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Biosciences in business

Dr . T.PRABHASH

Department of Biochemistry

**INTERNATIONAL FRAMEWORK
FOR THE PROTECTION OF IP, IP
AS A FACTOR IN R AND D , IPS
OF RELEVANCE TO
BIOTECHNOLOGY AND FEW
CASE STUDIES**

INTRODUCTION:

- The international framework for the protection of intellectual property (IP) provides a set of rules, treaties, and conventions that harmonize and enforce IP rights globally.
- These frameworks help countries protect and manage intellectual property, encouraging innovation and creativity while balancing public and private interests.

World Intellectual Property Organization (WIPO):

- WIPO is a United Nations agency that coordinates international IP laws and treaties. It aims to promote the protection of IP globally through cooperation among nations.
- Key Treaties Administered by WIPO:
 - Paris Convention
 - Berne Convention
 - Madrid System
 - Patent Cooperation Treaty
 - Hague System

- **Paris Convention (1883):** Protects industrial property (patents, trademarks, industrial designs) and ensures “national treatment” across member countries, where foreigners receive the same rights as nationals.
- **Berne Convention (1886):** Protects literary and artistic works (copyright). It establishes automatic copyright protection without requiring formal registration.

- **Madrid System (1891):** Simplifies the process of registering trademarks internationally by enabling applicants to file one application for protection in multiple countries.
- **Patent Cooperation Treaty (PCT, 1970):** Provides a unified procedure for filing patent applications in multiple countries, making it easier and less costly to seek protection internationally.
- **Hague System (1925):** Allows for international registration of industrial designs through a single application.

World Trade Organization (WTO) and the TRIPS Agreement (1995):

- The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is one of the most comprehensive international IP agreements, signed by all WTO members.
- TRIPS establishes minimum standards for IP protection across member countries, addressing:
- **Copyright and related rights:** Protects creators of literary, musical, and artistic works.
- **Trademarks:** Ensures that marks distinguish goods/services from one enterprise to another.

- **Patents:** Requires member states to provide patent protection for inventions in all fields of technology.
- **Geographical indications:** Protect that have a specific origin, such as “Champagne” from France.
- **Trade secrets:** Requires legal protection of undisclosed information.
- **Industrial designs:** Provides protection for the visual design of products.

Regional IP Organizations and Treaties :

- Regional organizations help streamline IP protection within specific geographic regions. Examples include:
- European Patent Office (EPO): Administers the European Patent Convention, allowing for a single patent application that can be validated in multiple European countries.

International IP Classifications and Standards:

- WIPO also plays a role in setting standards and classifications for intellectual property:
- International Patent Classification (IPC): Provides a uniform system for classifying patents.
- Nice Classification: Standardizes the classification of goods and services for trademark registration.
- Vienna Classification: Standardizes the classification of figurative elements in trademarks.

Ip as a factor in r and d :

- Intellectual Property (IP) plays a crucial role in Research and Development (R&D), as it provides a legal framework for protecting innovations and discoveries, incentivizing investment in R&D activities, and ensuring that the benefits of innovation can be commercially realized.

Incentivizing Innovation :

- **Patents**: One of the most significant ways IP incentivizes R&D is through patent protection. By granting inventors exclusive rights to their inventions for a certain period (usually 20 years), patents provide a financial incentive for companies and researchers to invest in R&D.

- **Licensing Agreements:** IP allows for the structured sharing of knowledge and technology through licensing agreements. Companies or research institutions can collaborate, share technology, or outsource R&D activities, knowing that their IP rights will be legally protected.
- **Public-Private Partnerships:** IP frameworks encourage partnerships between public research institutions and private enterprises, enabling the commercialization of publicly funded R&D outcomes.

Risk Management and Protection of Investments :

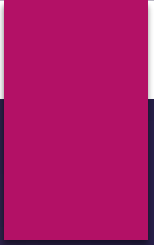
- Securing R&D Investments: R&D projects typically require significant time and financial resources. IP rights ensure that these investments are protected from free riders.
- By securing exclusive rights over new technologies or processes, companies can manage the risks associated with large-scale investments in R&D.

Challenges and Balancing in R&D:

- R&D Costs and IP Protection: While IP incentivizes R&D, the costs of obtaining and maintaining IP rights (especially patents) can be high, particularly for smaller companies or startups.
- Filing patents internationally can be expensive, and ensuring IP enforcement requires additional legal resources.

IPS OF RELEVANCE TO BIOTECHNOLOGY AND FEW CASE STUDIES :

- In the biotechnology sector, intellectual property (IP) is critical for safeguarding innovations, particularly in areas like pharmaceuticals, genetic engineering, molecular biology, and biopharmaceuticals.



Introduction to GATT, WTO, WIPO, TRIPS, Plant Variety Protection, and the Farmer's Act

INTRODUCTION

- ▶ In the modern global economy, international trade and intellectual property rights (IPR) are essential components of economic growth and development. To regulate trade and protect IPR, various agreements and organizations have been created over the past century, shaping the global market and the legal systems surrounding innovation, trade, and plant varieties.

GATT (General Agreement on Tariffs and Trade)

Establishment:

- ▶ GATT was established in 1947 as a multilateral treaty to regulate international trade. It emerged after World War II when many nations were striving for economic recovery and global cooperation
- ▶ Main Purpose: GATT aimed to reduce tariffs, eliminate trade barriers, and promote free trade. It provided a framework for negotiating trade agreements and settling disputes between member countries
- ▶ Key Features:
- ▶ Rounds of Negotiations: GATT hosted several rounds of negotiations, the most notable being the Uruguay Round (1986-1994), which led to the creation of the WTO.

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- ▶ **Tariff Reductions:** During its tenure, GATT succeeded in reducing tariffs globally by more than 50%.
 - ▶ **Non-discrimination:** GATT enforced the principle of Most-Favored-Nation (MFN), ensuring that trade concessions granted to one member had to be extended to all member
 - ▶ **Limitations:** GATT focused mainly on trade in goods but lacked enforcement power and a comprehensive framework for services and intellectual property, leading to the need for a stronger organization

Transition to the WTO (World Trade Organization)

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- ▶ - **Establishment**:

- ▶ The **World Trade Organization (WTO)** was established on January 1, 1995, following the conclusion of the **Uruguay Round** of negotiations under GATT. WTO absorbed GATT and expanded its mandate.

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- ▶ - **Purpose and Role**:

- ▶ The WTO is the only global international organization that deals with the rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably, and freely as possible.

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- ▶ - **Key Functions**:

- ▶ - **Trade Negotiations**: Facilitating ongoing trade negotiations and agreements.

- ▶ - **Dispute Settlement**: Providing a robust and enforceable system for settling trade disputes among members.

- ▶ - **Trade Monitoring**: Monitoring and reviewing national trade policies to ensure transparency.

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- ▶ - **Major Agreements**:

- ▶ - **General Agreement on Trade in Services (GATS)**: Expanded coverage to services, not just goods.

- ▶ - **Trade-Related Aspects of Intellectual Property Rights (TRIPS)**: Addressed the need for a global framework for intellectual property protection.

WIPO (World Intellectual Property Organization)

- Establishment: WIPO was founded in 1967 as a specialized agency of the United Nations. It is responsible for the global protection of intellectual property (IP), including patents, copyrights, trademarks, and designs.
- Mission: To encourage creative activity, promote the protection of intellectual property rights worldwide, and ensure that innovators are rewarded for their efforts
- Key Treaties: Paris
- Convention (1883): Focused on industrial property (patents, trademarks, and industrial designs).
- Berne Convention (1886): Focused on
- .Patent Cooperation Treaty (PCT): Simplifies the patent application process for inventors in multiple countries
- WIPO's Role: WIPO administers various international treaties aimed at harmonizing IP laws across countries and facilitating the filing and protection of patents, trademarks, and copyrights globally.

TRIPS (Trade-Related Aspects of Intellectual Property Rights)

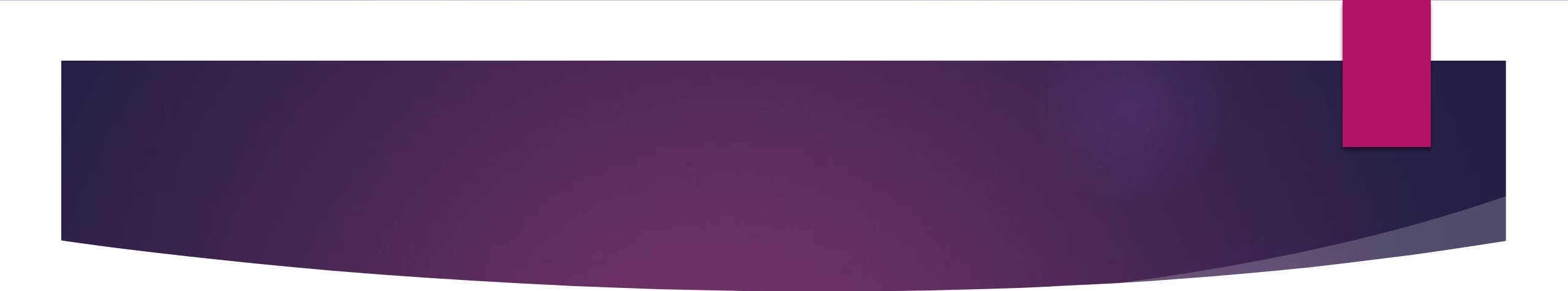
- ▶ Adopted: TRIPS was adopted in 1994 as part of the Uruguay Round and is administered by the WTO. It is the most comprehensive multilateral agreement on intellectual property (IP).
- ▶ Main Features
- ▶ Global Standards: Establishes minimum standards for IP protection that WTO members must comply with, covering copyright, trademarks, geographical indications, patents, and trade
- ▶ .Technology Transfer: Encourages the transfer of technology from developed to developing countries, particularly in critical areas like
- ▶ .Enforcement: Provides mechanisms to enforce IP rights and resolve disputes at the WTO
- ▶ Significance: TRIPS is a crucial tool in ensuring that countries offer adequate protection to the intellectual property of foreign inventors, artists, and companies.
- ▶ It balances IP protection with public policy, particularly for issues such as access to medicines.

Plant Variety Protection (PVP)

- ▶ Purpose: Plant variety protection grants exclusive rights to plant breeders over new plant varieties they develop.
- ▶ It helps encourage innovation in plant breeding by ensuring breeders can benefit from their investment and research.
- ▶ UPOV Convention: The International Union for the Protection of New Varieties of Plants (UPOV), established in 1961, governs PVP internationally. It sets out the criteria for new varieties, which include novelty, distinctness, uniformity, and stability (NDUS).
- ▶ Breeder's Rights:
- ▶ Breeders have exclusive control over the propagation, reproduction, and commercialization of their plant varieties.
- ▶ They can license or sell their rights to others
- ▶ Impact on Agriculture: PVP has incentivized the development of improved plant varieties, contributing to higher yields, resistance to pests, and better adaptation to environmental conditions. La

The Farmer's Act (India) Protection of Plant Varieties and Farmers' Rights Act (PPVFR), 2001

- ▶ This act was passed by India to provide an alternative to strict patent laws that could potentially harm small farmers.
- ▶ The PPVFR Act aims to:
- ▶ Breeders Rights: Recognize and protect the rights of plant breeders in line with the UPOV convention
- ▶ Farmers' Rights: Farmers have the right to save, use, sow, resow, exchange, share, or sell their farm produce, including seeds of protected varieties
- ▶ However, they cannot sell branded seeds without the breeder's permission.
- ▶ Significance: The act was seen as a compromise between protecting the rights of breeders and the traditional practices of farmers, acknowledging the contribution of farmers in conserving plant varieties and ensuring food security.

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- ▶ Connections Between TRIPS, PVP, and the Farmer's Act
TRIPS and Plant Variety Protection:
 - ▶ TRIPS requires WTO member states to provide IP protection for plant varieties either through patents or a sui generis (unique) system like Plant Variety Protection
 - ▶ India's Response: India implemented a sui table generis system under the PPVFR Act to balance breeders' rights and farmers' rights.
 - ▶ This system is often cited as a model for developing countries where farmers' traditional rights to seeds are integral to agricultural practices

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- ▶ . Conclusion
 - ▶ GATT to WTO: The evolution from GATT to WTO represents the global move towards more regulated and structured international trade
 - ▶ WIPO and TRIPS: Both have played critical roles in setting global standards for intellectual property protection, balancing the interests of innovators with public needs.
 - ▶ Plant Variety Protection and Farmers: Striking a balance between protecting new plant varieties and safeguarding farmers' rights is key to ensuring sustainable agricultural development.
 - ▶ Future Outlook: With ongoing challenges in global trade, technology, and food security, these frameworks will co

Prior art & Patent Data bases

Prior art

- Prior art is a legal concept in patent law that refers to any information about an invention that is already publicly available. It's used to determine if an invention is patentable, especially if it meets the criteria for novelty and non-obviousness.

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- Prior art can include:
 - U.S. and foreign patents and published patent applications
 - Journal and magazine articles
 - Books, manuals, and catalogs
 - Websites
 - Conference proceedings
 - Scientific papers
 - Existing products on the market

Procedure

- A patent application is compared to prior art to determine if it describes a new invention and if it should be granted a patent. If prior art includes a description of the invention, it's usually not considered novel. If prior art shows that the invention would be obvious to someone with ordinary skill in the field, a patent can't be issued.
- Inventors should conduct a thorough prior art search before filing a patent application. This can be a lengthy process that involves searching hundreds or thousands of references. It's recommended to use a variety of search tools and strategies, and to consult with a patent professional.

Examples of Prior Art



Prior art searches

- Patent offices deal with prior art searches in the context of the patent granting procedure. A patent search is frequently carried out by patent offices or patent applicants in order to identify relevant prior art.
- Prior art may also be submitted by the public for consideration in examination or in opposition or invalidity proceedings. Relevant prior art identified by patent offices or patent applicants are often cited by patent applicants in patent applications and by patent offices in patent search reports.

Prior Art Search



Patent databases

- Patent databases are valuable tools for accessing information about existing patents, pending applications, and related technical literature. Some widely-used patent databases include:
- United States Patent and Trademark Office (USPTO)
- European Patent Office (EPO) – Espacenet
- World Intellectual Property Organization (WIPO) – PATENTSCOPE
- Google Patents
- Lens.org
- Japanese Patent Office (JPO) – J-PlatPat
- China National Intellectual Property Administration (CNIPA)
- Korean Intellectual Property Rights Information Service (KIPRIS)

USPTO

- The United States Patent and Trademark Office (USPTO) is the federal agency responsible for granting patents and registering trademarks in the United States.
- Patent Application Process
 - Filing
 - Examination
 - Issuances
 - Maintenance

Function

- Role and Functions of USPTO Patents:
- The USPTO examines and grants patents for inventions, providing legal protection to inventors. selling their invention for a limited time (typically 20 years from the filing date for utility patents).
- Trademarks: It also registers trademarks, which protect brand names, slogans, and logos used in commerce. Trademark registration helps businesses secure their brand identity and prevents confusion in the marketplace.
- Public Search Facilities: The USPTO offers public access to a variety of intellectual property databases and tools, including patent and trademark search systems.

European Patent Office

- European Patent Office (EPO) is a key institution in the European patent system. It is responsible for examining and granting European patents, which provide protection in multiple European countries under the European Patent Convention (EPC).
- Role and Functions of the EPO
- Granting European Patents: The EPO examines patent applications to ensure they meet the requirements for novelty, inventiveness, and industrial applicability before granting European patents.
- Supporting National Patent Offices: It collaborates with national patent offices of European countries to strengthen the overall intellectual property landscape in Europe.

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- **Promoting Patent Harmonization:** The EPO works to harmonize patent procedures across Europe and with other global patent offices to create more efficient systems for patent filing and examination.
 - **Appeals and Opposition:** The EPO also handles opposition proceedings (challenges to the validity of granted patents) and appeals through the Boards of Appeal.

Indian Patent Advanced Search System (InPASS)

- India has several databases and platforms for accessing patent and intellectual property information. These databases are managed by the Indian Patent Office (IPO), which is part of the Office of the Controller General of Patents, Designs, and Trademarks (CGPDTM).