World Wildlife Day to raise global awareness of migratory species conservation.

The Ramsar Convention on Wetlands

Adopted in 1971, the Ramsar Convention on Wetlands was one of the first global treaties focused on ecosystem conservation. The Convention promotes the protection and sustainable management of wetlands, recognizing their critical role in maintaining biodiversity and ecosystem services. Over the years, nearly 600 wetland sites have been designated under the Ramsar List of Wetlands of International Importance.

Challenges and Criticism of the Ramsar Convention

- **Lack of enforcement**: Unlike national environmental laws, Ramsar lacks compliance mechanisms.
- **Legal limitations**: International treaties cannot be enforced unless countries voluntarily accept their provisions.

  Weak enforcement tools: There is no binding legal system to hold nations accountable for violations.
- **Non-mandatory recommendations**: Although Ramsar issues **"soft law"** recommendations, they are not legally binding.

  Proposed Solutions for Strengthening Ramsar
- Enhancing **public awareness** about wetland conservation
- Increasing **local stakeholder engagement**
- Strengthening **funding mechanisms** for wetland protection
- Expanding **research and eco-tourism** opportunities

UPOV (International Union for the Protection of New Varieties of Plants)

The International Union for the Protection of New Varieties of Plants (UPOV) is an intergovernmental organization headquartered in Geneva, Switzerland. It was founded in 1961 through the International Convention for the Protection of New Varieties of Plants, commonly known as the UPOV Convention. The primary objective of UPOV is to establish and promote an efficient system for protecting plant varieties, aiming to stimulate the innovation and development of new plant varieties for the betterment of society.

Under the UPOV Convention, member countries encourage plant breeding by providing intellectual property rights to breeders of new plant varieties, known as the breeder's right. This legal protection ensures that breeders receive recognition and incentives for their innovations, fostering further advancements in agriculture and horticulture.

Background and History

- Established in 1961 by the UPOV Convention, which has been revised in 1972, 1978, and 1991.
- It provides a Plant Breeders' Rights (PBR) system, which allows breeders to commercialize new plant varieties while giving them exclusive control over their propagation for a certain period.

Headquartered in Geneva, Switzerland, and administered by the World Intellectual Property Organization (WIPO).

Key Features of UPOV System

1. **Protection of New Plant Varieties**
   - A new plant variety must be Distinct, Uniform, Stable, and Novel (DUSN) to qualify for protection. o The breeder is granted exclusive rights to produce, sell, and distribute seeds or propagating material of the new variety.
2. **Duration of Protection**
   - The rights are granted for 20 years for most plants and 25 years for trees and vines.
3. **Exemptions**
   - Breeder's Exemption: Other breeders can use a protected variety to develop new ones.
   - Farmer's Privilege: In some countries, farmers are allowed to save and reuse seeds for their own use. However, large-scale commercial use may be restricted.

UPOV Membership

- As of today, over 70 countries are UPOV members.
- Countries that join must align their national laws with UPOV standards.
- India follows its own sui generis system under the Protection of Plant Varieties and Farmers' Rights Act (PPV&FRA), 2001, rather than UPOV.

Criticism of UPOV

- Impact on Farmers: Critics argue that UPOV favors large corporations and restricts farmers' traditional rights to save and exchange seeds.
- Biodiversity Concerns: Some claim it encourages monocultures, reducing agricultural biodiversity.
- Limited Flexibility: The 1991 UPOV Convention is stricter than earlier, reducing farmers' privileges in many countries.

PGRFA (Plant Genetic Resources for Food aAnd Agriculture)

The ex-situ conservation of Plant Genetic Resources for Food and Agriculture (PGRFA) is a critical global effort aimed at ensuring food security for the future. This conservation

approach involves preserving germplasm in genebanks, which may be managed by public or private institutions.

There are different types of ex-situ genebank collections, including:

- Seed gene banks, where seeds are dried to low moisture levels and stored in cold conditions to maintain their viability for decades. This is the predominant method, with 90% of genebank holdings being seeds (FAO, 1998).
- Field genebanks, used for species that are difficult to store as seeds, such as certain fruit trees and tuber crops.
- In vitro and cryopreservation, which involve storing plant tissues or propagules under controlled conditions to preserve genetic material of vegetatively propagated or recalcitrant seed species.

Globally, there are approximately 1,750 ex situ genebanks that house 7.4 million accessions (FAO, 2010). The majority of these collections belong to cereals (45%), followed by food legumes (15%), and vegetables, fruits, and forage crops (6–9%). Major conserved crops include wheat, rice, barley, maize, beans, sorghum, soybeans, oats, groundnuts, and cotton (FAO, 2010).

One of the most significant initiatives in global seed conservation is the Svalbard Global Seed Vault (SGSV), established in 2008. Located in the permafrost 130 meters inside a mountain on an island near the North Pole, it serves as a backup for global seed collections. By August 24, 2014, the vault housed 824,625 accessions from 899 genera and 4,740 species. The deposited materials remain the property of the original contributors, serving as a safeguard against biodiversity loss.

Conclusion:

The legal frameworks governing genetic resource management play a pivotal role in biodiversity conservation, agricultural sustainability, and intellectual property rights. The Paris Convention has laid the foundation for the protection of industrial property rights, fostering international trade and innovation. The Convention on Biological Diversity (CBD) has established a comprehensive framework for the sustainable use of biodiversity and fair benefit-sharing, further reinforced by the Cartagena Protocol on Biosafety, which regulates Living Modified Organisms (LMOs).

The UPOV Convention provides an intellectual property system for plant breeders, granting exclusive rights to new plant varieties while balancing the interests of breeders and farmers. However, concerns over farmers' rights and biodiversity loss highlight the need for more inclusive policies. The Plant Genetic Resources for Food and Agriculture (PGRFA)

framework, including ex situ conservation strategies and the Svalbard Global Seed Vault, plays a crucial role in safeguarding genetic diversity against climate change and genetic erosion.

Despite these legal frameworks, significant challenges remain, including equitable access to genetic resources, enforcement gaps, and conflicts between intellectual property rights and traditional agricultural practices. Addressing these issues requires enhanced international cooperation, stronger legal enforcement mechanisms, and sustainable innovation policies to ensure that genetic resource management supports both economic growth and environmental sustainability. A balanced approach that integrates scientific advancements, legal protections, and ethical considerations will be key to securing global biodiversity and food security for future generations.

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Chapter 7

NAVIGATING ECONOMIC, ETHICAL AND DEPOSITORY CHALLENGES FOR BIOTECHNOLOGY PATENTS

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Abstract:

A patent is an exclusive right granted to an inventor by providing them legal protection and benefits for a specific period for their invention. Biotechnology Patents protect genetically modified organisms, gene sequences, biopharmaceuticals and novel bioprocesses. These patents can be filed under the Patent Act, 1970 by disclosing the invention, prior art, application drafting, followed by submission and examination of the invention by Patent Officers. Patents are granted on the basis of novelty, non-obviousness and industrial applicability of the invention. Patents protect the inventor economically but limit the accessibility of essential technologies in the healthcare and agriculture sectors. Patenting the genetic materials, life forms and indigenous knowledge has induced ethical concerns of bioethics and social justice. To ensure the reproducibility and transparency of bioprocesses, depositing the biological materials in the assigned repositories has been made mandatory. These concerns impact the potential of biotechnology and influence the patent filing decisions and growth of biotechnology across the globe. It is the need of the hour to understand the interplay between economic benefits, ethical dilemmas and legal obligations for equitable advancements. By addressing the concerns and decisions, we can balance innovation with accessibility and ethical responsibility.

Keywords: Biotechnology Patents; Ethical Challenges; Economic Challenges; Depository Challenges; Biomaterials

Introduction:

A patent is an exclusive right granted to an inventor by providing them legal protection and benefits for a specific period for their invention. A patent is designed to incentivize the inventor's innovation and grant exclusive rights that can only be used by the inventor for a specific period, usually 20 years from the day of filing the patent. This exclusive right helps the patentee to commercially exploit the invention and recover the cost of research and development during the inventing process and finally generate profits. Therefore, a patent is a contract between the inventor and the respective state where a temporary monopoly is granted to the

inventor in exchange for the disclosure of the invention by the inventor to the state, thus making it publicly available after the patent term expires (Elliot, 2007).

A patent usually provides the inventor with exclusive rights for using, selling and manufacturing the invention which helps in encouraging investment in the Research and Development sector as this ensures that their efforts can be protected from being replicated and prevented from unauthorized use. For an invention to be patentable, it must meet certain criteria: Novelty, Non-obviousness (inventive step), and Industrial Applicability (utility). Novelty refers to the invention that has prior not been disclosed to the public and has not been ever discovered before. When an invention is not an obvious modification of an existing technology to a person skilled in the art, it then fulfills the criteria of non-obviousness. Industrial applicability implies that the invention can be made or used at and in the industries (Atherton *et al.,* 2017).

Biotechnology Patent and it's Types

As the World Health Organization (WHO) defines biotechnology as the application of "engineered biological processes", therefore concluding the biotechnology sector into five different segments, mainly, Biopharamaceuticals, Bioagriculture, Bioservices, Bioindustrial and Bioinformatics. Biotechnology has many applications in the fields of medicine, therapeutics, diagnostics, investigations, vaccines & its production along with synthesis of the antibiotics and drug development (Gupta *et al.,* 2016).

Biotechnology harnesses biological systems and living organisms/their derivatives to produce products and technologies. This is an interdisciplinary field that integrates biology and technology to produce effective results and new technologies under the various biotechnology fields, such as (Bhapkar, R.A. *et al.,* 2024):

- **Medical Biotechnology:** This domain focuses mainly on healthcare systems and human health through advancements in therapeutics via personalized medicines, gene therapies, and vaccines. Production of synthetic insulin from *Escherichia coli* and mRNA vaccines for COVID-19, stem cell therapies and 3-D printed organs are the boon of biotechnology.
- **Agricultural Biotechnology:** Enhancing crop resilience and yield through genetic modifications has been the main target for benefiting the agriculture sector by using biotechnology.
- **Industrial Biotechnology:** Increased production of antibiotics, acids and other fermentation products along with the production of biodegradable plastics and biofuels for reduction of reliance on non-renewable sources.

- **Environmental Biotechnology:** Bioremediation for the pollution removal from the soil, microorganisms helping in recycling the waste and reduction in greenhouse emission gases has been helpful in bettering the environment.

Legal Framework of Biotech Patents in India

In India, the legal framework of all patents is governed by the Patents Act, 1970 and the Patent Rules, 2003. The Patents Act, 1970 defines "invention" as any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof. The Patents Act, 1970 also provides patent protection to biological materials and such as microorganisms, plants and animals provided that it meets the patentability criteria. This act also provides the provision of compulsory licensing which allows a third party to use a patented invention without the consent of the patent owner in certain circumstances like public health emergencies and when the patented invention is not being used in India to a certain extent (Syed, 2019). The TRIPS agreement has played a significant role in shaping the intellectual property rights regime in India, mandating that member countries provide patent protection for pharmaceutical products (Kumari, 2023; Mahajan, 2011). The Guidelines for the Examination of Biotechnology Applications for Patents were released in the year 2016 stating specific regulations and guidelines for the examination of the patent applications in the field of biotechnology. These guidelines explain in detail the criteria for the patentability of the biological products, the amount of disclosure of the invention for patentability along the other requirements needed to fulfill the patent application. All these guidelines and regulations help in encouraging innovation, research and development in the field of biotechnology with a proper balance by patenting the IP rights with the public interest (Giugni & Giugni, 2010).

Challenges faced by Bio-Patentees

Biotechnology Patents are essential for fostering innovation but they present numerous challenges that impact the investors, regulatory frameworks and the research organizations and their ecosystems. The multifaceted challenges faced by biotechnology patents intersect economic incentives, ethical dilemmas and logistical obligations. Economically, the high costs of research and development (R&D) in biotechnology from gene editing tools to biologics manufacturing, necessitate patent protection to attract investment and recoup expenses. However, monopolistic pricing practices hinder access to essential innovations, particularly in healthcare and agriculture. For example, patents on critical therapies like monoclonal antibodies or genetically modified seeds can inflate prices, limiting affordability for low-income populations and creating dependency cycles for farmers. Small and Mediumsized Enterprises (SMEs) often struggle to secure venture capital due to the high risk of failure in biotech research and development. These

dynamics strain the foundational goal of balancing innovation with public access (Fuglie *et al.,* 2019). Ethical challenges arise from the commodification of life forms and genetic materials. Patenting human genes such as BRCA1/BRCA2 or indigenous biodiversity sparks debate over bioethics and social justice as seen in the cases of biopiracy and restricted access to genetic testing. Ethical licensing frameworks such as restrictions on germline editing or tobacco-related applications attempt to mitigate harm but lack democratic legitimacy and global coordination. Further, patents on traditional knowledge or biological resources often marginalize indigenous communities, raising concerns about equity and cultural appropriation. These tensions undermine the public trust in the patent system and its foundation, thus complicating the regulatory harmonization across jurisdictions (Brody, 2010). Depository requirements introduce logistical and financial burdens. To ensure reproducibility, inventors must deposit biological materials such as microorganisms and cell lines in recognized repositories under the Budapest Treaty. While this promotes transparency, maintaining viability and accessibility of deposits demands significant infrastructure and costs that affect the SME's and research and developments. Failure to comply to the requirements and procedures leads to invalidation of the patents as seen in legal disputes over insufficient disclosure. Additionally, evolving technologies like CRISPR Cas9 challenge traditional depository frameworks, necessitating adaptive protocols for novel bioprocesses.

Beyond these core challenges, systemic barriers such as regulatory fragmentations, slow approval processes and inconsistent international patent standards further stifle innovation. Patent litigation rists and the rise of open source alternatives pressure traditional models of intellectual property. Collectively, these issues strain the patent system's capacity to foster equitable innovation, necessitating reforms like compulsory licensing, ethical oversight committees and streamlines depository mechanisms to align intellectual property frameworks with societal and scientific advancements (Dreyfuss, 2020).

Economic Consideration

Economic considerations are central to the biotechnology patent system. Patents are intended to incentivize innovation by providing inventors with exclusive rights to their inventions, allowing them to recoup R&D costs and generate profits. However, the economic impact of biotechnology patents is complex and multifaceted.

1. Incentivizing Innovation

The biotechnology industry thrives on innovation, requiring substantial investments in research and development (R&D) to advance medical, agricultural, and industrial applications. Patents play a crucial role in incentivizing innovation by providing legal protection to inventors

and companies, ensuring that they can reap the benefits of their discoveries. Without patent protection, there is little incentive for businesses to invest in highrisk biotechnology projects, as competitors could easily replicate and commercialize their innovations without compensating the original inventor. Patents grant exclusive rights for a limited period (typically 20 years), allowing inventors to market their products without competition, recover their R&D investments, and gain financial returns. This exclusivity motivates researchers to explore novel technologies, such as gene editing, synthetic biology, and personalized medicine, which require significant upfront costs and long-term experimentation. Additionally, patents foster innovation by promoting knowledge sharing. Patent applications require detailed descriptions of the technology, ensuring that scientific advancements are documented and can serve as a foundation for further research. However, critics argue that the current patent system sometimes stifles innovation by creating patent thickets—overlapping patents that make it difficult for new entrants to develop related technologies. Striking a balance between rewarding innovation and ensuring open access to essential technologies is key to sustaining growth in the biotechnology sector (Grabowski *et al.,* 2015).

2. Market Exclusivity and Pricing

Market exclusivity granted by patents is one of the most significant economic factors in biotechnology, particularly in the pharmaceutical industry. When a biotech company secures a patent for a new drug, therapeutic process, or genetically modified organism, it gains the legal right to exclude competitors from producing or selling the same product for a specific duration. This exclusivity allows companies to set prices that reflect their R&D expenses, manufacturing costs, and expected returns on investment. While this model benefits biotech firms by ensuring profitability, it has significant implications for healthcare affordability and accessibility. The high cost of patented pharmaceuticals, for example, often places essential medications out of reach for patients in low-income regions. A well-known example is the case of life-saving cancer drugs and insulin, which remain expensive due to patent protections, despite increasing global demand. The issue of "evergreening" further exacerbates concerns—companies make minor modifications to existing drugs to extend patent protection, delaying the introduction of more affordable generic versions. Governments and international organizations attempt to address these issues through compulsory licensing, parallel imports, and price regulation policies. However, balancing the need for profit-driven innovation with equitable access to biotechnological advancements remains a challenge in global healthcare and agriculture (Ribeiro *et al.,* 2020).

3. Licensing and Technology Transfer

Patent licensing and technology transfer play a vital role in the commercialization and dissemination of biotechnology innovations. Licensing allows patent holders to grant other companies or institutions the right to use their patented technology in exchange for royalties or licensing fees. This system promotes collaboration between research institutions, startups, and larger corporations, accelerating the development and deployment of new technologies. In the pharmaceutical and agricultural biotechnology sectors, licensing agreements enable smaller biotech firms to partner with established companies that have the resources and infrastructure to bring innovations to market. For example, many universities and research institutes license their biotech patents to pharmaceutical companies, facilitating the production of new drugs and therapies. Additionally, technology transfer initiatives help bridge the gap between academic research and commercial application. Government and international agencies often encourage technology transfer to developing countries to improve access to biotechnology-based healthcare, agriculture, and environmental solutions. The Bayh-Dole Act in the U.S. is a prime example of a policy that allows publicly funded research institutions to patent their discoveries and license them for commercial use, thus promoting public-private partnerships. Despite its advantages, licensing can also lead to monopolization issues if dominant firms acquire exclusive rights to critical biotechnologies, limiting competition and hindering access. Ensuring a fair and transparent licensing system is crucial to fostering inclusive innovation (Ribeiro *et al.,* 2020).

4. Investment and Funding

Investment and funding are crucial drivers of success in the biotechnology industry, and patents significantly influence investor confidence. Biotechnology startups, which often require years of R&D before commercializing a product, rely heavily on venture capital, government grants, and private investment. A strong patent portfolio enhances a company’s valuation, making it more attractive to potential investors who seek assurances of exclusivity and market competitiveness. Patents serve as a tangible asset that can be used for securing funding, forming strategic partnerships, or attracting acquisitions by larger firms. Venture capitalists and angel investors assess a biotech company's intellectual property (IP) portfolio when deciding to invest, as patents indicate the company's ability to protect its innovations and maintain a competitive edge. Additionally, government agencies such as the National Institutes of Health (NIH) and the European Research Council (ERC) offer grants for biotech R&D, often prioritizing projects with patent potential. However, while patents can facilitate funding, they also introduce financial challenges. The cost of obtaining and maintaining patents, including legal fees for filing, prosecution, and enforcement, can be prohibitively high for small biotech firms. Furthermore,

aggressive patent litigation and disputes can divert resources away from research, impacting innovation. Ensuring that patent-related costs do not discourage promising biotech startups from pursuing groundbreaking research is essential for sustaining long-term growth and innovation in the industry (Ribeiro *et al.,* 2020).

Ethical Considerations

Ethical considerations are paramount in the realm of biotechnology patents. The patenting of life forms, genetic material, and biological processes raises profound ethical questions about ownership, access, and the potential impact on society.

1. Patenting of Life Forms

The patenting of living organisms, genetic sequences, and biological materials is one of the most controversial aspects of biotechnology patents. The ethical debate centers on whether life forms should be considered intellectual property or remain part of the shared biological heritage of humanity. Proponents argue that granting patents on genetically modified organisms (GMOs), cell lines, and synthetic biology innovations encourages scientific advancement and commercial investment. However, critics contend that assigning ownership to life forms commodifies nature and raises concerns about the moral implications of altering and claiming exclusive rights over biological entities. A notable example is the controversy over gene patents, such as Myriad Genetics' patents on BRCA1 and BRCA2 genes, which are linked to breast and ovarian cancer risk. Opponents argued that patenting naturally occurring human genes restricted research and access to genetic testing. The U.S. Supreme Court ruled in Association for Molecular Pathology v. Myriad Genetics, Inc. (2013) that naturally occurring genes cannot be patented, although synthetic DNA (cDNA) remains patentable. This decision highlights the fine ethical line between incentivizing biotechnology research and maintaining open access to genetic information. The debate continues as new advancements in genome editing (e.g., CRISPR-Cas9) raise further questions about ownership and the ethical limits of biotechnological innovations (Lee, 2024).

2. Access and Equity

Biotechnology patents can create economic barriers that restrict access to essential medicines, agricultural innovations, and diagnostic tools. The high cost of patented drugs and therapies can disproportionately impact low-income populations, particularly in developing countries where healthcare systems may lack the resources to provide life-saving treatments. The HIV/AIDS epidemic in Africa illustrated the impact of patents on drug accessibility, as patented antiretroviral drugs were initially priced beyond the reach of many patients. Global pressure eventually led to the introduction of compulsory licensing, allowing the production of generic

versions at lower costs. Similarly, agricultural biotechnology patents can influence food security. Large agribusiness companies that hold patents on genetically modified seeds often impose strict licensing agreements that prevent farmers from saving and reusing seeds. This has led to dependence on commercial seed suppliers, raising concerns about food sovereignty and the rights of farmers, particularly in developing nations. Organizations such as the World Health Organization (WHO) and the United Nations (UN) emphasize the need for policies that balance patent rights with public health and sustainability objectives. In response to these concerns, initiatives like the Medicines Patent Pool (MPP) and open-source biotechnology platforms seek to enhance affordability and accessibility while still providing financial incentives for innovation. The ethical challenge lies in ensuring that patent protection does not come at the expense of fundamental human rights, including the right to health and food security (Kachigian, 2020).

3. Bioethics and Morality

The patenting of biotechnology inventions that involve human genetic material, stem cells, or embryos raises deep ethical and moral concerns. The debate often centers on the extent to which human biological materials should be patentable and how such patents impact medical research, clinical applications, and individual autonomy. For example, stem cell research has been at the forefront of ethical discussions, particularly regarding the use of human embryonic stem cells (hESCs). Some jurisdictions allow patents on stem cell-derived treatments, while others impose restrictions based on ethical considerations. In 2011, the European Court of Justice ruled in Brüstle v. Greenpeace that patents on inventions involving human embryonic stem cells were unethical if they resulted in the destruction of human embryos. This decision reflects the ongoing global divide regarding the moral and legal status of embryonic materials in patent law. Additionally, the use of CRISPR-Cas9 gene-editing technology to modify human embryos for therapeutic or enhancement purposes raises questions about genetic privacy, eugenics, and the potential for unintended consequences. Ethical frameworks, such as those outlined by UNESCO's International Bioethics Committee, call for responsible governance to prevent misuse and to ensure that biotechnological advancements align with societal values and ethical principles (Macer *et al.*).

4. Traditional Knowledge and Biopiracy

The intersection of biotechnology patents and traditional knowledge (TK) has given rise to significant ethical and legal challenges, particularly concerning biopiracy—the unauthorized use of indigenous knowledge and biological resources for commercial gain. Many traditional communities have cultivated medicinal plants, agricultural techniques, and biodiversity

conservation practices for centuries. However, multinational corporations have, at times, patented these resources without recognizing or compensating the indigenous groups who developed and preserved them. A well-documented case is the patenting of turmeric (Curcuma longa) for wound healing by the University of Mississippi Medical Center in 1995.

The patent was later revoked after India successfully challenged it by demonstrating that the healing properties of turmeric had been known and used in Ayurvedic medicine for generations. Similarly, controversies over patents on neem (Azadirachta indica) and basmati rice highlight the ethical implications of appropriating traditional knowledge without proper acknowledgment or benefit-sharing. To address this issue, international agreements such as the Nagoya Protocol (2010) under the Convention on Biological Diversity (CBD) emphasize fair and equitable sharing of benefits arising from the use of genetic resources. Many countries have also established Traditional Knowledge Digital Libraries (TKDLs) to document indigenous knowledge and prevent unjustified patents. Ethical frameworks demand that patent laws incorporate principles of informed consent, benefit-sharing, and respect for cultural heritage to prevent exploitation while still fostering innovation (Rao, 2012).

Depository Considerations

Depository considerations play a vital role in the patenting process of biotechnology inventions, particularly those involving biological materials that cannot be adequately described through written documentation alone. Many biotechnological innovations, such as genetically modified microorganisms, cell lines, hybridoma cells, plasmids, and other living materials, require a physical deposit in a recognized biological repository to ensure their reproducibility and accessibility. The depository process helps address legal, technical, and scientific challenges associated with patenting biological materials and supports transparency in biotechnology research.

1. Purpose of Depositing Biological Materials

The primary purpose of depositing biological materials in an internationally recognized depository is to ensure that the patented invention is reproducible by a person skilled in the field. Unlike chemical compounds or mechanical inventions, many biological materials cannot be fully described in writing due to their complex and evolving nature. Depository requirements allow patent examiners and other researchers to verify the validity of an invention and ensure that it meets patentability criteria, including novelty, nonobviousness, and industrial applicability. Biological deposits also facilitate licensing agreements and technology transfer by providing researchers and industries with access to patented biological materials. This fosters collaboration,

innovation, and the practical application of biotechnological advancements in fields such as medicine, agriculture, and environmental biotechnology.

2. Legal Framework and International Treaties Governing Depository Requirements

Depository considerations are governed by international treaties and national patent laws. The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977), administered by the World Intellectual Property Organization (WIPO), establishes a uniform system for depositing microorganisms and biological materials. Under this treaty: A biological material deposited in any International Depository Authority (IDA) is recognized by all contracting states, reducing the need for multiple deposits. The deposit must be made before the patent application is filed to ensure availability for examination. The depositor must submit detailed information regarding the biological material, including its properties, source, and method of isolation. The depository institution is responsible for maintaining the viability and purity of the material for at least 30 years. Upon the granting of a patent, the deposited material must be accessible to qualified individuals under strict conditions to protect proprietary rights. Countries that are signatories to the Budapest Treaty follow these depository guidelines, while others may have additional national requirements for biological patent deposits (Georgios, 2006).

3. Requirements for Depositing Biological Materials

The specific requirements for depositing biological materials vary by jurisdiction, but they generally include (Demirkan *et al.,* 2012):

3.1. Deposit in a Recognized Culture Collection: The biological material must be placed in an internationally recognized depository institution, such as the American Type Culture Collection (ATCC), Deutsche Sammlung von Mikroorganismen und Zellkulturen (DSMZ), or National Collection of Type Cultures (NCTC). These institutions ensure that the material remains viable, uncontaminated, and accessible for scientific verification.

3.2. Pre-filing Deposit: The deposit must be made before or at the time of filing a patent application to comply with legal requirements. This ensures that the material is available for patent examiners to verify and that the invention meets disclosure requirements.

3.3. Detailed Description of the Biological Material: The depositor must provide comprehensive documentation describing the biological material, including its taxonomic classification, properties, methods of isolation, and applications. Some jurisdictions require genetic sequencing data and functional characterization of the biological material.

3.4. Maintenance of Viability and Purity: The depository authority is responsible for ensuring that the deposited material remains viable and uncontaminated for at least the duration of the

patent's life (typically 20 years from the filing date). Regular checks and quality control measures must be performed to confirm the integrity of the biological material.

3.5. Access to Deposited Materials: During the patent prosecution stage, access to deposited materials is restricted to patent examiners. Once the patent is granted, qualified researchers and institutions may request access under regulated conditions to prevent unauthorized commercial exploitation.

4. Challenges Associated with Depository Considerations

Despite the importance of biological depositories, several challenges complicate their implementation in the biotechnology patenting process:(Shelke *et al.,* 2025)

4.1. High Costs and Accessibility Issues: Depositing and maintaining biological materials in recognized repositories can be expensive, particularly for small biotech startups, individual researchers, and institutions in developing countries. The costs associated with long-term storage, periodic viability checks, and compliance with international standards can create financial burdens and limit participation in biotechnological innovation.

4.2. Legal and Jurisdictional Conflicts: While the Budapest Treaty provides a standardized approach to biological deposits, variations in national patent laws can create inconsistencies. Some countries impose additional disclosure requirements or restrict access to certain biological materials due to biosecurity and ethical concerns. These differences can lead to patent disputes and hinder international collaborations.

4.3. Ethical and Biodiversity Concerns: The depository system raises ethical concerns, particularly regarding the patenting of genetic resources derived from biodiversityrich regions. The Convention on Biological Diversity (CBD) and the Nagoya Protocol emphasize fair and equitable sharing of benefits arising from the use of genetic resources. However, cases of biopiracy—where biological materials and traditional knowledge are patented without proper acknowledgment or compensation to indigenous communities— highlight the need for stronger ethical oversight in the depository process.

4.4. Security Risks and Biocontainment: Depositing biological materials that have potential pathogenic or dual-use applications poses security challenges. Institutions handling hazardous microorganisms or genetically modified organisms (GMOs) must adhere to strict biosafety and biosecurity regulations to prevent accidental release or misuse. The rise of synthetic biology further complicates these concerns, as novel biological constructs may require new regulatory frameworks.

Conclusion:

The biotechnology sector stands at the intersection of groundbreaking innovation and complex challenges that test the resilience of intellectual property frameworks globally. As this paper has explored, the economic, ethical, and depository considerations surrounding biotechnology patents demand a nuanced balance between incentivizing innovation and safeguarding public welfare. These challenges are not isolated; they intertwine to shape the trajectory of scientific progress, access to critical technologies, and the ethical boundaries of intellectual property rights. Economically, patents are essential for recovering the high costs of biotechnological research and development, as seen with CRISPR-Cas9 technology. However, the monopolistic control granted by patents often leads to inflated prices for lifesaving therapies, exacerbating healthcare inequities, particularly in developing nations. Ethically, biotechnology patents raise significant concerns about the commodification of life and the exploitation of indigenous knowledge through biopiracy. Additionally, depository requirements under treaties like the Budapest Convention ensure reproducibility but impose financial burdens on small enterprises, complicating compliance and innovation. Addressing these challenges is crucial for balancing commercial interests with societal needs. Beyond these core challenges, systemic issues like regulatory fragmentation and slow approval processes hinder global harmonization. The Patent Cooperation Treaty (PCT) streamlines international filings but cannot resolve jurisdictional disparities in ethical standards or enforcement. Moving forward, policymakers must foster collaboration among governments, industry leaders, and civil society to craft inclusive policies. Initiatives like patent pools for essential medicines, ethical oversight committees, and subsidies for SMEs can bridge gaps between innovation and accessibility.

In conclusion, biotechnology patents are a double-edged sword: they drive progress but risk entrenching inequities. Navigating this landscape requires a commitment to balancing commercial interests with ethical imperatives and public health priorities. By reimagining intellectual property frameworks through a lens of equity and sustainability, we can ensure that biotechnological advancements serve humanity as a whole, rather than a privileged few. The path forward lies not in dismantling patents but in recalibrating their role to align with the greater good.

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Chapter 8

TOOLS AND SOURCES FOR PATENT LITERATUER EXPLORATION

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Abstract:

A patent is a property right given to an inventor for an invention which is new, innovative and problem solving for the society. A patent should be novel, new and can be useful for business purpose. More patent filing indicates that the country is going towards innovation. Before filing a patent, one should do the patentability assessment search, current technology search, clearance search, and validity search. of the idea or product, he/she seeking the right of property for. Prior art search includes the patent literature search, which basically includes all the published documents related to patents, including patent applications, granted patents, and related publications. There are a lot of patent and non-patent information databases in order to have a complete picture. These information databases can be retrieved from various database retrieval systems. In this chapter we learn various information sources in patent literature search and their retrieval systems.

Introduction

Patent:

A patent is a legal document with technical/scientific content. It is property right given to the inventor for an invention. It is given in order to protect the innovation from being copied or reproduced. Starting from the date of filing of the application, the validity of the grant is usually 20 years. The Patent Renewal Fees has to be paid annually after the grant of the patent.

1. Patent Criteria:

The patent should follow the following criterion:

1. **Novelty** - the innovation should be new and not known to anybody. The people should not know about the innovation and there should not be any paper publication. It should not be claimed in other application.
2. **Inventive step** – the patent should be a technical innovation over the existing knowledge. It should not be obvious to a skilled person skilled in that field.
3. **Utility** - the invention should be useful. It must function according to its claimed purpose. For example: if it is a novel molecule, then it must exhibit its intended utility.

1.1 Understanding Patent Information and Documentation:

(1) Patent Information - Patent information comprises the technical and legal details found within documents issued by patent offices. These documents, which are regularly published, include both granted patents and pending patent applications. They serve as valuable resources for understanding technological advancements and the legal rights associated with inventions.

(2) Patent documents - Patent documents encompass a range of materials that provide both technical and legal information related to inventions. These documents, regularly published by patent offices, include: published patent applications, granted patents, inventors' certificates, utility certificates and utility models. Each patent document typically contains: bibliographic information, abstract, detailed description, claims.

1.2 Benefits of Using Patent Information

(1) Access to the latest information: The publication of a patent application helps us to have up to date information on which patents are granted and which patented products are released in the market.

(2) Standardized format of patent documents: Patent documents follow a consistent and internationally recognized structure, which enhances their readability and facilitates efficient information retrieval. This uniformity is particularly beneficial for researchers, legal professionals, and businesses engaged in patent analysis.

(3) Detailed description: It provides clear and complete description which includes the background, description and drawings and much more detailed information about a technology.

(4) Unique source of information: About 70% of the information given in patent documents have never been published. In every technical field there is estimated 50 million patent documents published. Each year about two million documents are added to it.

1.3 Types of Patent Information Search:

(1) Current Technology Search: It gives information about technological field as it includes wide range of patent and non-patent literature in connection with it. It reveals studies, published papers, other non-patent literature, published patent applications worldwide. Along with information of expired and non-expired patents.

(2) Patentability Assessment: Patent qualification search should be done during the preparation and before claiming it in patent application. It will help in decision making such as: (1) filing a patent application, (2) proceeding with the current application (3) enhancing the invention.

(3) Clearance or freedom to operate search: This search is done to avoid any infringement after the publication of the patent product. It gives freedom to the operator to make, sell, import or use a patent product. It gives a brief information of all the claims comprising the relevant patents. It helps one to avoid any action which will be assumed to be an infringement of a patent which is still not expired.

(4) Patent invalidity search: Invalidity searches help to avoid any anticipated litigation which challenges the patent product. The validity of a patent can be searched using documents that could challenge its novelty or inventive step and uncover granted patents or other published papers that may make a patent partially or fully invalid.

2. Patent Literature:

Patent literature is all the published documents related to patents, including patent applications, granted patents, and related publications. It serves as a valuable source of technical, legal, and commercial information.

2.1 Types of Patent Literature:

1. **Patent Applications** – Documents filed with patent offices, describing new inventions. These may be pending or abandoned.
2. **Granted Patents** – Approved patents that gives property rights to the inventor for a limited time period of 20 years.
3. **Patent Specifications** – Detailed descriptions of the invention, including claims, drawings, and prior art references.
4. **Patent Examination Reports** – Official reports from patent office assessing the patentability of an invention.
5. **Patent Classifications** – Systems like IPC (International Patent Classification) and CPC (Cooperative Patent Classification) that categorize patents based on technology areas.
6. **Patent Citations** – References to prior patents or documents relevant to an invention.

3. Information Sources in Patent Literature Search:

1. Primary Sources

Primary sources consist of original patent documents, applications, and legal filings from official patent offices. These are the most authoritative and direct sources of patent information.

a) Official Patent Office Databases

Patent offices worldwide maintain publicly accessible databases that provide direct access to original patent documents:

- **United States Patent and Trademark Office (USPTO)** (https://www.uspto.gov)
- **European Patent Office (EPO) – Espacenet** (https://worldwide.espacenet.com)

- **World Intellectual Property Organization (WIPO) – PATENTSCOPE** (https://patentscope.wipo.int)
- **China National Intellectual Property Administration (CNIPA)** (http://english.cnipa.gov.cn)
- **Japan Patent Office (JPO)** (https://www.j-platpat.inpit.go.jp)
- **Korean Intellectual Property Office (KIPO)** (https://www.kipo.go.kr)

These databases provide full-text search options, patent images, classification searches, and legal status tracking.

2. Secondary Sources

Secondary sources interpret, analyze, or organize information derived from primary sources. These include commercial and professional databases that enhance search capabilities.

a) Commercial Patent Databases

These databases offer advanced analytics, patent family grouping, and expert-curated indexing:

- **Derwent Innovation (Clarivate)** – Provides advanced patent analysis tools.
- **LexisNexis PatentSight** – Features AI-based patent search capabilities.
- **PatBase** – A global patent search tool with legal status tracking.
- **Questel's Orbit Intelligence** – Offers AI-driven analytics and competitive insights.
- **Google Patents** (https://patents.google.com) – A free resource with machine-learning-based search features.

3. Tertiary Sources Tertiary sources compile and summarize information from both primary and secondary sources, providing overviews, guides, and indexes.

a) Patent Classification Systems

These systems organize patents into structured categories based on their technical content. These systems help patent offices, inventors, and researchers quickly locate relevant patents and assess innovation trends:

- **International Patent Classification (IPC)** – A hierarchical system for patent categorization.
- **Cooperative Patent Classification (CPC)** – A detailed classification system used by EPO and USPTO.
- **Derwent World Patents Index (DWPI)** – Provides structured abstracts and enhanced indexing.

b) Patent Search Guides and Databases

These provide step-by-step instructions on conducting effective patent searches. They help users navigate classification systems, keyword searches, and legal status tracking:

- **WIPO Patent Search Guide** – A comprehensive guide for global patent searching.
- **Patent Office Examination Guidelines** – Help understand patentability criteria and legal interpretations.

4. Other Sources

Patent literature searches are often complemented by other relevant sources, including non-patent literature (NPL) and industry insights.

a) Non-Patent Literature (NPL)

During patent research, in order minimize the crossing of data between patent and non-patent documentation it is important to analyze another scientific, technological, market and economic information:

- **Scientific and Technical Journals** – IEEE Xplore, PubMed, Springer, ScienceDirect.
- **Conference Proceedings** – ACM Digital Library, SPIE Digital Library.
- **Industry Standards and Reports** – ISO, ASTM, IEC, Gartner, Forrester Reports.

b) AI-Powered Patent Analytics Tools

These are software solutions that use artificial intelligence, machine learning, and natural language processing (NLP) to analyze patents and related intellectual property (IP) data:

- **The Lens –** Open-source patent and scholarly data platform.
- **PatSnap** – AI-enhanced IP analysis with innovation trends.

c) Open-Access and Government Databases

These provide free access to global intellectual property (IP) data:

- **DEPATISnet** – German Patent and Trade Mark Office search.
- **India's IP India Portal** – Indian patent search.
- **FreePatentsOnline** – Aggregated search tool for multiple patent offices.

Table 3.1: Brief information about popular information retrieval systems

Patent database	Developed by	Number of patent documents	Volume of information provided	Information about the patent document
Espacenet	European Patent Office	>80 million	Full text (not for all documents)	Patent document number; publication date; name of the invention; inventors; applicants; classification; abstract; description (not for all documents); claims (not for all documents); figures; cited in patent application sources (not for all documents); legal status.
Free Patents Online	Patents Online LLC	>30 million	Full text	Name of the invention; patent application number; abstract; inventors; publication date; priority date; classification; International Classification; similar patent applications; claims; description; additional materials.
Google	Google Inc.	n/d	In volume provided by patent offices, to which Google has access	Name of the invention; publication number; abstract; claims; description; type of publication; application area; application number; publication date; declared; priority date; other patent numbers; publication number; inventors; applicant; other patents; non-patent documents; classification; legal events; external links (Patentscope, Espacenet).

The Lens	Cambia	>85 million	Full text	Name of the invention; patent number; abstract; claims; full text (description); owners; applicants; inventors; publication date; IPC; US classification; document history (publication, patent applications, priority); patent family; non-patent citations
PATENTSCOPE	World Intellectual Property Organization	≈33 million	Full text	Name of the invention; publication number; international application number; abstract; publication date; international filing date; IPC; applicants; inventors; priority date; designated states; language of publication; language of filing; claims (in the language of the applicant); description (in the language of the applicant); additional materials (including figures).
USPTO	United States Patent and Trademark Office	>5 million	Full text	Number of patent document; publication date; name of the invention; abstract; inventors; applicants; application number; filing date; information about similar patent documents; cited in patent application sources; claims; description; drawings and figures.

Non-patent databases	Short description	Link
Databases of the European Bioinformatics Institute	Contains a wide range of molecular databases, as well as more than 100 different services. The resource allows complex queries, and analysis of the results.	http://www.ebi.ac.uk/services
Web of Science	Core Collection provides access to some 12 000 high-ranking journals all over the world, including open access, as well as to 160 000 conference proceedings from 1900. It covers articles in 250 different scientific area. The system allows searching and filtering articles by subject, author, title, journal, publisher, year, editor, etc. Service indicates the number of citations of each article.	http://apps.webofknowledge.com/
Scopus	The resource includes some 55 million documents, including 21,000 medical and scientific journals, 50,000 books and 6.5 million conference proceedings, as well as 24 million patent documents. The system allows to search and filter articles by author, subject, title, abstract, keywords, journal, publisher, language, list of references, conferences, ISSN (International Standard Serial Number), DOI (digital object identifier), or country. Service indicates the number of citations of each article.	http://www.scopus.com/
PubMed	The database provides access to over 3.3 million articles on medicine, chemistry, biology, etc. PubMed contains more than 24 million links to biomedical literature from MEDLINE, to scientific journals and online books. Citations may include links to full text. It enables full-text search, by abstract, title, author, journal, book, year of publication, pages, reviewer, language, and by other fields in combination.	http://www.ncbi.nlm.nih.gov/pubmed/

IEEE Xplore Digital Library	It contains some 3.8 million technical articles. The resource allows to search articles by author, title, abstract, keywords, publication, journal number, article number, ISSN, etc., combining these fields. It is also possible to individually select articles with open access and filter the results by date, author, journal title and other parameters.	http://ieeexplore.ieee.org/
DOAJ – Directory of Open Access Journals	The resource provides access to 1.8 min articles on various topics from over 10,000 journals with open access from 136 countries. DOAJ provides all the necessary output data about the article and a link to the full text. It allows searching by name, subject, abstract, author, journal, year, language, country of publication, ISSN, DOI, and others.	http://doaj.org/
Google Scholar	The resource provides access to articles on different topics. It allows searching by keyword, author, publication year / period. Google Scholar allows an author to create a profile with scientific publications and track their citations, as well as automatically update citation index and h-index. It indicates the number of citations of each article, and direct links to these papers.	http://scholar.google.ru/

4. Patents In Biotechnolgy:

Biotechnological patents are the property rights given for an invention in biological processes, materials and products. It protects the invention from being copied by other scientists or companies. It is very crucial step to encourage the scientists to make new inventions.

4.1 Types of Biotechnology Patents:

- **Utility patents in Biotechnology:**

  Utility patents in biotechnology are given for innovative biological processes, new DNA sequences, genetically engineered organisms, and novel ways of making biological products.

- **Design patents:**

  In biotechnology, design patents are given for the unique shape or configuration of a laboratory apparatus and tools or medical device.

- **Genetic sequence patents:**

  These are patents that are given for a specific gene sequence or gene fragment.

- **Diagnostic assay patents:**

  In biotechnology, diagnostic assay patents are given for new assays or diagnostic tools that detect specific genetic markers or biomolecules.

4.2 Information Sources in Biotechnology Patent Literature Search:

The information on biotechnology patent literature can be obtained from the previously mentioned information sources. Some additional on-line sources are given below:

Table 4: Brief information about On-line biotechnology patent information sources:

Database	Short description	Update frequency	Availability
Derwent Biotechnology Abstracts	200 words abstracts; essentially identical to printed version; no graphics	Monthly	Dialog Information Services, Orbit Search Service, STN software, Data Star
Intelligenetics/Derwent GeneSeq	Nucleic acid and amino acid sequence searching; Intelligenetics software	Bi-weekly	Intelligenetics BioNet
Chemical Abstracts/Registry	Nucleic acid and amino acid sequence searching; chemical structure searching; STN software	Bi-weekly	STN software

MARPAT	Markush structure file corresponding to Chemical Abstracts	Bi-weekly	STN software
MicroPatent/BiotechNet	United States of America (US) patents only; frontpage data	Weekly	BiotechNet
Current Biotechnology Abstracts	European Patent Office (EPO), United Kingdom, Patent Cooperation Treaty (PCT), US abstracts; keywords; sectional classification	Monthly	Dialog Information Services, Data Star
BioBusiness	US abstracts only; keyword and classification fields	Monthly	Dialog Information Services, Data Star, STN software
BioWorld	US, EPO, PCT patents from the newsletter; concise summaries	Bi-weekly	Cartermill
Japan Patents	Authoritative source of Japan documents; complete coverage	Quarterly	Questel, Dialog Information Services, Orbit Search Service

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Chapter 9

PATENT SUBJECT MATTER AND LEGAL ASPECTS OF TRANSFER OF BIOTECHNOLOGY IN INDIA

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Introduction:

The patent subject matter is characterized as a discussion regarding the eligibility of an invention to have patent protection in the country. Various conditions are essential for every person who wants to secure his invention by acquiring a right of patent by registration in the patent office. Majorly three standards are essential for most of patent systems to decide on whether the patent can be granted by the government or not including invention novelty, inventive steps, and application of patent at the industrial level. The new invention is characterized as subject matter that is not utilized in the country or have not fallen in the public domain before patent application filing which simply indicate, to achieve any patent, in any matter invention should not be present anywhere in the world or use in any other method. Theoretical assumptions or scientific concepts and simple discoveries are not acceptable. Furthermore, the discovery of non-living things and living things in nature not acceptable. For example, DNA sequence bound discovery in specific plant species. Recent innovations in the biotechnology field gaining a huge attention. The introduction of the biotechnology field to develop new molecules or products is associated with various challenges which may be ethical or technical. The most valuable asset of a biotechnology company is the intellectual property and patents need to be provided to the most important intellectual properties relating to biotechnology companies. The potential of India in the biotechnology sector is high, but a major issue faced by the industry is the current regulatory and legal framework. Patents are considered a controversial issues in the modern biotechnology filed and are very interesting to public than any other technical field. Recent advancements in biotechnology are bound up in political, legal, ethical and religious issues

Patenting of Biotechnology Material: The Emerging Issues and Challenges

In comparison to the simple task of enacting statutes and legislation, the more challenging issue is patenting tissues, living cells, life or animate organisms. Biotechnological inventions patenting has emerged as a controversial issue due to various factors. Certain key challenges that are majorly associated with the patenting about biotechnology include (a)

Obviousness has been characterized as the major sticky subject as similar techniques are utilized by scientists to isolate different gene sequences (b) it is suggested that utility standards have been increased for biotechnological innovations. However, many of the new innovations in the biotechnology field seem to be unbelievable, due to which maximum patents have been refused by the public for lack of utility. (c) Identify the novelty in living things like gene sequences and animals is a huge challenge which is a major criteria for granting the patent as living things exist naturally.

Legal Issues

Legal issues related to the patenting of life form depend upon whether or not patents to life forms may be granted under existing terms and conditions of patentability. It is very difficult to create a line between invention and discovery specifically when for the isolation of genetic materials, DNA techniques have been established. With rapid progression, the conflict between science and law has significantly increased that result into a world creation that majorly focuses on technological innovations to produce a change in our lives in an efficient manner and to produce a better tomorrow for each individual. Nowadays, government laws are stagnant and is focusing to stay strict with the rapid rise in development and progress. The biotechnology industry has produced various infinite prospective from tailoring individuals treatment to the genetic make up of individuals, establishing new vaccines and disease prevention by intervening in the genome. Various unique concepts are utilized in the biotechnology industry which make it different from various other sectors, like significant financial resources, lengthy product development lifecycles, complex intellectual property issues and partnerships needed for marketing and manufacturing objectives. The rapid development in biotechnology research in cutting-edge areas in recent years has potentiate huge discussion on the framing of appropriate laws to raise the new technology benefits.

Certain key areas of concern have been highlighted here:

Human Cloning

Cloning is characterized by large number of reproductive technologies performed at the industrial and laboratory level. A huge population of genetically similar cells, plants or animals can be generated by using Cloning technology. Due to the huge potential of cloning technique to generate cells, plants, molecules or certain animals, its clinical applications are extraordinary broad. However, there exist various controversial issues with human cloning like deformed offspring possibility, designer babies and legal rights protection for cloned humans. Further, huge concerns have been raised regarding the clones premature aging probability. The nature of clones is not responsible for serious concerns about cloning but clones effects on society is major

reason. However, on the other side, there is a presence of concerns in certain scientific communities that legislation extent against human cloning might be responsible for stifling research into the field of human embryology that could give rise to new therapeutic interventions for disease management. The potential benefits include the cloning used by infertile couples who want to generate a genetically related child.

Human Genome Project

Human genome project (HGP) completion and DNA sequencing of other organisms, is widely characterized as a major turning point in field of medicine and biology. Nowadays, with the evolution of HGP, genes are identified by Geneticists that control aging, diseases and various other specific traits. This potentiates the great option for the human race to protect themself from various diseases and unwanted genetic traits. However, huge interest in various questions regarding the legal, social and ethical use of human genetic sequences has been raised by the HGP. Certain concerns regarding the human rights have been raised by HGP. Advancements in human reproduction in the genetic field provide the new potential to transform life and lead to a Universal declaration on the human rights and human genome. Fears also exist regarding the confidentiality and privacy of genetic information, including control of genetic information and consent to use and disclosure of genetic information, these fears arise from various issues like as medical information privacy, which is a controversial subject nowadays. With the addition of information regarding genetic information into medical files, there exist controversies that such information could go in the wrong hands.

Conclusion:

Technologies are developed by companies with the objective to benefit humankind, ethical questions may also arise with the discovery of these technologies. The biotechnology field is associated with a significant ability to raise the health of people in the developing world, but the to the progression of therapeutics, vaccines and diagnostics, for infectious disease with high incidence rate in developing countries, significant impediments can exist. IPRs for biotechnology innovations, complex problems can exist about relation to technologies access, like fair and equitable sharing of financial benefits and unfair exploitation of genetic resources. A significant steps are quite important to implement to preserve biodiversity and to raise equity in international obligations, genetic access legislation financial benefits may often be increased. To conclude with the ethical issues it would be pertinet to suggest that as far as the law of patent is concerned, for a patent a modified organism is certainly good subject matter if it fulfils the conditions. Ethical issues are not however connected with patent law.

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Chapter 10

GEOGRAPHICAL INDICATIONS AND INTERNATIONAL TRADE: OPPORTUNITIES AND CHALLENGES UNDER WTO'S TRIPS AGREEMENT

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Abstract:

Geographical Indications (GIs) play a crucial role in international trade by protecting products that have unique qualities, reputation, or characteristics linked to their place of origin. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organization (WTO) provides a legal framework for GI protection, ensuring fair competition and preventing the misuse of regional product names. However, the implementation of GIs at the global level presents both opportunities and challenges. On the opportunity side, GIs enhance market access, promote rural development and strengthen brand value for local producers, contributing to economic growth and cultural preservation. They also serve as tools for differentiation in global trade, offering competitive advantages for products such as Champagne (France), Darjeeling Tea (India), and Parmigiano Reggiano (Italy).

This paper explores the evolving significance of Geographical Indications (GIs) within the framework of international trade, focusing on the opportunities and challenges presented under the WTO's TRIPS Agreement. This research identifies key obstacles to securing GIs internationally and proposes strategic policy interventions that can help developing economies like India to fully leverage their rich heritage of unique, origin-based products in global markets. It also examines policy recommendations to enhance GI protection globally while balancing the interests of producers, consumers, and trade partners.

Introduction:

In the modern era the intellectual property rights (IPRs) plays a significant role for protecting innovations, traditional knowledge, and the economic interests of producers. Among this intellectual property right Geographical Indications (GIs) are very unique because they indicate the particulars of goods related to specific place of origin (country, region or locality), capturing the qualities, reputation, or characteristics which are attribute to particular geographical area. This special character, quality, reputation etc. are basically due to the specific environment of that area like raw material, soil, moisture, regional climate, temperature and other natural factors. In case of man-made things human factors plays a significant role like concentration on same kind of business in the same region, specialization in the production or

preparation of certain products and maintaining quality standards. Some well-known examples of GIs is Darjeeling Tea, Basmati Rice, Kanjeevaram Silk, Kalamata olive and Alphonso Mangoes from India and in other countries 'Champagne' (France), 'Feta Cheese' (Greece), 'Tequila'(Mexico), Ceylon tea (Sri Lanka), Antigua coffee (Guatemalan) etc.

On the basis of quality, reputation and special character GIs, has a lot of commercial value. So, some traders, businessmen, sellers, started misusing the name of these special things to earn more profit and the buyers get cheated by such practices. So, to ensure the quality it was necessity to have some protection, rules and regulations regarding special goods. Thus, to ensure global protection of such rights, the World Trade Organization (WTO) introduced GIs under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995. TRIPS mandate minimum standards for GI protection among member countries, aiming to prevent the unauthorized use of regional names and enhance the credibility of traditional products in international trade.

For India, GIs offer a significant opportunity to boost exports, preserve cultural identity, support rural economies, and add value to agricultural and handicraft sectors. However, the benefits come with notable challenges. There are legal conflicts between GIs and trademarks, limited international recognition, and implementation issues, especially in developing countries like India that face resource constraints. Moreover, the TRIPS Agreement offers higher protection primarily to wines and spirits, which has led to ongoing debates about extending equal protection to other products.

Objectives of GI Tag

In order to function as a GI, there must be a sign to identify a producer that product is originated in a specific area, this sign is known as GI tag. The main objects of GI tag as follows:

1. It protects the authenticity of products and provides a safeguard to original products from being counterfeit.
2. It gives recognition to the farmers, artisans, traders for their special product.
3. It enhances the economical value of products, thus boost the local economy.
4. It preserves and protects the legacy of traditional products.
5. It ensures the quality of product.
6. Due to specific character, reputation and quality, GI tag increases the global trust and market demands.

Geographical Indications and Trips Agreement

The TRIPS agreement is most comprehensive agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is administered by the World Trade Organization (WTO). It sets minimum standards for the protection, enforcement and dispute settlement of

various forms of IPRs. Articles 22 to 24 are specifically deals with Geographical Indications (GIs) as follows:

- **General Protection (Article 22):** Article 22 provides a basic level of protection for all GIs, prohibiting the use of any indication that misleads the public about the geographical origin of a product or constitutes unfair competition. This protection is available for all products, not limited to any specific category.
- **Additional Protection for Wines and Spirits (Article 23):** This article grants stronger protection exclusively to wines and spirits, regardless of whether consumers are misled. For example, even if a wine labeled "Champagne-style" does not deceive consumers, it is still not permitted under Article 23 if it does not originate from the Champagne region of France. This higher level of protection has been a major point of contention, especially among developing countries seeking equal protection for non-alcoholic goods such as teas, spices, handicrafts, and textiles.
- **Exceptions and Negotiations (Article 24):** This Article outlines exceptions, including "grandfathering" provisions that allow continued use of certain GIs under specific conditions. It also mandates ongoing negotiations to expand GI protection beyond wines and spirits—a negotiation that has made slow progress due to differences between developed and developing member countries.

India's Position Under Trips

India is one of the signatories to TRIPS agreement. So, to align with international principles of Geographical indications enacted the Geographical Indications of Goods (Registration and Protection) Act, 1999, which came into effect in 2003. This legislation provides for the registration, legal protection, and enforcement of GIs in India. The country has since registered over 600 GIs covering a wide variety of products ranging from agricultural produce to handloom and handicrafts, making it one of the most active users of GI protection in the developing world.

India has a very good number of registered GIs, but still Indian GIs often face challenges in global markets, such as lack of international recognition, difficulty in enforcement abroad, and the dominance of EU-style protection systems that do not always align with Indian realities.

Opportunities of Geographical Indications in International Trade

Geographical Indications plays a very crucial role to preserve the identity and ensuring the quality of goods. It offers a various kind of economic, cultural, and trade-related opportunities and also acts as powerful tools for rural development, export promotion, product differentiation, and cultural identity preservation. The following are the main opportunities of GIs in international trade:

1. **Market differentiation and higher value realization:** The ability of GIs to differentiate products in markets with intense competition is one of their main advantages. Because GItagged products are frequently linked to authenticity, quality, and heritage, they can fetch higher prices than their generic counterparts. For instance, because of their GI designation,

   Kashmiri Pashmina, Basmati Rice, and Darjeeling Tea are all sold at premium prices. Additionally, this differentiation increases brand recognition and customer loyalty, both of which are critical in global marketplaces where traceability and quality assurance are highly prized.
2. **Rural development and inclusive growth**: GI protection can significantly contribute to rural and regional economic development by creating value chains that are localized, sustainable, and inclusive. Since GI goods are closely tied to specific communities and traditional knowledge systems, they generate: Employment opportunities Increased income for small producers and artisans Greater participation of women and marginalized communities This is evident in regions like Kancheepuram, where GI recognition of Silk Sarees has supported thousands of weavers and preserved indigenous skills.
3. **Preservation of traditional knowledge and culture:** By officially acknowledging customs, knowledge, and workmanship that have been carried down through the centuries, GIs contribute to the protection of intangible cultural heritage. This not only stops cultural goods from being stolen, but it also revives local industries and dying art forms. For instance, Channapatna Toys, Madhubani Paintings, and Pochampally Ikat have seen a resurgence in demand in both domestic and international markets as a result of their GI status in India.
4. **Increased export potential for GI products:** GI products with strong marketing have demonstrated substantial export potential. Countries like France, Italy, and Spain profit billions of euros per year from cheeses, wines, and agricultural products bearing the GI designation. The usage of GIs as a branding strategy for exports has also started in India, particularly in the EU, Gulf, and ASEAN markets. Global consumers are increasingly looking for items that are made ethically and authentically, therefore GI products can give businesses a competitive edge in the global market.
5. **Leverage in bilateral trade agreements:** GIs are becoming more and more significant in regional trade agreements (RTAs) and free trade agreements (FTAs). Mutual GI recognition, for instance, has been discussed in the India-EU free trade agreement negotiations. These kinds of agreements can: Encourage reciprocal defense and enforcement. Expand GI products' access to the market Cut down on litigation and trade

barriers With the help of these diplomatic instruments, developing nations like India can increase the protection and international visibility of their GI products.

6. **Promotion of sustainable and eco-friendly practices:** By connecting products to regionally specific and traditional methods, GIs support sustainable agricultural and production practices. This aids in: Preserving biodiversity Minimizing the impact on the environment Promoting environmentally conscious travel (e.g., wine trails, craft clusters) Localized, environmentally conscious production is naturally supported by the focus on authenticity and place of origin, which fits in nicely with global trends toward sustainability and conscientious consumption.

Major Challenges in Securing Geographical Indications

Geographical Indications (GIs) present a number of structural and legal obstacles to their protection and enforcement, especially in the global context, despite the fact that they have enormous potential for rural development, cultural preservation, and trade competitiveness. The following major problems still prevent GI benefits from being effectively realized worldwide, particularly for developing nations like India. Despite the potential of GIs, several legal and systemic challenges persist:

1. **Lack of harmonization in GI laws across countries:** One of the primary obstacles is the lack of a unified international legal framework for GI protection. The TRIPS Agreement gives member states a great deal of latitude in how they apply GI protection, even though it sets a baseline. As a result, legal approaches are fragmented: With its sui generis system, the European Union offers GIs complete and independent protection. However, under trademark law, nations like the US, Canada, and Australia rely on certification or collective trademarks.

   This inconsistency creates barriers to mutual recognition, legal disputes, and enforcement delays in cross-border markets.

2. **Two-tier protection in TRIPS, privileging wines and spirits:** Only wines and spirits are granted greater protection under the TRIPS Agreement (Article 23), which forbids the use of terms like "type" or "style" for non-origin goods (for example, "Champagne-style wine" is forbidden). Only Article 22, which necessitates evidence of unfair competition or consumer confusion, provides protection for other goods, including rice, tea, coffee, textiles, and handicrafts. This two-tiered system has drawn criticism for undermining the export potential of developing countries with GIs and favoring the interests of European and wine-producing countries. Consensus at the WTO is still elusive despite repeated calls to give all goods protection at the level of Article 23.

3. **Conflicts between trademarks and GIs:** Complex legal battles are frequently created when new GI claims clash with existing trademarks. For example, "Feta" is regarded as a generic term in the US and Australia but as a generic term in the EU. Likewise, the widespread usage of "Parmesan" and "Basmati" has led to conflicts between traditional producers and commercial trademark holders. An additional layer of ambiguity is introduced by TRIPS Article-24(5), which favors earlier trademark registrations over customary usage patterns.
4. **High cost and procedural complexity for registration:** The Significant expenditures are associated with obtaining GI recognition, particularly in foreign jurisdictions, for documentation, quality assurance, legal services, and enforcement mechanisms. Small cooperatives, traditional craftspeople, and rural producers may find these obstacles prohibitive. It's also challenging for producers to participate in the GI registration process at international forums because of a lack of institutional support and legal knowledge in developing nations.
5. **Limited awareness among producers:** The advantages and protocols for GI protection are frequently not well understood at the grassroots level. Producers might not know how much a GI is worth commercially, or they might not have the organizational framework to apply for and keep GI status. The application is frequently spearheaded by governmental or commercial organizations with little involvement from the real parties, which erodes benefitsharing and post-registration enforcement.
6. **Weak enforcement in foreign jurisdictions:** The Geographical Indications of Goods (Registration and Protection) Act, 1999, has improved domestic enforcement of GIs in nations like India, but there is still little international enforcement of Indian GIs. The reputation and profitability of genuine GI goods are lowered by the continued flood of fake goods and deceptive labels into international markets in the absence of bilateral or regional agreements and legal frameworks.
7. **Absence of a global GI registry under WTO:** WTO members have not reached a consensus on the establishment of a multilateral register for GIs, especially for goods other than wines and spirits, despite TRIPS provisions Article- 23(4). Global recognition and litigation would be streamlined by such a register, but negotiations have been stalled for more than 20 years due to differences between developed and developing nations.

Case Studies on Geographical Indications and International Trade

There are important case studies regarding the challenges in securing GI tags. Which are discussed as follows:

- **Darjeeling Tea (India):** It is first Indian product to receive GI status. International enforcement remains weak despite its global recognition. Darjeeling Tea gained global recognition in 2004, it is known for its unique flavor and aroma, it has strong brand value. However, challenges include misuse in international markets, enforcement difficulties, and limited production control. It is verified that only about 10 million kg of authentic Darjeeling Tea is produced annually yet 40 million kg is sold under the name globally. The case underscores the need for international recognition and enforcement mechanisms for effective GI protection.
- **Basmati Rice (India):** Basmati Rice is subject to multiple legal disputes, especially in the US and EU, over the use of the term by non-Indian entities. In the late 1990s, RiceTec Inc. attempted to patent Basmati rice varieties, sparking controversy with India and Pakistan. India strengthened domestic GI law in 1999, highlighting the need for multilateral GI protection to prevent bio-piracy and unauthorized use.
- **Champagne (France):** Champagne, a globally recognized GI, has been protected under TRIPS Article 23 due to high global awareness, legal infrastructure, lobbying power, and diplomatic pressure. This case demonstrates developed countries' benefits from TRIPS.
- **Feta Cheese (EU):** A successful case of GI protection by the EU, showing how cultural branding and legal support ensure international recognition.

Policy Recommendations

In order to enhance the effective implementation of TRIPs Agreement and to ensure the validity of GI tag some steps must be taken. By these steps cultural and economic benefits of Geographical Indication be maximized and can overcome the challenges which are associated with GI. Some of the recommendations are as follows:

- To Strengthen the strong protection of GI the registration process should be simplified and make easily accessible.
- It is noted that producers are not much aware about the GI registration and rights related thereto. So it is necessary to educate and empower producers through training. The legal aid should also be available for dispute resolution.
- There should be Integrate GIs into trade policy and must introduce branding campaigns like “Make in India”, “One District one Product” and showcase them at international expos and trade fairs.
- There must be push for multilateral GI registry applicable to all products not only restricted to wines and spirits.
- WIPO and FAO must engage with international bodies to gain technical assistance and participate in GI knowledge exchange platforms.

- Digital support must be Promote to create a centralized digital information so that anyone can easily access all registered GIs. It can be done through tools like blockchain etc.
- There should be regular monitoring of GI impact on social, economic and cultural life on the producer communities and markets.
- It is also recommended to introduce feedback mechanism for producer, regulators and marketers. So that product position, packaging and consumer satisfaction can be improved.

Conclusion:

Geographical Indications have emerged as a crucial tool for promoting regional identity, preserving traditional knowledge and enhancing trade competitiveness. GI represents a powerful intersection between trade, culture, and development. However, the current global framework under TRIPS provides significant opportunities to develop the quality and originality of the products. But still TRIPs agreement requires reform to ensure equitable access and protection because it has limited scope particularly the two-tier protection favoring wines and spirits. This limited scope poses challenges for developing economies. Legal fragmentation, enforcement difficulties, trademark conflicts and lack of international consensus continue to hinder the full realization of potential of GIs in International trade. These hinders can be cured by adopting strategic national policies, advocating for stronger international mechanisms, educating producer about registration and rights, so that developing countries like India can unlock the full value of their traditional products and secure a competitive position in global markets.

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Chapter 11

BIOTECHNOLOGY PATENTS AND ITS ECONOMIC, ETHICAL AND DEPOSITORY CONSIDERATIONS

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Abstract:

We are living in a society where knowledge has been recognized as a potent force. The 21st century, as rightly said by noted futurologist, Alvin Tofler, is the century of "mind power." Modern era is the era of science and technology. Emergence of strong intellectual property regime and its global impact has opened endless opportunities for creating wealth. The biotechnology revolution is gaining momentum all around the world. Biotechnology is the science where biological systems and living organisms are used to create new products or processes. It functions like a fruit on a tree having roots of biological sciences, microbiology, genetics, molecular biology and biochemistry and trunk of chemical engineering. Various aspects of intellectual property protection in the sphere of biotechnological invention are emerging as a subject-matter of fierce debate at national and international level. So, it is indeed difficult to define the precise scope and extent of the applications of biotechnology. Unlike the information technology sector, the biotechnology sector, is highly regulated. Intellectual property is the most valuable asset of a biotechnology company and the most important intellectual property rights relating to biotechnology companies tend to be patents. India has tremendous potential in the biotechnology sector, but one of the significant hurdles facing the industry is the current legal and regulatory framework. In modern biotechnology, patents are a controversial issue and are more interesting for the public than any other technical field. Advances in biotechnology are bound up in ethical, religious, political and legal issues. The present research paper focus to the moral, ethical issues and its depository considerations brought about by biotechnological inventions.

Keywords: Biotechnology, Patent, Patent Doctrine, Intellectual Property Rights, IPSE Dixit, Novelty, Non-Obviousness, Utility, Inventive Step.

Introduction:

We are living in a society where knowledge has been recognized as a potent force. Human beings are superior from other living creatures because they possess intellect. Creative genius of human being creates intellectual property; which in turn, when properly exploited, can

earn wealth. Since it is essentially a creation of mind, therefore, it is called intellectual property. The 21st century, as rightly said by noted futurologist, Alvin Tofler, is the century of "mind power." Modern era is the era of science and technology. Emergence of strong intellectual property regime and its global impact has opened endless opportunities for creating wealth. In between that the biotechnology revolution is gaining momentum all around the world. Intellectual property laws and protection, is not new, it can be traced to ancient Greece, and as developed by English common law, followed by industrial revolution in 19th century which gave impetus to inventions. On the other hand, much in biotechnology, is relatively new. In the past years, dramatic new developments in the ability to select and manipulate genetic material have created heightened interest in the commercial uses of living organisms. Biotechnology is the science where biological systems and living organisms are used to create new products or processes. Broadly defined, it includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses. Although people have used organisms since the dawn of civilization to improve agriculture, animal husbandry, baking, and brewing, it is the novel uses of such biological techniques (e.g., recombinant DNA techniques, cell fusion techniques, monoclinal antibody technology, and new bioprocesses for commercial production) that have caught the imagination of many people. Patents have come to be viewed by many as vital to protecting commercial interests and intellectual property rights in biotechnology. It functions like a fruit on a tree having roots of biological sciences, microbiology, genetics, molecular biology and biochemistry and trunk of chemical engineering. Various aspects of intellectual property protection in the sphere of biotechnological invention are emerging as a subject-matter of fierce debate at national and international levels. In modern biotechnology, patents are a controversial issue and are more interesting for the public than any other technical field. Advances in biotechnology are bound up in ethical, religious, political and legal, economic issues.

Patents And Biotechnology

Patents

Patents are a part of intellectual property law that work to help protect the innovative processes across all different fields.[1] The term 'patent' has its origin from Latin word 'patene' which means 'To open'. In legal parlance the patent is a legal grant of monopoly right for some fixed term to the creator of new and useful invention in return of his disclosing the invention. It is an important species of intellectual property. The grant and use of patent is regulated by law as there is no ipse dixit claim of patent nor there is suo motu grant of patent by authorities. The Supreme Court, in a significant judgment **M/s. Bishwanath Prasad Radhey Shyam v.**

Hindustan Metal Industries[2], has aptly explained the object of patent law in following words : "The object of patent law is to encourage scientific research, new technology and industrial progress. Grant of exclusive privilege to own, use or sell the method or the product patented for a limited period, stimulates new inventions of commercial utility. The price of the grant of the monopoly is the disclosure of the invention at the Patent Office, which after expiry of the fixed period of the monopoly, passes into the public domain"

The considerations which are said to constitute the quid pro quo for the grant of a patent monopoly are : (1) the working of the invention within the country so as to result in the establishment in the country of a new industry or an improvement of an existing industry which would profitably employ the labour and capital of the country and thus increase the national wealth, and (2) disclosure to the public of the invention and the manner of its working so that on the expiry of the life of the patent the public are enabled to work the invention themselves and in competition with each other.

Biotechnology

It refers to a wide range of techniques that make use of living organisms. The word “biotechnology” is a compound word, made up of the prefix bio-, meaning biological and technology. *Karl Ereky*, a Hungarian scientist, first devised the term “biotechnology” in 1919. Since its inception, the notion of biotechnology has been variously defined.[3] Biotechnology exploits biological materials, living or non-living, and is broadly classified as *classical and modern biotechnology*. The age-old fermentation process for producing alcohol, isolation of antibiotics from moulds or other micro-organisms are only a few examples of classical biotechnology. Modern biotechnology started with the gene-splicing technology or genetic engineering which developed in the late seventies of the last century. By using genetic engineering, many useful things like human insulin, human growth factors, monoclonal antibodies, etc. have been developed.[4]

The biotechnological inventions therefore include products and/ or processes of gene engineering technologies, methods of producing organisms, methods of isolation of microorganisms from culture medium, methods of mutation, cultures, mutants, transformants, plasmids, processes for making monoclonal antibodies, cell lines for making monoclonal antibodies, etc. While on the one side, biotechnological inventions have resolved many problems and branched out to several fields, on the other side, they have invoked many debates. The application of genetic engineering in plants and animals has resulted in exciting and yet debatable technological developments such as transgenic plants, animals and isolation of human genes for using them to produce medicaments. Scientists across the world are using

bioinformatics tools, ingenious techniques and genomes of organisms to probe the mysteries of biological processes and the living world thereby generating vast amounts of information which may provide the keys to new medical treatments, improved crops and so on.[5]

Types of Biotecnology Patents

In most every field of research, there are two basic types of patents:

1. Product patents; 2. Process patents.

This also applies to biotechnology. An inventor can protect a certain product they've created or a new process they've made. Because of the nature of biotechnology, there are some rules regarding what can and cannot be patented. Inventions are patentable but discoveries aren't. It has to pass through the triple requirement of newness (novelty), non-obviousness and usefulness. If come up with a specific product or process through Discoveries in biotechnology are nature things or processes that essentially belong to nature, so they cannot be "owned" by one person through a patent. However, if one the use of natural, living things, it's worth looking into a patent for it. This can lead to some complicated cases when trying to patent a biotechnology invention.

Prior to Patents Amendments Act, 2005 for certain categories of inventions relating to food, drugs and pharmaceuticals only process patent was granted and no product patent was granted. However, as per the requirement of Article 27 of TRIPs, Indian Patents Act has shifted to product patent regime.[6]

Emerging Trends in Biotechnology

The traditional biotechnology which was largely confined to three major areas, viz., *(i) plant breeding, (ii) animal breeding, and (iii) industrial microbiology* has made a paradigm shift. Recombinant *DNA* technology, *Protoplast fusion* technology and *Hybridism technology* have changed the whole complexion of plant, animal and human life. These technologies have been employed in production of genetically engineered organisms and altered genes DNA falling in the area of genetic engineering, protein engineering, cell fusion, tissue culture, gene therapy and fermentation technology.

Human Genome Project (HGP) launched in 1990 is one of the biggest breakthroughs in the realm of science of genetics. Successful discovery of human genome by Craig Venter is a herculean task completed in an international co-operative effort involving no. of countries and laboratories. Yet another landmark in the field of biotechnology is successful *Cloning of Mammals*. Recent claim of human cloning has taken the whole world by surprise and disguise. Cloning of human beings is still a grey area of creative genius of bio-scientist surrounded by host of ethical and legal issues.[7]

U.S. Law- The Trend Setter

It is generally said that everything on the earth is patentable in USA. The patent jurisprudence of USA encourages and rewards innovations and its commercial exploitation.

The Chakrabarty Case [8]

The Supreme Court's single foray into biotechnology occurred in 1980 with its ruling in the patent law case. Chakrabarty had developed a genetically modified bacterium capable of breaking down multiple components of crude oil. Because this property was not possessed by any naturally occurring bacteria, Chakrabarty invention was thought to have significant value for cleaning up oil spills. Chakrabarty's claims to the bacteria were rejected by PTO on two grounds:

- Micro-organisms are "products of nature;" and
- As living things, micro-organisms are not patentable subject matter under 35 u.s.c. 101.

Following two levels of appeals, the case was heard by the u.s. supreme court, which in a 5-4 ruling, held that a live, human-made microorganism is patentable subject matter under section 101 as a "manufacture" or "composition of matter." This historic decision of usa supreme court opened a new chapter in the patent law of usa.

Patenting of Life-Forms (Micro-organisms)

Nature's creation, which includes everything that has life on our earth and is considered holy, has its own integrity. Micro-organisms as per classical definition are organisms too small to be visible to the naked eye; organisms include all the living things which may be a single cell or a group of differentiated but inter-dependent cells. It includes viruses which depend entirely upon the machinery of reproduction of the host cells and which could be visible only under electron microscope. Micro-organisms ordinarily do not include various tumour forming cell lines and monoclonals as these are not natural organisms but are produced under abnormal stress conditions or under human interventions. Moreover, most of the transformed cell lines and all the monoclonals are not considered as micro-organisms. Therefore, while defining micro-organisms the cell and tissues of higher life forms including vertebrates and non- vertebrates may be kept out of definition.[9] Many people believe that the plants, animals, and microbes that make up life on Earth are part of the natural environment into which humans are born, and that turning these species, their molecules, or components into corporate property is against the public interest. Prior to 2002, there was a shift in India's understanding that ideas linked to biological forms were not protected by patents.[10]

The Calcutta High Court has given a landmark decision in ***Dimminaco A.G v. Controller***[11] allowing claim for grant of Patent to genetically engineered micro-organism called infectious bursitis vaccine. According to the Court, even if the finished product contains a live

virus, the method involved in pulling it out becomes an invention. It should be emphasised that no judgement has been made specifically on the application of inventive step requirements to biotech patent inventions in India to yet. Microorganisms can be patented in India, however there is no definition of the word under the Patent Act. This has sparked far too many debates over the patentability of microorganisms. Due to the lack of an uniform description of the microorganism and microbiological process in the TRIPS Agreement, it is necessary for the nation to create a distinction between the outcome of unique human activity and that which occurs naturally. But the judgement has opened new opportunities for obtaining patents in India on micro-organism-related inventions which were hitherto not granted.

National and International Conventions on Biotechnology

At the international level, there is no single comprehensive legal instrument that covers all aspects of biotechnology or biotech products. However, a number of existing international agreements are directly relevant to biotechnology. Many international organizations have also undertaken the task of setting standards, in particular dealing with the impacts of biotechnology on health, the environment, agriculture, trade, ethical and socio-economic aspects. [12]

There are significant differences in the kinds of regulatory approaches countries adopt on biotechnology. The United States has adopted a regulatory approach closest to a laissez-faire model. The great majority of countries have, so far, adopted some form of regulation on biotechnology and biotech products. The core elements for regulation on biotechnology include laboratory control, environmental release, risk analysis, and socio- economic considerations for pre-marketing authorization; also subject to regulation are labelling, traceability and other monitoring measures for post-approval surveillance.

The IPR issues before India and the developing countries include the stand that has to be taken on the distinctions between discoveries and inventions in biological area, the definitions and the scope of patentable micro-organisms, the scope of patentability or protection of other living materials like the plants and the animals, the conditions of depositions connected with the patentable inventions involving living entities including viruses, bacteria, fungi, plasmids, genes, polynucleotide sequences with useful properties, plasmids, cosmids, vectors, gene cassettes, etc. In many of these issues, the stand of the WTO is also not clear; WTO has not made any definite recommendations in most of these facets and the subject matter is left to speculations and conjectures to the member countries. However, the IPR issues related to modern biotechnology have been raised in a number of international forums of WTO, apart from the following:

Convention on Biological Diversity (CBD), Food and Agriculture Organization (FAO), Organization for Economic Cooperation and Development (OECD), World Health Organization

(WHO), World Intellectual Property Organization (WIPO), Asia Pacific Economic Cooperation (APEC), Office of International Epizootics (OIE), International Plant Protection Convention (IPPC), Codex Alimentarius Commission (CAC), World Bank

Many international agreements relating to biotechnology are legally binding or strongly political consensus, including, inter alia, the UN Convention on the Law of the Sea (UNCLOS, 1982), the Convention on Biological Diversity (1992), the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement, 1994), the WTO Agreement on Technical Barriers to Trade (TBT Agreement, 1994), the International Plant Protection Convention (1997), the UNESCO Universal Declaration on Human Genome and Human Rights (1997), The Aarhus Convention (1998), the Biosafety Protocol (2000), the UNESCO International Declaration on Human Genetic Data (2003), and the UNESCO Universal Declaration on Bioethics and Human Rights (2005).

The most important among these are the **Cartagena Protocol on Biosafety** to the United Nations Convention on Biological Diversity and FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) apart from WTO Agreement on Trade-Related Aspects of Intellectual Property Rights. Thus, realising the potential of biotechnology and its relevance to the needs of society, the Department of Biotechnology, under the Ministry of Science and Technology, which is the nodal ministry for all policy issues, has always emphasised on the development of all facets of IPR in biotechnology.[13]

Issues Related to Biotechnology

Economic Considerations:

The basic economic foundations of intellectual property are straightforward and increasingly recognized by the courts. The problems lie in applying them in particular situations which can be highlighted by considering how intellectual property deals with new technologies and in the present case biotechnology. Biotechnology issues a new challenge to the courts to effect the constitutional mandate to promote the Progress of Science and useful Arts. But courts, as well as commentators, seem to have lost sight of the ultimate purpose of patent awards-promoting technological progress. In considering this new technology from the point of view of intellectual property rights, it is useful to keep in mind that there are in principle three options for each new technology.

First, do not protect at all. Second, protect in principle while applying the rules in such a way as to balance incentive and access. A variant of this second option is to protect in principle but because of some societal judgement, to decide -often case by case - to emphasize access over

incentive in particular situations. Third, protect not through patent, but through a tailored, sui generis system.

Theories[14] - There are some economic theories, explaining, how patents promote biotechnological progress:

1. The Incentive-To-Invent Theory- Under the incentive-to-invent theory, patents permit inventors to reap returns on their inventions sufficient to recover investment in research and development. To reach this goal, patent scope must be broad enough to recompense the cost of invention. On the other hand, patent scope should not extend further than necessary to accomplish this objective, because patents restrict distribution of the invention and reduce incentives for others to make improvements. Broad patent scope therefore reduces the social benefits of patented inventions. If, as the critics assert, alternative incentives to invent remain despite the absence of patent rewards, or if nonpatent barriers provide sufficient protection to the inventor in the market, efficiency dictates narrower patent scopes.[15]

2. The Incentive-To-Disclose Theory- The incentive-to-disclose theory holds that, without patent protection, inventors would conceal their inventions in order to prevent exploitation by competitors. Concealment deprives the public of a full range of benefits: wider distribution, alternative uses and price-cutting competition for the market. Secrecy can also lead to waste to the extent that competitors duplicate. research. This theory contains several potential flaws, because patents may not necessarily promote disclosure of inventions that would otherwise remain secret.[16] The patent system must solves this problem by permitting inventors to disclose their patented inventions to potential users without losing their exclusive rights. The patent holder should be able to sue unauthorized users for infringement.[17]

3. The Incentive-To-Innovate Theory - The incentive-to-innovate theory recognizes that inventions may require considerable further investment beyond mere discovery for commercial exploitation. Commercial feasibility may demand further research and development, and large-scale development may necessitate the construction of new plants and equipment. A new invention may require refinements to suit the tastes of consumers, as well as advertising to persuade consumers to buy it. "Innovation" denotes these necessary steps between inventing a product or process and bringing it to market.[18] Joseph Schumpeter was first to distinguish innovation from invention. Schumpeter noted that the invention itself produces "no economically relevant effect at all. Innovation, on the other hand, engenders revolutionary changes in the economic system through "a process of Creative Destruction. Schumpeter therefore maintained the necessity of patent monopolies to induce investment in "innovation." Schumpeter's notion that monopoly surpasses competition in stimulating innovation finds support in biotechnology.[19]

4. The Prospect Theory- According to the prospect theory, patents promote efficient development of patented inventions by allowing patent owners to coordinate further research and development efforts. If the patent owner holds the exclusive right to exploit and to improve the technology defined in the patent claims, others will not invest in improving this technology without prior arrangements with the patent owner. However, these firms may still achieve the efficiency of coordination if the patent holder brings in talented individuals to develop selected areas using selective licensing, which does not increase real competition. However, tailoring licenses to particular licensees entails high transaction costs.

Government Initiatives

In the globally competitive world, the industrial and technological superiority of a country will certainly give it economic advantages. India is now recognized as a major economic and industrial power with strong scientific and technology support. To further strengthen the research and development the Government of India has provided series of fiscal incentives to individuals, industries and Research institutions. They are as follows

1. Startup Bonanza

The patent rules have been brought in line with the government's 'Startup-India' initiative and as also with the recently released National IPR Policy. To achieve the Amended Rules treat start-ups legally at par with natural individual persons. The Amended Draft Rules have defined 'start-ups' in accordance with the Startup India Action Plan. It must be working towards innovation, development, deployment or commercialization of new products, processes or services driven by biotechnology or intellectual property.

2. Financial Incentives

To encourage innovation and growth, the government initiatives offer a range of financial incentives to biotechnology start-ups.

a. Excise duty waiver on patented products
b. Exemption from Drug Price Control Order
c. Weighted tax deduction on R&D expenditure @150% is available to companies engaged in the business of biotechnology.
d. Tax holiday to R&D companies
e. Income-tax relief on R&D expenditure
f. Tax deduction for sponsoring research
g. Tatkal Patents

Ethical Considerations/Dilemma

The biotechnology is one of the most rapidly increasing fields of scientific and industrial innovation in modern times, it has earned a position in the public debate, particularly in terms of the ethical ideals linked with it.[21] Like the technology that it is applied to protect, it is a system that needs to be subject to ethical analysis to examine whether it is suitable for a moral society. The patenting of higher life forms such as human cells, genes, mice, and other living things has sparked a slew of ethical concerns. Many of them are religious in nature, believing that patenting God's creations reduces them to simple material items and lowers the God-given dignity of living forms by making them one's personal property. However, there should be some form of check on humans who try to play God by inventing new technologies and obtaining patents on them. The European Court of Justice addressed this problem in the **Relaxin Case[22]** also. The principle benefit claimed for patents is that rewarding an inventor creates a positive environment for progress of research that leads to the betterment of society. If this is true than this is consistent with the ethical principle of beneficence. History suggests that the financial interest in a free market creates more funding for research, and faster overall progress in research in important areas has been the result of the intense research efforts. This point has been used by industry to oppose moves to block patents on biotechnological inventions that arise from other ethical concerns. [23] The issue is however more complex than a simple examination of the benefits of intellectual property to one society, because there are always winners and losers in trade. We have to consider the ethical principles of justice, and non-maleficence. Even more complex is deciding just who are the actors involved in the equation. Some key ethical issues in patenting in scientific research include:

1. Is life a patentable commodity?
2. Is patenting of life forms subserve the animal and human welfare?
3. Is majority of world population living in developing countries and least developed countries going to be benefited by patent of biotechnological invention?
4. Should invention leading to cruelty on animals, plants, microorganisms without bringing any advantage to human welfare be patented?
5. What yardstick should be applied to patentable and not patentable invention?
6. Do developing and underdeveloped countries have capabilities and resources to reap the benefit of new age biotechnological invention?
7. What are the tolerable limits of doing harm by rigid enforcement of patents if price becomes a barrier to use of a product by persons in need?

8. Ethically can anyone own a product of their mind, a product of nature, a product of a designed process, a discovery or even an invention?
9. Should we expect the practical law to share the same goals as that of ethics, namely can we expect ideal ethical laws or some compromise?

Recently, the "UN Panel on Medical Ethics in the Age of Genetic Engineering" discussed the human and social implication of the biomedical researches conducted during the past 50 years. The panel attempted to explore as to how these researches will benefit human beings.[24] A great debate is going on around the world about the functioning pattern of WTO and TRIPs Agreement. Partisan attitude of its dispute settlement body in favour of developed nations, especially USA, raises the doubts about the so-called fair and equitable justice dispensation system. Jayshree Watal who had the distinction of participating in formative Uruguay rounds of talks in her scholarly book on IPR has aptly commented that, monopoly sans humanism, is the essence of patents without fear of loss or control over their use.[25]

It is not easy to find answer to the above raised ethical issues. In this age of technology and commerce, the human values have been relegated. practically speaking, the ethics can change with time and with the societal needs. Similarly, the societal morals can also change with the change in time. However, at a particular time every country has the right to set the floor limits of ethics, which can be binding for the inventors over a period of time. The TRIPs of WTO is neutral in setting any limits of ethical issues, which can be globally acceptable.[26] It is only through enlightened global debate and firm political stand that the damage likely to be caused to the interests of developing nations can be mitigated.

Depository Considerations

In Biological invention, it is not possible to adequately describe the living substance nor it is possible to reproduce the invention without the biological material. Consequently, the world community has accepted that all biological materials be deposited in recognized international depositories. Thus, came **THE BUDAPEST TREATY** on the International Recognition of Deposit of micro-organisms for the purposes of patent procedure.[27] The treaty provides for recognition of culture collection as **International Depository Authorities (IDAS**) in any one of which a new stain of micro-organism can be deposited for the purposes of a patent application in any member-State.

Development of the Deposit Requirement

Inventions incorporating micro-organisms have been recognized as patentable subject matter for over a century. For several decades, the microbes used in these inventions were known and readily available to researchers in the biotech field. As a result of rapid advances in

antibiotic development during the 1940s and 1950s, researchers began using artificially modified strains of micro-organisms designed to improve and increase the yields of antibiotics. Many of the organisms used in the production of antibiotics were neither familiar to other biotech researchers, nor isolatable from known and publicly available sources without undue experimentation. It was increasingly difficult for patent applicants in the biotech field to meet the enabling disclosure and best mode requirements of a particular state's patent laws. To facilitate compliance with these provisions, applicants began supplementing patent applications by depositing samples with a recognized culture depositary of the relevant micro-organism. Hoping that the courts and patent offices of the various states would approve, inventors worldwide adopted the deposit practices.

The Budapest Treaty: An Attempt to Harmonize Deposit

As the number of states that required patent applications for biotechnological inventions to be supplemented by deposit increased, so did the burden on applicants hoping to patent inventions in more than one of these states because a separate deposit would be required for each state's application. To relieve this burden and to encourage continued research and development in biotechnology, cooperation was necessary. Cooperation took the form of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest Treaty or the Treaty), which concluded in 1977 and entered into force in 1980. Article 7 of the Treaty provides for the establishment of international depositary authorities in which micro-organisms may be deposited. Article 3 obligates the contracting states to recognize the deposit of a micro-organism in any depositary institution authorized by the Treaty. 5 The Budapest Treaty heavily regulates procedures, and certain mechanical aspects of depositing and releasing samples76 within the depositary institutions. The Treaty, however, has minimal influence on the substantive law of each contracting state.

Problems Arising from the Deposit Requirement

Although the deposit requirement eliminates the difficulty involved in providing an adequate written description of a novel micro-organism, it creates new difficulties in other aspects of the microbiological patent process. One major cause for concern among inventors and potential patent applicants arises from the dual nature of the micro-organism, which incorporates both tangible and intangible property. Another problem arises in states that have amended their national patent law to provide for early publication of patent applications, often prior to examination by the patent office.

A. The Dual Nature of Micro-organisms

An inventor who creates a new micro-organism simultaneously generates valuable intangible property-the idea embodied in the invention. The micro-organism itself, however, constitutes tangible personal property. The deposit requirement does not alter the scope of patent protection with respect to the invention claimed, because the deposited sample merely functions as a supplement to, or substitute for, the compulsory written description.[28]

The additional burden placed on the inventor by requiring a sample to be deposited is arguably minimal when viewed in light of the simplified disclosure. The inventor's lost property rights could be justified as an additional cost imposed on the inventor in exchange for patent protection. Furthermore, because the Budapest Treaty allows the inventor to make only a single deposit, which will be recognized in all contracting states, the inventor arguably has little cause for complaint. But this lack of grounds for complaint would be true only if a sample deposit were all that is required of inventors of biotechnology. Consequently, inventors of biotechnology face an unwarranted additional burden, that is not imposed upon inventors in any other field of technology. An inventor who employs a novel micro-organism in an invention is obligated to supply not only the information necessary to reproduce the invention, but also the actual invention. The only readily apparent difference in the two situations is the difficulty encountered when verbally describing the micro-organism. This single difference hardly justifies the substantially different treatment under the same laws.

B. Problems Created by Early Publication

In the wake of the EPC's harmonizing effect, publication of unexamined patent applications eighteen months after the filing or priority date became the standard in most European states.[29] Although these revolutionary changes may have aided European industry, they placed the patent applicant in a vulnerable position. Most patents generally will not have issued within eighteen months. Consequently, the inventor's rights in the invention go unprotected for the entire period between publication and the patent grant. In the worst case scenario in which the application is rejected altogether and no patent issues, the applicant has lost not only the opportunity to patent the invention, but also the opportunity to protect the invention as a trade secret because the secrecy of the invention already has been destroyed by the laying open of the application. Arguably this loss of trade secret protection is reasonable when the application is rejected for substantive reasons, such as improper subject matter. Moreover, this result ignores the long-standing principle of patent law that an inventor must not be made to surrender the technical teaching of an invention to the public domain until the granting of exclusive rights therein. The system of early publication forces the applicant to relinquish rights prior to patent

issuance in exchange "for the mere prospect of patent protection. The only way to avoid publication, and thereby preserve the possibility of trade secret protection, is to withdraw the application at least ten weeks prior to its being laid open. Generally, however, not even a novelty report would be available from the examining office within this time. Thus, the applicant is in no better position to assess the patentability of the invention immediately prior to early publication than at the time of filing the application.[30]

The Viability of Trade Secret Protection for Biotechnological Inventions

Faced with the problems inherent in the patenting of biotechnological inventions and micro- organisms, inventors may attempt to protect their discoveries by alternative means. One alternative to patent protection is the trade secret law. In the United States, an inventor reserves the right to hold in secret any invention and to claim it as a trade secret. This protection remains an especially attractive option for inventors whose inventions are, for some reason, not patentable. Often these nonpatentable inventions are a source of economic value or competitive advantage that demands some mode of protection against misappropriation by competitors. Trade secret protection is also available to protect inventions whose infringement would be difficult to detect or to prevent. Biotechnological inventors are discovering that the patent laws of many states do not provide sufficient protection against subsequent misuse. Consequently, these inventors are turning to trade secret law for protection.

Conclusion:

To summarize, the patenting of biotechnological inventions is a fusion of legal, ethical, and social dimensions in one basket. It is perhaps for this very reason that India treads carefully, ensuring that the balance between these competing pulls tilts more in favour of stimulating innovation rather than just protecting private interests or vice versa. Continuous dialogue based on adaptive policies is of utmost importance to navigate the patentability dilemma and achieve optimum social benefits of biotechnological developments for societal applications.

A number of differences exist between nations regarding intellectual property protection for biotechnological inventions. Included in these differences is the issue of what constitutes patentable subject matter. Patent protection for biotechnology did not require a ‘go/no go’ decision by either legislature or courts. The only question was under what circumstances biotech patents met the standards of novelty, utility, inventive step and non-obviousness. Addressing these complex implications will enable the realisation of maximum benefits of genetic testing and other biotechnological innovations, hence improving health outcomes and facilitating sustainable development across the world and in India.

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29. Early publication especially became commonplace after Article 93 of the EPC was enacted in 1973.
30. Under the European patent system, the possibility of preventing the applicant's publication exists up until ten weeks before the eighteenth month after the application is filed.

Chapter 12

INFORMATION SOURCES IN PATENT LITERATURE SEARCH

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Abstract:

A patent literature search is a crucial step in research and innovation, aiding in assessing patentability, avoiding infringement, and understanding technological advancements. Patent information sources include national and international patent databases, scientific literature, and commercial platforms that facilitate comprehensive prior art searches. In India, the Indian Patent Advanced Search System (InPASS), maintained by the Indian Patent Office (IPO), allows access to published and granted patents. Additionally, Traditional Knowledge Digital Library (TKDL) plays a key role in preventing biopiracy by documenting indigenous knowledge. Researchers also utilize academic and industrial databases such as CSIR's NISCAIR and DERWENT Innovation Index for broader insights. Globally, major sources include USPTO (United States Patent and Trademark Office), EPO (European Patent Office), and WIPO (World Intellectual Property Organization), offering extensive databases like Espace net, Patent scope, and Google Patents. Specialized commercial databases such as LexisNexis Total Patent, Questel Orbit, and Derwent World Patents Index (DWPI) provide advanced analytics, citation tracking, and legal status monitoring. Additionally, non-patent literature (NPL), including research articles, conference proceedings, and technical reports, is vital for a comprehensive prior art search. Despite these resources, challenges such as language barriers, incomplete data, and evolving classification systems persist. Integrating AI-driven search tools, improving database interoperability, and expanding open-access repositories can enhance the efficiency of patent searches. This paper explores Indian and international patent information sources, their role in innovation management, and strategies to optimize patent search methodologies, contributing to robust intellectual property protection and research development.

Keywords: Patent Literature Search, Patent Information Sources, Intellectual Property (IP), Prior Art Search, Patent Databases, Indian Patent Office (IPO), Traditional Knowledge Digital Library (TKDL), USPTO (United States Patent and Trademark Office), EPO (European Patent Office), WIPO (World Intellectual Property Organization, ETC

1. Introduction:

"*The value of an idea lies in the using of it."*

- Thomas A. Edison

Innovation is the cornerstone of technological and economic progress, but the true impact of an idea is realized only when it is protected, refined, and shared. In this context, patents play a pivotal role by safeguarding intellectual property, promoting transparency, and encouraging further innovation. A systematic patent literature search is not merely a formality in the innovation process—it is an essential practice for determining the novelty of an idea, avoiding infringement, and gaining insight into existing technological landscapes.

Patent documents are rich reservoirs of technical information, often disclosing details not found in academic publications or commercial products. However, locating relevant patent information requires access to robust databases, effective search strategies, and a clear understanding of global patent systems. With the increasing volume of patent filings worldwide, navigating this data has become complex, necessitating advanced tools and methodologies for efficient prior art search.

In India, platforms such as the Indian Patent Advanced Search System (InPASS) and the Traditional Knowledge Digital Library (TKDL) offer vital resources for researchers and policymakers alike. On the global stage, databases maintained by the USPTO, EPO, and WIPO—along with commercial platforms like LexisNexis TotalPatent and the Derwent World Patents Index (DWPI)—have revolutionized the way patent information is accessed and analysed.

Despite these advances, challenges persist. Language barriers, evolving patent classification systems, and fragmented data structures hinder comprehensive search efforts. Moreover, integrating non-patent literature (NPL), such as academic research, conference proceedings, and technical reports, is often overlooked but critical for thorough prior art analysis. This study seeks to bridge these gaps by systematically exploring the landscape of patent information sources, both Indian and international. It aims to evaluate their role in innovation management, identify prevailing challenges, and propose strategies—such as AI integration and database interoperability—to enhance the overall efficiency and effectiveness of patent searches.

Objectives of Study:

This paper aims to analyse different aspects of information sources in patent literature research. The primary objectives of this study are :

1. To explore various Indian and International patent information sources and their roles in facilitating prior art searches.

2. To analyse the effectiveness of platforms such as In PASS, TKDL, USPTO, EPO, and WIPO in providing accessible and reliable patent data.
3. To assess the contribution of commercial and non-patent literature databases in enhancing patent search outcomes.
4. To identify the key challenges faced by researchers and innovators during patent literature searches, including data gaps and language barriers.
5. To propose strategies for optimizing patent search methodologies through technological integration, such as AI tools and database interoperability.
6. To highlight the significance of patent information in promoting innovation management and intellectual property protection.

Methodology:

This study adopts a qualitative and descriptive research approach, incorporating the following methods:

1. **Literature Review:**
   An extensive review of academic publications, patent documentation guidelines, and technical reports was conducted to understand the structure, scope, and usage of various patent information sources.
2. **Comparative Analysis:**
   Indian and global patent databases (e.g., InPASS, TKDL, USPTO, EPO, WIPO) were analysed for their accessibility, coverage, search functionalities, and user-friendliness.
3. **Database Exploration:**
   Practical exploration and navigation of open-access and commercial patent search platforms (e.g., Google Patents, Patentscope, LexisNexis TotalPatent, DWPI) were performed to assess their utility in conducting comprehensive prior art searches.
4. **Case Examples and Use Cases:**
   Real-world examples from research institutions and industry were examined to illustrate the application and effectiveness of different patent search tools.
5. **Challenges Identification:**
   Key issues such as language limitations, outdated or incomplete records, and complexity in classification systems were identified through secondary data and expert opinions.
6. **Strategic Framework Development:**
   Based on findings, strategies involving AI, interoperability improvements, and open-access expansion were proposed to improve the overall patent search process.

2. Global Patent Information Sources:

Patent systems across countries vary in procedure and coverage, yet they collectively contribute to a rich, interconnected body of technical knowledge. The most prominent international sources include:

2.1 United States Patent and Trademark Office (USPTO):

The USPTO provides access to U.S. patent data dating back to 1790. Its advanced search system allows users to perform full-text searches, view citation analysis, and access legal status.

2.2 European Patent Office (EPO) – Espacenet:

Espacenet offers access to over 140 million patent documents from more than 100 countries. It includes translation tools, classification assistance through the Cooperative Patent Classification (CPC), and family grouping of related patents.

2.3 World Intellectual Property Organization (WIPO) – Patentscope:

WIPO's Patentscope allows access to international Patent Cooperation Treaty (PCT) applications and national collections. It supports machine translation, multilingual searching, and cross-jurisdictional citation mapping.

2.4 Google Patents:

Google Patents aggregates patent data from USPTO, EPO, WIPO, and other sources. It incorporates machine learning tools for prior art suggestions and links to non-patent literature.

2.5 Commercial Databases:

Platforms such as LexisNexis TotalPatent, Questel Orbit, and Derwent World Patents Index (DWPI) provide powerful analytics, visualization, and legal monitoring tools. While subscription-based, they offer functionalities like semantic search, litigation tracking, and competitive intelligence.

3. Patent Information System in India:

India's intellectual property regime has seen rapid modernization, particularly in the digitalization of patent data and promotion of transparency.

3.1 Indian Patent Advanced Search System (InPASS):

Maintained by the Indian Patent Office (IPO), InPASS allows public access to published applications, granted patents, patent legal status, and examination reports. It is a vital resource for inventors, researchers, and patent agents in India.

3.1 Traditional Knowledge Digital Library (TKDL):

TKDL is a collaborative project between CSIR and AYUSH, aimed at documenting India's traditional medicinal knowledge in a digital, searchable format to prevent biopiracy. It contains over 290,000 formulations translated into major international languages.

3.2 National Scientific Repositories:

Platforms like NIScPR (formerly NISCAIR), CSIR-URDIP, and India Science, Technology and Innovation Portal support researchers with patent statistics, bibliometric tools, and policy insights.

4. Importance of Non-Patent Literature (NPL):

While patent databases are central to prior art searches, non-patent literature (NPL) is equally important.

Sources such as:

- IEEE Xplore, ScienceDirect, Springer, and arXiv
- Technical reports, white papers, and conference proceedings

NPL can often reveal similar or overlapping innovations not yet patented, especially in academic or opensource domains. Including NPL in patent searches helps prevent the granting of weak or redundant patents.

5. Challenges in Patent Literature Research:

Despite the availability of extensive patent information systems, several challenges hinder the efficiency and effectiveness of search operations:

5.1 Language Barriers:

Many patent documents are in native languages, especially in jurisdictions like China, Japan, and Korea. Although machine translation has improved, technical accuracy remains a concern.

5.2 Evolving Classification Systems:

Changes in classification schemes (e.g., transition from IPC to CPC) may lead to inconsistencies and incomplete search results unless regularly updated.

5.3 Data Fragmentation:

With different jurisdictions using separate databases and standards, retrieving comprehensive, harmonized data requires navigating multiple interfaces and reconciling formats.

5.4 Search Expertise:

Effective patent searching often demands specialized knowledge in boolean operators, classification codes, and legal terminology—skills not all researchers possess.

5.5 Accessibility and Cost:

Many advanced databases are subscription-based, making them inaccessible to researchers in developing regions or startups with limited resources.

6. Case Studies:

Case Study 1: Preventing Biopiracy Through TKDL

In 2005, a European company attempted to patent the use of turmeric for wound healing. India successfully challenged the application by providing documented evidence from TKDL that turmeric's medicinal properties were already known in Ayurveda. The patent was subsequently revoked, illustrating how traditional knowledge documentation can be used as defensive prior art.

Case Study 2: AI in Patent Search – IBM Watson and DWPI

IBM collaborated with Clarivate to integrate Watson's AI with the Derwent database, enabling semantic search and automated classification. In a pilot conducted with a pharmaceutical firm, AI reduced prior art search time by over 60% and improved the relevance of retrieved documents, showing how AI enhances productivity and accuracy.

Case Study 3: Patent Landscaping for Green Technology in the EU

The European Patent Office conducted a patent landscape study to support green innovation under the EU Green Deal. By using Espacenet's CPC tools and legal status filters, researchers identified technology gaps and prioritized funding for sustainable inventions in renewable energy and battery storage.

7. Strategic Recommendations:

To overcome the limitations identified and strengthen global and local patent search processes, the following strategies are proposed:

7.1 AI and Natural Language Processing Integration:

AI-driven search engines using natural language understanding (NLU) can improve relevance ranking, suggest synonyms or related concepts, and reduce dependency on manual classification-based searches.

7.2 Database Interoperability:

Developing APIs and open protocols to integrate major databases (e.g., InPASS with WIPO or EPO) can provide researchers with unified, comprehensive access points.

7.3 Multilingual Search Enhancements:

Investments in better machine translation tools for patent and scientific terminology can lower language barriers and increase accessibility to non-English patents.

7.4 Capacity Building and Training:

Patent offices, universities, and research institutions should conduct regular training on search strategies, patent classification systems, and legal interpretation to build internal IP literacy.

7.5 Open Access Expansion:

Encouraging open-access publishing and public patent data sharing (especially for publicly funded research) will support innovation in lower-income regions and foster equitable development.

Conclusion:

Patent literature search is a vital element in the innovation ecosystem, enabling researchers and innovators to evaluate novelty, monitor trends, and build on existing knowledge responsibly. The global patent infrastructure—spanning USPTO, EPO, WIPO, and commercial databases—offers powerful tools but also presents challenges that must be addressed through strategic reforms.

India's progress in digitalizing patent data through InPASS and safeguarding indigenous knowledge via TKDL offers a model for other emerging economies. As patent filings rise and technologies converge, integrating AI tools, expanding access, and fostering international collaboration will be crucial in transforming patent searches from a technical hurdle into a strategic advantage.

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Chapter 13

GLOBAL AGREEMENTS ON INTELLECTUAL PROPERTY RIGHTS AND BIODIVERSITY GOVERNANCE – INSIGHTS FROM PARIS CONVENTION, CBD, UPOV AND PGRFA

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Abstract:

Global governance frameworks increasingly intersect intellectual property rights (IPR) and biodiversity, with multiple international agreements shaping the landscape. This paper critically examines the interplay between key global treaties—the Paris Convention for the Protection of Industrial Property (1883), the Convention on Biological Diversity (CBD, 1992), the International Union for the Protection of New Varieties of Plants (UPOV), and the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA, 2001). Each agreement reflects unique priorities, ranging from innovation and commercial protection to conservation and equitable access to genetic resources. The paper explores the tensions and synergies among these agreements, particularly in light of developing countries' concerns over biopiracy, benefit-sharing, and food sovereignty. Real-world examples and case studies are used to illustrate how these frameworks function in practice. The analysis concludes with policy recommendations aimed at harmonizing IPR enforcement with biodiversity protection and equitable development. The intersection of intellectual property rights (IPR) and biodiversity conservation has emerged as a central theme in international law and policy. Various global agreements such as the Paris Convention (1883), the Convention on Biological Diversity (CBD, 1992), the International Union for the Protection of New Varieties of Plants (UPOV), and the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA, 2001) seek to address innovation, biodiversity protection, and equitable access to genetic resources. However, these treaties often present overlapping jurisdictions and contrasting priorities, leading to legal and ethical challenges, especially for biodiversity-rich developing nations like India. This paper explores the dynamics among these treaties through the lens of Indian legal and policy frameworks, backed by case laws such as the neem and turmeric patent disputes, the Basmati rice controversy, and the development of India's Traditional Knowledge Digital Library (TKDL). Comparative insights from international case studies and forums such as the International Court of Justice (ICJ) and national biodiversity laws also contribute to a

comprehensive analysis. The study concludes by proposing a framework for harmonizing IPR with biodiversity governance through informed policy reform, stronger community rights, and a more coherent global legal order.

Keywords: Intellectual Property Rights (IPR), Biodiversity Governance, Paris Convention, CBD, UPOV, PGRFA, Traditional Knowledge, India, Biopiracy, Access and Benefit Sharing (ABS), International Court of Justice (ICJ), Farmers' Rights.

1. Introduction:

In the contemporary era of biotechnology and globalization, the interface between intellectual property rights (IPRs) and biodiversity governance has emerged as a critical area of legal and ethical inquiry. The drive for innovation and commercial protection through legal instruments such as patents, trademarks, and plant variety protections frequently intersects with the ethical, ecological, and socio-economic imperatives of biodiversity conservation and the equitable sharing of its benefits.

The global legal architecture governing this interplay comprises several key international agreements. The Paris Convention (1883), one of the earliest treaties on IPR, laid the foundation for protecting industrial inventions globally. Decades later, the Convention on Biological Diversity (CBD) reoriented the discourse toward sustainable use and equitable access to genetic resources, giving rise to access and benefit-sharing (ABS) regimes. Simultaneously, the UPOV system introduced a standardized mechanism for protecting plant breeders' rights, whereas the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA) emphasized farmers' rights and food security.

Each agreement offers a unique perspective on ownership, access, and use of biological materials and innovations. Understanding how these frameworks interrelate is critical for shaping policies that respect both innovation and traditional knowledge, particularly in biodiversity-rich but economically vulnerable regions.

While these treaties aim to address distinct legal and policy concerns, their interactions have led to jurisdictional overlaps and normative contradictions. For instance, the proprietary model under UPOV may undermine farmers' seed-saving practices, directly contradicting the principles enshrined in the PGRFA and the CBD. Similarly, while the Paris Convention and TRIPS Agreement facilitate the patenting of genetic materials and biotechnological inventions, such provisions often clash with national biodiversity laws and indigenous rights regimes.

India, a megadiverse country with a rich heritage of indigenous knowledge systems and traditional agriculture, stands at the crossroads of these intersecting legal regimes. As a signatory to multiple global treaties, India has developed a sui generis legal framework that includes the

Biological Diversity Act, 2002, and the Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPVFR Act). These laws attempt to reconcile the demands of international IPR obligations with national priorities for biodiversity conservation and food security.

This research paper undertakes a comprehensive study of four major international instruments—the Paris Convention, CBD, UPOV, and ITPGRFA—to critically assess how they influence biodiversity governance. It further analyzes India's legal response, explores international jurisprudence including the role of the International Court of Justice (ICJ), and proposes solutions for achieving coherence, justice, and sustainability in global IPR and biodiversity laws.

2. Historical Evolution of IPR and Biodiversity Governance

Historically, intellectual property law focused on industrial innovations, with little concern for biological or genetic resources. The Paris Convention of 1883 laid the groundwork for international IPR protection. However, the emergence of biotechnology in the late 20th century complicated this framework, introducing new legal and ethical challenges.

By the 1990s, the global community acknowledged the need for environmental protection and equitable access to genetic resources. The 1992 Convention on Biological Diversity marked a paradigm shift, recognizing the sovereignty of states over their biological resources and the importance of fair benefit-sharing mechanisms.

Parallel to this, UPOV (established in 1961) and later the PGRFA Treaty addressed plant variety protection and agricultural biodiversity. These agreements collectively demonstrate a shift from exclusive ownership models to more nuanced approaches balancing innovation with sustainability and equity.

The development of intellectual property rights and biodiversity governance has followed two largely parallel trajectories, each evolving from distinct historical imperatives and legal traditions. While IPR regimes have traditionally been associated with innovation, trade, and industrial advancement, biodiversity treaties emerged from ecological, ethical, and developmental concerns. Understanding the historical context of these legal regimes is crucial to analyzing their eventual convergence and conflict.

2.1 The Paris Convention (1883): Foundations of IPR

The Paris Convention for the Protection of Industrial Property, adopted in 1883, marked the beginning of international cooperation in protecting inventions, trademarks, and industrial designs. It introduced the principle of **"National Treatment"** and the **"Right of Priority,"** enabling inventors to claim their rights across multiple jurisdictions. While the Convention did

not originally address biological materials, its framework later served as a foundation for extending patents to life forms, especially with the advent of biotechnology.

2.2 The Trips Agreement and Globalization of IPR

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), incorporated into the WTO framework in 1995, significantly expanded the global enforcement of IPR. TRIPS made it mandatory for member states to grant patent protection for inventions, including biotechnological processes and genetic material, subject to certain exceptions under Article 27.3(b). While TRIPS aimed to harmonize IPR globally, it also raised concerns about the erosion of traditional knowledge, bio-piracy, and the commodification of natural resources.

2.3 Emergence of the CBD (1992): A Paradigm Shift

In contrast to the proprietary logic of TRIPS, the Convention on Biological Diversity (CBD) adopted at the Earth Summit in Rio de Janeiro in 1992 emphasized conservation, sustainable use, and equitable benefit-sharing (ABS). CBD explicitly recognized the sovereign rights of states over their biological resources and underscored the role of indigenous and local communities in conserving biodiversity. It also introduced the concept of prior informed consent (PIC) and mutually agreed terms (MAT) for accessing genetic resources.

This treaty marked a shift from a "global commons" approach to a national sovereignty model, thereby altering how genetic materials were accessed and commercialized. However, the lack of strong enforcement mechanisms in the CBD has led to tensions between provider countries and users, especially when IPR is granted without respecting ABS protocols.

2.4 UPOV and the Protection of Plant Varieties

The International Union for the Protection of New Varieties of Plants (UPOV), established in 1961 and revised in 1991, provides a sui generis system for protecting plant breeders' rights. It grants exclusive rights to breeders over the production, reproduction, and commercialization of new plant varieties. However, the 1991 Act of UPOV restricts farmers' rights to save and exchange seeds, a practice deeply embedded in traditional agricultural systems in the Global South.

India, notably, has not joined UPOV but has instead enacted the Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPVFR)—a more balanced framework that acknowledges both breeders' and farmers' rights, partly in response to UPOV's inadequacies in addressing food security and indigenous knowledge.

2.5 PGRFA and the Global Commons Approach

The International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA), adopted in 2001 under the aegis of the Food and Agriculture Organization (FAO), complements

the CBD by focusing on the conservation and sustainable use of plant genetic resources for food and agriculture. Unlike UPOV, it supports a Multilateral System (MLS) of access and benefitsharing that applies to a list of 64 key crops.

Importantly, the PGRFA enshrines Farmers' Rights—a concept developed largely through the advocacy of India and other developing countries—to protect traditional agricultural knowledge, allow seed-saving, and ensure participation in benefit-sharing mechanisms. However, the non-binding nature of many of its provisions remains a challenge.

3. India's Legal Response – Harmonizing Global Norms with National Interests

India, as a biodiversity-rich and culturally diverse nation, has had to navigate the complexities of global intellectual property regimes while safeguarding its traditional knowledge, community rights, and ecological wealth. Its legal response to international treaties like the CBD, TRIPS, UPOV, and PGRFA reflects a nuanced attempt to reconcile global obligations with national priorities.

3.1 The Biological Diversity Act, 2002: Domesticating the CBD

India's most direct legislative response to the Convention on Biological Diversity is the Biological Diversity Act, 2002, which operationalizes the CBD's core principles, including sovereignty over genetic resources, access and benefit-sharing (ABS), and prior informed consent (PIC).

The Act establishes a three-tiered institutional structure:

- National Biodiversity Authority (NBA)
- State Biodiversity Boards (SBBs)
- Biodiversity Management Committees (BMCs) at the local level

The Act prohibits unauthorized access to biological resources and associated traditional knowledge by foreign entities and imposes benefit-sharing obligations. For instance, any patent or IPR application involving Indian biodiversity requires NBA approval.

The Act was crafted to resist biopiracy and unauthorized commercialization. However, challenges persist, including lack of awareness, limited implementation at local levels, and conflicts with other laws such as the Indian Patents Act and Seed Laws.

3.2 Traditional Knowledge Digital Library (TKDL): A Preventive Innovation

India pioneered the Traditional Knowledge Digital Library (TKDL) as a defensive mechanism against biopiracy. This digital repository contains codified knowledge from Ayurveda, Unani, Siddha, and Yoga, translated into five international languages. By sharing this database with patent offices globally, India has effectively pre-empted the misappropriation of traditional knowledge.

The TKDL has successfully prevented the granting of wrongful patents, including in the famous turmeric and neem cases, by submitting prior art documentation. It has become a model for other developing nations seeking to protect indigenous knowledge within the IPR system.

3.3 Case Studies from India: Defending Biodiversity and Traditional Knowledge

a) Neem Patent Case (European Patent Office, 2000)

In 1995, the European Patent Office (EPO) granted a patent to the U.S. Department of Agriculture and a multinational company for an antifungal formulation derived from neem. Indian NGOs and the government challenged the patent, arguing that neem's properties were part of traditional Indian knowledge. The EPO revoked the patent in 2000, establishing a landmark in the fight against biopiracy.

b) Turmeric Case (USPTO, 1997)

A U.S. patent was granted to two Indian expatriates for the use of turmeric in wound healing—a practice well-known in Indian households. The Council of Scientific and Industrial Research (CSIR) filed a re-examination request and proved prior art. The USPTO revoked the patent, affirming the value of oral and community-based traditional knowledge.

c) Basmati Rice Controversy (India vs. RICETEC, 1997)

In 1997, Texas-based RiceTec Inc. patented a new variety of Basmati rice, claiming novel characteristics. The Indian government challenged the patent at the USPTO, arguing that Basmati was a geographical indication and a product of traditional breeding. The patent was partially revoked after global pressure. This case emphasized the need for stronger protection of traditional varieties and geographical indications under IPR frameworks.

3.4 India's PPVFR Act, 2001 – A Balanced Response to UPOV

Unlike UPOV, which largely favours commercial breeders, India's Protection of Plant Varieties and Farmers' Rights (PPVFR) Act, 2001 offers a sui generis system of protection that recognizes both plant breeders' rights and farmers' rights.

Farmers can:

- ✓ Save, use, exchange, and sell farm-saved seeds
- ✓ Register traditional varieties
- ✓ Claim compensation if a registered variety fails to perform as claimed

This approach directly challenges the restrictive provisions of UPOV 1991 and aligns better with India's agricultural and socio-economic realities. The Act reflects India's position at the FAO negotiations on the PGRFA treaty, where it championed the inclusion of Farmers' Rights.

3.5 Judicial Trends and Constitutional Backing

Indian courts have upheld environmental and biodiversity-related principles under Article 21 of the Constitution, which guarantees the right to life. In ***Vellore Citizens' Welfare Forum v. Union of India*** **(1996)** and ***T.N. Godavarman Thirumulpad v. Union of India*** **(1997)**, the Supreme Court integrated the principles of sustainable development, precautionary principle, and polluter pays into Indian environmental jurisprudence. Though not directly related to IPR, these rulings provide a constitutional foundation for biodiversity governance and reinforce India's legislative efforts in resisting biopiracy and unfair exploitation of genetic resources.

4. Comparative Global Examples–Challenges and Best Practices

The governance of intellectual property and biodiversity presents a global challenge, with diverse responses shaped by national legal systems, traditional knowledge structures, and levels of economic development. While India has taken strong legislative and institutional measures, experiences from other countries offer valuable insights into the success and shortcomings of implementing international treaties like the **CBD**, **UPOV**, and **PGRFA** This section presents key comparative case studies and examines the role of global forums such as the **International Court of Justice (ICJ)** in shaping norms and resolving disputes.

4.1 Enola Bean Case – United States

One of the most cited examples of potential biopiracy is the Enola bean case in the United States. In 1999, a US citizen, Larry Proctor, patented a yellow bean variety (Enola bean), claiming it was distinct from Mexican yellow beans. The patent allowed him to demand royalties and block Mexican imports. However, Mexican farmers and NGOs argued that the bean was not novel and had been traditionally grown in Mexico for centuries.

The International Center for Tropical Agriculture (CIAT) and others challenged the patent by submitting samples from their genebank. After nearly a decade, the US Patent and Trademark Office (USPTO) revoked the patent in 2008, citing lack of novelty. This case illustrates the dangers of weak prior art documentation and the potential of global germplasm repositories in combating illegitimate IPR claims.

4.2 Peru – Protecting Indigenous Rights and ABS

Peru has emerged as a pioneer in protecting indigenous knowledge and implementing access and benefit-sharing (ABS) provisions of the CBD. It enacted Law No. 27811 (2002) on the Protection of Collective Knowledge of Indigenous Peoples, which:

- Recognizes communal ownership over traditional knowledge
- Requires prior informed consent (PIC) before access to genetic resources
- Establishes a National Public Register for documentation

Peru's regulatory approach demonstrates a community-driven legal framework that places indigenous peoples at the centre of biodiversity governance, reinforcing the Nagoya Protocol's objectives.

4.3 Costa Rica-Model Implementation of The CBD

Costa Rica has developed one of the most integrated systems for implementing the CBD and sustainable use of biological resources. Its Biodiversity Law (1998):

- Emphasizes conservation and equitable benefit-sharing
- Requires environmental impact assessments for bioprospecting
- Integrates indigenous participation through local conservation areas

Costa Rica also collaborated with the pharmaceutical company Merck in a bioprospecting partnership, managed by the Instituto Nacional de Biodiversidad (INBio), where monetary and non-monetary benefits were shared. Though the project faced criticism, it became a prototype for regulated ABS agreements.

4.4 African Union Model Law-Collective Sovereignty Over Biodiversity

In response to UPOV and biopiracy risks, the African Union proposed a Model Law on the Protection of the Rights of Local Communities, Farmers and Breeders, and the Regulation of Access to Biological Resources.

This law:

- ✓ Prohibits patenting of life forms
- ✓ Recognizes collective custodianship of resources
- ✓ Ensures ABS based on community consent

While not binding, this model law reflects a broader Southern discourse on decolonizing IPR regimes and reasserting community-based legal traditions in biodiversity protection.

4.5 The Role of the International Court of Justice (ICJ) in Biodiversity and Environmental Governance

Although the International Court of Justice (ICJ) has not directly ruled on biodiversity and IPR-related disputes, its advisory opinions and jurisprudence in environmental matters provide a foundation for understanding state responsibilities and customary international law.

a. Pulp Mills Case (Argentina V. Uruguay, 2010)

The ICJ addressed transboundary environmental harm and emphasized the importance of Environmental Impact Assessments (EIA). This ruling affirms that states must ensure that activities within their jurisdiction do not cause environmental damage to other states, a principle relevant to biodiversity and genetic resource exploitation.

b. Nuclear Weapons Advisory Opinion (1996)

In this landmark opinion, the ICJ acknowledged the precautionary principle and the obligation of states to protect the environment, even during armed conflict. These principles underpin global biodiversity governance.

c. Gabčíkovo–Nagymaros Case (Hungary/Slovakia, 1997)

The Court emphasized sustainable development as a balancing principle between environmental protection and economic interests—a key concern when reconciling IPR and Biodiversity.

d. Potential Role in Biodiversity Disputes

The ICJ may, in the future, serve as a forum for disputes between states regarding:

- Misappropriation of genetic resources
- Violations of ABS agreements
- Conflicts between IPR obligations and biodiversity treaties

Though current access is limited to states, Advisory Opinions requested by the UNGA or specialized agencies could clarify treaty interpretation, especially where conflicts arise between the CBD, TRIPS, and national laws.

5. Conflicts, Challenges, and Areas of Harmonization Between the Treaties

The interplay between international agreements on intellectual property rights and biodiversity governance is characterized by both synergies and systemic conflicts. While these treaties aim to regulate innovation, trade, and conservation, their normative foundations often clash—especially between proprietary models of innovation and collective rights over genetic resources.

5.1 CBD vs. TRIPS: A Normative Conflict

One of the most debated legal tensions in global governance is between the CBD's emphasis on sovereign rights and equitable benefit-sharing and the TRIPS Agreement's push for minimum standards of IPR protection.

i. Access vs. Protection:

CBD stresses regulated access to genetic resources based on prior informed consent (PIC) and mutually agreed terms (MAT), whereas TRIPS allows for patents on genetic materials, potentially undermining PIC and benefit-sharing.

ii. Public vs. Private Knowledge:

CBD and indigenous knowledge frameworks treat traditional knowledge as community property, while TRIPS tends to view innovation through the lens of individual/private ownership.

iii. Legal Status of Traditional Knowledge:

TRIPS do not currently mandate the disclosure of origin of genetic resources or associated knowledge in patent applications, creating loopholes for biopiracy. Proposals at the WTO to mandate such disclosure are yet unresolved.

5.2 UPOV Vs. PGRFA: Exclusive Rights Vs. Farmers' Rights

The UPOV Convention (especially the 1991 version) grants strong exclusive rights to plant breeders, limiting the rights of farmers to reuse and exchange seeds—practices foundational to agriculture in the Global South.

In contrast, the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA) recognizes:

- Farmers' rights to save, use, exchange, and sell farm-saved seed
- Rights to participate in decision-making
- Rights to share in benefits arising from plant genetic resources

This creates friction in countries attempting to comply with both treaties. For example, India refused to join UPOV and instead enacted its PPVFR Act, offering a more balanced solution.

5.3 Legal Pluralism and Forum Shopping

Countries are often party to multiple treaties that intersect and, at times, contradict each other. This legal pluralism allows for:

- Strategic interpretation of norms
- Forum shopping by corporations seeking the most favorable IPR regime
- Regulatory uncertainty for indigenous communities and smallholder farmers

For instance, a company may use TRIPS-based national patent laws to claim a plant-derived drug while bypassing the CBD's ABS provisions in the provider country.

5.4 Towards Harmonization: Emerging Models

Despite conflicts, efforts are underway to harmonize these overlapping regimes:

- Disclosure of Origin in Patent Applications:
- Ongoing negotiations at the WTO and WIPO aim to make disclosure of origin mandatory to prevent biopiracy and strengthen ABS compliance.

a. The Nagoya Protocol (2010):

A Supplementary Agreement To The Cbd, the Protocol operationalizes ABS mechanisms and provides clearer guidance on compliance, monitoring, and user obligations.

b. Regional Frameworks:

African Union's Model Law and India's sui generis systems are examples of customized legal approaches that reconcile biodiversity protection with IP compliance.

c. Digital Sequence Information (DSI):

A new area of debate concerns how DSI, which can be used to recreate biological materials digitally, fits within ABS frameworks. The CBD COP-15 began addressing this, but global consensus is still evolving.

5.5 Challenges to Implementation

Weak Enforcement Mechanisms:

CBD lacks binding dispute resolution procedures unlike TRIPS, making it harder for biodiversity-rich countries to enforce ABS obligations.

- **Asymmetric Capacities:**

  Developing countries often lack legal, financial, and technical capacity to monitor compliance or participate effectively in international forums.

- **Corporate Influence and Lobbying:**

  Powerful multinational corporations often shape IPR policies in their favor, sidelining indigenous rights and environmental justice.

6. Conclusion and the Way Forward

The intersection of intellectual property rights (IPR) and biodiversity governance sits at the core of 21st-century legal, ethical, and environmental challenges. As explored through the lens of global treaties—the Paris Convention, CBD, UPOV, and PGRFA—and reinforced by national models like India's sui generis approach, this complex legal terrain demands balance between innovation and equity, private rights and community ownership, and economic development and ecological sustainability.

6.1 Key Takeaways

1. India's legal architecture, especially the Biological Diversity Act and PPVFR Act, provides a rights-based model for integrating global obligations with local realities.
2. International cases such as Enola bean, turmeric, neem, and Basmati rice reflect how developing countries have had to resist exploitative patent regimes to safeguard indigenous knowledge.
3. Judicial interventions—both domestic (e.g., Indian Supreme Court cases) and global (e.g., ICJ environmental jurisprudence)—highlight the growing role of courts in interpreting environmental and biodiversity obligations.

4. There remain normative and procedural tensions among major treaties. TRIPS tends to privilege corporate patent regimes, while CBD and PGRFA advocate for sovereign and communal rights.
5. Effective implementation remains a challenge due to lack of harmonized laws, weak enforcement mechanisms, and asymmetric global power dynamics.

6.2 Recommendations and Future Directions

1. Mandating Disclosure of Origin and Compliance with ABS Norms

WIPO and WTO should finalize negotiations to mandate the disclosure of origin in patent applications, accompanied by proof of benefit-sharing arrangements. This would align IPR enforcement with CBD objectives.

2. Strengthening Community Participation and Capacity-Building

Legal reforms must be matched with awareness-building among local communities and capacity development in biodiversity-rich countries for monitoring and enforcing ABS regimes.

3. Reforming TRIPS to Align with Environmental Norms

TRIPS should be amended to incorporate environmental safeguards, traditional knowledge protection, and allow for public interest exceptions in patent regimes.

4. Digital Sequence Information (DSI) Governance

As synthetic biology and AI-driven genomics evolve, DSI must be brought under the scope of ABS frameworks, ensuring fair and equitable sharing even in virtual bioprospecting.

5. Greater Role for International Courts and Arbitration

While the ICJ currently has limited jurisdiction, mechanisms should be explored through the UN General Assembly or UNEP to request advisory opinions on treaty conflicts and environmental obligations.

The future of biodiversity governance and intellectual property law lies in pluralism, adaptability, and justice. Countries like India demonstrate that resistance to homogenized IPR regimes is not only possible but necessary for protecting the rights of farmers, indigenous peoples, and ecosystems. Global frameworks must evolve towards equity-centered legal norms, capable of addressing the dual imperatives of innovation and environmental sustainability. The path forward must be inclusive, democratic, and grounded in ecological consciousness, lest we commodify nature beyond repair.

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