1. Concept of Intellectual Property Rights (IPR)

- Intellectual property (IP) refers to **creations of the mind:** inventions, literary and artistic works, and symbols, names, images, and designs used in commerce.
- IPRs are **central to encouraging investment** in research as without some form of protection, investors and inventors would not be able to benefit from their creative efforts.

2. Types of IPR

Types	Details
1. Patents	**An exclusive right granted for an invention.** A patent provides the patent owner with the right to decide how - or whether - the invention can be used by others.
2. Copyright	A legal term used to describe the rights that creators have over their **literary and artistic works.**
3. Trademarks	It is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises.
4. Industrial Designs	An industrial design constitutes the **ornamental or aesthetic aspect** of an article. It protects that appearance or aesthetic style.
5. Geographical indications	Signs used on goods that have a specific geographical origin and possess qualities, a reputation or characteristics that are essentially attributable to that place of origin.
6. Trade Secrets	A trade secret is a **formula, practice, process, design or compilation of information** used by a business to obtain an advantage over competitors. The unauthorized acquisition, use or disclosure of such secret information is regarded as an unfair practice.

3. International Arrangements for IPR

3.1. World Intellectual Property Organization (WIPO)

3.1.1. About WIPO

- The World Intellectual Property Organization is the **United Nations agency** dedicated to the use of intellectual property (patents, copyright, trademarks, designs, etc.) as a means of stimulating innovation and creativity.
- It was **created in 1967** and **headquartered in Geneva, Switzerland.**
- WIPO currently has **193 member states. India became a member of WIPO in 1975.**

- It publishes the **Global Innovation Index,** an annual ranking of countries by their capacity for, and success in innovation.

3.1.2. Objectives

WIPO's two main objectives are:

- To promote the protection of intellectual property worldwide.
- To ensure administrative cooperation among the intellectual property Unions established by the treaties that WIPO administers.

3.1.3. Decision-making Structures

- The terms governing WIPO's mandate, functions, finances and procedures are set out in the WIPO Convention.
- All decisions governing WIPO's strategic direction and activities are made by the member states.
- The WIPO Secretariat coordinates formal and informal meetings of the member state bodies throughout the year.
- It **administers 26 treaties** including the WIPO Convention.

3.1.4. WIPO Convention

The Convention establishing the World Intellectual Property Organization (WIPO), **concluded in Stockholm on July 14, 1967** (Article 2(viii)) provides that intellectual property shall include rights relating to:

- literary, artistic and scientific works,
- performances of performing artists, phonograms and broadcasts,
- inventions in all fields of human endeavor,
- scientific discoveries,
- industrial designs,
- trademarks, service marks and commercial names and designations,
- protection against unfair competition,
- all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.

3.2. Trade Related Intellectual Property Rights (TRIPS)

3.2.1. Introduction

- TRIPS is the most important and comprehensive international agreement on intellectual property rights which **came into effect on 1 January 1995.**
- The Agreement on TRIPS was negotiated with other international trade agreements during the **Uruguay Round trade negotiations of the GATT** (General Agreement on Tariffs and Trade) **from 1986 to 1994.**
- As one of the World Trade Organization (WTO) agreements, it is totally **binding for all WTO Member States.**
- The Agreement covers most forms of intellectual property including patents, copyright and related rights (i.e. the rights of performers, producers of sound recordings and broadcasting organizations), industrial designs, trademarks, geographical indications, trade secrets, exclusionary rights over new plant varieties, etc.
- The **TRIPS Council** is responsible for **administering and monitoring the operation** of the TRIPS Agreement. In its regular meetings, the TRIPS Council serves as a forum for discussion between members on key issues.

3.2.2. Main Features of the Agreement

Standards

- In respect of each of the main areas of intellectual property covered by the TRIPS Agreement, the Agreement sets out the minimum standards of protection to be provided by each Member.
- Each of the main elements of protection is defined, namely the subject-matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection.
- The Agreement sets these standards by requiring, first, that the substantive obligations of the main conventions of the WIPO, the Paris Convention for the Protection of Industrial Property (Paris Convention) and the Berne Convention for the Protection of Literary and Artistic Works (Berne Convention) in their most recent versions must be complied with. The TRIPS Agreement is thus sometimes referred to as a Berne and Paris-plus agreement.

Enforcement

- The Agreement lays down certain general principles applicable to all IPR enforcement procedures.
- In addition, it contains provisions on civil and administrative procedures and remedies, provisional measures, special requirements related to border measures and criminal procedures, which specify, in a certain amount of detail, the procedures and remedies that must be available so that right holders can effectively enforce their rights.

Dispute settlement

- The Agreement makes disputes between WTO members about the respect of the TRIPS obligations subject to the WTO's dispute settlement procedures.
- The obligations under the Agreement will apply equally to all member countries, but developing countries have a longer period to phase them in.
- The TRIPS Agreement is a minimum standards agreement, which allows members to provide more extensive protection of intellectual property if they so wish.
- Members are left free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice.

3.2.3. Substantive standards of protection under TRIPS

Copyright

- It gives the creators of a wide range of material, such as literature, art, music, sound recordings, films and broadcasts, economic rights enabling them to control use of their material in a number of ways, such as by making copies, issuing copies to the public, performing in public, broadcasting and use on-line.
- It also gives moral rights to be identified as the creator of certain kinds of material, and to object to distortion or mutilation of it.
- The purpose of copyright is to allow creators to gain economic rewards for their efforts and so encourage future creativity and the development of new material which benefits us all.
- However, copyright protection extends to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such.
- **Computer programs,** whether in source or object code, **are protected as literary works.**

- Databases are eligible for copyright protection provided that they by reason of the selection or arrangement of their contents constitute intellectual creations.

Related rights

- The provisions on protection of performers, producers of phonograms and broadcasting organizations constitute the related rights.
- Performers shall have the possibility of preventing the unauthorized fixation of their performance on a phonogram (e.g. the recording of a live musical performance).
- The fixation right covers only aural, not audiovisual fixations.
- Broadcasting organizations have the right to prohibit the unauthorized fixation, the reproduction of fixations, and the rebroadcasting by wireless means of broadcasts, as well as the communication to the public of their television broadcasts.
- The term of protection is **at least 50 years for performers and producers of phonograms, and 20 years for broadcasting organizations.**

Trademarks

- The system helps consumers identify and purchase a product or service because its nature and quality, indicated by its unique trademark, meets their needs.
- Trademark provides protection to the owner of the mark by ensuring the exclusive right to use it, to identify goods or services, or to authorize another to use it in return for payment.
- The period of protection varies, but a trademark can be renewed indefinitely beyond the time limit on payment of additional fees.
- Trademark protection is enforced by the courts, which in most systems have the authority to block trademark infringement.
- Trademarks may be **one or a combination of words, letters, and numerals.**
- They may consist of drawings, symbols, three- dimensional signs such as the shape and packaging of goods, audible signs such as music or vocal sounds, fragrances, or colors used as distinguishing features.

Patent

- Patent **protects new inventions** and covers how things work, what they do, how they do it, what they are made of and how they are made.
- If a patent application is granted, it gives the owner the **ability to take a legal action under civil law** to try to stop others from making, using, importing or selling the invention without permission. This may involve suing the alleged infringer through the courts.
- The TRIPS Agreement requires member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability.

There are three permissible exceptions to the basic rule on patentability:

- One is for **inventions contrary to ordre public or morality**-this explicitly includes inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment.
- The second exception is that **members may exclude from patentability diagnostic, therapeutic and surgical methods** for the treatment of humans or animals.

- The third is that members may exclude plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.
- Any country excluding plant varieties from patent protection must provide an effective *sui generis* system of protection. (Article 27.3 (b).

Geographical Indication (GI)

- A geographical indication is a **sign used on goods that have a specific geographical origin** and possess qualities, reputation or characteristics that are essentially attributable to that place of origin.
- Most commonly, a geographical indication includes the name of the place of origin of the goods.
- Agricultural products typically have qualities that derive from their place of production and are influenced by specific local factors, such as climate and soil.
- Whether a sign is recognized as a geographical indication is a matter of national law.
- Geographical indications may be used for a wide variety of products, whether natural, agricultural or manufactured.

Industrial Designs

- Articles 25 and 26 of the agreement says members must ensure that **fresh or unique industrial designs generated independently are protected.**
- The Agreement promises to preserve industrial designs for a **minimum of 10 years.**
- When such activities are conducted for commercial objectives, the right holder can ban third parties who do not have the holder's agreement from producing, importing or selling items that incorporate the protected design.

Layout-Designs of Integrated Circuits

- TRIPS Agreement requires Member countries to protect the layout-designs of integrated circuits in accordance with the provisions of the IPIC Treaty (the Treaty on Intellectual Property in Respect of Integrated Circuits), negotiated under the auspices of WIPO in 1989.
- These provisions deal with, inter alia, the **definitions of "integrated circuit" and "layout-design (topography)",** requirements for protection, exclusive rights, and limitations, as well as exploitation, registration and disclosure.

Protection of Undisclosed Information

- Article 39 of the Agreement requires member states to provide trade secret protection in accordance with the Agreement's provisions.
- TRIPS mandates that member countries should create national legislation to prevent such information from being revealed to, obtained by, or used by third parties without the agreement of the person who is lawfully in possession of it, in a manner that is inconsistent with fair trade practices.
- Such information must be confidential, have commercial value as a result of its confidentiality, and have been subjected to reasonable efforts to keep it hidden in order to be granted protection.

Control of Anti-competitive Practises in Contractual Licenses

- The TRIPS Agreement recognizes some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.
- Member countries may adopt, consistently with the other provisions of the Agreement, appropriate measures to prevent or control practices in the licensing of intellectual property rights which are abusive and anti-competitive.

3.3. Plant Breeder's Rights

- Plant breeder's rights came into international discourse in the 1960s, when improved varieties of crop plants began to usher several developed and developing nations in the era of high farm productivity or Green Revolution.
- Plant Breeders' Rights offers legal protection for the investment plant breeders make in breeding and developing new varieties.
- This protection is open to breeders of any species of plant; agricultural, horticultural and ornamental.
- Plant Breeders' Rights are thus a form of intellectual property designed specifically to protect new varieties of plants.

UPOV

- The **International Union for the Protection of New Varieties of Plants**, known as “UPOV,” is an intergovernmental organization with **headquarters in Geneva.**
- The mission of UPOV is to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society.
- It was established by the International Convention for the Protection of New Varieties of Plants (the “UPOV Convention”), which was **signed in Paris in 1961.**
- The Convention entered into force in 1968. It was revised in Geneva in 1972, 1978 and 1991. The 1991 Act **entered into force on April 24, 1998.** This is the presently accepted version of the UPOV Convention.
- The purpose of the UPOV Convention is to ensure that the members of the Union acknowledge the achievements of breeders of new varieties of plants, by granting to them an intellectual property right, on the basis of a set of clearly defined principles.
- To be eligible for protection, varieties have to be (i) distinct from existing, commonly known varieties, (ii) sufficiently uniform, (iii) stable and (iv) new in the sense that they must not have been commercialized prior to certain dates established by reference to the date of the application for protection.
- The UPOV Convention sets out a minimum scope of protection and offers members the possibility of taking national or regional circumstances into account in their legislation.

4. Indian Patent Act, 1970

- The Indian Patent Act (IPA) 1970 which **came into force in 1972** was in many ways a watershed in the history of the patent system.
- It not only disallowed the grant of product patents in the highly sensitive and socially relevant health sector, but also **restricted the validity period for process patents in**

these sectors to seven years from the date of filing or five years from the date of sealing whichever was earlier.

- Since the period required for discovering and developing a new drug is not less than 10 years, the provision for process patent with the shortened period of validity had made the system itself redundant.
- The consequence of such a radical change in the Indian patent system led to a major shift in the nature and character of the Indian industry.
- Many foreign companies discouraged by the provisions of IPA 1970 and the Foreign Exchanges Regulation Act (FERA) which allowed new investments only for companies with a foreign equity holding of 40 per cent or less opted not to operate in India.
- If India today is an accepted leader in the production of generic drugs of high quality to meet the needs of practically all the global markets, the credit should go to this piece of legislation.
- In fact, within a decade of IPA 1970, the pecking order of the Indian industry changed wholly with Indian companies occupying seven of the top ten positions, a reversal of the pre-1970 era.

4.1. The Patents Act, 1970 (as amended up to 2005)

- Through the **three amendments** to the Patents Act, 1970, India has made the India Patent Laws, **TRIPS compliant,** substantially.
- Of these the most important amendment is the inclusion of food, pharma and chemical industry within the ambit of patent protection for both process and product.
- It may be recalled that the **original Patents Act, 1970** had kept these three sectors out of product patenting and they were given a rather brief period of process patent protection.
- The Act also introduced a section which deals with compulsory licensing of pharmaceuticals for export purposes.
- This is meant to facilitate the Indian industry to continue supplying cheaper generic versions of patented drugs to those least developed countries that do not have adequate domestic manufacturing capabilities.

The Novartis case

- Novartis v. Union of India & Others was a landmark case, which was heard by a two-judge bench of the Supreme Court of India. The matter pertained to the issue of evergreening of pharmaceutical patents.
- The decision in the matter was pronounced on April 01, 2013, thus culminating a seven-year-long litigation fought by Novartis for the **granting of an Indian patent on imatinib mesylate in beta crystalline form.**
- A patent, as desired by Novartis, would have restrained Indian generic pharmaceutical manufacturers from producing drugs based on the compound.
- However, the Supreme Court decided that the substance which Novartis sought to patent is already known and thus does not qualify the test of invention as laid down in **section 2(1)(j) and section 2(1)(ja)** of the Indian Patent Act, 1970 (as amended in 2005). As a result, the Court rejected the patent application.
- Essentially, the Supreme Court upheld the Intellectual Property Appellate Board's decision to deny patent protection to Novartis's application covering a beta crystalline form of

imatinib —the medicine Novartis brands as Glivec, and which is very **effective against the form of cancer known as chronic myeloid leukaemia** (CML).

- The decision came as a decisive blow to Novartis, which attempted monopolising the Indian market for Imatinib - a widely used drug to check the spread of a specific type of Leukaemia.

Significance of the Judgement

- The significance of the Supreme Court judgment on Novartis's patent application lies in restoring the connection between patents and innovation by upholding and legitimizing a regime with a higher threshold of inventiveness.
- The decision for the **first time tested the validity and ambit of section 3(d)** of the Indian Patent Act which prevents the grant of a patent for new forms of known substances, unless the applicant can establish the new form demonstrates an increased efficacy.
- The decision also ensures steady availability of low cost generic versions of life saving drugs based on imatinib or imatinib mesylate polymorphs.

4.2. Compulsory Licensing & The Nexavar case

Compulsory License

- Compulsory licenses are generally defined as authorizations permitting a third party to make, use, or sell a patented invention without the patent owner's consent.
- In 2012, Patent office issued India's first Compulsory license (CL) to Natco for Nexavar - sorafenib tosylate, an anti-cancer drug produced by Bayer

Laws prevailing with respect to the Compulsory license: Patents Act, 1970

- **As per Section 84,** any person who is interested can make a request for grant of Compulsory Licence on patent after three years from the date of grant of that patent on the condition that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or that the patented invention is not available to the public at a reasonably affordable price, or that the patented invention is not worked in the territory of India.

The Nexavar Case

- The Intellectual Property Appellate Board (IPAB) in March 2013 upheld the grant of compulsory licence (CL) to the Hyderabad-based Natco Pharma Limited, a generic drug maker, **to produce and market Sorafenib,** a patented cancer drug of multinational pharma major Bayer Corporation sells under the brand name Nexavar. The order paved the way for reduction in the prices of costly life saving drugs.
- Disposing an appeal filed by Bayer Corporation, the Board held that various international conventions and Indian laws allowed the member countries to grant such compulsory licence in order to make life-saving medicine cheaply available to the public.
- As per the licence conditions imposed by Controller, Natco had to pay a six per cent royalty to Bayer from the sales of generic drug Sorafenib. Modifying this, the IPAB directed Natco to pay seven percent royalty.

A short background

- The case involves a drug called Sorafenib, used to treat advanced liver and kidney cancer to extend the life of a patient.
- The patent — both in India and in the United States — for the drug is held by the multinational company, Bayer Corporation. Bayer obtained a patent in India in 2008.

- **Nexavar costs Rs. 2.8 lakh for a pack of 120 tablets,** equivalent to a month's dosage. The drug is a blessing for such patients to extend their life expectancy. But, the availability of the drug from Bayer at a selling price of Rs. 2.8 lakh for a month's dose is too exorbitant for India.
- On March 9, 2011, the Controller of Patents, Mumbai, granted the first-ever compulsory license to Natco to make 'sorafenib tosylate', a generic version of Bayer's high-priced anti-cancer drug Nexavar. **Natco was told to sell the pack at Rs. 8,800.**
- Bayer then appealed against the Controller's order before the IPAB. Among other reasons, it contended that Cipla had started selling its generic version at a lower price, rendering the compulsory licence unnecessary as the drug was available at a reasonable price.
- Upholding the compulsory license, the IPAB pointed out that even after obtaining a patent, Bayer had not made the drug available on a large scale and at an affordable price within the stipulated time.
- Going into various submissions and affidavits filed by Bayer, the Board also came to the conclusion that its pricing of Rs.2.8 lakh was not affordable.
- Among other setbacks for Western drug companies, India has revoked patents granted to Pfizer Inc's cancer drug Sutent, Roche Holding AG's hepatitis C drug Pegasys and Merck & Co's asthma treatment aerosol suspension formulation.

4.3. Patents (Amendment) Rules, 2021

- The Patents Rules, 2003 were amended by the Patents (Amendment) Rules, 2021 which **came into force on 21st September 2021.**
- The rules **reduced the fee for patent filing and prosecution** for educational institutions by 80 percent.
- The move has been taken to strengthen innovation and creativity in the knowledge economy.
- The "educational institution" category can be claimed by filing supporting documentary evidence to this effect. However, the nature of documentary evidence has not been specified.
- The fee applicable for an educational institution has been made the same as that for a natural person, startup or small entity.