IDHAYA COLLEGE FOR WOMEN, KUMBAKONAM

DEPARTMENT OF MICROBIOLOGY

COURSE	**:**	**M.Sc., II MICROBIOLOGY**
SEMESTER	**:**	**IV**
TOPIC	**:**	**UNIT-V**
SUBJECT NAME	**:**	**BIOPROCESS TECHNOLOGY**
SUBJECT CODE	**:**	**P16MB42**

Presented by

Dr.M.NITHYA M.Sc., Ph.D., PGDCA

Assistant Professor,

Dept. of Microbiology

GENERAL AGREEMENT ON TARIFFS AND TRADE

General Agreement on Tariffs and Trade (GATT)**,** set of multilateral trade agreements aimed at the abolition of quotas and the reduction of tariff duties among the contracting nations. When GATT was concluded by 23 countries at Geneva, in 1947, it was considered an interim arrangement pending the formation of a United Nations agency to supersede it. When such an agency failed to emerge, GATT was amplified and further enlarged at several succeeding negotiations.

It subsequently proved to be the most effective instrument of world trade liberalization, playing a major role in the massive expansion of world trade in the second half of the 20th century. By the time GATT was replaced by the World Trade Organization (WTO) in 1995, 125 nations were signatories to its agreements, which had become a code of conduct governing 90 percent of world trade.

GATT's normal business involved negotiations on specific trade problems affecting particular commodities or trading nations, but major multilateral trade conferences were held periodically to work out tariff reductions and other issues. Seven such "rounds" were held from 1947 to 1993, starting with those held at Geneva in 1947 (concurrent with the signing of the general agreement); at Annecy, France, in 1949; at Torquay, Eng., in 1951; and at Geneva in 1956 and again in 1960–62. The most important rounds were the so-called Kennedy Round (1964–67), the Tokyo Round (1973–79), and the Uruguay Round (1986–94), all held at Geneva. These agreements succeeded in reducing average tariffs on the world's industrial goods from 40 percent of their market value in 1947 to less than 5 percent in 1993.

The Uruguay Round negotiated the most ambitious set of trade-liberalization agreements in GATT's history. The worldwide trade treaty adopted at the round's end slashed tariffs on industrial goods by an average of 40 percent, reduced agricultural subsidies, and included ground breaking new agreements on trade in services. The treaty also created a new and stronger global organization, the WTO, to monitor and regulate international trade. GATT went out of existence with the formal conclusion of the Uruguay Round on April 15, 1994. Its principles and the many trade agreements reached under its auspices were adopted by the WTO.

World Trade Organization (WTO)

World Trade Organization (WTO)**,** international organization established to supervise and liberalize world trade. The WTO is the successor to the General Agreement on Tariffs and Trade (GATT), which was created in 1947 in the expectation that it would soon be replaced by a specialized agency of the United Nations (UN) to be called the International Trade Organization (ITO). Although the ITO never materialized, the GATT proved remarkably successful in liberalizing world trade over the next five decades. By the late 1980s there were calls for a stronger multilateral organization to monitor trade and resolve trade disputes. Following the completion of the Uruguay Round (1986–94) of multilateral trade negotiations, the WTO began operations on January 1, 1995.

Origins

The ITO was initially envisaged, along with the International Monetary Fund (IMF) and the World Bank, as one of the key pillars of post-World War II reconstruction and economic development. In Havana in 1948, the UN Conference on Trade and Employment concluded a draft charter for the ITO, known as the Havana Charter, which would have created extensive rules governing trade, investment, services, and business and employment practices. However, the United States failed to ratify the agreement. Meanwhile, an agreement to phase out the use of import quotas and to reduce tariffs on merchandise trade, negotiated by 23 countries in Geneva in 1947, came into force as the GATT on January 1, 1948.

During negotiations ending in 1994, the original GATT and all changes to it introduced prior to the Uruguay Round were renamed GATT 1947. This set of agreements was distinguished from GATT 1994, which comprises the modifications and clarifications negotiated during the Uruguay Round (referred to as “Understandings”) plus a dozen other multilateral agreements on merchandise trade. GATT 1994 became an integral part of the agreement that established the WTO. Other core components include the General Agreement on Trade in Services (GATS), which attempted to supervise and liberalize trade; the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which sought to improve protection of intellectual property across borders; the Understanding on Rules and Procedures Governing the Settlement of Disputes, which established rules for resolving conflicts between members.

OBJECTIVES

The WTO has six key objectives:

(1) to set and enforce rules for international trade,

(2) to provide a forum for negotiating and monitoring further trade liberalization,

(3) to resolve trade disputes,

(4) to increase the transparency of decision-making processes,

(5) to cooperate with other major international economic institutions involved in global economic management, and

(6) to help developing countries benefit fully from the global trading system.

Although shared by the GATT, in practice these goals have been pursued more comprehensively by the WTO. For example, whereas the GATT focused almost exclusively on goods—though much of agriculture and textiles were excluded—the WTO encompasses all goods, services, and intellectual property, as well as some investment policies. In addition, the permanent WTO Secretariat, which replaced the interim GATT Secretariat, has strengthened and formalized mechanisms for reviewing trade policies and settling disputes. Because many more products are covered under the WTO than under the GATT and because the number of members.

The rules embodied in both the GATT and the WTO serve at least three purposes. First, they attempt to protect the interests of small and weak countries against discriminatory trade practices of large and powerful countries. The WTO's most-favoured-nation and national-treatment articles stipulate that each WTO member must grant equal market access to all other members and that both domestic and foreign suppliers must be treated equally. Second, the rules require members to limit trade only through tariffs and to provide market access not less favourable than that specified in their schedules (i.e., the commitments that they agreed to when they were granted WTO membership or subsequently). Third, the rules are designed to help governments resist lobbying efforts by domestic interest groups seeking special favours.

Intellectual property RIGHTS (IPR)

Intellectual property (IP) is a category of property that includes intangible creations of the human intellect. There are many types of intellectual property, and some countries recognize more than others. The most well-known types are copyrights, patents, trademarks, and trade secrets. Early precursors to some types of intellectual property existed in societies such as Ancient Rome, but the modern concept of intellectual property developed in England in the 17th and 18th centuries. The term "intellectual property" began to be used in the 19th century, though it was not until the late 20th century that intellectual property became commonplace in the majority of the world's legal systems.

The main purpose of intellectual property law is to encourage the creation of a wide variety of intellectual goods. To achieve this, the law gives people and businesses property rights to the information and intellectual goods they create, usually for a limited period of time. This gives economic incentive for their creation, because it allows people to profit from the information and intellectual goods they create. These economic incentives are expected to stimulate innovation and contribute to the technological progress of countries, which depends on the extent of protection granted to innovators.

The intangible nature of intellectual property presents difficulties when compared with traditional property like land or goods. Unlike traditional property, intellectual property is "indivisible", since an unlimited number of people can "consume" an intellectual good without it being depleted. Additionally, investments in intellectual goods suffer from problems of appropriation: a landowner can surround their land with a robust fence and hire armed guards to protect it, but a producer of information or literature can usually do very little to stop their first buyer from replicating it and selling it at a lower price. Balancing rights so that they are strong enough to encourage the creation of intellectual goods but not so strong that they prevent the goods' wide use is the primary focus of modern intellectual property law.

Intellectual property rights

Intellectual property rights include patents, copyright, industrial design rights, trademarks, plant variety rights, trade dress, geographical indications, and in some jurisdictions trade secrets. There are also more specialized or derived varieties of *sui generis* exclusive rights, such as circuit design rights supplementary protection certificates for pharmaceutical

products and database rights. The term "industrial property" is sometimes used to refer to a large subset of intellectual property rights including patents, trademarks, industrial designs, utility models, service marks, trade names, and geographical indications.

Patents

A patent is a form of right granted by the government to an inventor or their successor-in-title, giving the owner the right to exclude others from making, using, selling, offering to sell, and importing an invention for a limited period of time, in exchange for the public disclosure of the invention. An invention is a solution to a specific technological problem, which may be a product or a process and generally has to fulfill three main requirements: it has to be new, not obvious and there needs to be an industrial applicability. To enrich the body of knowledge and stimulate innovation, it is an obligation for patent owners to disclose valuable information about their inventions to the public.

Copyright

A copyright gives the creator of an original work exclusive rights to it, usually for a limited time. Copyright may apply to a wide range of creative, intellectual, or artistic forms, or "works". Copyright does not cover ideas and information themselves, only the form or manner in which they are expressed.

Industrial design rights

An industrial design right protects the visual design of objects that are not purely utilitarian. An industrial design consists of the creation of a shape, configuration or composition of pattern or color, or combination of pattern and color in three-dimensional form containing aesthetic value. An industrial design can be a two- or three-dimensional pattern used to produce a product, industrial commodity or handicraft. Generally speaking, it is what makes a product look appealing, and as such, it increases the commercial value of goods.

Plant varieties

Plant breeders' rights or plant variety rights are the rights to commercially use a new variety of a plant. The variety must amongst others be novel and distinct and for registration the evaluation of propagating material of the variety is considered.

Trademark

A trademark is a recognizable sign, design or expression which distinguishes products or services of a particular trader from similar products or services of other traders.[36][37][38]

Trade dress

Trade dress is a legal term of art that generally refers to characteristics of the visual and aesthetic appearance of a product or its packaging (or even the design of a building) that signify the source of the product to consumers.

Trade secrets

A trade secret is a formula, practice, process, design, instrument, pattern, or compilation of information which is not generally known or reasonably ascertainable, by which a business can obtain an economic advantage over competitors and customers. There is no formal government protection granted; each business must take measures to guard its own trade secrets

Object of intellectual property law

The main purpose of intellectual property law is to encourage the creation of a wide variety of intellectual goods for consumers. To achieve this, the law gives people and businesses property rights to the information and intellectual goods they create, usually for a limited period of time. Because they can then profit from them, this gives economic incentive for their creation.[9] The intangible nature of intellectual property presents difficulties when compared with traditional property like land or goods. Unlike traditional property, intellectual property is indivisible – an unlimited number of people can "consume" an intellectual good without it being depleted. Additionally, investments in intellectual goods suffer from problems of appropriation – while a landowner can surround their land with a robust fence and hire armed guards to protect it, a producer of information or an intellectual good can usually do very little to stop their first buyer from replicating it and selling it at a lower price. Balancing rights so that they are strong enough to encourage the creation of information and intellectual goods but not so strong that they prevent their wide use is the primary focus of modern intellectual property law.

By exchanging limited exclusive rights for disclosure of inventions and creative works, society and the patentee/copyright owner mutually benefit, and an incentive is created for inventors and authors to create and disclose their work. Some commentators have noted that the objective of intellectual property legislators and those who support its implementation appears to be "absolute protection". "If some intellectual property is desirable because it encourages innovation, they reason, more is better. The thinking is that creators will not have sufficient incentive to invent unless they are legally entitled to capture the full social value of their inventions".This absolute protection or full value view treats intellectual property as another type of "real" property, typically adopting its law and rhetoric. Other recent developments in intellectual property law, such as the America Invents Act, stress international harmonization.

Financial incentive

These exclusive rights allow owners of intellectual property to benefit from the property they have created, providing a financial incentive for the creation of an investment in intellectual property, and, in case of patents, pay associated research and development costs. In the United States Article I Section 8 Clause 8 of the Constitution, commonly called the Patent and Copyright Clause, reads; "The Congress shall have power 'To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.Some commentators, such as David Levine and Michele Boldrin, dispute this justification.

In 2013 the United States Patent & Trademark Office approximated that the worth of intellectual property to the U.S. economy is more than US $5 trillion and creates employment for an estimated 18 million American people. The value of intellectual property is considered similarly high in other developed nations, such as those in the European Union. In the UK, IP has become a recognised asset class for use in pension-led funding and other types of business finance. However, in 2013, the UK Intellectual Property Office stated: "There are millions of intangible business assets whose value is either not being leveraged at all, or only being leveraged inadvertently".

Economic growth

The WIPO treaty and several related international agreements underline that the protection of intellectual property rights is essential to maintaining economic growth. The *WIPO Intellectual Property Handbook* gives two reasons for intellectual property laws:

One is to give statutory expression to the moral and economic rights of creators in their creations and the rights of the public in access to those creations. The second is to promote, as a deliberate act of Government policy, creativity and the dissemination and application of its results and to encourage fair trading which would contribute to economic and social development.

The Anti-Counterfeiting Trade Agreement (ACTA) states that "effective enforcement of intellectual property rights is critical to sustaining economic growth across all industries and globally".

Economists estimate that two-thirds of the value of large businesses in the United States can be traced to intangible assets. "IP-intensive industries" are estimated to generate 72 percent more value added (price minus material cost) per employee than "non-IP-intensive industries".

A joint research project of the WIPO and the United Nations University measuring the impact of IP systems on six Asian countries found "a positive correlation between the strengthening of the IP system and subsequent economic growth."

Morality

According to Article 27 of the Universal Declaration of Human Rights, "everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author".Although the relationship between intellectual property and human rights is a complex one, there are moral arguments for intellectual property.

The arguments that justify intellectual property fall into three major categories. Personality theorists believe intellectual property is an extension of an individual. Utilitarians believe that intellectual property stimulates social progress and pushes people to further innovation. Lockeans argue that intellectual property is justified based on deservedness and hard work.

Various moral justifications for private property can be used to argue in favor of the morality of intellectual property, such as:

1. *Natural Rights/Justice Argument*: this argument is based on Locke's idea that a person has a natural right over the labour and products which are produced by their body. Appropriating these products is viewed as unjust. Although Locke had never explicitly stated that natural right applied to products of the mind, it is possible to apply his argument to intellectual property rights, in which it would be unjust for people to misuse another's ideas. Locke's argument for intellectual property is based upon the idea that laborers have the right to control that which they create. They argue that we own our bodies which are the laborers, this right of ownership extends to what we create. Thus, intellectual property ensures this right when it comes to production.

2. *Utilitarian-Pragmatic Argument*: according to this rationale, a society that protects private property is more effective and prosperous than societies that do not. Innovation and invention in 19th century America has been attributed to the development of the patent system. By providing innovators with "durable and tangible return on their investment of time, labor, and other resources", intellectual property rights seek to maximize social utility. The presumption is that they promote public welfare by encouraging the "creation, production, and distribution of intellectual works". Utilitarians argue that without intellectual property there would be a lack of incentive to produce new ideas. Systems of protection such as Intellectual property optimize social utility.
3. *"Personality" Argument*: this argument is based on a quote from Hegel: "Every man has the right to turn his will upon a thing or make the thing an object of his will, that is to say, to set aside the mere thing and recreate it as his own". European intellectual property law is shaped by this notion that ideas are an "extension of oneself and of one's personality".Personality theorists argue that by being a creator of something one is inherently at risk and vulnerable for having their ideas and designs stolen and/or altered. Intellectual property protects these moral claims that have to do with personality.

Lysander Spooner (1855) argues "that a man has a natural and absolute right—and if a natural and absolute, then necessarily a perpetual, right—of property, in the ideas, of which he is the discoverer or creator; that his right of property, in ideas, is intrinsically the same as, and stands on identically the same grounds with, his right of property in material things; that no distinction, of principle, exists between the two cases".

Infringement, misappropriation, and enforcement

Violation of intellectual property rights, called "infringement" with respect to patents, copyright, and trademarks, and "misappropriation" with respect to trade secrets, may be a breach of civil law or criminal law, depending on the type of intellectual property involved, jurisdiction, and the nature of the action.

As of 2011 trade in counterfeit copyrighted and trademarked works was a $600 billion industry worldwide and accounted for 5–7% of global trade.

Patent infringement

Patent infringement typically is caused by using or selling a patented invention without permission from the patent holder. The scope of the patented invention or the extent of protection[63] is defined in the claims of the granted patent. There is safe harbor in many jurisdictions to use a patented invention for research. This safe harbor does not exist in the US unless the research is done for purely philosophical purposes, or in order to gather data in order to prepare an application for regulatory approval of a drug. In general, patent infringement cases are handled under civil law but several jurisdictions incorporate infringement in criminal law also.

Copyright infringement

Copyright infringement is reproducing, distributing, displaying or performing a work, or to make derivative works, without permission from the copyright holder, which is typically a publisher or other business representing or assigned by the work's creator. It is often called "piracy". While copyright is created the instant a work is fixed, generally the copyright holder can only get money damages if the owner registers the copyright. Enforcement of copyright is generally the responsibility of the copyright holder. The ACTA trade agreement, signed in May 2011 by the United States, Japan, Switzerland, and the EU, and which has not entered into force, requires that its parties add criminal penalties, including incarceration and fines, for copyright and trademark infringement, and obligated the parties to actively police for infringement. There are limitations and exceptions to copyright, allowing limited use of copyrighted works, which does not constitute infringement. Examples of such doctrines are the fair use and fair dealing doctrine.

Trademark infringement

Trademark infringement occurs when one party uses a trademark that is identical or confusingly similar to a trademark owned by another party, in relation to products or services which are identical or similar to the products or services of the other party. In many countries, a trademark receives protection without registration, but registering a trademark provides legal advantages for enforcement. Infringement can be addressed by civil litigation and, in several jurisdictions, under criminal law

TRIPS AGREEMENT

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international legal agreement between all the member nations of the World Trade Organization (WTO).

It sets down minimum standards for the regulation by national governments of many forms of intellectual property (IP) as applied to nationals of other WTO member nations.[3] TRIPS was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) between 1989 and 1990 and is administered by the WTO.

The TRIPS agreement introduced intellectual property law into the multilateral trading system for the first time and remains the most comprehensive multilateral agreement on intellectual property to date.

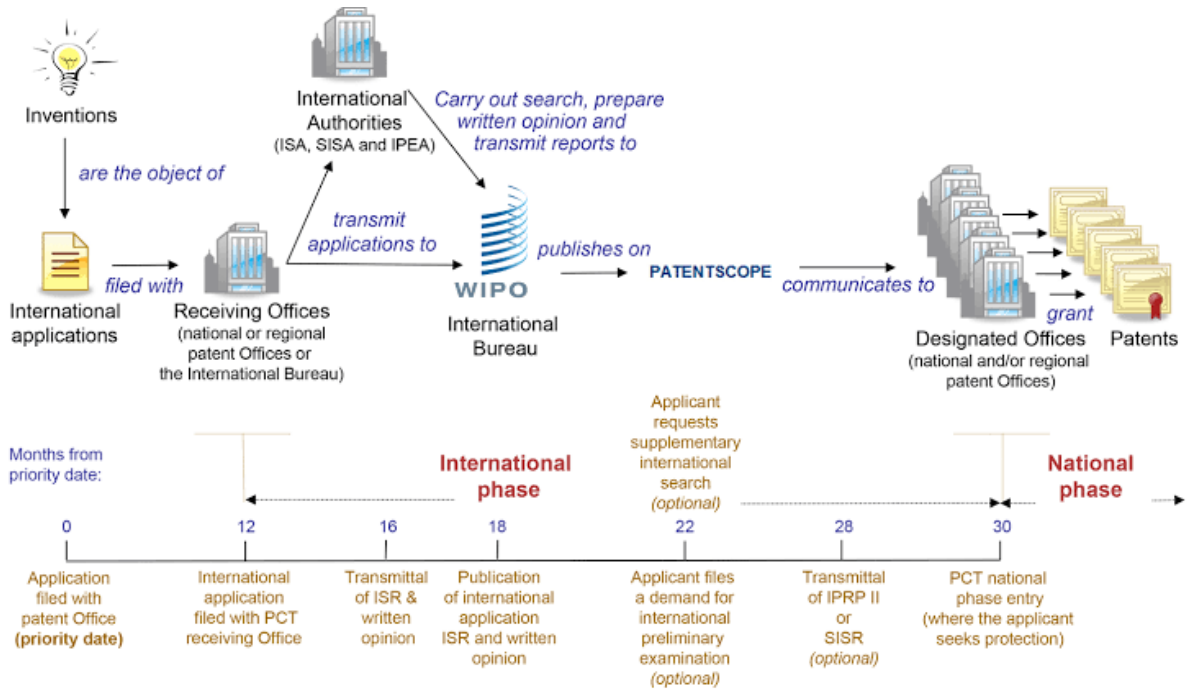
In 2001, developing countries, concerned that developed countries were insisting on an overly narrow reading of TRIPS, initiated a round of talks that resulted in the Doha Declaration. The Doha declaration is a WTO statement that clarifies the scope of TRIPS, stating for example that TRIPS can and should be interpreted in light of the goal "to promote access to medicines for all."

Specifically, TRIPS requires WTO members to provide copyright rights, covering authors and other copyright holders, as well as holders of related rights, namely performers, sound recording producers and broadcasting organisations; geographical indications; industrial designs; integrated circuit layout-designs; patents; new plant varieties; trademarks; trade names and undisclosed or confidential information. TRIPS also specifies enforcement procedures, remedies, and dispute resolution procedures.

Protection and enforcement of all intellectual property rights shall meet the objectives to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

PATENT CO OPERATION TREATY

- The patent Cooperation Treaty (PCT) is an international patent law treaty, concluded in 1970
- It provides a unified procedure for filing patent applications to protect inventions in each of its contracting states.
- A patent application field under the PCT is called an international application, or PCT application.
- A single filing of PCT application is made with a Receiving Office (RO) in one language.



TYPES OF PATENTS

- There are Four different types of patent

- Utility patents
- Provisional patent
- Plant patents
- Design patents

Utility patents

- A utility patent us what most people think of when they think about a patent. It is a long technical document that teaches the public how to use a new machine or system

Provisional patent

- A provisional patent goes hand in glove with a utility patent. United states law allows inventors to file proves the inventor was in possession of the invention.
- And had adequately figured out how to make the invention work once that is on file the invention is patent pending.
- Design patent
- A design patent protects an ornamental design on a useful item. The shape of a bottle or the design of a shoe, for example can be protected by a design patent.
- In recent years software companies have used design patents to protect elements of user interfaces and even the shape of touch screen devices.

FORMS OF PATENTS

There are four types of applications,

- Standard application
- Provisional application
- Continuation application
- Divisional application

Standard application

- A standard patent application is a patent application containing all of the necessary parts (e.g. a written description of the invention and claims) that are required for the grant of a patent.

Patentability

- To be protected by a patent an invention must be novel, inventive have industrial applicability and be lawful.

The notion of invention

- Above all it must be a true invention. No legal definition of invention exists. However, we generally define an invention by the fact that it must have a technical character which means that it provides a technical solution to a technical problem.

Process of patenting

Document disclosure

- The patent process starts with ‘document disclosure’ when an inventor first reduces his/her idea to sketches on paper, a disclosure needs to be filled.
- Even if someone else steals the idea, at least there is some evidence on record hence the filing of the disclosure is ideally done at the earliest stage of the ‘idea generation’ phase.

Patent search

- In fact, the actual patent process begins with a ‘patent search’ the main objective of patent search is to determine when an inventors creation already exits and remains actively protected under the patent act.

Patent application

- After the patent search is over, an application is made by the inventor and sent to the patents and trademarks office

Patent Examination

- Now the patent office makes the through examination of patent application filed by the inventor, then as its decision specifies the claims and/or problems to be solved by the inventor.

Patent grant

- This is the last step involved in the patent process. The patent office documents the new patent grants in its records. finally letter of patent grant is sent to the inventor thus the inventors invention gets finally patented.

INDIAN AGENCIES INVOLVED IN IPR

- Whether you're resident in and doing business in India, or trading internationally with the country, there are a number of professional organisations that can offer you advice and support:
- The British high commission, New Delhi offers advice on working with India, including details of cultural relations. It provides a full range of diplomatic, consular and business-related services:
- https://www.gov.uk/government/wprld/organisations/british-high-commission-new-delhi
- The UK India business council (UKIBC) helps and supports British businesses with regard to trade with India: http://www.ukibc.com
- The department of international trade (DIT) India has a range of online information on doing business in India:
- https://www.gov.uk/government/world/organisations/department-for-international-trade-india
- Local law firms in india can offer you legal advice and services specific to your business. The chambers and partners website offers a search facility listing Indian local law firms:
- https://www.chambersandpartners.com/asia/search/location/110

International Agencies involved in IPR

- World intellectual property organization
- African region intellectual property organization
- African intellectual property organization

GLOBAL SCENARIO Of PATENTS & INDIA'S POSITION

- Patents are a form of intellectual property intended to be an incentive to inventors or to the institutions that pay for the inventors' work.
- Patents allow the patentee to exclude others from practicing the claimed invention for a limited time in order to enjoy a profit from the invention, and to recoup the costs of development. (That is, the patentee can exclude others from making, using or selling the patented invention).
- The benefits offered by a patent provide an incentive to develop new and improved technology that advances society.
- This is a generally recognized concept in modern times, and the grant of patent rights in some form has been adopted by nearly every country in the world.
- As a property right, patents have limited territorial scope. Put simply, patents are only good in the country that issues them.
- For example, a patent issued in the United States cannot generally be used to stop an infringer in Canada or Japan.
- Since an invention that works in Chicago usually works in Toronto or London as well patent applicants need to know how to protect their invention in multiple countries if there is a commercial justification for doing so.

Paris Convention – One Year To File In Other Countries

- The basis of international patent filing is the Paris Convention for the Protection of Industrial Property, an international treaty known as the "Paris Convention."
- Under the Paris Convention as it now stands, the general rule is that a patent applicant has one year after the first patent application filing to file a subsequent patent application in other "Paris Convention" countries and claim the benefit of the date of the first filing or "priority filing."
- Operationally, the idea is that the first patent application is filed in the home country of the inventor.
- The applicant then files an application for the same invention in any other country that adheres to the Paris Convention no later than on the one year anniversary of the first filing date.
- Under the Paris Convention the application filed in the other countries is given the benefit of the filing date of the first application (i.e., the priority filing) if the applicant claims such priority, and the invention claimed in the other countries is adequately described in the first application.
- Under those circumstances, the other countries may not use the priority filing as prior art against the corresponding applications filed in those other countries.

FILING PROCEDURE UNDER THE PCT

1) International Phase

2) National Phase

International Phase

- India being one of the contracting state in the "PCT", any Indian applicant may file an international application in the standard format through any of the Indian Patent Offices as the Receiving Office i.e. The Patent Office, Kolkata, and its branch Offices at New Delhi, Mumbai, Chennai along with the copy of Specification and Statutory Fees.
- Language of filing may be either in English or Hindi.

National Phase

- Once the formalities under step one are duly complied and the applicant receives the International Search Report or once the Final International Preliminary Examination Report is complete and issued, the application enters the National Phase.
- Filing of National Phase Application in India requires the request for the grant of patent to be made to the competent Receiving Office i.e. The Patent Office, Kolkata, and its branch Offices at New Delhi, Mumbai, Chennai in the prescribed form i.e. Form 1A.
- Language of filing may be either in English or Hindi.

PATENTS IN THE INDIAN SCENARIO:

- The laws pertaining to Patent in India is governed by the Patents Act, 1970 which has been amended twice by The Patents (Amendment) Act, 1999 and The Patents (Amendment) Act, 2002.
- The new Patent Act, 2002 has although been notified on June 25th 2002, however, currently only limited sections of it have been made applicable vide Gazette Notification from the Government of India, dated May 20, 2003. Although, it is being implemented in phased manner, however, it is a matter of time before the new Act shall be applicable in its entirety.
- In the current scenario, the old Acts i.e. The Patent Act, 1970 and The Patent Rules, 2003 are applicable except for the sections made applicable through the Gazette Notification, as stated above.

WHO CAN APPLY

- Both the Indian nationals and foreigners can make an application for patent in India. But, in case of foreigners applying for patent in India, it is necessary that the country of such applicant should also be providing such reciprocal rights to the Indian nationals.
- Application for patents can be made by any person claiming to be the true and first inventor of the invention or by his assignee or legal representative.
- An application for patent can be made by any of these persons either alone or jointly with any other person. Two or more companies as assignees may also make an application jointly.

STEPS INVOLVED IN GRANT OF PATENT

1. Filing of an application for grant of a patent accompanied by either a provisional specification or a complete specification before any public disclosure of the invention.
2. In case provisional specification accompanies the original application, then filing of the complete specification within 12 months from the date of filing of the provisional specification. The said period may be extended by a further period of 3 months by paying appropriate fee for extension.
3. Over coming objections, if any laid by the examiner after the technical examination of the application by the patent office.
4. Acceptance of the application and advertisement of such acceptance in the official gazette.
5. Overcoming opposition, if any, to the grant of a patent.
6. Grant and sealing of the patent.
7. Maintenance of patent by payment of renewal fee.
8. Enforcement/revocation.

Biological patents

- Patenting of biological materials is called biological patents.
- A biological patent is a patent on an invention in the field of biology that by law allows the patent holder to exclude others from making, using, selling, or importing the protected invention for a limited period of time.
- The scope and reach of biological patents vary among jurisdictions, and may include biological technology and products, genetically modified organisms and genetic material.
- The applicability of patents to substances and processes wholly or partially natural in origin is a subject of debate.
- Since biotechnological developments heavily depend of the sustainable exploitation of micro-organisms and processes incorporating micro-organisms, patents play an important role in bio-economics.

What is patentable?

Biological inventions shall be patentable if they concern. biological material which is isolated from its natural environment or technically produced even if it previously occurred in nature.

- e.g. nucleic acid molecules, proteins, cells
- plants or animals if not confined to a particular plant or animal variety
- e.g. transgenic plants or animals
- microbiological processes and products

What is NOT patentable?

- Exceptions to patentability,
- cloning of human beings
- modifying the human germ line
- industrial or commercial use of human embryos
- the generation of genetically modified animals if their production causes suffering without substantial medical benefit

Patents & The human body (a biological material)

- **Patentable may be:**

an element isolated from the human body or produced by technical means including the sequence or partial sequence of a gene even if its structure is identical to that of a natural element may constitute a patentable invention.

- **NOT patentable:**

- The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence of a gene, cannot constitute patentable inventions.
- The industrial application of a sequence or partial sequence of a gene must be disclosed in the application.