# IDHAYA COLLEGE FOR WOMEN, KUMBAKONAM

# DEPARTMENT OF MICROBIOLOGY

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| **CLASS** | **: I M.Sc MICROBIOLOGY** |
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## UNIT-V

## INTELLECTUAL PROPERTY

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

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.

## 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.

### 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 (sometimes called "design right" or *design patent*) 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.

**Trademarks**

A trademark isarecognizable sign, design or expression which stinguishes products or services of a particular trader from similar products or services of other traders.

**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**

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 (e.g., Formula of its soft drinks is a trade secret for Coca-Cola.)

## GENERAL AGREEMENT ON TARIFFS AND TRADE

The General Agreement on Tariffs and Trade (GATT) is a legal agreement between many countries, whose overall purpose was to promote international trade by reducing or eliminating trade barriers such as tariffs or quotas. According to its preamble, its purpose was the "substantial reduction of tariffs and other trade barriers and the elimination of preferences, on a reciprocal and mutually advantageous basis."

The GATT was first discussed during the United Nations Conference on Trade and Employment and was the outcome of the failure of negotiating governments to create the International Trade Organization (ITO). It was signed by 23 nations in Geneva on 30 October 1947, and took effect on 1 January 1948. It remained in effect until the signature by 123 nations in Marrakesh on 14 April 1994, of the Uruguay Round Agreements which established the World Trade Organization (WTO) on 1 January 1995. The WTO is the successor to the GATT, and the original GATT text (GATT 1947) is still in effect under the WTO framework, subject to the modifications of GATT 1994. Nations that were not party in 1995 to the GATT need to meet the minimum conditions spelled out in specific documents before they can accede; in September 2019, the list contained 36 nations

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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.

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

The World Trade Organization (WTO) is an intergovernmental organization that is concerned with the regulation of international trade between nations. The WTO officially commenced on 1 January 1995 under the Marrakesh Agreement, signed by 123 nations on 15 April 1994, replacing the General Agreement on Tariffs and Trade (GATT), which commenced in 1948. It is the largest international economic organization in the world.

The WTO deals with regulation of trade in goods, services and intellectual property between participating countries by providing a framework for negotiating trade agreements and a dispute resolution process aimed at enforcing participants' adherence to WTO agreements, which are signed by representatives of member governments and ratified by their parliaments. The WTO prohibits discrimination between trading partners, but provides exceptions for environmental protection, national security, and other important goals. Trade-related disputes are resolved by independent judges at the WTO through a dispute resolution process.

### Ministerial conferences

The World Trade Organization Ministerial Conference of 1998, in the Palace of Nations (Geneva, Switzerland).

The highest decision-making body of the WTO, the Ministerial Conference, usually meets every two years. It brings together all members of the WTO, all of which are countries or customs unions. The Ministerial Conference can take decisions on all matters under any of the multilateral trade agreements. Some meetings, such as the inaugural ministerial conference in Singapore and the Cancun conference in 2003 involved arguments between developed and developing economies referred to as the "Singapore issues" such as agricultural subsidies; while others such as the Seattle conference in 1999 provoked large demonstrations. The fourth ministerial conference in Doha in 2001 approved China's entry to the WTO and launched the Doha Development Round which was supplemented by the sixth WTO ministerial conference (in Hong Kong) which agreed to phase out agricultural export subsidies and to adopt the European Union's Everything but Arms initiative to phase out tariffs for goods from the Least Developed Countries.

The Twelfth Ministerial Conference (MC12) is set to be held in Nur-Sultan, Kazakhstan, in June 2020.

**Principles**

1. Non-discrimination. It has two major components: the most favoured nation (MFN) rule, and the national treatment policy. Both are embedded in the main WTO rules on goods, services, and intellectual property, but their precise scope and nature differ across these areas. The MFN rule requires that a WTO member must apply the same conditions on all trade with other WTO members, i.e. a WTO member has to grant the most favourable conditions under which it allows trade in a certain product type to all other WTO members. "Grant someone a special favour and you have to do the same for all other WTO members." National treatment means that imported goods should be treated no less favourably than domestically produced goods (at least after the foreign goods have entered the market) and was introduced to tackle non-tariff barriers to trade (e.g. technical standards, security standards et al. discriminating against imported goods).
2. Reciprocity. It reflects both a desire to limit the scope of free-riding that may arise because of the MFN rule, and a desire to obtain better access to foreign markets. A related point is that for a nation to negotiate, it is necessary that the gain from doing so

be greater than the gain available from unilateral liberalization; reciprocal concessions intend to ensure that such gains will materialise.

3. Binding and enforceable commitments. The tariff commitments made by WTO members in a multilateral trade negotiation and on accession are enumerated in a schedule (list) of concessions. These schedules establish "ceiling bindings": a country can change its bindings, but only after negotiating with its trading partners, which could mean compensating them for loss of trade. If satisfaction is not obtained, the complaining country may invoke the WTO dispute settlement procedures.
4. Transparency. The WTO members are required to publish their trade regulations, to maintain institutions allowing for the review of administrative decisions affecting trade, to respond to requests for information by other members, and to notify changes in trade policies to the WTO. These internal transparency requirements are supplemented and facilitated by periodic country-specific reports (trade policy reviews) through the Trade Policy Review Mechanism (TPRM). The WTO system tries also to improve predictability and stability, discouraging the use of quotas and other measures used to set limits on quantities of imports.
5. Safety values. In specific circumstances, governments are able to restrict trade. The WTO's agreements permit members to take measures to protect not only the environment but also public health, animal health and plant health.

**Convention on Biological Diversity**

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The Convention on Biological Diversity (CBD), known informally as the Biodiversity Convention, is a multilateral treaty. The Convention has three main goals including: the conservation of biological diversity (or biodiversity); the sustainable use of its components; and the fair and equitable sharing of benefits arising from genetic resources.

In other words, its objective is to develop national strategies for the conservation and sustainable use of biological diversity. It is often seen as the key document regarding sustainable development. The Convention was opened for signature at the Earth Summit in Rio de Janeiro on 5 June 1992 and entered into force on 29 December 1993. CBD has two supplementary agreements - Cartagena Protocol and Nagoya Protocol.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international treaty governing the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another. It was adopted on 29 January 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11 September 2003.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity is a supplementary agreement to the Convention on Biological Diversity. It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources. The Nagoya Protocol on ABS was adopted on 29 October 2010 in Nagoya, Japan and entered into force on 12 October 2014, 90 days after the deposit of the fiftieth instrument of ratification. Its objective is the fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity.

Conference of the Parties: The convention's governing body is the Conference of the Parties (COP), consisting of all governments (and regional economic integration organizations) that have ratified the treaty. This ultimate authority reviews progress under the Convention, identifies new priorities, and sets work plans for members. The COP can also make amendments to the Convention, create expert advisory bodies, review progress reports by member nations, and collaborate with other international organizations and agreements.

The Conference of the Parties (COP) uses expertise and support from several other bodies that are established by the Convention.

In addition to committees or mechanisms established on an ad hoc basis, the main organs are:

Secretariat: The CBD Secretariat, based in Montreal, Quebec, Canada, operates under UNEP, the United Nations Environment Programme. Its main functions are to organize meetings, draft documents, assist member governments in the implementation of the programme of work, coordinate with other international organizations, and collect and disseminate information.

Subsidiary Body for Scientific, Technical and Technological Advice (SBSTTA): The SBSTTA is a committee composed of experts from member governments competent in relevant fields. It

plays a key role in making recommendations to the COP on scientific and technical issues. The next two meetings of the SBSTTA will be 25–29 November 2019 in Montreal, Canada (SBSTTA-23), and 18–23 May 2020 in Montreal, Canada (SBSTTA-24). The current chair of the SBSTTA Bureau is Mr. Hesiquio Benitez Diaz of Mexico.

Subsidiary Body on Implementation (SBI): In 2014, the Conference of the Parties to the Convention on Biological Diversity established the Subsidiary Body on Implementation (SBI) to replace the Ad Hoc Open-ended Working Group on Review of Implementation of the Convention. The four functions and core areas of work of SBI are: (a) review of progress in implementation; (b) strategic actions to enhance implementation; (c) strengthening means of implementation; and (d) operations of the convention and the Protocols. The first meeting of the SBI was held on 2–6 May 2016 and the second meeting was held on 9–13 July 2018, both in Montreal, Canada. The third meeting of the SBI will be held on 25–29 May 2020 in Montreal, Canada. The Bureau of the Conference of the Parties serves as the Bureau of the SBI. The current chair of the SBI is Ms. Charlotta Sörqvist of Sweden.

**PATENT COOPERATION TREATY (PCT)**

The Patent Cooperation Treaty (PCT) makes it possible to seek patent protection for an invention simultaneously in each of a large number of countries by filing an "international" patent application. Such an application may be filed by anyone who is a national or resident of a PCT Contracting State. It may generally be filed with the national patent office of the Contracting State of which the applicant is a national or resident or, at the applicant's option, with the International Bureau of WIPO in Geneva.

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 filed under the PCT is called an international application, or PCT application.

A single filing of a PCT application is made with a Receiving Office (RO) in one language. It then results in a search performed by an International Searching Authority (ISA), accompanied by a written opinion regarding the patentability of the invention, which is the subject of the application. It is optionally followed by a preliminary examination, performed by an International Preliminary Examining Authority (IPEA) Finally, the relevant national or regional

authorities administer matters related to the examination of application (if provided by national law) and issuance of patent.

A PCT application does not itself result in the grant of a patent, since there is no such thing as an "international patent", and the grant of patent is a prerogative of each national or regional authority. In other words, a PCT application, which establishes a filing date in all contracting states, must be followed up with the step of entering into national or regional phases to proceed towards grant of one or more patents. The PCT procedure essentially leads to a standard national or regional patent application, which may be granted or rejected according to applicable law, in each jurisdiction in which a patent is desired.

The contracting states the states which are parties to the PCT, constitute the International Patent Cooperation Union.

**Procedure**

The main advantages of the PCT procedure, also referred to as the international procedure, are the possibility to maximally delay: (a) the national or regional procedures; (b) the respective fees and translation costs; and, (c) the unified filing procedure. From a practical standpoint, this could allow new ventures more time to locate strategic partnerships, funding, and markets, before their technology becomes public.

A PCT application (also called "international patent application") has two phases.[12] The first phase is the international phase in which patent protection is pending under a single patent application filed with the patent office of a contracting state of the PCT. The second phase is the national and regional phase which follows the international phase in which rights are continued by filing necessary documents with the patent offices of separate contracting states of the PCT. A PCT application, as such, is not an actual request that a patent be granted, and it is not converted into one unless and until it enters the "national phase"

**TYPES OF PATENTS**

Patents protect inventions and new discoveries that are new and non-obvious. There are three types of patents: utility patents, design patents, and plant patents. Each type of patent has its own eligibility requirements and protects a specific type of invention or discovery; however, it's possible for one invention or discovery to potentially have more than one type of patent available

for it. For example, if a person invents an object and he or she wishes to patent both the functional features and the design of the object, the inventor would have to apply for two separate patents (both a utility and design patent).

**Utility Patents**

A utility patent is the most common type of patent that people seek. This type of patent covers processes, compositions of matter, machines, and manufactures that are new and useful. A utility patent can also be obtained for new and useful improvements to existing processes, compositions of matter, machines, and manufactures. Processes refer to any acts or methods of doing something, usually involving industrial or technical processes. Compositions of matter are basically chemical compositions, which can include a mixture of ingredients or new chemical compounds. Machines include things that are generally defined as a machine, such as a computer, while manufactures are defined as goods that are manufactured or made.

**Design Patents**

In terms of obtaining a design patent, a design is defined as the "surface ornamentation" of an object, which can include the shape or configuration of an object. In order to obtain this type of patent protection, the design must be inseparable from the object. While the object and its design must be inseparable, a design patent with only protect the object's appearance. In order to protect the functional or structural features of an object, a person must also file for a utility patent.

**Plant Patents**

A plant patent can be obtained to protect new and distinctive plants. A few requirements to obtain this type of patent are that the plant is not a tuber propagated plant (i.e. an Irish potato), the plant is not found in an uncultivated state, and the plant can be asexually reproduced. Asexual reproduction means that instead of being reproduced with seed, the plant is reproduced by grafting or cutting the plant. Plant patents require asexual reproduction because it's proof that the patent applicant can reproduce the plant.

## PATENTABILITY

Within the context of a national or multilateral body of law, an invention is patentable if it meets the relevant legal conditions to be granted a patent. By extension, patentability also refers to the substantive conditions that must be met for a patent to be held valid.

### Requirements

The patent laws usually require that, for an invention to be patentable, it must be:

- Patentable subject matter, i.e., a kind of subject-matter eligible for patent protection
- Novel (i.e. at least some aspect of it must be new)
- Non-obvious (in United States patent law) or involve an inventive step (in European patent law)
- Useful (in U.S. patent law) or be susceptible of industrial application (in European patent law)

Usually the term "*patentability*" only refers to "substantive" conditions, and does not refer to formal conditions such as the "sufficiency of disclosure", the "unity of invention" or the "best mode requirement".

Judging patentability is one aspect of the official examination of a patent application performed by a patent examiner and may be tested in post-grant patent litigation.

Prior to filing a patent application, inventors sometimes obtain a patentability opinion from a patent agent or patent attorney regarding whether an invention satisfies the substantive conditions of patentability.

## PATENT PROCESS

The patent process for obtaining a patent protection involves 1) a patentability opinion, 2) preparation and filing of the patent application, 3) prosecution of the patent application, 4) issuance, abandonment or appeal of the patent application and 5) maintenance fees.

### Step 1: Patentability Opinion

The first step of the patent process is the patentability opinion which includes a search of the prior art. During the search, we develop an opinion as to whether the patent office is like to grant a patent on the invention. You don’t have to go out and search for prior art references that

might invalidate your patent. However, you do have to disclose relevant information that you know of to the patent office. In other words, there is no duty to search for prior art but there is a duty to disclose relevant information to the patent office.

**Step 2: Preparation and filing of a patent application**

In the second step of the patent process, we write your patent application. Upon your approval, we file the patent application with the Patent Office. The preparation and filing of the patent application involves preparation of a document that describes your invention. This document must be able to allow another person to make and use your invention. The patent application is not a check the box type of application.

**Step 3: Patent prosecution**

Prosecution of a patent application refers to the correspondence between the patent attorney representing the inventor and the Patent Office. Correspondence includes documents such as a written response to an Office Action from the Patent Office. This response is an argument trying to convince the examiner that your invention is worthy of a patent. The Office Action is the official stance of the Patent Office whether they will grant you a patent or not.

**Step 4: Issuance, Appeal or Abandonment**

If the patent applicant is successful in the prosecution stage of the patent process, then the patent application will issue as a patent. If the patent applicant is unsuccessful in the prosecution stage then the patent applicant may abandon the patent application or appeal the decision of the examiner to an independent board for review as to whether the examiner is correct.

**Step 5: Maintenance Fees**

If you are successful in obtaining a patent, then there are maintenance fees 3 ½, 7 ½ and 11 ½ years that are due after issuance of your patent. This is the overall general process for obtaining a patent.

**INTELLECTUAL PROPERTY RIGHTS IN INDIA**

To enjoy most types of intellectual property (IP) rights in India, you should register them. For patents, individual registrations must be made in India, but for rights other than industrial designs you can apply under the terms of the Patent Cooperation Treaty, which is usually easier and quicker. For trade marks, you should register them within India, either through the domestic trade mark system or under the Madrid system. For copyright, no registration is required but registering copyrights with the copyright authorities is advisable. ‘Priority rights’ under the Paris

Convention can help in the local registration of trade marks, designs and patents by allowing rights previously registered elsewhere to become effective in India, if filed within a time limit.

**Enforcing IP rights in India**

IP rights can be enforced by bringing actions to the civil courts or through criminal prosecution. India's IP laws set out procedures for both civil and criminal proceedings, as does the Competition Act. Criminal proceedings do not apply to patent and design infringements. A disadvantage of civil litigation is that you are unlikely to recover large damages, and punitive damages against an infringer are rare. However, if you have an identified infringer, it may be advisable to launch civil litigation, because if an interim injunction is granted the infringement can be halted pending the outcome of the case. Damages are routinely awarded in cases of copyright piracy and trade mark infringement (which come under criminal litigation); less so in patent cases. Over the years, however, decisions in favour of foreign companies against local infringers have demonstrated the judiciary's impartial approach. As in other countries, the Indian Government brings actions in criminal cases, although in most cases actions follow complaints to magistrates or police authorities by rights owners. Criminal proceedings against infringers carry the prospect of much harsher remedies, including fines and imprisonment. Mediation or negotiation with an infringer can also be effective as an alternative form of dispute resolution. The Civil Procedure Code provides for a formal mediation process.

**International organisations**

- European Patent Organisation (EPO) ...
- World Intellectual Property Organization (**WIPO**) ...
- European Free Trade Association (EFTA) ...
- European Union Intellectual Property Office (EUIPO) ...
- Nordic Patent Institute (NPI)

**BIOLOGICAL PATENT**

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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.

## GOOD LABORATORY PRACTICE

**Good laboratory practice** or good laboratory practices are accepted methods to carry out activities or operations in a laboratory. The authorities and laboratory organizations say that these practices help ensure safety. They also have a positive influence on the quality of the result. For pharmaceutical companies, for example, GLP compliance is extremely important.

Good laboratory practices are not guidelines; they have the force of law. We also refer to good laboratory practice as **GLP**. GLP is part of the quality assurance that ensures that organizations consistently produce and control goods to a high quality standard.

Good laboratory practice is not only concerned with production, but also quality control.

According to the *European Commission*:

"The principles of Good Laboratory Practice (GLP) promote the quality and validity of data generated in the testing of chemicals and prevent fraudulent practices."

## GOOD MANUFACTURING PRACTICE

**Good manufacturing practices** (**GMP**) are the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices, These guidelines provide minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use. The rules that govern each industry may differ significantly; however, the main purpose of GMP is always to prevent harm from occurring to the end user. Additional tenets include ensuring the end product is free from contamination, that it is consistent in its manufacture, that its manufacture has been well documented, that personnel are well trained, and that the product has been checked for quality more than just at the end phase. GMP is typically ensured through the effective use of a quality management system (QMS).

Good manufacturing practices, along with good agricultural practices, good laboratory practices and good clinical practices, are overseen by regulatory agencies in the United Kingdom, United States, Canada, Europe, China, India and other countries.

All guideline follows a few basic principles

- Manufacturing facilities must maintain a clean and hygienic manufacturing area.
- Manufacturing facilities must maintain controlled environmental conditions in order to prevent cross-contamination from adulterants and allergens that may render the product unsafe for human consumption or use.
- Manufacturing processes must be clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
- Manufacturing processes must be controlled, and any changes to the process must be evaluated. Changes that affect the quality of the drug are validated as necessary.
- Instructions and procedures must be written in clear and unambiguous language using good documentation practices.
- Operators must be trained to carry out and document procedures.
- Records must be made, manually or electronically, during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the food or drug was as expected. Deviations must be investigated and documented.
- Records of manufacture (including distribution) that enable the complete history of a batch to be traced must be retained in a comprehensible and accessible form.
- Any distribution of products must minimize any risk to their quality.
- A system must be in place for recalling any batch from sale or supply.
- Complaints about marketed products must be examined, the causes of quality defects must be investigated, and appropriate measures must be taken with respect to the defective products and to prevent recurrence.