# TIP 451 Intellectual Property Rights and Applications in Biotechnology (1+0)

## Lecture 1. Intellectual Property (IP) - Introduction- Importance

Intellectual property rights (IPR) were a general term of human rights based on the results of their intellectual and creative production. Thus, it is a collection of concepts like copyrights, patents, trademarks, registered (industrial) design, protection of IC layout design, geographical indications, and protection of undisclosed information. As a social system for promoting innovation, the intellectual property system was first established in the Western countries and its course in those countries has gone through three main stages, namely, stage of germination, stable development and internationalization.

**i) Germination Stage**

Patent law was the first system in the world to build a human intellectual property system. At the early 13$^{th}$ century, the King of Britain had granted a license (a patent) to the inventors. At the 15$^{th}$ century, the Mediterranean countries experienced the advent of technological innovation and therefore, those countries had to establish a new legal system to protect technology. The Republic of Venice city constituted the first world's Patent Law in 1474. The advent of the industrial revolution in the whole Europe led some countries to establish a national patent system. The United States even established the principle of protection of proprietary technology in its Constitution and made patent protection to the height to constitutional level. Copyrights had the same colour with a strong monarchical power. Before the birth of the copyright system, various countries had long-standing system of printing privileges. According to this franchise system, the King can grant a printing right to license the printer rather than the copyright owners.

In 1709, Britain built the first modern copyright law - "the Queen Anne Act." Then, France and Germany established the copyright system. Under the influence of these countries as a pioneer, the copyright system has been gradually accepted by other Governments. Trademark is an Intellectual Property Right (IPR) which is closely related to technology trade and trade in services. Trademarks originated in Spain. The trademark system in the modern sense began in the 19$^{th}$ century. In 1857, France set the first legal system to protect trademarks in world.

Subsequently, the trademark system rapidly developed in the rest of the world.

**ii) Stage of Stable Development**

During the stage of stable development, the framework of the intellectual property (IP) system which included of copyright, patent and trademark rights has been established. Many countries accepted various forms of IPRs in different attitude. All these developments demonstrated that the historical development of the IP system has entered a stage of steady development. By the end of the 80's of the twentieth century, the new wave of civil legislation began to rise. Many countries tried to develop the Code of Intellectual Property and integrate intellectual property law into the Civil Code. These activities set off a wave of codification of IPRs. France promoted such movement by issuing the first "Intellectual Property Code" which is the collection of all IP system.

**iii) Internationalization Stage**

Since the late 19$^{th}$ century, along with the high-tech development and the expansion of international trade, intellectual property transactions in the international market have also begun with the formation and development. At the same time, there were a huge contradiction between international demand for IPRs and regional restrictions. In order to resolve this contradiction, some countries have signed the International Convention for the protection of intellectual property, and set up a number of global or regional international organizations. A system of international protection of IPRs has been set up in the world. The "Paris Convention for the Protection of Industrial Property" (which was launched by France, Germany, Belgium, and 10 other countries in 1883) was the first international convention in protecting Industrial Property. The Berne Convention for the Protection of Literary and Artistic Works, usually known as the Berne Convention, is an international agreement governing copyright, which was first accepted in Berne, Switzerland, in 1886. The foundation of International Conventions indicated that the intellectual property system had come to the international stage.

According to the World Intellectual Property Organization (WIPO), intellectual property refers to creations of the mind, inventions, literary and artistic works, symbols, names, images and designs used in commerce.

Broadly, intellectual property is divided into two categories. The first category covers industrial property, which includes patents, industrial designs and trademarks which have industrial applications. The other refers to copyright laws which are applied to such things as

literary, dramatic and artistic works; rights relating to performing artists, the production of phonograms; and rights of broadcasters in their radio and television programmes. Intellectual property (IP) rights as a term can be collectively used for multiple protection of different aspects of an inventive work as given below:

i) Patents including the protection of new varieties of plants
ii) Copyrights and related rights (i.e., the rights of performers, producers of sound recordings and broadcasting organizations)
iii) Trademarks, including service marks
iv) Registered (industrial) design
v) Layout-designs (topographies) of Integrated Circuits (IC)
vi) Geographical indications including appellations of origin, and
vii) Undisclosed information, including trade secrets and test data

**Difference between Intellectual Property and Intellectual Property Rights**

Intellectual property (IP) is an umbrella term covering patents, trademarks, copyrights and so on. Intellectual property rights (IPRs) are specific abilities, granted by law to rights holders, for the control of intellectual properties. IPR confers on individuals, enterprises or other entities the right to exclude others from the use of their creations. Consequently, IPRs may have a direct and substantial impact on industry and trade as the owner of an IPR and may - through the enforcement of such a right - prevent others to manufacture, use or sale of a product which incorporates the IPR.

**Benefits of Securing IPRs**

i) IPRs give protection to the Patentee or inventor, enabling him to enjoy the right and to raise the capital for working his invention on a commercial scale. Monopolies over inventions, brand names, aesthetic designs and other works of the mind requiring skill and effort are protected based on the justification that any benefits flowing from such creations should be the property of the creator as a result of the creator's contribution in terms of time, effort, skill and financial investment.

ii) The recognition of employee contributions during the identification, protection and exploitation of IPRs provides strong incentive for employees to innovate and develop a protective culture.

iii) In case, the Patentee is not able to work the invention commercially, he would be able to make a profitable use of his invention by selling his patent or by granting license to others, permitting the use of his invention.

iv) IP protection offers the creation and establishment of credibility and confidence in the business space and consumer space. Businesses with strong intellectual property portfolios are generally regarded more favourably, especially by professional investors. Patent acts as tradable industrial asset for the enterprise and, thus the strength of patent portfolio of the company is the indication of the good economic health of the company.

v) Patent System helps for industrial growth by introducing new technologies.

vi) The scientific knowledge, i.e., the inventive and creative ideas contained in the patent specification helps as a "stepping stone" for further R & D efforts in the field.

vii) After the term of patent is over, or patent is not kept in force, the patented invention is available to the public for free use.

**Nature of Intellectual Property Rights**

IPRs are largely territorial rights except copyright which is global in nature in the sense that it is immediately available in all the members of the Berne Convention. These rights are awarded by the State and are monopoly rights implying that no one can use these rights without the consent of the right holder. It is important to know that these rights have to be renewed from time to time for keeping them in force except in case of copyright and trade secrets.

IPRs have fixed term except trademark and geographical indications, which can have indefinite life provided these are renewed after a stipulated time specified in the law by paying official fees. Trade secrets also have an infinite life and therefore, they do not have to be renewed. IPR can be assigned, gifted, sold and licensed like any other property. Unlike other moveable and immoveable properties, these rights can be simultaneously held in many countries at the same time.

IPR can be held only by legal entities i.e., who have the right to sell and purchase property. In other words, an institution, which is not autonomous, may not be in a position to own an intellectual property. The IP rights are associated with something new or original and therefore, what is known in public domain cannot be protected through the rights mentioned above. Improvements and modifications made over known things can be protected. It would however, be possible to utilize geographical indications for protecting some agriculture and

traditional products.

**Need for Intellectual Property Rights**

New laws and regulations continue to emerge, and the scope of intellectual property's objects has continued to grow. In spite of this, the establishment of IPR system has become an irresistible trend. In today's world, many countries have a more understanding of the social progress and political and economic interests from knowledge. Developed countries take its monopoly of advanced scientific knowledge as a magic weapon for technology leadership. Developing countries take the absorbing and creating knowledge as an important way to catch up with developed countries. It can be expected that the next era is not only to develop and possess substantial social resources, but also to develop and possess knowledge resources. Moreover, with the deepening of global economic integration, the international process of intellectual property system will be further accelerated. Protection of IPRs has not only become the necessary conditions of a country to promote for economic development, but also a pre-requisite as the maintenance of international competitiveness.

With the advent of the new knowledge economy, there is urgency on understanding and managing knowledge based assets such as innovations and know-how. The time for grasping knowledge has become an important parameter for determining the success of an institution, enterprise, government and industry; the shorter the time better are the chances of success.

IPRs have become important in the face of changing trade environment which is characterized by the following features namely global competition, high innovation risks, short product cycle, need for rapid changes in technology, high investments in research and development (R&D), production and marketing and need for highly skilled human resources. Geographical barriers to trade among nations are collapsing due to globalization, a system of multilateral trade and a new emerging economic order. It is therefore quite obvious that the complexities of global trade would be on the increase as more and more variables are introduced leading to uncertainties.

Many products and technologies are simultaneously marketed and utilized in many countries. With the opening up of trade in goods and services, intellectual property rights (IPR) have become more susceptible to infringement leading to inadequate return to the creators of knowledge. Developers of such products and technologies would like to ensure R&D costs and other costs associated with introduction of new products in the market are recovered and enough

profits are generated for the further investment on R&D efforts. One expects that a large number of IP rights would be generated and protected all over the world including India in all areas of science and technology, software and business methods. It is also important to realize that each product is amalgamation of many different areas of science and technologies.

More than any other technological area, drugs and pharmaceuticals need to have IPR protection. As the introduction of a new drug into the market may involve huge cost along with all the associated risks at the developmental stage, no company will like to risk its intellectual property becoming a public property without adequate returns. Creating, obtaining, protecting and managing intellectual property must become a corporate activity in the same manner as the raising of resources and funds. Therefore, the knowledge revolution will also encompass the intellectual property and its management in the overall decision - making process.

Many industries experiencing severe competition at global level would like to share their expertise in order to respond to market demands quickly and keep their products' prices competitive. In order to maintain a continuous stream of new ideas and experimentations, public private partnership in R&D would need to be nurtured to arrive at a win-win situation. Therefore, all publicly funded institutions need to take positive steps to direct research suitably to generate more intellectual property rights, protect and manage them efficiently.

Today, the IPR not only has expanded the traditional content of property rights system, but also made a profound impact on mankind in the 21$^{st}$ century. However, with the development of new technologies and human cognitive ability, as an implement to balance the private rights and public interests, the intellectual property system always encounter challenges and controversies.

**Lecture 2. Forms of IPR –Patent- types of patent-Utility patent, Design patent, plant patents**

**Intellectual Property** (**IP**) rights are the legally recognized exclusive rights to creations of the mind. Under intellectual property law, owners are granted certain exclusive rights to a variety of intangible assets, such as musical, literary, and artistic works; discoveries and inventions; and words, phrases, symbols, and designs. Common types of intellectual property rights include copyright, trademarks, patents, industrial design rights, trade dress, and in some jurisdictions, trade secrets.

**i) Patent - Definition**

The term 'patent' has been derived from the Latin word "*Litterae Patentes*" which means 'Open Letters' or 'an Open Document' and it was used by medieval European kings to confer rights and privileges. In the modern times, patent enunciates a contract between an inventor and the Government. A patent is an exclusive privilege and monopoly legal right granted by the Government to the inventor for his disclosed invention of an industrial product or process of manufacture which should be new, non-obvious, useful and patentable as per the patentability criteria laid down in the domestic Patents Act.

A patent is an exclusive right granted by a country to the owner of an invention to make, use, manufacture and market the invention, provided the invention satisfies certain conditions stipulated in the law. Exclusive right implies that no one else can make, use, manufacture or market the invention without the consent of the patent holder. This right is available for a limited period of time. In spite of the ownership of the rights, the use or exploitation of the rights by the owner of the patent may not be possible due to other laws relating to health, safety, food, security etc. of the country which has awarded the patent. Further, existing patents in similar area may also come in the way.

A patent in legal terms is a property right and hence, can be gifted, inherited, assigned, sold or licensed. As the right is conferred by the State, it can be revoked by the State under very special circumstances even if the patent has been sold or licensed or manufactured or marketed in the mean time. The patent right is territorial in nature and inventors/their assignees will have to file separate patent applications in countries of their interest, along with necessary fees, for obtaining patents in those countries. A new chemical process or a drug molecule or an electronic

circuit or a new surgical instrument or a vaccine is a patentable subject matter provided all the stipulations of the law are satisfied.

**Advantages of Patents**

i) Patent system encourages an inventor to disclose his invention instead of keeping it secret.

ii) As the patent right is proprietary in nature, it gives protection to the patentee. The patentee or his agent or licensee has the exclusive right to make, use, and sell an invention and thereby he can prevent all others, not just imitators but even independent devisors of the same idea from using the invention for the duration of the patent.

iii) The patentee can get higher returns for working his invention on a commercial scale.

iv) If the patentee could not commercially work on the invention, he can make profit by selling his patent or by granting license to others, permitting the use of his invention.

v) Patent System encourages the inventors to advance the state of technology by awarding them special rights to benefit from their inventions. Thus, it helps for industrial growth by introducing new technologies.

vi) Scientific knowledge contained in the patent specification provides inventive and creative ideas and helps as a "stepping stone" for further R & D in the field.

vii) Patent acts as tradable industrial asset for the enterprise and, thus the strength of patent portfolio of the company is the indication of the good economic health of the company.

viii) After the term of patent is over, or patent is not kept in force, the patented invention is available to the public for free use.

**TRIPS Agreement:** The TRIPS agreement says that granting protection through patent should have following provisions:

- Patent protection must be available for inventions for at least 20 years.
- Patent protection must be available for both products and processes, in almost all fields of technology.
- Governments can refuse to issue a patent for an invention if its commercial exploitation is prohibited for reasons of public order or morality.
- Governments can also exclude diagnostic, therapeutic and surgical methods, plants and animals (other than microorganisms), and biological processes for the production of plants or animals (other than microbiological processes).
- Plant varieties, however, must be protectable by patents or by a special system (such as the

breeder's rights provided in the conventions of UPOV).

- TRIPS Agreement also allows certain exceptions. A patent owner could abuse his rights, for example, by failing to supply the product on the market. To deal with that possibility, the agreement says governments can issue "compulsory licenses", allowing a competitor to produce the product or use the process under license. But this can only be done under certain conditions aimed at safeguarding the legitimate interests of the patent-holder.
- If a patent is issued for a production process, then the rights must extend to the product directly obtained from the process. Under certain conditions alleged infringers may be ordered by a court to prove that they have not used the patented process.
- The TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Member countries underscored countries' ability to use the flexibilities that are built into the TRIPS Agreement. And they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016. They assigned further work to the TRIPS Council — to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can import patented drugs made under compulsory licensing.
- The agreement describes the minimum rights that a patent owner must enjoy. A patent shall confer on its owner the following exclusive rights:

  (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product;

  (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process; and

  (c) patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.
- Member countries may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

- An applicant for a patent shall disclose the invention in a clear and complete manner for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.
- When a Member country allows the subject matter of a patent for other use without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
  - authorization of such use shall be considered on its individual merits;
  - such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public non- commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
  - the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive; and
  - such use shall be non-exclusive.

**What is an invention?**

An invention may be defined as a proposal for the practical implementation of an idea for the purpose of solving a technical problem. For the purpose of grant of a patent, an invention is defined in the Patents Act, 1970 as:

i) any new and useful art, process, method or manner of manufacture;

ii) a machine, an apparatus or other article; and

iii) a substance produced by manufacture, and includes any new and useful improvement of any of them, and an alleged invention.

The Patent Act, 1970 envisages that 'any invention that has a commercial application and which is not exempted under the Act is eligible for grant of patent. The Second Amendment Bill, 1999 introduced a new definition of invention: “Invention means a new product or process involving an invention step and capable of industrial application”.

**What is patentable?**

To qualify for a patent, the invention must meet three basic tests. First, it must be novel, meaning that the invention did not previously exist. Second, the invention must be non-obvious, which means that the invention must be a significant improvement to existing technology. Simple changes to previously known devices do not comprise a patentable invention. Finally, the proposed invention must be useful. Legal experts commonly interpret this to mean that no patent will be granted for inventions that can be used for an illegal or immoral purpose.

**i) Novelty:** An invention is said to be new if, prior to the date of filing or to the priority date accorded to the application from an earlier application for the same invention, it was not already known to the public in any form (written, oral or through use), i.e., it did not form part of the state of the art. Information appearing in magazines, technical journals, books, newspapers, etc. constitutes the state of the art. Oral description of the invention in a seminar/conference can also spoil novelty. Novelty is assessed in a global context. An invention will cease to be novel if it has been disclosed in the public through any type of publications anywhere in the world before filing a patent application in respect of the invention. Prior use of the invention in the country of interest before the filing date can also destroy the novelty. Novelty is determined through extensive literature and patent searches. It should be realized that patent search is essential and critical for ascertaining novelty as most of the information reported in patent documents does not get published anywhere else.

**ii) Inventiveness (Non-obviousness):** An invention is said to involve an inventive step (or lack of obviousness) if, in the light of what is already known to the public, it is not obvious to a so-called skilled person, i.e., someone with good knowledge and experience of the field. The prior art should not point towards the invention implying that the practitioner of the subject matter could not have thought about the invention prior to filing of the patent application. Inventiveness cannot be decided on the material contained in unpublished patents. The complexity or the simplicity of an inventive step does not have any bearing on the grant of a patent. In other words, a very simple invention can qualify for a patent, if there is an inventive step between the

proposed patent and the prior art at that point of time, then an invention has taken place.

**iii) Usefulness:** An invention must possess utility for the grant of patent. An invention is capable of industrial application, if it can be made or used in any kind of industry, including agriculture, as distinct from purely intellectual or aesthetic activity.

**Effect of Patent**

A patentee gets the exclusive monopoly right against any person or legal entity to use, sell or manufacture his patented device, apparatus or process or assign the same to others. Period during which the owner enjoys the benefits is called term of the patent. Registration is a prerequisite for patent protection and the protection granted is territorial in nature, i.e., patent granted in a country will confer the ownership right to the patentee only within that country.

i) A Patentee can enforce his monopoly right against any infringement in the Court of Law for suitable damages or profit of account.
ii) The Government ensures full disclosure of the invention to the public for exchange of exclusive monopoly patent right to the inventor.

**What is not patentable?**

The following subject matter is not patentable under the Patents Act, 1970:

i) An invention which is frivolous or claims anything obviously contrary to well established natural laws; (No one can obtain a patent on a law of nature or a scientific principle even if he is the first one to discover it. For example, Isaac Newton could not have obtained a patent on the laws of gravity).
ii) An invention the primary or intended use or commercial exploitation of which could be contrary to pubic order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;
iii) A mere discovery of a scientific principle or the formulation of an abstract theory; [or discovery of any living thing or non-living substances occurring in nature].
iv) The Patent Act has a set of exceptions stated in Section 3 clause (d) by which certain things cannot be protected by the law. A mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. This provision prevents patenting of minor improvements in chemical and pharmaceutical entities unless the invention results in the enhancement of known efficacy of that substance. This provision sets

safeguard for public health purposes and sets a higher threshold which has been interpreted as therapeutic efficacy for the grant of a patent on pharmaceuticals;

v) A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

vi) A mere arrangement or rearrangement or duplication of known devices, each functioning independently of one another in a known way;

vii) A method of agriculture or horticulture;

viii) Any process for the medicinal, surgical, curative, prophylactic [diagnostic or therapeutic] or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products;

ix) In the case of inventions relating to substances prepared or produced by chemical processes (including alloys, optical glass, semiconductors and inter-metallic compounds) or claiming substances intended for use, or capable of being used, as drug, or as food, or as medicine, no patent will be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture only will be patentable. The meaning of the word "drug" here includes agro chemicals excluding fertilizer and manure. However, as per the Patents (Amendment) Act, 1999, it is now possible to make an application for patent claiming for a substance itself, intended for use or capable of being used as a Medicine or Drug, excepting the intermediate for the preparation of drug. However, these applications for product claims for medicine or drug will be kept as "Mailbox Applications" and will not be processed until the end of 2004;

x) Plants or animals in whole or any part thereof other than micro organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

xi) A mathematical or business method or a computer programme *per se* or algorithms;

xii) A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television production;

xiii) A mere scheme or rule or method of performing mental act or method of playing game;

xiv) A presentation of information;

xv) Topography of integrated circuits;

xvi) An invention which in effect, is traditional knowledge or which is an aggregation of

duplication of known properties of traditionally known component or components; and

xvii) Inventions relating to atomic energy.

**Types of patents:** The TRIPS Agreement stipulates that countries shall grant patents for inventions in all fields of technology and for both: (i) Products, and (ii) Processes, including those used in manufacturing products. The different types of patents are as follows: (i) Utility patents, (ii) Design patents, and (iii) Plant patents.

**i) Utility patents:** It can be granted to anyone who invents any new and useful process, machine, manufacture or composition of matter, or any new and useful improvement thereof. Utility patent period is of 20 years. "Process" refers to industrial and manufacturing (production) method. "Manufacture" refers to articles manufactured. "Composition of matter" refers to chemical compositions and may include mixtures of ingredients as well as new chemical compounds.

**ii) Design patents**: They can be granted to anyone who invents a new, original ornamental design for an article of manufacture. A design patent protects the ornamental design (i.e., appearance) of the article. A design patent has duration of 15 years from the date of filing.

**iii) Plant patents**: They can be granted to anyone who invents or discovers and reproduces a new variety of plant. A plant patent has a term of 20 years from the date of filing.

## Lecture 3. Copy right and Geographical Indication(GI)

### Copyrights - Definition

Copyright is one of the intellectual property rights designed to encourage creativity and is given by law to safeguard, protect and reward the rights of creators of original literary or dramatic or musical or artistic works in their respective creations and productions. Writers, artists, designers, dramatists, musicians, architects, producers of sound recordings, cinematographers, computer software developers and so on are encouraged to create original works in different fields like literature, art and music by rewarding them with the exclusive right for a limited period of exploit the work for monetary gain. Cinematographic films including sound track and video films and recordings on discs, tapes, perforated roll or other devices are covered by copyrights. Theoretically, copyright acts as an incentive for people to come out with newer and newer copyrightable works, which add to the knowledge stock of mankind. The creator of a work can prohibit or authorize:

- its **reproduction** in various forms, such as printed publication or sound recording;
- its **public performance**, as in a play or musical work;
- **recordings** of it, for example, in the form of compact discs, cassettes or videotapes;
- its **broadcasting**, by radio, cable or satellite; and
- its **translation** into other languages, or its **adaptation**, such as a novel into a screenplay.

### History of Copyright Law

Initially, copyright law only applied to the copying of books. The concept of copyright arose as an exclusive right of the author to copy the literature produced by him. Actually, it originated not as a shield to protect the author's right but as a sword to prevent unauthorized publication of books that were against the Church and the King during the medieval period in England, which necessitated control. The British Statute of Anne 1709 entitled, "An Act for the Encouragement of Learning, by Vesting the Copies of Printed Books in the Authors or Purchasers of such Copies, during the Times therein mentioned", was the *first copyright statute* and the subsequent *Act of Anne (8 Anne c.19)* in 1710 was the *first legislation* on copyright, which declared the author's exclusive right of copying and publishing for a limited period in the case of books and imposed criminal penalties for violations. Simultaneously, the birth of the printing press led to a manifold increase in the capacity to copy and made authors also conscious

of their rights and the profits that could be made. In 1662, Licensing Act of Charles II recognized the rights of the authors for the first time by controlling printing in a major way. With the development of society, the scope of copyright continued to expand by including things like sculpture, art, engravings etc. within its ambit by various enactments.

In 1911, the Imperial Copyright Act was passed, which consolidated the law relating to copyright through bringing different copyrightable subject matters that were governed by different legislation. The Act declared copyright to be a statutory right, settling the confusion hitherto existed as to whether copyright is common law right or statutory right. Subject matters of copyright continued to expand by including newer subject matters like cinematograph films. Copyright Act of 1956 in England substituted the 1911 Act. Copyright now covers a wide range of works, including maps, dramatic works, paintings, photographs, sound recordings, motion pictures and computer programs. **Copyright itself does not depend on official procedures. A created work is considered protected by copyright as soon as it exists.** According to the Berne Convention for the Protection of Literary and Artistic Works, literary and artistic works are protected without any formalities in the countries party to that Convention. The World Intellectual Property Organization (WIPO) does not offer any kind of copyright registration system. However, many countries have a national copyright office and some national laws allow for registration of works for the purposes.

Although there are consistencies among nations' copyright laws, each jurisdiction has separate and distinct laws and regulations about copyright. National copyright laws on licensing, transfer and assignment of copyright still vary greatly between countries and copyrighted works are licensed on territorial basis. Some jurisdictions also recognize moral rights of creators, such as the right to be credited for the work. Today, copyright laws have been standardized through international and regional agreements. The main international treaties governing the law of Copyright and Neighbouring rights are: Berne Convention, 1886; Universal Copyright Convention, 1952; Rome convention, 1961; TRIPs Agreement, 1994; WIPO Copyright Treaty, 1996; and WIPO Performance and Phonograms Treaty, 1996.

**Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)**

Important developments on copyright at international level in the 1990s include the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights, known as TRIPS Agreement. TRIPs was negotiated at the end of the Uruguay Round of the General Agreement on

Tariffs and Trade (GATT) and contains a number of provisions on copyright. Compliance with the TRIPS Agreement is required of states wishing to be members of the World Trade Organization (WTO). TRIPS agreement on copyright ensures the following:

- States need to be signatory of the Berne Convention and comply with all its provisions, except for the provision on moral rights (Article 9(1)).
- Copyright protection shall extend to expressions and not to ideas, procedures, and methods of operation or mathematical concepts as such.
- Computer programs will be protected as literary works under the Berne Convention which also outlines how databases should be protected (Article 10).
- States need to provide for rental rights in at least computer programs and films (Article 11). Authors of computer programs and producers of sound recordings must have the right to prohibit the commercial rental of their works to the public. A similar exclusive right applies to films where commercial rental has led to widespread copying, affecting copyright - owners' potential earnings from their films.
- Where copyright term, that is duration of copyright, is calculated other than by reference to the life of a natural person, States need to give a minimum term of 50 years calculated from either the date of authorized publication or the creation of the work.
- Performers must also have the right to prevent unauthorized recording, reproduction and broadcast of live performances (bootlegging) for no less than 50 years.
- Producers of sound recordings must have the right to prevent the unauthorized reproduction of recordings for a period of 50 years.

**Indian Law for the Protection of Copyright**

In India also, simultaneous developments took place with the Indian Copyright Act of 1847 based on the 1842 Act in England. The Indian Copyright Act, 1914 was an extension of the Copyright Act, 1911, to India with necessary modifications and then in 1957, a new Copyright Act was passed which was modeled along the English Copyright Act of 1956. The Copyright Act, 1957 today is compliant with the most international conventions and treaties in the field of copyrights. This Act protects the works such as 'original' literary, dramatic, musical and artistic works, and cinematograph films and sound recording from unauthorized uses. The Copyright Act, 1957, as amended in the years 1984, 1994 and 1999, to accommodate the obligations under international treaties, governs the present law relating to copyright.

Copyright is a bundle of exclusive rights granted by statute to the author of the works to exploit or authorize the exploitation of the copyright work, based on international norms like Berne Convention, TRIPs Agreement and WIPO Copyright Treaty (WCT). India is a member of the Berne Convention of 1886 (as modified at Paris in 1971), the Universal Copyright Convention of 1951 and TRIPS. Though India is not a member of the Rome Convention of 1961, the Copyright Act, 1957 is fully compliant with the provisions of this Convention.

The Collection of Laws for Electronic Access (CLEA) database of WIPO can be consulted to search copyright laws of a wide range of countries. Under most national copyright laws, it is permissible to use limited portions of a work, including quotes, for purposes such as news reporting and private personal use. These treaties were negotiated essentially to provide for protection of the rights of copyright holders, performers and producers of phonograms in the Internet and digital era. Although India is not a member of these treaties, the current set of amendments made seeks to bring the Copyright Act law in conformity with these treaties.

Along with the copyright for the author, various neighbouring rights to protect the interests of performers, broadcasters etc. have also developed to safeguard their interests. "Performers rights" was introduced as Section 38 by the 1994 amendment to the Copyright Act in India. Under Performer's rights, protection is given to various types of performers like actors, dancers, musicians, jugglers, acrobats etc. These rights are also available for a period of 25 years and guarantee rights such as reproduction of sound or visual recording of the performances and its broadcast or other communication to the public etc. Under Section 37 right known as "Broadcasting Reproducing Right" is given to every broadcasting organization in respect of its broadcasts for a period of 25 years.

The Copyright (Amendment) Bill, 1999 seeks to comply with the TRIPs requirements. Under Article 14 of the TRIPs agreement, the term of protection, available to performers, shall last at least until the end of a period of fifty years computed from the end of the calendar year in which the performance takes place. Section 38 of the Indian Copyright Act, 1957, *inter alia*, provided for the performers' right to subsist for twenty five years from the beginning of the next calendar year following the year in which the performance had taken place. Thus, the amended Act has extended the term of protection of performers' rights from twenty five to fifty years. A new section has been inserted after Section 40 of the principal Act and provides for power to the Government to extend the provisions of the Copyright act to broadcasts and performances made

in other countries, provided these countries extend similar protection to broadcasts and performance made in India. This provision shall benefit Indian broadcasting organizations and performers and allow them to receive reciprocal protection for their rights in other countries, which are signatories to TRIPs. This has ushered in comprehensive changes and brought the copyright law in line with the development in satellite broadcasting, computer software and digital technology. The amended law has made provisions for the first time, to protect performer's rights as envisaged in the Rome Convention. Several measures have been adopted to strengthen and streamline the enforcement of copyrights. These include the setting up of a Copyright Enforcement Advisory Council, training programs for enforcement officers and setting up special policy cells to deal with cases relating to infringement of copyrights.

Copyright is a set of exclusive rights granted to the author or creator of an original work and implies protection against copying, distributing and adapting of his work by another. The interesting aspect of copyright protection is that the acquisition of copyright is automatic and it does not need any protection under law, i.e., it does not require any formality of registration with any authority. Copyright comes into existence as soon as a work is created. Unlike the case with patents, copyright protects the expressions or fixation and not the ideas, procedures, and methods of operation or mathematical concepts as such. That is, it protects only the tangible expression of an idea and not an idea itself. This has led to many a litigation to settle the idea-expression dichotomy. Registration of a work with the copyright registry in the country provides evidence of the existence of a work on a given date. The registration also creates a *prima facie* evidence about the facts about the work stated in the application for registration. These are of help in settling legal disputes regarding ownership and infringement, even though they are not direct evidence of ownership by themselves.

Copyright owners have the exclusive statutory right to exercise control over copying and other exploitation of the works for a specific period of time, after which the work is said to enter the public domain. Uses which are covered under limitations and exceptions to copyright, such as fair use, do not require permission from the copyright owner. All other uses require permission and copyright owners can license or permanently transfer or assign their exclusive rights to others.

**Use of the "©" symbol**

When a work is published by authority of the copyright owner, a notice of copyright may

be placed on publicly distributed copies. As per the Berne Convention for protection of literary and artistic works, to which India is a signatory, use of copyright notice is optional. It is, however, a good idea to incorporate a copyright notice. Anyone who claims copyrights in a work can use copyright notice to alert the public of the claim. It is not necessary to have a registration to use the designations though it is highly advisable to incorporate a copyright notice like the symbol, Letter "c" in a circle "©" or the word "Copyright" followed by name of copyright owner and year of first publication, e.g., TNAU, 2014.

**Copyright Law and Patent Law**

Copyright law and patent law provide different types of protection. Copyright protects only to expressions, such as novels, poems, films, musical compositions, paintings etc. whereas a patent is an exclusive right granted for an invention, which is a product or a process. Copyright protection is formality-free in countries party to the Berne Convention for the Protection of Literary and Artistic Works, which means that protection does not depend on compliance with any formalities such as registration or deposit of copies. A patent is granted after completing an examination procedure by a government agency.

## Is computer software protected by copyright?

In the 1970s and 1980s, there were extensive discussions on whether the patent system, the copyright system, or a *sui generis* system, should provide protection for computer software. These discussions resulted in the generally accepted principle that computer programs should be protected by copyright, whereas apparatus using computer software or software-related inventions should be protected by patent. In India, computer software is patentable, if embedded with hardware. Previously, the Intellectual Property Rights (IPR) protections with regard to software are limited to copyrights. According to the Section 14 of the Copyright Act, the computer program is considered to be literary work and protected as such.

**Geographical Indications (GIs)**

The term "Geographical Indications(GI)" in relation to goods means an indication which identifies such goods as agricultural goods, natural goods or manufactured goods as originating, or manufactured in the territory of a country, or a region or locality in that territory, where a given quality, distinctiveness, reputation or other characteristics of such goods is essentially attributable to its geographical origin and in case where such goods are manufactured goods, one

of the activities of either the production or of processing or preparation of the goods concerned takes place in such territory, region or locality, as the case may be.

Most geographical indications relate to agricultural products as those derived from them, more specifically as in the case of wines and spirits. For example, "Tuscany" for olive oil produced in a specific area of Italy (protected, for example, in Italy by Law No. 169 of February 5, 1992), or "Roquefort" for cheese produced in France (protected, for example, in the European Union under Regulation (EC) No. 2081/92, and in the United States under US Certification Registration Mark No. 571.798), or Champagne wine for a sparkling wine produced from grapes grown in the Champagne region of France and Scotch whisky. During the December 1998 TRIPS Council meeting, the following geographical indications were noted as protected in the respective territories of the countries:

- China: Chinese silk
- United States: Idaho potatoes, Washington State apples, Vidalia onions and Florida oranges.
- Bulgaria: Bulgarian yoghurt, Traminer from Khan Kroum (wine) and Merlou from Sakar (wine)
- Canada: Canadian" Rye Whisky and Canadian Whisky.
- Czech Republic: Pilsen and Budweis (beers), various wines, liqueurs, Saaz hops, Auscha hops, Jablonec jewellery, Bohemia crystal and Vamberk lace.
- European Communities: Venetian glass; Champagne, Sherry, Porto, Chianti, Samos, Rheinhessen, Moselle Luxembourgeoise, Mittleburgenland (all wines); Cognac, Brandy de Jerez, Grappa di Barolo, Berliner Kümmel, Genièvre Flandres Artois, Scotch Whisky, Irish Whiskey, Tsikoudia (from Crete) (all spirits); and a range of other products, such as Newcastle brown ale, Scottish beef, Orkney beef, Orkney lamb, Jersey Royal potatoes, Cornish Clotted Cream, Cabrales, Tequila, and Roquefort cheese.
- Hungary: Eger (wine) and Szatrademarkar (plum).
- Liechtenstein: Malbuner (meat products) and Balzer (Hi-tech products).
- Slovak Republic: Korytnická minerálna voda (mineral water), Karpatská perla (wine), Modranská majolica (hand-painted pottery) and Piešťanské bahno (healing mud).
- India: Darjeeling tea is among the 28 Indian products registered with the Geographical Indications (GI) Registry (Darjeeling tea has been registered twice in the GI Registry). The other products registered are: Pochampally Ikat (Andhra Pradesh); Chanderi saree (Guna,

Madhya Pradesh); Kotpad Handloom fabric (Koraput, Orissa); Kota Doria (Kota, Rajasthan); Kancheepuram silk saree (Tamil Nadu); Bhavani Jamakkalam (Erode, Tamil Nadu); Mysore Agarbathi (Mysore, Karnataka); Aranmula Kannadi (Kerala); Salem fabric (Tamil Nadu); Solapur terry towel (Maharashtra); Mysore silk (Karnataka); Kullu shawl (Himachal Pradesh); Madurai Sungudi saree (Tamil Nadu); Kangra tea (Himachal Pradesh); Coorg Orange (Karnataka); Mysore betel leaf (Karnataka); Nanjangud banana (Karnataka); Mysore sandal wood oil (Karnataka); Mysore sandal soap (Karnataka); Bidriware (Karnataka); Channapatna toys and dolls (Karnataka); Coimbatore wet grinder (Tamil Nadu); Mysore rose wood inlay (Karnataka); Kasuti embroidery (Karnataka); Mysore traditional paintings (Karnataka) and Orissa Ikat (Orissa).

**Need for Protection of Geographical Indications**

- History speaks of Christopher Columbus charting out a new route to India, lured by the wealth of its spices, while English breeders imported Albian horses to sire Derby winner's. China silk, Dhaka muslin, Venetian glass all have reputations carefully built up and meticulously maintained by the masters of that region, combining the best of nature and man. False use of geographical indications by unauthorized parties is detrimental to consumers and legitimate producers. The former are deceived and led into believing to buy a genuine product with specific qualities and characteristics, while they in fact get a worthless imitation. The latter suffer damage because valuable business is taken away from them and the established reputation for their products is damaged.
- Besides the commercial aspect, the GIs also protect the usurpation of the national heritage of a country by associating a product worldwide with a particular country. As the quality of product is not only attributable to the climate, topography but also to the know-how of the producers of the region, the GIs are also important tools for protecting the traditional knowledge of the producers. GIs have emerged as one of the important features of the IPR regime of India. After the Geographical Indications Act came into force on September 15, 2003, many famous products of India such as Darjeeling tea, Ponchampalli and Chanderi silk have been notified as GIs.

**Advantages of Registering a Geographical Indication**

- While registration of a Geographical Indication is not compulsory, it offers better legal protection for action for infringement.

- The registered proprietor and authorized users can exercise an exclusive right to use the Geographical Indication in relation to goods in respect of which it is registered and they can prevent unauthorized use of a Registered Geographical Indication by others.
- It provides legal protection to Indian Geographical Indications which in turn boost exports and promotes economic prosperity of producers of goods produced in a geographical territory.

**Geographical Indications Protected on the International Level**

A number of treaties administered by the World Intellectual Property Organization (WIPO) provide for the protection of GIs, most notably the Paris Convention for the Protection of Industrial Property of 1883 and the Lisbon Agreement for the Protection of Appellations of Origin and Their International Registration. Under Articles 1(2) and 10 of the Paris Convention for the Protection of Industrial Property, GIs are covered as an element of IPRs. In addition, Articles 22 to 24 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) deal with the international protection of GIs within the framework of the World Trade Organization.

Member countries must provide legal means so that "interested parties" can stop the use of such geographical indications for products that do not originate from the used place name or do not have the usual characteristics associated with that place name. Protection of such marks prevents third parties from passing off their products as those originating in the given region. India has requested for additional protection, as given to wines and spirits, be extended to other products as well under Article 24 of TRIPS. This was addressed in the Doha Declaration too but due to subsequent confusion among member countries on other issues, this could not be sorted out as proposed during the Cancun summit.

**TRIPS Agreement on Geographical Indications**

- Wine and spirits makers are particularly concerned about the use of place-names to identify products, and the TRIPS Agreement contains special provisions for these products. But the issue is also important for other types of goods.
- Using the place name when the product was made elsewhere or when it does not have the usual characteristics can mislead consumers, and it can lead to unfair competition. The TRIPS Agreement says countries have to prevent this misuse of place names.
- For wines and spirits, the agreement provides higher levels of protection, i.e., even where there is no danger of the public being misled.

- Some exceptions are allowed, for example, if the name is already protected as a trademark or if it has become a generic term. For example, "cheddar" now refers to a particular type of cheese not necessarily made in Cheddar, in the UK. But any country wanting to make an exception for these reasons must be willing to negotiate with the country which wants to protect the geographical indication in question.

One of the most important conditions that most governments have required before registering a name as a GI is that the name must not already be in widespread use as the generic name for a similar product. Of course, what is considered a very specific term for a well-known local specialty in one country may constitute a generic term or genericized trademark for that type of product. For example, Parmigiano cheese in Italy is generically known as Parmesan cheese in Australia and the United States.

**Indian Law for the Protection of Geographical Indications**

WTO Members and their nationals are increasingly recognizing that GIs are valuable as marketing tools in the global economy. The TRIPS Agreement is the, first multilateral agreement dealing with GIs. GIs are protected in accordance with national laws and under a wide range of concepts, such as laws against unfair competition, consumer protection laws, laws for the protection of certification marks or special laws for the protection of geographical indications. India, as a member of the World Trade Organization (WTO), enacted the **Geographical Indications of Goods (Registration and Protection) Act, 1999** which has come into force with effect from 15$^{th}$ September 2003. The Act is administered by the Controller General of Patents, Designs and Trade Marks who is the Registrar of Geographical Indications. The Geographical Indications Registry is located at Chennai in July 2001.

Unless a geographical indication is protected in the country of its origin, there is no obligation under the TRIPs Agreement for other countries to extend reciprocal protection. Nevertheless, it is difficult to get similar protection in other countries, even if the GIs are accorded protection within a country. This could be achieved through bilateral agreements. So, if India and the EU decide to include GIs in the trade and investment agreement that they are currently negotiating, they would be according protection to their GIs in each other's markets.

According to the Act, the term 'geographical indication', means an indication which identifies goods such as agricultural or manufactured goods as originating, or manufactured in a country, or a region, whose characteristics are essentially attributable to the geographical area.

The features of the GI Act, 1999 include: Registration of GI in specified classes, Prohibition of registration of certain GI, compulsory advertisement of all accepted GI, provision of infringement, higher level of protection, GI prohibited for registration as Trade Mark, appeal provision, penalties and protection of homonymous GI. The Act provides for activities of processing in case of manufactured goods.

**Difference between a Geographical Indication and a Trademark**

Geographical indications serve the same functions as trademarks, because like trademarks they are: (a) source-identifiers; (ii) guarantees of quality, (iii) and valuable business interests. However, the differences between GI and Trademark could be explained as follows:

A trademark is a sign used by an enterprise to distinguish its goods and services from those of other enterprises. It gives its owner the right to exclude others from using the trademark. A geographical indication tells consumers that a product is produced in a certain place and has certain special characteristics that are due to that place of production. It may be used by all producers who make their products in the place designated by a GI and whose products share typical qualities. Whereas Trademark identifies the products with the manufacturer, the GIs identify products with the place of production or origin. Another important difference is that the GIs are the community rights whereas the trademark is individual right. As regards the use, the Trademark can be assigned as well as licensed, but a Geographical indication is a public property belonging to the producers of the concerned goods. GI shall not be subject matter of assignment, transmission, licensing, pledging, mortgaging or such other agreement. However, when an authorized user dies, his right devolves on his successor in title.

**"Generic" Geographical Indication**

If a geographical term is used as the designation of a kind of product, rather than an indication of the place of origin of that product, this term does no longer function as a geographical indication. Where that has occurred in a certain country over a substantial period of time, that country may recognize that consumers have come to understand a geographical term that once stood for the origin of the product - for example, "Dijon Mustard," a style of mustard originally from the French town of Dijon - to denote now a certain kind of mustard, regardless of its place of production.

**Difference between Geographical Indication and Appellation of Origin**

A geographical indication is a sign used on goods that have a specific geographical origin

and possess qualities or a reputation that are due to that place of origin. Geographical indications may be not only place names but also other names and indicators used to refer to a product. On the other hand, an appellation of origin is a special kind of geographical indication, used on products that have a specific quality that is exclusively or essentially due to the geographical environment in which the products are produced. All appellations are geographical indications but all geographical indications need not be appellations. Agricultural products typically have qualities that derive from their place of production and are influenced by specific local factors, such as climate and soil. Thus, the concept of appellations of origin is subsumed in that of geographical indication.

Appellation of origin is a geographic indication that declares the quality of goods derived essentially or exclusively from an area of production. This instrument is being administered by WIPO as per Lisbon Agreement, 1958 and was limited to some EU countries *viz.*, Italy, France etc. Plant varieties developed with traditional knowledge and associated with a particular region can also be protected as GIs. The advantage in such protection is that there is no limitation of time but the benefits from this protection emanates over time and familiarity.

**Application for the Registration of a Geographical Indication**

- Any association of person, producers, organization or authority established by or under the law can apply for the Registration of a GI. Their name should be entered in the Register of Geographical Indication as a registered proprietor for the Geographical Indication applied for.
- The applicant must represent the interests of the producers.
- The application should be in writing in the prescribed Form.
- The application should be addressed to the Registrar of GI along with prescribed fee.

**Authorized User:** A producer of goods can apply for registration as an authorized user, with respect to a registered GI. He should apply in writing in the prescribed form along with prescribed fee.

**Producer in relation to a Geographical Indication:** A Producer is a person dealing with the following three categories of goods:

- Agricultural Goods including the production, processing, trading or dealing.
- Natural Goods including exploiting, trading or dealing.
- Handicrafts or Industrial Goods including making, manufacturing, trading or dealing.

**Geographical Indications Used for Products Other than of Agricultural Products:** The use

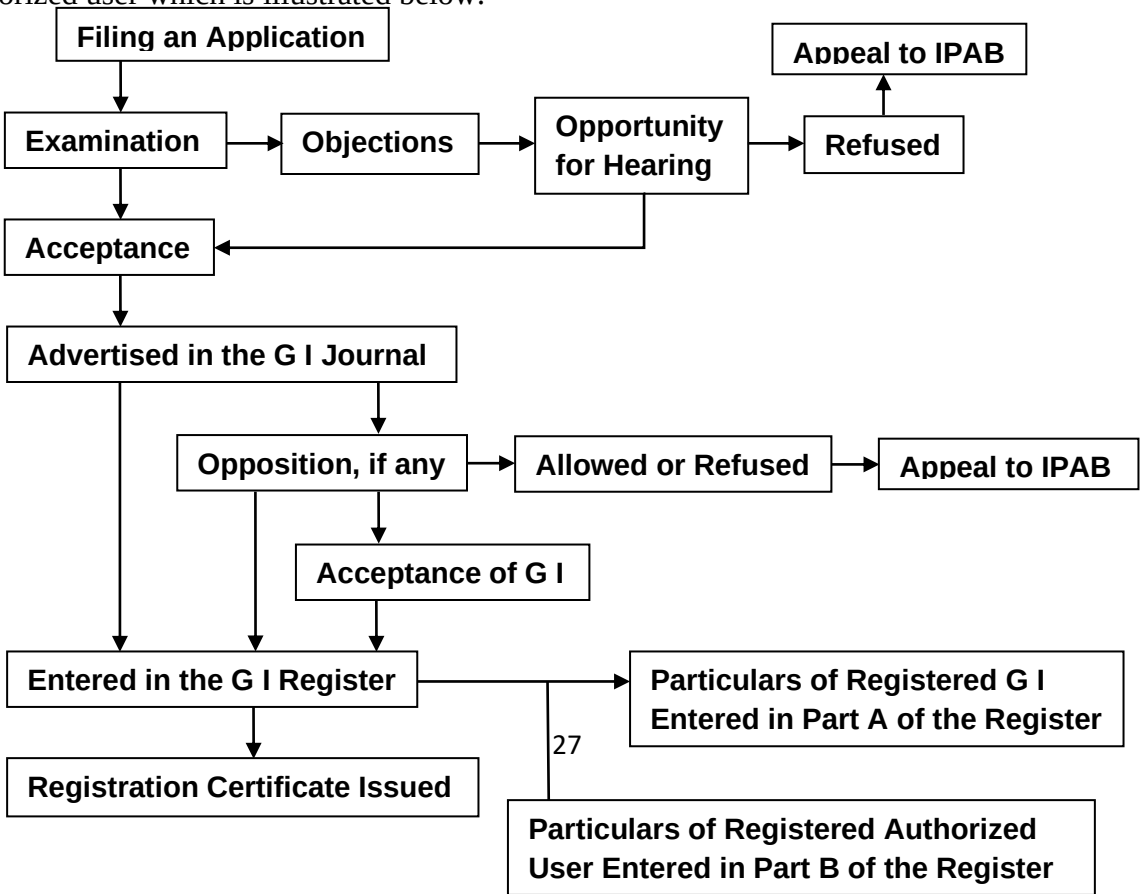
of geographical indications is not limited to agricultural products. They may also highlight specific qualities of a product which are due to human factors that can be found in the place of origin of the products, such as specific manufacturing skills and traditions. That place of origin may be a village or town, a region or a country. An example for the latter is "Switzerland" or "Swiss," which is perceived as a geographical indication in many countries for products that are made in Switzerland and, in particular, for watches.

**Products that cannot be registered as geographical indications are those products:**

- the use of which would be likely to deceive or cause confusion or contrary to any law;
- which comprises or contains scandalous or obscene matter or any matter likely to hurt religion susceptibility of any class or section of citizens of India which would otherwise be disentitled to protection in a court; and
- which are determined to be generic names or indications of goods and are, therefore, not or ceased to be protected in their country of origin or which have fallen into disuse in that Country which, although literally true as to the territory, region or locality in which the goods originate, but falsely represent to the persons that the goods originate in another territory, region or locality, as the case may be.

**The Registration Process of a Geographical Indication**

The registration process is similar to both for registration of a geographical indication and authorized user which is illustrated below.



The Register of Geographical Indication is divided into two parts. Part 'A' consists of particulars relating to registered geographical indications and part 'B' consists of particulars of the registered authorized users.

**Term of Registration of Geographical Indication**

- The registration of a GI shall be for a period of ten years but may be renewed from time to time for an unlimited period by payment of the renewal fees.
- Renewal is possible for further periods of 10 years each.
- If a Registered GI is not renewed, it is liable to be removed from the register.

**Removal of a registered Geographical Indication or authorized user from the register:** The Appellate Board or the Registrar of Geographical Indication has the power to remove the Geographical Indication or an authorized user from the register. The aggrieved person can file an appeal within three months from the date of communication of the order and in such case, necessary action can be taken.

**Infringement of a registered Geographical Indication**

- When unauthorized use indicates or suggests that such goods originate in a geographical area other than the true place of origin of such goods in a manner, which misleads the public as to their geographical origins of such goods.
- When use of Geographical Indication results in unfair competition including passing off in respect of registered geographical indication.
- When the use of another geographical indication results in false representation to the public that goods originate in a territory in respect of which a geographical indication relates.
- A sentence of imprisonment for a term between six months and three years and a fine between Rs. 50,000 and Rs. two lakhs is provided in the Act as the punishment in the Act for falsifying GI. The court may reduce the punishment under special circumstances.

**Challenges in the Protection of Geographical Indications**

The initiative to obtain GIs protection for Pochampalli ikat came out of the efforts by industry associations and the state government to revive the cluster of the textile industry in a group of villages near Hyderabad, Andhra Pradesh. This involved organizing the weavers into two associations, depending on the raw material they were using and introducing various standards before moving the application for registration. Similar steps had to be undertaken in the case of Chanderi sari. The crucial issue was creation of awareness among stakeholders.

The economic consequences of registration of GIs for a developing country are difficult to assess. The main economic benefit of geographical indications would be to act as a quality mark which will play a part in enhancing export markets and revenues. But increased protection, particularly applied internationally, may adversely affect local enterprises which currently exploit GIs that may become protected by another party. Thus there will be losses to countries producing substitutes for goods that become protected by GIs.

For those countries, seeking and enforcing protection for geographical indications abroad may have economic gains. However, the costs involved in such actions, especially enforcement, might be prohibitively high. In addition, prior to seeking protection abroad, it is necessary both to develop and protect the geographical indication in the country of origin.

## Lecture 4. Trade Marks, Industrial Designs and Layouts and Trade Secrets

### Trademark

In order to widen the horizon of industrial activity, trademarks protection is given for an industrial product by the Government so that the public can identify as to from whom the product is emanating. A **trademark** or **trade mark** (popularly known as brand name in layman's language) is a distinctive visual symbol used by a specific person or an enterprise or legal entity or an undertaking on goods or services or other articles of commerce to distinguish them from other similar goods or services originating from a different undertaking. The right to proprietorship of a trade mark may be acquired by either registration under the Act or by use in relation to particular goods or service.

- A trademark indicates the following: an abbreviation, element, hologram, phrase, logo, symbol, design, image, name (including personal or surname of the applicant or predecessor in business or the signature of the person) or a combination of these elements;
- An invented word or any arbitrary dictionary word or words, not being directly descriptive of the character or quality of the goods or services;
- Letters or numerals or any combination thereof;
- Devices, including fancy devices or symbols;
- Monograms;
- Combination of colors or even a single color in combination with a word or device; and
- Sound marks when represented in conventional notation or described in words by being graphically represented.

There is also a range of non-conventional trademarks comprising marks such as those based on drawings, three - dimensional signs such as shape and packaging of goods, audible signs such as music or vocal sounds, fragrances, or colours used as distinguishing features.

### Advantages of Trade Mark

i) Owner of trademark has the **exclusive right** to use the trademark to identify the goods or services produced or provided by him, or to authorize another to use it in return for payment.

ii) In a larger sense, trademarks promote enterprises worldwide by rewarding the owners of trademarks with recognition and financial profit.

iii) Trademark enables people with skill and enterprise to produce and market goods and

services in the fairest possible conditions, thereby facilitating international trade.

iv) Trademark protection prohibits the efforts of unfair competitors, such as counterfeiters, to use similar distinctive signs to market inferior or different products or services.

v) It guarantees the identity of the physical origin of goods and services.

vi) The system of trademark registration and protection helps consumers to identify the nature and quality of a product or service by its unique trademark. The brand itself is the seal of authenticity.

vii) It creates an image for the goods or services and stimulates the customer further purchase.

viii) It serves as a badge of loyalty and affiliation. It may enable consumer to make a life style or fashion statement.

Thus, the trademark helps to identify the product and its origin, guarantees its unchanged quality and advertises the product. It also confers on the proprietor a kind of monopoly right over the use of the mark, essential to protect it and the goodwill attached to it, and prevents the use of fraudulent marks on merchandise.

**Types of Trade Marks**

The following are the different types of trademarks:

**i) Generic Trade Marks:** Words, symbols or devices that are not so distinctly distinguishing the goods from others are at the weakest ends, as they are common terms used to identify the goods themselves. These are termed as generic terms and are not protectable as trademarks.

**ii) Descriptive Trade Marks:** Descriptive trademarks clearly denote or inform the specific purpose, functions, physical characteristic and end use of the product.

**iii) Suggestive Trade Marks:** Suggestive trademarks do not at a glance describe the goods for which the mark is used; yet they rather require some imagination or perception to arrive at a conclusion about the nature of the goods. These are inherently distinctive and protectable.

The other types of trademarks include arbitrary marks and fanciful marks which are inherently distinctive. In addition to trademarks, several **other categories of marks** exist.

**i) Collective Marks** are owned by an **association** whose members (not being a partnership within the meaning of the Indian Partnership Act, 1932) use them to identify themselves with a level of quality and other requirements set by the association. Examples of such associations would be those representing accountants, engineers, or architects.

**ii) Certification Marks** are given for compliance with defined standards, but are not confined to any membership. They may be granted to anyone who can certify that the products involved **meet certain established standards.** These marks are capable of distinguishing the goods or services which are certified by the proprietor of the mark in respect of origin, material, mode of manufacture of goods or performance of services, quality, accuracy or other characteristics from goods or services not so certified and registrable as such under Chapter IX in respect of those goods or services in the name as proprietor of the certification trade mark, of that person. The internationally accepted "ISO: 9000" quality standards are an example of such widely-recognized certifications.

**iii) Service Marks:** Service means service of any description which is made available by potential users and includes the provision of services in connection with business of any industrial or commercial matters such as banking, communication, education, financing, insurance, chit funds, real estate, transport, storage, material treatment, processing, supply of electrical or other energy, boarding, lodging, entertainment, amusement, construction, repair, conveying of news or information and advertising.

A trademark is designated by the following symbols:

- ™ - for an unregistered trademark, that is, a mark used to promote or brand goods
- SM - for an unregistered service mark, that is, a mark used to promote or brand services
- ® - for a registered trademark.

**Registration of Trade Mark – Global Scenario**

Almost all countries in the world register and protect trademarks. Each national or regional office maintains a **Register of Trade Marks** which contains full application information on all registrations and renewals, and potential opposition by third parties. In order to avoid the need to register separately with each national or regional office, WIPO administers a system of international registration of marks. This system is governed by two treaties, the **Madrid Agreement Concerning the International Registration of Marks** and the **Madrid Protocol**. A person (who has a link through nationality, domicile or establishment) with a country party to one or both of these treaties may, on the basis of a registration or application with the trademark office of that country, can obtain an international registration having effect in some or all of the other countries of the **Madrid Union**. The Madrid Agreement Concerning the International Registration of Marks, which dates from 1891, and the Protocol Relating to the

Madrid Agreement, which was adopted in 1989, entered into force on December 1, 1995, and came into operation on April 1, 1996. The Agreement facilitates protection of a trademark or service mark in several countries by means of a single international registration. The Agreement covers both trademarks and service marks.

The distinguishing trademarks constitute protectable subject matter under the provisions of the TRIPS Agreement. Registration of trademark is issued for definite period of time. However, in order to avoid confusion, encourage competitions and protect the inventor's good will, the registration may be renewed. With reference to intellectual property area, trademarks are national in origin and should comply with provision of TRIPS agreement.

The owner of a registered trademark may commence legal proceedings for trademark infringement to prevent unauthorized use of that trademark. However, registration is not required. The owner of a common law trademark may also file suit, but an unregistered mark may be protectable only within the geographical area within which it has been used or in geographical areas into which it may be reasonably expected to expand.

The term *trademark* is also used informally to refer to any distinguishing attribute by which an individual is readily identified, such as the well known characteristics of celebrities. When a trademark is used in relation to services rather than products, it may sometimes be called a service mark, particularly in the United States.

The law considers a trademark to be a form of property. Trademark protection is enforced by the courts, which also have the authority to block trademark infringement. Proprietary rights in relation to a trademark may be established through actual use in the market place, or through registration of the mark with the trademarks office (or "trademarks registry") of a particular jurisdiction. In some jurisdictions, trademark rights can be established through either or both means. Certain jurisdictions generally do not recognize trademarks rights arising through use. If trademark owners do not hold registrations for their marks in such jurisdictions, the extent to which they will be able to enforce their rights through trademark infringement proceedings will therefore be limited. In cases of dispute, this disparity of rights is often referred to as "first to file" as opposed to "first to use." Other countries such as Germany offer a limited amount of common law rights for unregistered marks where to gain protection, the goods or services must occupy a highly significant position in the marketplace — where this could be 40 per cent or more market share for sales in the particular class of goods or services.

Once trademark rights are established in a particular jurisdiction, these rights are generally only enforceable in that jurisdiction, a quality which is sometimes known as **territoriality**. However, there is a range of international trademark laws and systems which facilitate the protection of trademarks in more than one jurisdiction.

**TRIPS Agreement on Trademarks**

The agreement defines what types of signs must be eligible for protection as trademarks, and what are the minimum rights to be conferred on their owners. It says that service marks must be protected in the same way as trademarks used for goods. Any sign, or any combination of signs, particular words including personal names, letters, numerals, figurative elements and combinations of colours, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be eligible for registration as trademarks. Where signs are not inherently capable of distinguishing the relevant goods or services, Members may make registrability depending on distinctiveness acquired through use. Members may require, as a condition of registration, that signs be visually perceptible.

- Members may make registrability depending on use. However, actual use of a trademark shall not be a condition for filing an application for registration. An application shall not be refused solely on the ground that intended use has not taken place before the expiry of a period of three years from the date of application.
- Members shall publish each trademark either before it is registered or promptly after it is registered and shall afford a reasonable opportunity for petitions to cancel the registration or for the registration of a trademark to be opposed.
- The owner of a registered trademark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed. The rights described above shall not prejudice any existing prior rights, nor shall they affect the possibility of Members making rights available on the basis of use.
- Initial registration and each renewal of registration, of a trademark shall be for a term of no less than seven years. The registration of a trademark shall be renewable indefinitely.

- Members may determine conditions on the licensing and assignment of trademarks, it being understood that the compulsory licensing of trademarks shall not be permitted and that the owner of a registered trademark shall have the right to assign the trademark with or without the transfer of the business to which the trademark belongs.

**Indian Law for the Protection of Trademarks**

In view of developments in trading and commercial practices, increasing globalization of trade and industry, the need to encourage investment flows and transfer of technology and the need to simplify and harmonize trademark registration / management systems, it became necessary to bring out legislation on the subject. Accordingly, a comprehensive review of the Trade and Merchandise Marks Act, 1958 led to a Bill to repeal and replace the 1958 Act has since been passed by Parliament and notified in the Gazette on 30.12.1999. **The Trademarks Act, 1999 brought into force with effect from September 15, 2003.** The Act, 1999 was enacted to amend and consolidate the law relating to trademarks, to provide for registration and better protection of trademarks for goods and services and for the prevention of the use of fraudulent marks. This act not only makes trademarks law compliant with TRIPS, but also harmonizes it with international systems and practices. Enactment of the Trademarks Act 1999 is a big step forward from the Trade and Merchandise Marks Act 1958 and the Trademark Act 1940.

According to the Trademarks Act, 1999, 'trademark' means (i) a mark capable of being represented graphically and which is capable of distinguishing the goods or services of one person from those of others and may include shape of goods, their packing and combination of colours; (ii) a device, brand, heading, label, ticket, name, signature, word, letter, numeral, or any combination thereof. However, the definition of mark under the Act can be other than those mentioned in the definition also. For e.g., there could be a smell mark; and (iii) a mark used or proposed to be used in relation to goods or services for the purpose of indicating or so as to indicate a connection in the course of trade between the goods or services, as the case may be, and some person having the right, either as proprietor or by way of permitted user, to use the mark whether with or without any indication of the identity of that person, and includes a certification trademark or collective mark. In addition to this, such mark should represent the goods or services of one person (includes legal persons like company) and be capable of distinguishing the goods it represents from that of other persons.

**Legal requirements** to register a trademark under the Indian Trade Marks Act, 1999 are:

- The selected mark should be represented graphically (that is, in the paper form).
- It should be used or proposed to be used in relation to goods or services for the purpose of indicating a connection in the course of trade between the goods or services and some person having the right to use the mark with or without identity of that person.
- To choose a trademark, it is advisable to undertake a comprehensive search that includes both market study as well as a study of data base of the country one chooses to trade in, for ascertaining if same/similar mark is used in market.
- If it is a word, it should be easy to speak, spell and remember.
- The best trademarks are invented words or coined words.
- Avoid selection of a geographical name. No one can have monopoly right on it.
- Avoid adopting laudatory word or words that describe the quality of goods (such as best, perfect, super etc)
- **Avoid marks which:**
  - are descriptive;
  - have reference to character and quality of goods;
  - may serve in a trade to designate the intended purpose;
  - can be considered for registration on acquiring a distinctive character as a result of the use;
  - is a well known mark by virtue of extensive publicity;
  - is of such a nature as to deceive the public or likely to cause confusion;
  - is likely to hurt the religious susceptibilities of any class or citizen or society;
  - is containing scandalous or obscene matter which has Marks prohibited under law; e.g., Emblems and Names (Prevention of Improper Use) Act, 1950 or direction of the Central Government listing the non registrable marks; and
  - is containing official seals and identical marks.

**The newly enacted Act has some features not present in the 1958 Act and these are**:-

- Registration of service marks, collective marks and certification trademarks allowed for the first time in India.
- Exhaustive definitions for terms frequently used
- Simplified procedure for registration of registered users and enlarged scope of permitted use.

- Constitution of an Appellate Board for speedy disposal of appeals and rectification of applications which at present lie before High Court.
- Definition of trademark has been enlarged to include shape of goods, packaging and combination of colours which can be adopted as a trademark.
- Marks used in commerce can be applied to both agricultural and industrial products and services. For instance, trademarks are used to market seeds or spraying services and need to be built for an advantage.
- Single registration of trademark is permitted; a single application would be sufficient and no separate application is necessary for each category / class of goods or services; however, filing fee will be charged separately for each class of goods / services.
- The Act prescribes offences, penalties and procedures. Punishment has been enhanced for the offences relating to trademark on par with the Copyright Act, 1957 to prevent the sale of spurious goods. Further, the Act deals with criminal remedy for the trademark violation.
- Increasing the period of registration and renewal from 7 years to 10 years. The trademark is initially registered for a period of 10 years, which is calculated from the date of filing of the application and in case of convention application, from the date of priority. The registration is required to be renewed within 6 months before the date of expiry of the registration, i.e., 10 years from the date of the application or subsequent renewals. The renewal can be done from time to time for an unlimited period by payment of the renewal fees.
- Extension of application of convention countries in India.
- Compulsory licensing of trademark is not permitted.

**Registration of a Trademark in India**

The Trade Marks Registry was established in India in 1940 and presently it administers the Trade Marks Act, 1999 and the rules thereunder. It acts as a resource and information centre and is a facilitator in matters relating to trade marks in the country. The objective of the Trade Marks Act, 1999 and Rules, 2002 is to register trademarks applied for in the country and to provide for better protection of trademark for goods and services and also to prevent fraudulent use of the mark. The main function of the Registry is to register trademark which qualifies for registration under the Act and Rules.

**Benefits of Registering a Trademark**

The registration of a trade mark confers upon the owner the exclusive right to the use of the registered trademark and indicates so by using the symbol (R) in relation to the goods or services in respect of which the mark is registered and seek the relief of infringement in appropriate courts in the country. The exclusive right is however subject to any conditions entered on the register such as limitation of area of use etc. Also, where two or more persons have registered identical or nearly similar mark due to special circumstances, such exclusive right does not operate against each other.

**Procedure for Registration of Trade Marks**

First, an application for registration of a trademark must be filed at the head office or regional trademark office according to territorial jurisdiction. Trade Marks Registry is located at Mumbai (Head Quarters), Chennai, Delhi, Kolkata and Ahmadabad. The application must contain a clear reproduction of the sign filed for registration, including any colours, forms, or three-dimensional features. The application must also contain a list of goods or services to which the sign would apply. It must be distinctive, so that consumers can distinguish it as identifying a particular product. It must neither mislead nor deceive customers or violate public order or morality. Finally, the rights applied for cannot be the same as, or similar to, rights already granted to another trademark owner. This may be determined through search and examination by the national office or by the opposition of third parties who claim similar or identical rights.

**Protection of Undisclosed Information including Trade Secrets**

The protected subject matter is information lawfully within the control of a natural person or legal person, that is, a secret that has a commercial value. It is a secret because it has been subject to reasonable steps by the person lawfully in control of the information, to keep it secret. Secret is defined in the sense that it is not, as a body or in the precise configuration and assembly of its components, known among or readily accessible to persons within the circles that normally deal with the kind of information in question. Undisclosed information, generally known as trade secret or confidential information includes formula, pattern, compilation, programme, device, method, technique or process.

Protection of undisclosed information is the least known to players of IPR and also least talked about, although it is perhaps the most important form of protection for industries, Research and Development (R&D) institutions and other agencies dealing with IPRs. Protection of undisclosed information or trade secret is not really new to humanity; at every stage of

development, people have evolved methods to keep important information secret, commonly by restricting the knowledge to their family members.

A trade secret is an IPR that is with the holder indefinitely or rather as long as he can keep his secret as a trade secret. To enable an enterprise to keep something as a trade secret, the holder must ensure secrecy agreements with the employees in the business. As the maximum number of trade secrets appropriation takes place through current or past employees, corporates, as a rule, enforce a Non-disclosure Agreement on every employee at the time of joining, so that, breach of contract can be used as the legal instrument for prosecution in case of violation. Some MNCs prevent through a service contract agreements, former employees from working for a competitor for a limited period. For information to be treated as a trade secret, it is necessary that there should be commercial value associated with the information, that this commercial value would be lost, damaging the commercial interests of the holder of the trade secret and that the holder had taken reasonable care to protect the secret so that its loss would be possible only through an illegal access. The most quoted trade secret and the one which has established the credibility that trade secrecy can be ensured is the case of the Coca-Cola formula, which is kept locked in a bank vault in Atlanta, can be opened only by a resolution of the company's board and is known to only two employees at the same time. The public has no access to the names of those employees and they are not allowed to fly on the same air plane. It is obvious that such extreme systems and standards for protection of trade secrets are neither necessary nor practiced by many other corporations.

Unlike other types of Intellectual property, the trade secret is fundamentally a "do-it-yourself' type of protection, i.e., it is essentially an internal instrument, the responsibility for its protection remains with the owner of the secret. It is not disclosed to anyone including the Government and is kept confidential. For engineers, inventors, and designers, the trade secrets such as some formulae, programmes, methods, progresses or data collections etc. are to be maintained confidentially. If there is any improper disclosure or use of the trade secret by another person, the inventor may claim and recover damages resulting from illegal use. Enforcement of IPR is definitely private rights. If anybody uses the material without the inventors' permission, the IPR owners can use any remedies available under the civil law.

**TRIPS Agreement**

Undisclosed information or trade secrets have been provided protection by the TRIPS

agreement for the first time in international law. This explicitly requires undisclosed information - trade secrets or know-how – to benefit from protection.

1) In the course of ensuring effective protection against unfair competition as provided in Article 10 of the Paris Convention (1967), Members shall protect undisclosed information in accordance with this agreement.

2) The Agreement does not demand that undisclosed information should be treated as a form of property, but it does stipulate that the natural and legal persons lawfully in control of such information must have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret (Part II, Section.7: Art 39.1 & 2 of TRIPS).

3) Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use (Art 39.3).

Trade secret protection can be used by the agricultural sector to protect, for instance, hybrid plant varieties. Thus, even in countries that do not recognize plant breeders' rights, the use of hybrids gives a certain degree of appropriability as long as it can be kept secret. Trade secrets can be protected against third party misappropriation through laws relating to unfair competition or to restrictive trade practices or to contract law. In the United States, there are separate trade secret laws at the State Level. Protection of trade secrets is not limited in time, unlike patents; the disadvantage of this type of protection is that it is lost the moment it is discovered independently by a third party. If the information of a trade secret is available through any legitimate means and if any inventor is responsible illegally for such leaking, then the trade

secret may become ineligible for protection. The advantage, at least to the proprietor, is that, unlike patents, there is no obligation to disclose the inventive or creative ideas to society.

Some developed countries protect test data submitted for obtaining marketing approval of agricultural chemicals from use by third parties for a limited period of time, generally for 5 or 10 years. Such protection gives exclusive marketing rights to the proprietor. In agriculture, it is for drugs and agricultural chemicals. Although developing countries also require the submission of such test data, no exclusivity is conferred on the originator for any period of time (Watal, 1998). Thus this instrument assumes importance for major institutions and costs for keeping this are enormous.

**Trade Secrets Protection in India**

India has yet to introduce an effective system for data protection that is compliant with Article 39.3 of TRIPS though the system is in place with existing National Official Secrets Act that binds public servants from disclosing or using confidential information in unauthorized manner that affects the sovereignty and integrity of the country.

At the institutional level, it becomes evident that agreements on confidentiality gain prominence in the light of multi party research programs involving testing at multi locations and many employees. In agricultural research, questions of Material Transfer Agreements (MTA) for exchange of plant / animal material and questions of ownership become important. MTAs are agreements between collector and appropriate authorities and govern the arrangements of confidentiality, ownership or acquisition without affecting research for development.

Under Article 39 of TRIPS, members are obliged to ensure protection of undisclosed information through systems developed through appropriate legislations. Trade secrets and other types of “undisclosed information” which have commercial value are to be protected against breach of confidence and other acts contrary to honest commercial practices. But reasonable steps have to be taken to keep the information secret. Test data submitted to governments in order to obtain marketing approval for new pharmaceutical or agricultural chemicals must also be protected against unfair commercial use. Documentation of this knowledge in India is being done to bring it under legal protection.

Apart from the need for prevention of illegal use of trade secrets, India has yet another relatively unique situation, where a large repository of knowledge and practices are locked up with our traditional vaidyas, hakims, artists and artisans, which remain as trade secrets and have

current or potential commercial value. Their protection is vital for the survival of these systems and practices.

Laws relating to all forms of IPR are at different stages of implementation in India, but there is no separate and exclusive law for protecting undisclosed information or trade secret or confidential information. The Contract Act of 1872 would however cover many aspects of trade secrets. To protect the vast repository of Undisclosed Information and knowledge kept as trade secrets by their practitioners, India has taken pro-active initiatives as provided for under Article 10 of the Paris Convention and Article 39(2) and 39(3) of TRIPS. These steps along with provisions under Breach of Contract or Non-disclosure Agreement would go a long way in developing a culture in the industrial circles to respect trade secrets and undisclosed information as proprietary assets of their owners.

## Lecture 5. Plant Variety Protection and Farmers Rights Act (PVPFRA)

### Historical Outline

The TRIPS of WTO recognizes the creation of Intellectual Property Rights (IPR) as essential for the development of mankind. IPR is the property created by the human intellect which can be incorporated in tangible objects and reproducible in different locations. The types of IPR are copy rights, trademarks, patents, geographical indications, industrial designs, Integrated circuits and Trade secrets. IPRs confer legal ownership to the person or a business of a discovery or an invention attached to a particular product or process, which prohibits others from unauthorized use. Among the listed IPR's, the main concern is on patents, as India being a member of WTO, needs to provide for protection of plant varieties (PPV) either through patents or by an effective *sui generic* system or a combination there of and thus the whole issue of plant variety protection (PVP) (Plant Breeders Rights – PBR) became an intensely debatable subject.

The adoption of IPRs in agriculture has a recent origin, but in the USA, the Plant Patent Act was enacted in 1930. This Act, however, covered only asexually propagated plants (plants not normally sown from seeds), and was thus aimed at excluding the major food species and so prevented the emergence of grain monopolies. The European plant breeders pushed for Plant Breeders' Rights (PBRs), which were more comprehensive in the coverage of varieties to be granted legal protection. The origins of this movement for Intellectual Property Protection (IPP) for agricultural products go back to the late 19$^{th}$ century with the growth in the European seed trade and the development of breeders' associations, which was followed by various seed control systems and attempts to provide Plant Variety Protection (PVP).

In the early part of the 20$^{th}$ century, the potential benefit of systematic plant breeding to society and lack of an effective protection and reward system were felt and this led to the formation of the Inter Governmental International Union for the Protection of New Varieties of Plants commonly known as UPOV (based on its initials in French – (Union Internationale pour la Protection des Obtentions Végétales) with mostly developed countries as member states, after an International Convention in Paris in 1961. The UPOV is an intergovernmental organization with headquarters in Geneva (Switzerland). Belgium, France, the Federal Republic of Germany (FRG), Italy and the Netherlands were the original signatories on 2 December 1961. UPOV came into force only in August 1968 after the UK, FRG and the Netherlands had ratified it.

The convention has undergone revisions in 1972, 1978 and 1991 and has as on today, there are 53 member states. The purpose of the UPOV convention is to ensure Plant Breeders' Right (PBR) by making available to them an exclusive property right on new plant varieties in order to provide incentive to the development of agriculture and to safeguard the interests of plant breeders. To be eligible for protection, varieties have to be (i) distinct from existing commonly known varieties, (ii) sufficiently uniform, and (iii) stable and new in the sense that they must not have been commercialized.

UPOV '78 did not limit the farmers' rights and kept the rights of plant breeders within levels supported by some developing countries. Under the UPOV '78, the breeder could produce a new plant variety and had a monopoly via marketing right sale of seed. But the system allowed two important exemptions. One, the breeder's exemption, which allowed other plant breeders to use the protected variety for breeding purposes and the other one was that of the farmer's rights. The farmers were allowed to use seeds from their harvest to plant the next crop, even if the seed was protected by the PBR.

While the first two amendments of UPOV, in 1972 and 1978, kept the basic structure almost unchanged, the last amendment in 1991 introduced far reaching changes to the structure of protection, significantly strengthening PBRs. The more significant of these are the restrictions on the reuse of seeds, which could have implications for the farming communities using the protected varieties; in addition, the inclusion of Essentially Derived Varieties (EDVs) affects the ability of breeders to freely use protected varieties for research. Thus, UPOV '91, urged upon the WTO by the USA, contains an extensive protection for plant breeders to the prejudice of farmers' rights and severely restricts the scope of other breeders to innovate around protected varieties (the breeders' exemption), thereby disturbingly affecting the food security and equity goals of developing countries on the whole. The breeder's exemption was almost done away with in the UPOV '91 making way for royalty payments to the PBR holder from the breeders, if their new variety bears some resemblance to the protected variety even if the new variety has been bred for different characters. Besides, farmers cannot use farm saved seeds from protected varieties, without paying compensation. The methods of compensation are being currently discussed in various fora in Europe and the issue is a bone of contention between farmers and breeders.

The UPOV '91 raises the alarm that unfavourable regimes could be imposed on unwilling developing countries by incorporating the obligations of UPOV '91 into the WTO agreement, making them enforceable under the WTO dispute settlement system, when they were not negotiated in the Uruguay Round to include them in the WTO. The response of some developing countries to these developments in the UPOV Convention has been the adoption of alternative *sui generis* options for the protection of plant varieties. The major differences in the protection between the UPOV '61 and Plant Patent Regime are given in Table 2.

**Table 2 Protection under UPOV '61 and Plant Patent Regime**

| S.No. | UPOV '61 | Plant Patent Regime |
|---|---|---|
| 1. | Plant breeders can obtain protection for discoveries | Patents only for inventions |
| 2. | Criteria for protection: (i) Novelty, (ii) Distinct, (iii) Homogeneity, and (iv) Stability | Criteria for protection: (i) Novelty, (ii) Inventive step involved, and (iii) Industrial Applicability |
| 3. | Forfeiture of rights if a protected variety loses its essential expressions of characteristics | No corresponding provision |
| 4. | Submitting of propagating material to the national authority designated for the purpose necessary in most laws | No such requirement |
| 5. | Initially covered a small canvas | Specified exceptions |
| 6. | Flexibility in favour of users | Rigid application to secure rights to patentee |
| | (i) "farmers' privilege" | (i) dilution of "farmers' privilege" |
| | (ii) "breeders' exemption | (ii) introduction of EDVs to curb research exemption |

Note: The essential structure of UPOV '61 remained almost unchanged till 1991 when major amendments were carried out.

**India Scenario**

Protection of plant varieties is perhaps yet another important issue for researchers in agriculture. Article 27.3 (b) of the Agreement on TRIPs requires WTO members to protect plant varieties by patents or other means, which involves protecting rights of plant breeders, by effective *sui generic* systems but without spelling out its position on benefit sharing and farmers' rights. While formulating its strategy for protection of plant varieties, India resorted to consider

principles embodied in other allied international agreements. The US model of plant patents which differs from normal or utility patents. Several countries allow patents on cells too. The *sui generic* form of plant variety protection (PVP) is yet another type of plant breeders' rights. With biotechnology emerging as a major tool in research and developmental activities, plants on gene constructs and transformed plants can also be patented. The Organization of African Unity has developed a model law encompassing the various concerns in respect of African countries especially for the right to save, use, multiply and process farm saved seed but not to sell it on a commercial scale.

**Sui Generis Protection System**

***Sui generis*** (pronounced *SOO-eye jen-ER-ihs*) is a Latin expression, literally meaning *of its own kind / genus* or unique in its characteristics. The introduction of the *sui generis* concept reflects two broad elements. First, a number of countries rejected the compulsory introduction of plant patents. Second, negotiators did not agree on any specific alternative to patents. As a result, TRIPS gives member states a wide margin in determining how to implement their obligation to introduce plant variety protection. The introduction of plant variety protection is one that concerns mostly developing countries. Indeed, most developed countries had already introduced either plant patents or PBRs before the adoption of TRIPS. Developing countries that are member of WTO were left with the choice of either adopting the existing regime proposed in UPOV or to devise their own plant variety protection system adapted to their specific situation. A few countries have joined UPOV since 1994 but the majority has decided to adopt their own plant variety protection laws.

The Protection of Plant Varieties and Farmer's Rights (PPVFR) Act 2001 enacted by the Government of India has several unique features not found in similar acts of other countries.

The proposed draft ensures that the farmers shall be able to raise their own seeds and retain them even to distribute in exchange, among the village community as per the existing tradition. The researchers shall be able to produce new varieties from the protected varieties. This novel act not only introduces provisions for the protection of new plant varieties but also builds into the legislation features to protect farmers' rights, provides an administrative framework for benefit sharing between the beneficiaries which in combination of new Indian Patent Act, 1999 and 2002; Trademarks Act 1999; Geographical Indications Act, 1999; and also the Biodiversity Act, 2002. The act also includes for setting up of a Plant Varieties and Farmers'

Rights Protection Authority, National Community Gene Fund, Compulsory Licensing and Protection of Public Interest Appellate Board among others. It aims to protect the interests of all and also comply with standards as per the TRIPS. However, issues related to protection of transgenic crops need clear cut defining and implementation of this Act itself is a major challenge to researchers in agriculture.

**Highlights of Indian PPVFR Act, 2001**

The salient features of the Protection of Plant Varieties and Farmers' Rights (PPVFR) Act passed in October, 2001 are:

a) The legislation extends to all categories of plants except micro-organisms.
b) In order to be eligible for protection, a variety must be new, distinct, uniform and stable.
**c)** The legislation contains provisions for compulsory licensing in the public interest.

**i) Objectives**

The PPVFR Act aims to establish "an effective system for the protection of plant varieties, the rights of farmers and plant breeders, to encourage the development of new varieties of plants", in line with Article 27.3 (b) of TRIPS. Three key aims are:

a) to stimulate investments for research and development both in the public and the private sectors for the development of new plant varieties by ensuring appropriate returns on such investments;
b) to facilitate the growth of the seed industry in the country through domestic and foreign investment which will ensure the availability of high quality seeds and planting material to Indian farmers; and
c) to recognize the role of farmers as cultivators and conservers and the contribution of traditional, rural and tribal communities to the country's agro biodiversity by rewarding them for their contribution through benefit sharing and protecting the traditional right of the farmers for their contribution made at any time in conserving, improving and making available plant genetic resources for the development of new plant varieties.

**ii) Coverage of Varieties**

The Act specifies the range of plant varieties that can be protected. Section 14 lists three classes of varieties: (a) new varieties, (b) extant varieties, and (c) farmers' varieties.

**Variety:** A plant grouping except microorganisms within a single botanical taxonomy of the lowest known rank, which can be defined by the expression of the characteristics resulting from

a given genotype of a plant of that plant grouping.

**iii) Conditions for Protection**

a) A new variety shall be registered under this Act if it conforms to the criteria of **novelty, distinctiveness, uniformity and stability (NDUS)**, as described below [Section 15 (1)–(3)]**.** For extant varieties – distinctiveness, uniformity, stability as specified / relaxed by the authority.

- ***Novel,*** if, at the date of filing of the application for registration for protection, the propagating or harvested material of such a variety has not been sold or otherwise disposed of by or with the consent of its breeder or his successor for the purposes of exploitation of such variety
  (a) in India, earlier than one year, or
  (b) outside India, in the case of trees or vines earlier than six years, or, in any other case, earlier than four years, before the date of filing such applications. It is also subject to the condition that (i) a trial of a new variety which has not been sold or otherwise disposed off shall not affect the right to protection and that (ii) the fact that on the date of filing the application for registration, the propagating or harvested material of such variety has become a matter of common knowledge other than through the aforesaid manner shall not affect the criteria of novelty for such variety.
- **Distinct,** if it is clearly distinguishable by at least one essential characteristic from any other variety whose existence is a matter of common knowledge in any country at the time of filing of the application.
- **Uniform,** if subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in its essential characteristics.
- **Stable,** if its essential characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle. The variety will be subjected to such distinctiveness, uniformity and stability tests as shall be prescribed.

A new variety **shall not be registered** under this Act, if the denomination given to such variety:

- is not capable of identifying such variety;
- is liable to mislead or to cause confusion concerning the characteristics;
- is not different from every denomination which designates a variety of the same botanical species or of a closely related species registered under this Act; or

- is likely to deceive the public or cause confusion in the public regarding the identity of such variety; or
- is likely to hurt the religious sentiments respectively of any class or section of the citizens of India; or
- is prohibited for use as a name or emblem; and
- is comprised of solely or partly of geographical name.

b) Extant varieties have been defined using four benchmarks:

(i) varieties that have been notified under the Seeds Act, 1966;

(ii) farmer varieties; and

(iii) varieties about which there is common knowledge or any other variety that is in the public domain.

c) Farmers' varieties, however, have been defined as:

(i) varieties that have been traditionally cultivated and evolved by farmers in their fields; and

(ii) a wild relative or land race of a variety about which farmers possess common knowledge.

**Farmer:** Any person who

a) cultivates crops by cultivating the land himself, or

b) cultivates crops by directly supervising the cultivation of land through any other person, or

c) conserves and preserves, severally or jointly, with any person any wild species or traditional varieties, or adds value to such wild species or traditional varieties through selection and identification of their useful properties.

**Land Race:** A landrace is a local variety of a domesticated plant species which has developed largely adaptation to the natural and cultural environment in which it lives. It differs from a cultivar which has been selectively bred to conform to a particular standard of characteristics. Land race populations are often variable in appearance, but they can be identified by their appearance and have a certain genetic similarity.

**Notification of Crops Species:** As a first step towards implementation of the Act, the Government shall have to notify the crops in order to establish the system of listing of plant varieties for the purpose of registration. The criteria for selecting the crops could be the crops on which we are dependent for food and nutritional security, including major cereals, pulses, oilseeds, vegetables and fruits crops. Crop species important for India in the world trade, species of Indian origin, crops where India could benefit from introduction of new germ plasm and

foreign investment, could be the other priorities for consideration.

**Exclusion of Certain Varieties:** (a) Plant varieties can be excluded from registration in case where prevention of commercial exploitation of such varieties is necessary to protect public order or public morality or human, animal and plant life and health or to avoid serious prejudice to the environment.

b) Registration of plant varieties will not be allowed if the variety in question involves any technology such as "genetic use restriction technology" and "Terminator Technology", which is injurious to life or health of human beings, animals or plants.

**iii) PPVFR Authority**

**The PPVFR Authority** proposed to be established under the Act has a crucial role to play for effective implementation of the Act. The duty of the Authority is to promote, by such measures as it may think fit, the encouragement for the development of new varieties of plants and to protect the rights of the farmers and breeders [Section 8 (1)].

**iv) Registration of Plant Varieties**

Application can be made to Registrar for registration of any one of the following:

a) Genera or species notified by the Central Government for the purposes of registration of varieties.

b) Registration of new varieties, as notified by the Central Government

c) Registration of extant varieties, including varieties available in India which are notified under section 5 of the Seed Acts 1966

d) Farmers' variety / varieties about which there are common knowledge / variety which is in public domain.

- Section 14 thus provides opportunities to all the stakeholders in plant breeding, farmers and commercial plant breeders, to seek protection for the plant varieties that they develop. Breeders can exercise their rights over any variety that is essentially derived from the protected variety.
- An **Essentially Derived Variety (EDV)** is defined in the PPVFR Act as having one of the following characteristics:

  (a) predominantly derived from an initial variety while retaining the expression of the essential characteristics that results from the genotype or combination of the genotype of such initial variety,

(b) any variety that is not clearly distinguishable from a protected variety, or

(c) conforms (excepting for the differences which result from the act of derivation) to such initial variety in the expression of the essential characteristics that result from the genotype or combination of genotype of such initial variety. This is similar to that in UPOV '91.

- The office of the Registrar has started receiving applications for registration of twelve notified crops viz. rice, lentil, maize, green gram, kidney bean, black gram, chickpea, pearl millet, pigeon pea, sorghum, field pea and bread wheat.

**v) Plant Varieties Registry**

- The Central Government shall establish, a Registry which shall be known as the Plant Varieties Registry. The Authority shall appoint a Registrar-General of Plant Varieties.
- For the purposes of this Act, a Register called the National Register of Plant Varieties shall be kept at the head office of the Registry, wherein shall be entered the names of all the registered plant varieties with the names and addresses of their respective breeders, the rights of such breeders in respect of the registered varieties, the particulars of the denomination of each registered variety, its seed or other propagating material along with specification of salient features.

**vi) Conditions Imposed on Applicants**

Section 18 requires any applicant intending to register for protection of a plant variety in India to make the following declarations and also provide information about the origin of the genetic material that the variety uses.

a) denomination assigned to such variety by the applicant;
b) an affidavit sworn by the applicant that such variety does not contain any gene or gene sequence involving terminator technology;
c) the application should be in such form as may be specified by regulations;
d) a complete passport data of the parental lines from which the variety has been derived along with the geographical location in India from where the genetic material has been taken and all such information relating to the contribution, if any, of any farmer, village community, institution or organization in breeding, evolving or developing the variety;
e) a statement containing a brief description of the variety, bringing out its characteristics of novelty, distinctiveness, uniformity and stability as required for registration;
f) a declaration that the genetic material or parental material acquired for breeding, evolving or

developing the variety has been lawfully acquired;

g) information on the use of genetic material conserved by any tribal or rural families in its breeding;
h) such fees as may be prescribed; and
i) such other particulars as may be prescribed.

The conditions stated above (a–i), shall not apply in respect of application for registration of farmers' varieties.

**Lawfully Acquired Parental Material:** Section 18(f) regarding information to be submitted along with an application, requires the applicant to certify that the genetic or parental material used for breeding the variety has been lawfully acquired. Such declaration would be difficult in cases where the passport information relating to the material has not been recorded. Further, it would not always be possible for a breeder to get information relating to the contribution of a farmer, village community, etc. since there may not be an authentic source of such information. Such information, if not available, may be left to the Authority to decide, which can invite claims later through media/public notices, etc.

**vii) Breeders' rights**

- The certificate of registration for a variety issued under this Act shall confer an exclusive right on the breeder or his successor or his agent or licensee, to produce, sell, market, distribute, import or export of the variety of seed and/or propagating material of the protected variety [Section 28 (1)].
- These rights are consistent with those that have been provided under UPOV '91. However, if the breeder's variety protected under the Act is an EDV from a farmer's variety, the breeder cannot give any authorization without the consent of the farmers or communities from whose varieties the protected variety is derived.

**Registration:** Breeder shall furnish information on geographical location from where plant genetic material has been taken for development of the new variety.

- Certificate of registration issued by the registrar will prescribe the conditions of the entitlement.
- Registration will be forfeited if the annual fee is not paid.

**Duration of Plant Breeders' Rights:** The certificate of registration issued under section 24 or sub-section 98 of section 23 shall be valid for nine years in the case of trees and vines and six

years in the case of other crops, and may be reviewed and renewed for the remaining period on payment of such fees as may be fixed by the rules made on this behalf subject to the conditions that the total period of validity shall not exceed:

- in the case of trees and vines, eighteen years from the date of registration of the variety;
- in the case of extant varieties, fifteen years from the date of the notification of that variety by the Central Government under Section 5 of the Seed Act, 1996; and
- in the other case, fifteen years from the date of registration of the variety.

**Registration of Essentially Derived Varieties:** The breeder of the essentially derived variety shall have the same rights as the plant breeder of other new varieties, which include production, selling, marketing and distribution, including export and import of the variety. The other eligibility criteria for award of registration are also the same as for new variety registration under the Act [Section 23(1), (6)].

**viii) Researchers' Right**

The researchers have been provided free and complete access to protected varieties for *bona fide* research purposes in developing new varieties of plants [Section 30]. This Section states, 'Nothing contained in this Act shall prevent:

a) the use of any variety registered under this Act by any person using such variety for conducting experiments or research; and
b) the use of a variety by any person as an initial source of a variety for the purpose of creating other varieties provided that the authorization of the breeder of a registered variety is required where the repeated use of such variety as a parental line is necessary for commercial production of such other newly developed variety'.

**ix) Payment of Annual Fee**

The Authority may, with the prior approval of the Central Government, by notification in the Official Gazette, impose a fee to be paid annually, by every breeder of a variety, agent and licensee thereof registered under this Act determined on the basis of benefit or royalty gained by such breeder, agent or licensee, as the case may be, in respect of the variety, for the retention of their registration under this Act [Section 35(1)].

**The fee Structure:** The fee for registration and other processes as well as annual fee should be reasonably determined keeping in view the possible commercial value of the crop, the national interests, and the desirability of generating enough resources for financial autonomy of the

Authority. Section 19 of the Act requires a breeder to submit a quantity of seeds along with 'parental lines' according to the standards specified by the regulations. Also, the seeds deposited are to be conserved and regenerated if necessary for DUS testing for maintenance. A separate fee may be assigned for conservation and regeneration, besides a testing fee.

**x) Farmers' Right**

a) The farmers' rights of the Act define the privilege of farmers and their right to protect varieties developed or conserved by them [Chapter VI]. Farmer can save, use, sow, resow, exchange, share and sell farm produce **including seed** of a protected variety **under this Act** in the same manner as he was entitled before this Act. But the farmer shall not be entitled to sell branded seed of a variety protected under this Act. [Section 39 (1), (i)–(iv)].

b) Farmer who has bred or developed a new variety to be entitled for protection as a breeder of a variety.

c) Farmers' variety as part of the extant variety will be entitled for registration / protection.

d) Rights of communities in the evolution of any variety for the purpose of staking a claim will be accepted.

e) Further, the farmers have also been provided protection of innocent infringement when, at the time of infringement, a farmer is not aware of the existence of breeder rights [Section 42 (1)].

f) National Gene Fund to be utilized for making payment for benefit sharing, compensation to communities etc., and supporting the activities relating to conservation and sustainable use of genetic resources.

g) A farmer who is engaged in the conservation of genetic resources of land races and wild relatives of economic plants and their improvement through selection and preservation, shall be entitled in the prescribed manner for recognition and reward from the National Gene Fund, provided the material so selected and preserved has been used as donor of genes in varieties registrable under the Act.

h) The expected performance of a variety under given condition is to be disclosed to the farmers at the time of sale of seed / propagating material by the breeder of a variety registered under this Act.

i) A breeder or other person making application for registration of any variety shall disclose the information regarding the use of genetic material conserved by any tribal or rural families in the breeding or development of such variety.

j) **A farmer / farmer's organization** can claim compensation if a variety fails to give the expected performance under given conditions. Such a claim may have to be paid by the breeder as directed by the Authority after giving due hearing to both the parties, namely the farmer and the breeder. Since the variety is to be tested for DUS by the Authority at the time of registration, and if the performance of the variety is not found to be as claimed by the breeder, the Authority can deal with claims of failure of performance and could decide about such claims independently, instead of the courts. Section 42 regarding protection to farmers for innocent infringement is also not clear as to how to define innocent infringement. Such a clause may not stand in the court of law in view of the other laws where ignorance is not a reason to have protection from legal obligations.

k) A farmer who has bred or developed a new variety shall be entitled for registration and any other protection as a breeder. Since the definition of an extant variety according to section 2(j) includes a farmers' variety also, which may be land race or a wild relative about which farmers possess common knowledge, the uniformity criteria in case of registration of these varieties is difficult to ascertain. Such consideration may have to be included in the DUS guidelines for testing of these particular types of varieties. Further, there could be innumerable farmers' varieties (land races for registration and their data are scattered and sometimes overlapping). A technical questionnaire to bring out unique characters and area of adaptability could be developed initially to document these varieties. The time-frame to be provided for documentation of information relevant for registration of extant varieties (farmers' varieties or released varieties) under Section 15(2) may be restricted to three years.

l) Any person or any governmental or nongovernmental organization can stake a claim to the contribution of the people or local community, on behalf of any village or local community in India,

m) A right established under this Act shall not be deemed to be infringed by a farmer who at the time of such infringement was not aware of the existence of such right.

n) **Exemption from fees**: A farmer or group of farmers or village community shall not be liable to pay any fees in any proceeding before the Authority or Registrar or the Tribunal or the High Court under this Act.

**xi) Community's Rights**

- The rights of the communities as defined, provide for compensation for the contribution of communities in the evolution of new varieties in quantum to be determined by the PPVFR Authority [Section 41 (1)].

**xii) Compulsory License**

The authority can grant compulsory license, in case of any complaints about the availability of the seeds of any registered variety to public at a reasonable price. By Compulsory licensing, priority is attached to the public interest over the interests of the commercial breeders. Any person may make an application for compulsory license to undertake production, distribution and sale of the seed or other propagating material of a registered variety [Section 47(1)].if:

a) three years have elapsed from the date of registration of a variety;
b) reasonable requirements of the public for seeds or other propagating material of the variety have not been satisfied; and
c) the seed or other propagating material is not available to the public at a reasonable price.

**xiii) Benefit Sharing**

Sharing of benefits accruing to a breeder from a variety developed from indigenously derived plant genetic resources has also been provided [Section 26(1)]. The authority may invite claims of benefit sharing of any variety registered under the Act, and shall determine the quantum of such award after ascertaining the extent and nature of the benefit claim, after providing an opportunity to be heard, to both the plant breeder and the claimer.

**xiv) National Gene Fund**

The National Gene Fund to be constituted by the Central Government under the Act shall be credited thereto:

- the benefit sharing received from the breeder of a variety or an essentially derived variety registered under this Act;
- the annual fee payable to the Authority by way of royalty paid annually, by every breeder of a variety, registered under this act;

- the compensation deposited in the Gene Fund due to any claim attributable to the contribution of the people of a village or local community as defined under Section 41(1); and
- the contribution from any national and international organization and other sources.

The Gene Fund is used to meet the expenditures of:

a) disbursing shares to benefit claimers, either individuals or organization, and for compensation to village communities;
b) recognizing and rewarding the contributions of farmers engaged in the conservation and enhancement of agro-biodiversity;
c) the compensation payable; and
d) supporting conservation and sustainable use of genetic resources, including *in situ* and *ex situ* collection and for strengthening the capabilities of the panchayat in carrying out such conservation and sustainable use through maintenance of gene banks [Section (45)].

effective implementation.

## Lecture 6. Bio-Technology Market in India-Patent & Patent claims in Bio Technology-Patentable & Non patentable inventions in Bio technology

### Overview

The biotechnology sector of India is highly innovative and is on a strong growth trajectory. The sector, with its immense growth potential, will continue to play a significant role as an innovative manufacturing hub. The sector is one of the most significant sectors in enhancing India's global profile as well as contributing to the growth of the economy.

India is among the top 12 biotech destinations in the world and ranks third in the Asia-Pacific region. India has the second-highest number of US Food and Drug Administration (USFDA)–approved plants, after the USA and is the largest producer of recombinant Hepatitis B vaccine. Out of the top 10 biotech companies in India (by revenue), seven have expertise in bio-pharmaceuticals and three specialise in agri-biotech.

India has no dearth of talent in biotechnology, as a number of institutions, both government and autonomous, provide the necessary opportunities for the students seeking to obtain a degree in this sector. The Government of India has provided adequate scope to this sector by providing facilities for Research and Development (R&D) in the field of biotechnology.

### Market size

The Indian biotech industry holds about 2 per cent share of the global biotech industry. The biotechnology industry in India, comprising about 800 companies, is growing at an average rate of about 20 per cent. The Indian biotechnology sector is expected to grow from the current US$ 11 billion to US$ 100 billion by 2025, growing at an average rate of 30 per cent, as per Union Minister for Science and Technology Mr Harsh Vardhan.

Biopharma is the largest sector contributing about 64 per cent of the total revenue followed by bioservices (18 per cent), bioagri (14 per cent), bioindustry (3 per cent), and bioinformatics contributing (1 per cent).

The high demand for different biotech products has also opened up scope for the foreign companies to set up base in India.

India has emerged as a leading destination for clinical trials, contract research and manufacturing activities owing to the growth in the bioservices sector.

**The EU/US Dispute**

The US is the world's largest grower of GM crops. By contrast, GM crop activity in EU member states is minimal, partly because the EU only ended a six-year moratorium on growing GM crops in 2003. The situation is unlikely to change quickly as individual applications to import GM seeds into the EU need the approval of all 25 member states. Some EU member states such as Austria, Germany and Italy, remain strongly opposed to growing GM crops.

**Why do Europe and the US take such sharply differing approaches to the regulation of GM technology in agriculture?**

Europe's approach is based on the precautionary principle. According to this, GM maize, for example, cannot automatically be considered the same as conventional maize and will need to be tested independently for any effects on human health and the environment before it can be commercialized. Though commercial GM crops are banned, processed food in the EU is allowed to contain GM ingredients, but any food product whose GM content exceeds 0.9 per cent needs to be labelled. This is because of another principle underlying EU policy – that the general public should be able to choose whether to consume GM food or not. In fact, many large European supermarkets have chosen to remove GM ingredients from their products. Campaigners in Europe want even stronger legislation to ensure that GM produce is kept separate from non-GM produce at every stage of production – growing, handling and transport, marketing and processing. They can accept the 'co-existence' of GM with non-GM products as long as they are clearly separated.

The US government is opposed to the precautionary principle in GM technology because it does not think that the technology needs special regulations. US policy-makers believe that the precautionary principle is a hindrance to technology development and, ultimately, to trade. They claim: that the EU ban is a barrier to trade costing US farmers several hundred million dollars a year in potential exports to Europe; that it has no scientific basis; and that it is preventing the development of an industry that could benefit the world's poorest people.

**Biosafety Procedures in India**

India has acceded to the Biosafety Protocol on 17th January 2003. Genetically modified organisms are regulated in India under the purview of the 1986 Indian Environment (Protection) Act. Ministry of Environment and Forests has notified the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or

Cells under this act. These rules also define the competent authorities and composition of such authorities for handling of various aspects of the rules. Presently, there are six competent authorities.

i) Recombinant DNA Advisory Committee (RDAC),
ii) Institutional Biosafety Committees (IBSC),
iii) Review Committee on Genetic Manipulation (RCGM),
iv) Genetic Engineering Approval Committee (GEAC),
v) State Biotechnology Coordination Committee (SBCC) and
vi) The District Level Committee (DLC)

The RCGM established under the Department of Biotechnology supervises research activities including small scale field trials, whereas approvals for large scale releases and commercialization of GMOs are given by the GEAC, established under the Ministry of Environment and Forests. The Rules also mandate that every institution engaged in GMO research establish an IBSC to oversee such research and to interface with the RCGM in regulating it. Bt. Cotton is the first and only transgenic crop approved by GEAC for commercial cultivation in 6 States namely Andhra Pradesh, Gujarat, Karnataka, Madhya Pradesh, Maharashtra and Tamil Nadu.

Recombinant DNA Pharmaceuticals approved for marketing in India

- Insulin, GM-CSF, G-CSF, Interferon alpha, Interferon gamma, Interleukin, Blood Factor VIII, Streptokinase, HBsAg vaccine, Human growth hormone, tPA, Erythorpoietin, Follicle Stiulating Hormone and Human protein C.

Recombinant DNA pharmaceuticals approved for manufacturing in India:

- HBsAg vaccine, Erythropoietin, G-CSF, Interferon alpha and Insulin.

Transgenic crops approved for commercial cultivation in India:

- Three Bt. cotton hybrids i.e., MECH 12, MECH 162 & MECH 184 expressing cry1Ac gene

**IPR Issues in Biotechnology** (Bindu Sharma)

Since R & D in biotechnology is extremely time consuming and requires huge investment, granting Intellectual Property Rights (IPR) is an effective tool to protect biotechnology inventions. There are, however, no internationally accepted guidelines for the management of IPR.

**Legislative Framework**

The legal protection remains very sensitive and complex in case of biotechnology in general and agricultural biotechnology in particular because of technical and ethical issues involved. Indian biotech industry at present is facing great challenges of the emerging Trade Related Aspects of Intellectual Property Rights (TRIPS) compliant patent system in India from January 1, 2005. Article 27.3 (b) of TRIPS excludes biological processes for the production of plants or animals as a patentable subject matter, but patents can be granted to the microorganisms, non-biological, and microbiological processes used in the production of plants and animals. This covers even the gene sequences, which may be for a particular character, or a promoter or genetic markers or similar ones.

IPR protection of new life forms raises a number of difficult technical and ethical issues because of which the patentability of new biological forms and processes is still not accepted in many countries. Indian Patent Act 1970 defines patentable invention as: a new product or process involving an inventive step and capable of industrial application. Since IPR protection is granted **only for invention and not for discoveries**, in case of biotechnology innovations, it is difficult to say whether the new life form in the form of gene, DNA, cell etc is a scientific discovery or a technological invention. Discovery is merely making available what already exists in nature. A substance freely occurring in nature, if merely found or discovered, is not patentable. However, if the substance found in nature has first to be isolated from its surroundings, and a process for obtaining it is developed, that process is considered invention and hence patentable.

The consideration of industrial application is yet another obstacle for securing patents for inventions in biotechnology. However, in India there are several ethical issues too related to patenting of life forms, the most important being extent of private ownership that could be extended to life forms. In the traditional cultural context, Indians have considerable problems fixing monetary value to anything that is not a tangible physical article that has market value. Hence, there is an urgent need for developing countries like India to define clear policies for IPR in case of scientific and technological innovations.

Several Civil Society Organizations (CSO) and Non-Governmental Organizations (NGO) argue that naturally occurring organisms are God’s gift, and are common property of the mankind, and therefore cannot be appropriated by any person(s) or organizations or entities by

just modifying it or tinkering with it. The idea of profit making by exploiting any common heritage of civilization or culture is unacceptable to lots of people and communities.

Farmers and indigenous peoples in developing countries such as India are facing serious problems as plants that they developed and conserved are being 'appropriated' by private entities leading to biopiracy and exploitation of traditional knowledge claiming the exclusive right to produce and sell many 'modified' plants and animals. This is a great matter of concern today that knowledge, innovation and efforts of these communities are not acknowledged when the legal 'intellectual property rights' systems grant patents on genetic and
biological materials and on living organisms to private corporations.

In 2000, CSIR found that almost 80 per cent of the 4,896 references to individual plant based medicinal patents in the United States Patents Office that year related to just seven medicinal plants of Indian origin. Three years later, there were almost 15,000 patents on such medicines spread over the United States, UK, and other registers of patent offices. In 2005, this number had grown to 35,000, which clearly demonstrates the interest of developed world in the knowledge of the developing countries. Whilst the corporations stand to make huge revenues from this process, the local communities are unrewarded and in fact face the threat in future of having to buy the products of these companies at high prices. Hence such system of IPR only benefits the private industries or multi-national corporations of industrially developed countries at the expense of the developing countries. There is need to define guidelines and policies for the implementation of IPR in India so that the people like farmers get recognition for their efforts and contributions and prevent bio-piracy. World Intellectual Property Organization (WIPO) is now developing guidelines to protect traditional and indigenous knowledge systems.

The new trait-genetic use restriction technology (T-GURT) is being employed as a part of biotechnology by means of terminator and traitor genes. In this case, users have to rely upon the chemically dependent plants with proprietory genes. Although this protection restricts unauthorized copying of patents and monopoly in the international marketing, these technologies have led to substantial conflicts between business ethic and humanitarian concerns because farmers cannot save seeds of their crops at the end of the crop season. It may therefore pose a potential threat to our food security. Therefore, the Consultative Group on International Agricultural Research (CGIAR) has decided not to incorporate T-GURT in forthcoming plant breeding programmes of international institutions as it may affect the sustainable agriculture due

to negative effects on biodiversity and uncertain effects on socio-economy of the country. For example, whether terminator seeds are consumable and safe for humans, animals, birds, beneficial insects and micro-organisms is uncertain; pre-soaking of seeds in tetracycline solution is dangerous to environment and human health; pollens of plant containing terminator gene pollinate and produce seeds that are self destructing.

**Policies on Biotechnology Patents**

The Government of India must develop a clear and stringent national IPR policy as well as regulations to:

i) prevent misuse of national biodiversity and plant genetic material and make set procedures to oppose and revoke patents that have been granted in other countries;

ii) have clear line drawn between patentable subject matter with regard to biotechnology and traditional knowledge, especially related to new life forms;

iii) spread awareness among farmers about the legislative framework of Protection Plant Varieties and Farmer's Rights to safe guard their interests and various provisions such as:

- Benefit sharing systems when their innovations get commercialized
- Reward they can get from National Gene Fund for their role in conservation of biodiversity
- Procedure involved in protection of new plant variety
- Their rights when plant variety gets protection
- Consequence of infringing others' right

iv) Make sure that farmers get their share of profit by means of appropriate benefit sharing arrangement when they play role in generating new plant variety or conservation of biodiversity.

**Convention on Biological Diversity**

Plant Genetic Resources (PGRs) are the foundation for the development of a food and nutritionally secure society. Over 90 percent of plant species for food and agriculture are located in the economically developing parts of the world namely, the Asian, African, Latin American and the Far East Islands. In a reversal of the normal economic pattern in the world, the richest nations are poor in plant genetic resources. Although the growth of applied sciences and modern technologies is seen as an opportunity to improve the living standards of human beings, concerns have been increasing to also protect the traditional gene rich resources and the indigenous wisdom. PGRs were treated as the 'heritage of mankind' and were shared freely among nations, till the concerns for conservation of biological diversity were raised by the Convention on

Biological Diversity (CBD), which came into force in 1993.

The Convention on Biological Diversity (CBD) has expressly provided for the rights of indigenous communities (Article 8 (i) of the CBD), and the International Undertaking on Plant Genetic Resources (IUPGR) has provided defined farmers' rights (CBD 1994, FAO 1983) *inter alia* affirm that "the past, present and future contributions of farmers in conserving, improving and making available the genetic resources is the basis of farmer's rights".

The Convention on Biological Diversity (CBD), known informally as the Biodiversity Convention, is a multilateral treaty. The Convention has three main goals:

i) conservation of biological diversity (or biodiversity);
ii) sustainable use of its components; and
iii) 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. 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. The year 2010 was the International Year of Biodiversity.

The convention recognized for the first time in international law that the conservation of biological diversity is "a common concern of humankind" and is an integral part of the development process. The agreement covers all ecosystems, species, and genetic resources. It links traditional conservation efforts to the economic goal of using biological resources sustainably. It sets principles for the fair and equitable sharing of the benefits arising from the use of genetic resources, notably those destined for commercial use. It also covers the rapidly expanding field of biotechnology through its Cartagena Protocol on Biosafety, addressing technology development and transfer, benefit-sharing and biosafety issues. Importantly, the Convention is legally binding; countries that join it ('Parties') are obliged to implement its provisions. The convention reminds decision-makers that natural resources are not infinite and sets out a philosophy of sustainable use. While past conservation efforts were aimed at protecting particular species and habitats, the Convention recognizes that ecosystems, species and genes must be used for the benefit of humans.

The safety and regulatory concerns associated with transgenic crops is a contentious issue because many lack the regulatory frameworks and technical capacity necessary to evaluate these crops and the conflicting claims surrounding them. There is less scientific consensus on the

environmental hazards associated with transgenic crops. Regulatory procedures should be strengthened and rationalized to ensure that the environment and public health are protected and that the process is transparent, predictable and science-based. Appropriate regulation is essential to command the trust of both consumers and producers, but duplicative or obstructionist regulation is costly and should be avoided.

**Cartagena Protocol on Biosafety:** Convention on Biological Diversity adopted a supplementary agreement known as the Cartagena Protocol on Biosafety on 29 January 2000. The protocol became international law in September 2003 and has since been ratified by more than 100 countries excluding USA. India has acceded to the Biosafety Protocol on 17th January 2003. [Cartagena is in Colombia].

**Scope:** The Protocol seeks to protect from the potential risks posed by Living Modified Organisms (LMOs) resulting from modern biotechnology intended for direct use for food, feed or processing. It incorporates procedure for import of LMOs with respect to Food, Feed and Product.

**Risk Assessment and Risk Management Framework and Capacity Building:** Risk management measures include food labeling, conditions on marketing approvals, post marketing monitoring and development of methods to detect or identify foods derived from modern biotechnology.

**Salient features** of the protocol are:

**i) Precautionary principle:** 'Precautionary principle', is the basis of the Cartagena Protocol. The Protocol reaffirms the Precautionary principle in decision procedures, risk assessment and risk management in the context of the protocol. The precautionary principle is similar to the idea of 'safety first'. When applied to new technologies, it means holding back from using a new technology until there is conclusive evidence that it will do no harm. Critics of GM technology say it is too early to say this conclusive evidence exists.

**ii) Advance Informed Agreement (AIA):** It establishes an advance informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. The objective is to allow a receiving country to assess potential risks to biological diversity and human health from such transfers.

**iii) Traceability:** Protocol calls for provision of detailed information for handling, packaging and transportation, and clear identification of LMOs. Importer of LMOs should be able to trace back the original exporter.

**iv) Liability and Redress:** The term "liability" is normally associated with the obligation under the applicable law to provide for compensation for damage resulting from an action for which that person is deemed to be responsible. Liability and redress in the context of the Protocol concerns the question of what would happen if the trans-boundary movement of living modified organisms (LMOs) has caused damage. Negotiators were unable to reach any consensus regarding the details of a liability regime under the Protocol.

**v) Biosafety Clearing-House [BCH]:** The Biosafety Clearing-House was established by the Protocol to facilitate the exchange of information on living modified organisms and to assist countries in the implementation of the Protocol.

The issues dealt under Convention on Biological Diversity of 2010 include:

- Measures and incentives for the conservation and sustainable use of biological diversity.
- Regulated access to genetic resources and traditional knowledge, including Prior Informed Consent of the party providing resources.
- Sharing, in a fair and equitable way, the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources (governments and/or local communities that provided the traditional knowledge or biodiversity resources utilized).
- Access to and transfer of technology, including biotechnology, to the governments and/or local communities that provided traditional knowledge and/or biodiversity resources.
- Technical and scientific cooperation.
- Coordination of a global directory of taxonomic expertise (Global Taxonomy Initiative).
- Impact assessment.
- Education and public awareness.
- Provision of financial resources.
- National reporting on efforts to implement treaty commitments.

**Nagoya Protocol**

At the 2010, 10$^{th}$ Conference of Parties (COP) to the Convention on Biological Diversity in October in Nagoya, Japan, the Nagoya Protocol was adopted. On 22 December 2010, the UN

declared the period from 2011 to 2020 as the UN-Decade on Biodiversity. They, hence, followed a recommendation of the CBD signatories during COP10 at Nagoya in October 2010. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization 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 thereby contributing to the conservation and sustainable use of biodiversity. The Protocol was adopted on 29 October 2010 in Nagoya, Aichi Province, Japan, and will enter into force on 12 October 2014. It has been ratified by 53 states and the European Union.

**Relevance:** The Nagoya Protocol is intended to create greater legal certainty and transparency for both providers and users of genetic resources by:

- establishing more predictable conditions for access to genetic resources; and
- helping to ensure benefit-sharing when genetic resources leave the contracting party providing the genetic resources.

By helping to ensure benefit-sharing, the Nagoya Protocol creates incentives to conserve and sustainably use genetic resources, and therefore enhances the contribution of biodiversity to development and human well-being.

**Scope:** The Nagoya Protocol applies to genetic resources that are covered by the CBD, and to the benefits arising from their utilization. It also covers traditional knowledge (TK) associated with genetic resources that are covered by the CBD and the benefits arising from its utilization.

**National Biodiversity Authority (NBA)**

NBA is a statutory autonomous body under the Ministry of Environment and Forests, Government of India established in 2003 to implement the provisions under the National Biological Diversity Act, 2002, after India signed Convention on Biological Diversity (CBD) in 1992. In 2012, NBA organized the first ever National Biodiversity Congress (NBC) at Thiruvananthapuram, Kerala. On this occasion, National Biodiversity Students' Congress was also held.

The International Treaty on Plant Genetic Resources (ITPGR) recognized the rights of farmers to save, use and exchange and sell farm saved seeds or propagating material. The Biological Diversity Act (2002) mandates implementation of the Act through decentralized

system with the NBA focusing on advising the Central Government on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising out of the utilization of biological resources; and advising the State Governments in the selection of areas of biodiversity importance as heritage sites and measures for the management of such heritage sites.

The State Biodiversity Boards (SBBs) focus on advising the State Governments, subject to any guidelines issued by the Central Government, on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of the benefits arising out of the utilization of biological resources. The SSBs also regulate, by granting of approvals or otherwise requests for commercial utilization or bio-survey and bio-utilization of any biological resource by Indians. The local level Biodiversity Management Committees (BMCs) are responsible for promoting conservation, sustainable use and documentation of biological diversity including preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stocks and breeds of animals and microorganisms and chronicling of knowledge relating to biological diversity.

**Status of India's Biodiversity:** India is one of the 17-mega biodiversity countries of the world. With only 2.4 per cent of the land area, India already accounts for 7-8 per cent of the recorded species of the world. Over 46,000 species of plants and 81,000 species of animals have been recorded in the country so far by the Botanical Survey of India and the Zoological Survey of India, respectively. India is an acknowledged centre of crop diversity, and harbors many wild relatives and breeds of domesticated animals and fish besides millions of microbial diversity, insects and other species.

**Implementation Structures of Biodiversity Act, 2002**

The NBA with its headquarters in Chennai, Tamil Nadu, delivers its mandate through a structure that comprises of the Authority, Secretariat, SBBs, BMCs and Expert Committees. Since its establishment, NBA has supported creation of SBBs in 28 States and, facilitated establishment of around 32,131 BMCs. The Act and the Rules are implemented in India through a decentralized system. A three tiered structure has been established under the Act at the national, state and local levels.

- At the local level, the Biodiversity Management Committees (BMCs) are to be established by institutions of local self-government for implementation of specific provisions of the Act and Rules.
- At the state level, the State Biodiversity Boards (SBBs) are established to deal with all matters relating to implementation of the Act and the Rules.
- At the national level, the National Biodiversity Authority (NBA) is established to deal with all matters relating to implementation of the Act and the Rules. Each of these structure are required to be connected for decision making processes on various issues, including on issues of access and benefit sharing (ABS).

**Checking of Biopiracy under the Act: In order to** check misappropriation of Indian biological resources, the Act provides that access to Indian biological resources and associated knowledge are subject to terms and conditions, which secure equitable sharing of benefits. Further, it would be required to obtain the approval of the National Biodiversity Authority before seeking any IPR based on biological material and associated knowledge obtained from India.

**Provision of Exemptions under the Legislation**

i) Exemption to local people and communities of the area for free access to use biological resources within India

ii) Exemptions to growers and cultivators of biodiversity and to Vaids and Hakims to use biological resources

iii) Exemption through notification of normally traded commodities from the purview of the Act only when used as commodity

iv) Exemption for collaborative research through government sponsored or government approved institutions subject to overall policy guidelines and approval of the Central Government and conforms to the central government guidelines.

**Benefit Claims**

- The benefit claimers are conservers of biological resources, creators and holders of knowledge and information relating to the uses of biological resources.
- The benefits could include monetary and non-monetary components. Examples could include grant of joint ownership of IPRs, transfer of technology, association of Indian Scientists in R&D, setting up of venture capital fund etc.

- Under Rule 22 (6) of the Biological Diversity Rules, 2004, the BMCs' main function is to prepare the People's Biodiversity Register (PBRs). These registers are used, where available, to identify the BMCs where from the biological resources are accessed and benefits will be provided to the Local Biodiversity Funds (LBFs) maintained by BMCs.
- In cases where specific individuals or group of individuals are identified, the monetary benefits will be paid directly to the Local Biodiversity Fund to be used by the Biodiversity Management Committee (BMC).

## Lecture 7. Patent laws at National Level and International level –Infringement

### Patent Infringement Law in India

A patent confers the exclusive right on the patentee to make, distribute or sell the invention in India. An infringement would be when any of three rights is violated. A patentee may assign license all or some of these rights. The exercise of the rights so transferred infavour of the assignee or the licensee by the assignor or the licensor would not amount to infringement of the patents.

In case of a product patents rights of the patentee are infringed by anyone who makes or supplies that substance commercially. In case of a process patent, the use of such a method or process in India by anyone other than the patentee amounts to infringement.

Whether the act of a person other than the patentee amounts to infringement or not would depend upon:

(i) The extent of the monopoly right conferred by the patent which is interpreted from the specification and claims contained in the application of the patentee. Any action which falls outside the scope of the claims would not amount to infringement.

(ii) Whether he is infringing any of the monopoly rights in the patentee to make, or sell the invention.

*What can amount to infringement*

(1) The colourable imitation of an invention.

(2) Immaterial variation in the invention.

(3) Mechanical equivalents.

(4) Taking essential features of the invention.

All the above acts often overlap each other when an infringement of a patent or process occurs.

A colorable variation or immaterial variation amounting to infringement is where an infringer makes slight modification in the process or product but in fact takes in substance the essential features of the patentee’s invention.

Infringement by mechanical equivalents would occur when he uses mere substitutes for those features so as to get the same result for the same purpose as obtained by the patentee.

**Patent Legal System of India**

The courts in India receive (a) Patent Administrative Cases and (b) Patent Infringement Cases. In patent administrative cases, the Indian Patent Office is the defendant. These types of cases includes dispute on grant of a patent, patent invalidation and upholding, and compulsory licensing. In patent infringement cases, patentee or patent assignees pursue damages against willful infringement conduct by the alleged infringer. These cases includes infringement of patent, disputes relating to ownership of patent, disputes regarding patent rights or right for application, patent contractual disputes, contractual disputes of assignment of patent right, patent licensing, and dispute relating to the revocation of patents.

Fig. 1 below shows the hierarchy of courts in patent administrative cases. As regards to the administrative cases the appeal is made to the Appellate Board under Sec. 117-A of the Patents Act, 1970.

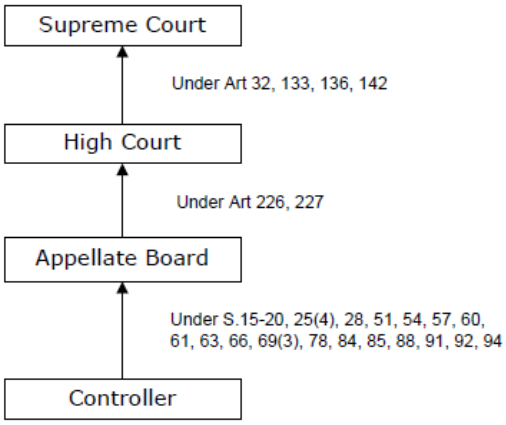



Fig. 1 Hierarchy of Courts in Patent Administrative Disputes

Fig. 2 below shows the hierarchy of courts in patent infringement cases. Regarding the disputes pertaining to infringement, Section 104 of The Indian Patents Act 1970 states that the patent infringement suit shall not be instituted in a court lower than District Court in India. Further, if the defendant files a counter-claim against revocation of the patent, then the suit, along with the counter-claim, shall be transferred to the High Court for decision

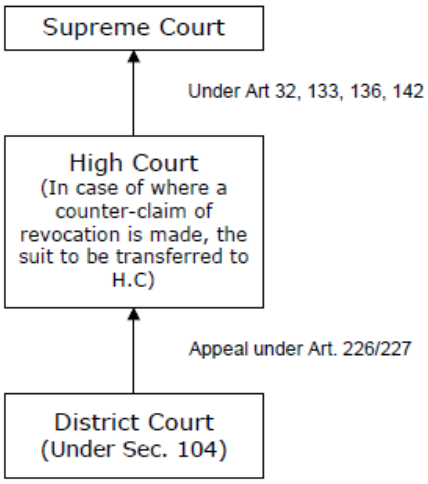



Fig. 2 Hierarchy of Courts in Patent Infringement Disputes

**Action of Infringement**

Whenever the monopoly rights of the patentee are violated, his rights are secured again by the Act through judicial intervention. The patentee has to institute a suit for infringement. The relief's which may be awarded in such a suit are –

(1) Interlocutory/ interim injunction.

(2) Damages or account of profits.

(3) Permanent injunction.

**When a suit can be instituted?**

A suit for infringement can be instituted only after the patent has been sealed. When a specification has been accepted and published *i.e.,* during the period when opposition has been called and is being decided, the applicants cannot institute a suit for infringement, but damages sustained due to the infringement, committed during the period i.e., between the date of publication of acceptance of complete specification and the date of grant may be claimed in another suit; a separate suit for damages but not suit for infringement.

When the term of the patent has expired and infringement occurred during the term of the patent, a suit can be instituted during the term of even after the expiry of the term.

In case a patent had lapsed and was subsequently restored, committed between the date on which the patent ceased to have effect and the date of publication of application for restoration.

When a patent was obtained wrongfully by a person and later granted to the true and first Inventor, no suit for infringement can be instituted for any infringement occurring before the period of such grant to the true and first inventor.

The plaintiff (person who makes a plaint, *i.e.,* institutes a suit) is not obliged to give a notice to the defendant (infringer) before instituting a suit. Court will issue a notice.

**Period of limitation**

The period a limitation for instituting a suit for patent infringement is three years from the date of infringement.

**Who is entitled to sue?**

Only the person who has a right in the patent can institute a suit for infringement. The following persons are entitled to sue:-

(1) The patentee.

(2) The exclusive licensee if the licence is registered.

(3) A compulsory licensee when the patentee refuses or neglects to institute proceedings.

(4) A licensee other than the above two licensees can bring an action for infringement upon the terms of the contract between the licensor and licensee.

(5) Assignee, he can sue only after the application for registration of the assignment in his favour has been filed. If a patent is assigned after the commencement of action, the assignee is to be joined as a co-plaintiff. An assignee cannot sue for infringement which occurred prior to assignment

## U.S. Patent Act & Infringement Laws

U.S. Patent Act

..Part III. Patents and Protection of Patent Rights

....Chapt. 28. Infringement of Patents

***Sect. 271. Infringement of patent***

(a) Except as otherwise provided in this title [35 USCS Sects. 1 et seq.], whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever sells a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a

material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following:

(1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent;

(2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent;

(3) sought to enforce his patent rights against infringement or contributory infringement;

(4) refused to license or use any rights to the patent; or

(5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1)It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit--

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 USCS Sect. 355(j)] or described in section 505(b)(2) of such Act [21 USCS Sect. 355(b)(2)] for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under section 512 of such Act [21 USCS Sect. 360b] or under the Act of March 4, 1913 (21 U.S.C. 151-158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or

other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, or selling of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)-

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, or sale of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, or sale of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285 35 USCS Sect. 285].

(f)(1)Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g)Whoever without authority imports into the United States or sells or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after-

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

## Licensing of Technologies and License Agreement

### License Agreement

Developers and owners of intellectual properties such as patents and trademarks may not wish to make utilize or commercialize what they own for various reasons. If others wish to do so, a license agreement is a good vehicle. The detail and complexity of such agreements will vary with the property being licensed and the business in which the license will be utilized. For both licensor and licensee, the license agreement is a vital part of the business plan and therefore, all possible details and arrangements of the license agreement should be considered.

**i) Licensed Property:** The licensed property may be technology, patents, patent applications, proprietary know-how, trade secrets or confidential information. The property being licensed should be meticulously defined in the intellectual property license to avoid conflicting interpretations.

**ii) Exclusive and Non Exclusive Licenses:** Licenses for intellectual property may be exclusive or non-exclusive. “Non-exclusive" means someone else might hold the same rights. "Exclusive" means no one else may hold those rights. Through an exclusive license, the licensor grants the right to use an intellectual property in a specified manner to one other user; this prohibits other users from using the same property for the duration of the license. A non-exclusive license also grants the right to use a given piece of intellectual property in a specified manner; however, the licensor can grant a non-exclusive license to several users simultaneously.

**iii) Grant of License:** The following aspects need to be addressed before a license agreement is made between licensee and licensor: Is the intellectual property license to be exclusive or non-exclusive? Do the contemplated arrangements include cross-licensing by which the parties grant each other licenses to their respective properties? Should there be a territorial limitation on the license, such as the right to use a trademark only in a certain city or state? Does the licensor wish to restrict how the licensed property will be used? Should the licensee have the right to assign the license or sublicense all or a portion of the licensed property?

**iv) Term of the License:** How long should the license last? Important factors to consider include: (a) the investment the licensee must make in order to use the licensed property; (b) the time required to develop a successful business with the licensed property; and (c) the possible appreciation or depreciation in the value of the licensed property over time.

**v) Changes and Improvements to the Licensed Property:** Is the licensee permitted to modify or improve the licensed property? If so, who owns the modifications or improvements? If the licensor makes changes or improvements, do these automatically fall under the license such that the licensee has rights to use them? Often intellectual property licenses do not adequately address these issues.

**vi) Royalties:** Royalties may be paid in a lump sum or over time for the use of the patented invention to the licensor by the licensee. They may be a sum certain or based on a calculation, for example as percentage of sales. Royalties might be adjusted downward periodically if the licensed property will decline in value over time, as may be the case with an expiring patent or know-how that eventually becomes public knowledge. Similarly, if the licensor continues to develop new property that comes under the license for the benefit of the licensee, the royalty formula agreed upon might yield higher payments to the licensor. In the case of patents related to food, drug or medicines, the royalty reserved to the patentee under a license shall not exceed 4 per cent of the net ex-factory sale price in bulk of the patented article.

**vii) Reports:** If royalty payments are based on a formula, the licensor will want adequate accounting and reporting requirements in the license agreement, along with an obligation of the licensee to maintain records. License agreements often contain audit provisions with cost shifting based on the outcome.

**viii) Infringement Matters:** Consider the extent to which the licensor will warrant that the licensed property does not infringe on the rights of others. All warranties and disclaimers should

be set forth in detail. In addition, will the licensor be obligated to take action against infringers, or will such action be optional? Should the licensee have the obligation to provide notice of infringement to the licensor? If there is a successful challenge to the licensor's ownership of the licensed property, are the royalties payable reduced? Should the parties have a right to terminate the license?

**ix) Confidentiality:** This is very important, especially if trade secrets or confidential proprietary information are included in the licensed property. A designated key employee within the licensee's organization will be responsible for limiting dissemination of such information, assuming control of its return and safeguarding, and reporting on the same to the licensor.

**x) Rights and Obligations upon Termination:** Will there be materials to be returned to the licensor? Should there be a non-competition agreement for a period of time after termination?

**xi) Miscellaneous:** Final matters such as choice of law, dispute resolution, no assignment, etc. must be considered and added. Although these matters are routinely included in well-written agreements, they require careful consideration and drafting, and may require negotiation.

**xii) Licensing Provisions:** Two types of licenses: compulsory licenses and license of rights. Compulsory licenses enabling another party to work the patent can be applied for any time after the expiry of three years from the date of sealing of the patent. In the area of food, drug, medicine or chemical, after the expiry of three years from the date of patent grant, they shall be endorsed with the word "License of Right". These enable any interested person as a matter of right to be entitled to work such patents.

**xiii) Use of Patented Inventions by the Government:** In order to ensure that scarcity of a patented article doesn't arise and lead to high prices, the government is vested with powers to make use of or exercise any patented invention merely for its own purpose.

**xiv) Appeals:** In all cases, appeals will be only with the High Court.

## Material Transfer Agreement and Research Collaboration Agreement

### Sharing of Biological Materials

There is a long history of sharing biological materials, such as plant germplasm or genetic stocks, and for the most part this has been done freely and often without any form of a legal agreement. Scientists have traditionally shared research materials freely, and, indeed, an important criterion for scientific publication has been the ability of other researchers to experimentally reproduce and thereby test published results. The ability to replicate results will

often rely on access to the underlying biological materials or information, but that access is not assured today. Probably this has been occurred due to the narrowing of the gap between fundamental research and commercial developments, particularly in agriculture. Materials that at one time would have been useful almost exclusively for fundamental research purposes are increasingly seen as having direct commercial value, and this trend has generated a new breed of researchers and companies to commercialize valuable traits, genes, or compounds. Particularly, the companies are reluctant to share their research materials without making sure that their business interests are protected. Universities and nonprofit research institutions have also become much more aware and protective of research materials. This attitude has slowed down the unrestricted transfers of research materials between scientists, in general, and particularly between industry scientists and those in universities.

Presently, with growing regularity, the sharing of research materials takes place under Material Transfer Agreements (MTAs). MTAs are legal agreements (bailments) that govern the transfer of a tangible property between parties. At the same time, the restrictions and obligations incorporated in MTAs have made them *more* complex. As a consequence, each MTA has begun to take on the complexity of a license agreement, and a high level of skill and time are required to ensure that the MTA can be executed without compromising key principles and will not conflict with other agreements. Further, a MTA can be a hybrid instrument: covering the transfer of both tangible property (via bailment and contract) and intangible Intellectual Property (IP) (via licensing of patent rights). To complicate things even further, provisions of an MTA may stipulate how any future IP rights, arising from the use of the materials transferred, will be allocated. Because MTAs are contractual agreements between two or more parties, the agreements typically do not have the geographic or temporal limitations of patented technologies (patents are territorial, issued by countries, with limited terms, typically 20 years from filing). It is interesting to note that an evaluation of the property rights associated with “Golden Rice” indicated that 44 patented products or processes and at least 15 materials, many of which were governed by MTAs, were potentially used in its development. In navigating the intellectual and technical property landscape surrounding “Golden Rice,” Potrykus reported that the restrictions imposed by one MTA had been particularly problematic.

**Material Transfer Agreement**

Fundamentally, an MTA is a *bailment*, that is, a transfer of tangible property without transfer of title. Under such an agreement, the provider maintains ownership of the property transferred. Transferred property is held by the receiving party according to terms stipulated in a legally binding contract. The contract, therefore, governs the transfer of tangible biological materials between two or more parties. In addition to the tangible property rights being owned by the provider, the material(s) may be the subject of a patent or patent application. In this case, the MTA may need to account for the transfer of IP rights as well as the transfer of tangible material. Transfer of IP rights would be in the form of a license, for example, to make, use, sell, and so forth, that is, a license is permission to do what would otherwise violate the provider's IP rights. MTA on materials that are intended to be used for research purposes is taken up usually in the absence of planned research collaboration between the provider and recipient. Such collaboration could be accommodated by a separate *collaboration agreement* that would accompany the MTA. The MTA defines the rights of the provider and recipient with respect to the materials and derivatives of the materials.

MTAs that are not signed by an institutional official may not be valid or enforceable. These functions usually reside in the Office of Research Administration (Sponsored Programs) or the office that manages IP and technology transfer for the institution. Because the researcher utilizing the material(s) is ultimately responsible for fulfilling the obligations of the MTA, most MTAs require the signature of the recipient of the material acknowledging their recognition of their responsibilities and duties under the agreement.

**Structure of a Material Transfer Agreement**

The structure of MTA may incorporate many if not all of the following:

i) a preamble
ii) definitions
iii) a description of use of the materials
iv) confidential information
v) IP rights
vi) warranties
vii) liability and/or indemnification
viii) publication

ix) governing law

x) termination

xi) signatures

xii) exhibits or appendices

## Lecture 8. Procedure to get patent – Patent Cooperation Treaty (PCT)

**Procedure for Granting Patent**

A patent is granted by a national patent office or by a regional office that does the work for a number of countries, such as the European Patent Office and the African Regional Industrial Property Organization. Under such regional systems, an applicant requests protection for the invention in one or more countries, and each country decides as to whether to offer patent protection within its borders. The WIPO - administered Patent Cooperation Treaty (PCT) provides for the filing of a single international patent application which has the same effect as national applications filed in the designated countries. In India, the Controller General of Patents, Designs and Trademarks is responsible for the administration of the Patents Act, 1970 through the Patent Offices located at Kolkata, Mumbai, Delhi and Chennai.

**i) Patent Information**

Every patent office throughout the world publishes the patent literatures and the information what one gets from these patent documents is called Patent Information. The advantages of the patent information are:

a) Patent documents are the main source of patent information.
b) Patent information is well classified according to the International Patent Classification System to enable easy approach and use.
c) Patent information can be used for further research as a stepping stone.
d) Patent Information plays a pivotal role in technology transfer.
e) Patent information is free to be utilized after the term of the patent expires or when the patent ceases to be in force.

**a) Forms of storage and retrieval of patent information:** The patent information is available in various media like:

i) Traditional printed hard copy form, i.e., paper copies from Patent Office.
ii) Micro film (From *Patent Information System* (PIS), Nagpur).
iii) On-line availability – Indian Patent Office Website *"www.ipindia.nic.in"* where from the public can access the details about patents and designs, the application forms and details about the patent procedures and Patent Offices.
iv) CD ROM – Various types of CD-ROMs provide Patent Information regularly, which is updated regularly.

v) Patent Information throughout the world is available in both abridged and detailed versions on various websites (E.g. Uspto.gov.com, etc.) and also in CD-ROM forms.

**b) Various storage tools facilities available from the patent office**

i) The Search Files containing the printed specifications of the earlier granted patents in hard copy form are classified according to the Indian and International Patent Classification.

ii) Abridgements / Abstracts classified according to the International Patent Classification Systems.

iii) Extraordinary Gazette of India, Part III, Section 2, exclusively for the Patent Office, publishes the information regarding the filling and grant of Patent.

iv) The Subject Matter Index (Serial Files) classified according to the Indian Classification System.

v) Name Index List.

**ii) Precautions to be taken by the Applicants**

**a) Before the grant of patent**

i) Do not publish the invention before applying for a patent protection.

ii) Before you start working on a problem, review the Patent Literature on the particular field of industry to which the problem relates so as to save wastage of time and money.

iii) Go through the Patent Search Files so as to get familiar with the intricacies of patent practices and to draft a good Patent Specification.

iv) Decide the question of securing foreign patents before it is too late to apply for such a patent.

v) Prosecute your patent application within the time limits prescribed at various stages of the application processing.

vi) Look upon the objections raised by the Patent Office as constructive criticisms offered to you, so that the Patent that might be granted to you could be a valid one.

**b) After the grant of patent, when you become a patentee**

i) Do not fail to pay the Renewal Fee in time.

ii) Try to work on the Patent, exploiting the invention commercially or else, grant license to a person, who has well equipped infrastructure to manufacture the patented product.

iii) Keep yourself in touch with the industrial progress by referring to the Patent Office Gazette and other publications. This will be helpful for keeping you updated with the latest scientific

and technological progress and provide guidance to perform new invention as advance steps to your earlier inventions.

**iii) How to apply for obtaining Patent?**

Any person who is true and first inventor is entitled to apply for a patent and to protect his invention through Patent Right. The inventor can either be a Natural Person or a Legal Entity. Disclosure of invention to the public before applying for patent will destroy the novelty of invention. The prescribed forms for applying to get a patent are forms 1, 2 and 3, which are available in the Patent Offices and at various websites.

**Types of Patent Application**

a) **Application for Ordinary Patent** is filed under the Patents Act, 1970. Ordinary patent can be obtained by any person, whether a citizen of India, or not, claiming to be the true and first inventor or his assignee.

b) **Application for Patent of Addition** is filed for improvement in or modification of an invention for which a patent has already been applied for. The applicant of the original patent to which the invention is an addition, can only file a patent of addition.

c) **Convention Application:** Patent grants under section (u/s) 135 in respect of reciprocatory arrangement for the nationals of countries covered under Paris Convention.

**iv) Requirements for the Patent**

The patent application should satisfy the following requirements:

a) Problem of invention.
b) Current report of the problem to be addressed.
c) Solution to the problem.
d) Extent of novelty.
e) Uses or application.
f) Inventor details

**Documents necessary for making an application for patent to the patent office:**

i) Application in the prescribed form with prescribed fees in duplicate.
ii) Provisional or complete specification along with drawings, if any, in duplicate.
iii) Abstract of invention in duplicate.

iv) A statement and undertaking regarding foreign filing under section 8 of the Act in the prescribed form in duplicate.

v) In case provisional specification is filed first or application is a conventional application, then a declaration as to inventorship in the prescribed form is to be field with complete specification.

vi) In the case of convention application, certified copy of the specification filed by the applicant in the convention country is required to be submitted.

vii) A duly stamped power of attorney in the prescribed form is required, in case the application is filed through a patent attorney.

**v) Appropriate Office**

Application is to be filed according to the territorial limits where the applicant or the first mentioned applicant in case of joint applicants for a patent normally resides or has a domicile or a place of business. If the applicant has no place of business, or domicile in India, the appropriate office will be as per the address for service in India given by the applicant.

**vi) Specification**

The applicant can file either the provisional or complete specification at the time of filing an application for patent. However, the application will be examined only when complete specification is filed, in case provisional specification is filed first [and a Request For Examination (RFE) is made in Form 18].

**a) Contents of provisional specification:** The inventor should disclose general aspects of invention in provisional specification. It is advisable to give all the pertinent information in respect of the invention. Purpose of filing provisional specification is to establish the priority date of invention. Thus, the provisional specification helps the inventor in getting preference over the person who might have applied for patent at a later date. The provisional specifications should not contain claims. No amendment that would add any fresh matter to, or extend the scope of the invention described in the provisional specification is allowable when complete specification is filed thereafter.

**b) Contents of complete specification**

i) The complete specification is a techno-legal document. As the patent rights are conferred on the applicant based on the information disclosed in the complete specification, it is essential

to disclose the invention fully, sufficiently and fairly in the complete specification. The Patent Act prescribes the directions regarding the content of the disclosure.

ii) The complete specification shall sufficiently and fairly describe the method by which it is to be performed, that is to say, the description of the method or the instructions for working of the invention, as contained in the complete specification, should be sufficient to enable a person in India possessing average skill in and average knowledge of the art to which the invention relates, to work the invention. In other words, the complete specification should disclose the best method of performing it which was known to the Applicant for the patent and for which he was entitled to claim protection.

**iii) Normally the complete specification shall contain the following subject matter:**

a) Title of Invention
b) Field of invention
c) Background of invention with regard to the drawbacks associated with the prior art.
d) Object of invention
e) Summary of invention
f) Brief description of the accompanying drawings
g) Detailed description of the invention with reference to drawings
h) Claim(s)
i) Abstract of invention

**The claims** should clearly define the scope and the salient features of the invention. There should be no ambiguity in respect of the nature of the invention and the scope of claims. While abstract covers the scientific aspects of the invention, the claims cover the legal aspect, namely, the protection sought by the inventor.

**Abstract of invention:** The abstract is the summary of the invention, preferably within 150 words. It should be prepared in such a way that one can understand the Technical problem and the Technical solution offered with its usefulness. However, it cannot be used for the purpose of interpreting the scope of protection in legal proceedings.

**Broad guidelines for drafting the complete specification:** Before drafting the complete specification, it is preferable to conduct a search for novelty from the data-bases and through other information sources. The complete specification should include critical examination of the Prior Art and cited documents and how the invention differs from the information known in the

prior act. Each part of the complete specification can be described in brief. A detailed description of any preferred embodiment of an invention with the help of drawing should be given. The utility and advantage of the invention should be clearly mentioned. The complete specification should end with a Statement of Claims, defining the scope of invention. Claims can be sufficiently broad to impart sufficient protection but not too wide, so as to be not justifiable by the information disclosed in the complete specification. The inventor should precisely demark the ambit of invention.

**vii) Publication of Applications**

All the applications for patents will not be open to the public for 18 months from the date of filing or date of priority whichever is earlier. After 18 months, every application will be published except the applications in which a secrecy direction is given under section 35, and the same will be notified in the Official Gazette. The publication includes the particulars of date of application, number of application, name and address of the applicant and abstract. Upon publication, the specification and drawings are made available to the public by Patent Office on payment of the prescribed fee and the biological materials mentioned in the specification will be made available to the public by the depository institutions.

**viii) Request for Examination (RFE)**

No application for a patent will be required to be examined unless the applicant or any other interested person makes a request in Form 18 within 48 months from the date of filing of the application for patent. In case of applications filed before 20.05.2003 (Date of commencement of the Patents [Amendment] Act, 2002), the request shall be made before 20.05.2004 or within 48 months from the date of application, whichever is later.

In case of applications in respect of a claim for a substance intended for use or capable of being used as medicine or drug except the chemical substances ordinarily used as intermediates, the request shall be made before 31.05.2005 or within 48 months from the date of application, whichever is later. In case a request is not made within the stipulated time, the application will be treated as withdrawn by the applicant. Also, the applicant may withdraw the application made by him before the grant of patent.

**ix) Examination and First Examination Report (FER)**

All the applications filed at the appropriate office shall be first subjected to formal screening and then to substantive Technical examination by the examiner [when a request in Form 18 is made]. As the novelty, inventive step and industrial application are the criteria for the Grant of Patent, these aspects are thoroughly studied by the Examiner. Further, the examiner will conduct a search for novelty, using the data-bases available at the patent office after the subject matter of invention is classified according to Indian and International classification, and also various other sources. The technical and legal defects observed by the Examiner are submitted to the Controller of Patents in the form of objections for his approval. A statement of objections known as the "**First Examination Report**" will be issued to the Applicant by the patent office. The applicant shall rectify all the legal and technical defects and put the application in order for acceptance within a period of 6 months, which cannot be extended. However, first reply to the First Examination Report shall be made within 4 months.

**x) Acceptance and Notification of Complete Specification**

The Controller of Patent shall accept the complete specification and inform the acceptance of complete specification to the applicant. Further, the acceptance of complete specification will be notified in the Gazette of India, Part III, section 2 which is published weekly, on every Saturday.

**xi) Opposition to the Grant of Patent**

Any person interested can oppose the grant of patent within a period of four months, extendable by another month. The desire to oppose the grant should be put in an appropriate form with appropriate fee. An opponent shall file a Notice of Opposition giving details of the grounds on which he wishes to oppose the Grant of Patent. The notice of opposition should be followed by full written statement explaining the various ground of opposition. The opposition to the Grant of Patent coming before the controller is a bi-party proceedings wherein, the Controller, being a quasi-judicial authority, will decide the case based on the written statement and evidence placed by the opponent and, also the reply statement and evidence filed subsequently by the Applicant.

**xii) Grant of Patent**

If the application is not opposed or the opposition is decided in favour of the applicant or is not refused otherwise, then the patent is granted and sealed upon request made by the applicant in the prescribed manner along with fees on payment of Sealing Fee within 6 months from the

date of advertisement of acceptance of complete specification. The period is extendable by three months. Patent rights will accrue to the applicant only when the patent is sealed and the rights are granted to him. The patentee gets the right to sue any third party for infringement of patent rights only after the patent is granted to him. However, the patentee can claim damages from the date on which complete specification was notified in the Gazette.

**xiii) Renewal Fee**

In order to keep the patent in force, Renewal Fee is to be paid in the Patent Office annually. Date of payment of renewal fees is counted from the Date of Patent. Grace period of six months is available on payment of extension fee. The first renewal fee is payable for third year of patent's life and must be paid before the end of second year. If the patent has not been issued within that period, Renewal Fee may be accumulated and paid immediately after the patent is sealed or within 3 months of its Recordal in the Register of Patents and or within the extended period not later than 9 months from the date of recording.

**xiv) Term of Patent**

The term of every patent granted after 20.05.2003 and the term of every patent not expired and not ceased to have effect on 20.05.2003 will be 20 years from the date of filling of the application for the patent.

**xv) Rights of Patentee**

Where the patent is for a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India; Where the patent is for a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India.

**xvi) Working of Patent**

The purpose of grant of patent in India is that the invention should be exploited by way of manufacturing the patented product in India. Every patentee should furnish periodical statement as to the extent to which the patented invention has been worked on a commercial basis in India. The non-worked patents are classified according to subjects and advertised in the Gazette of India for the benefit of public / person who is interested to approach the Controller for License to work such a patent.

**xvii) Compulsory License**

The principle of grant of patent is mentioned in the Patent Act which indicates that the patent is for the purpose of Industrial Development and it is mandatory for the Patentee to work with the patent on an industrial scale. Several measures are provided under the provisions of the Act to check or prevent the abuse of patent rights, which include granting compulsory license to an interested party, where an interested party can start manufacturing the patented article or process and simultaneously negotiate with the patentee in respect of royalty. The right to apply for compulsory license will be after the expiry of 3 years from the date of sealing of patent rights. If these provisions do not prevent the abuse of patent right then the government can invoke powers to revoke the grant of patent rights.

**xviii) Revocation**

When the patent rights are abused, either public or government can invoke the provisions of the Act for the revocation of the patent. Further, any person may move the court to revoke the grant of patent, on any of the grounds mentioned in the Patent Act for the purpose.

## PCT International and National Phase

**Traditional Patent System**

Traditional patent system requires filing of individual patent applications for each country for which protection is sought with the exception of regional patents such as the African Intellectual Property Organization (OAPI) system, the Harare Protocol System established in the framework of the African Regional Industrial Property Organization (ARIPO), the Eurasian Patent System and the European System. Under the traditional Paris Convention route, the applicant gets upto twelve months for filing in foreign countries. For the applicant, this involves preparation and filing of Patent documents within one year of the first application. This means expenses for translation, payment to patent attorneys in the various countries and payment of fees to all patent offices, all at a time, when the applicant does not know whether he is likely to obtain a patent or whether his invention is really new compared with the state of art.

**Patent Cooperation Treaty (PCT)**

Patent Cooperation Treaty is an arrangement under TRIPS for international cooperation in the field of patents. It is largely a treaty for rationalization and cooperation with regard to filling, searching and examination of patent applications and dissemination of the technical information contained therein. The PCT does not provide for the grant of international patents as

the task of granting patents lies exclusively in the hands of the patent offices where protection is sought [(i.e.,) the designated offices]. It is a special agreement under the Paris Convention and is open only to states, which are also party to Paris Convention.

**Principal Objective of PCT**

**PCT** simplifies and renders more effective and economical means of applying for Patent at a time in several countries for patent protection.

**Salient Features of PCT**

i) One single application in one language is filed in a single patent office and it has the effect of filing on the same day in each of the countries, the applicant designates in this application.

ii) One formal examination is done by the office of filing.

iii) The application is subject to an international search, which results in a report citing the relevant prior art.

iv) Centralized international publication of international applications with the related search reports.

v) Option for preliminary examination with a report containing an opinion as to whether the claimed invention meets certain international criteria for patentability.

Under the PCT system, by the time the international application reaches the national office, it has already been examined as to the form by the receiving office, searched by the international searching authority, and possibly examined by the international examination authority. Thus the National Patent Offices are provided with the important benefit of reducing their workloads since they have the benefit of these international phase centralized procedures and need not duplicate those efforts but merely supplement them if needed, and thus, the benefit is passed on to the applicants.

**Benefits of PCT to the Applicants**

The applicant by filing a single application is getting the benefit of filing it in all the designated countries, thus getting priority over those who file for the same invention before he enters the national phase in the different countries after getting the search and examination reports. He defers the attorney fees and payment of the fees in the designated countries till he gets the reports and decides to proceed further. He also gets time to enquire about the market value of the invention in the designated countries and also look out for collaboration in parallel.

**PCT Filing Procedure**

i) Along with PCT application form, four copies of specification comprising description, claims and drawings are required to be filed.

ii) The transmittal fee is charged for individual / legal entity by the Patent Office where the application is filled.

iii) The designation fee is dependent on the number of countries designated and a maximum of six designations is to be paid for.

iv) The search fee is dependent on the searching authority chosen.

v) Basic fee is charged based on the number of pages of the document i.e., request form + specification.

vi) The transmittal, designation, search and basic fee are to be paid within a month from the

vii) filing date.

**Minimum Requirements for Filling PCT Application**

i) At least one applicant must be either a national or resident of / in India.

ii) Specification should be in English.

iii) An indication that it is a PCT international application is required.

iv) At least one country should be designated.

v) Name of the applicant, address and the nationality should be clearly given.

vi) Part on the face of it appears to be description should be there.

vii) Part on the face of it appears to be a claim or claims is needed.

**Time Limits**

i) PCT international application can be filed within one year from the date of filing the national application in home country for the purpose of claiming the priority. It can be directly filed with International Bureau (i.e.,) WIPO at Geneva.

ii) Search report is sent to the applicant within sixteen months from priority date (if priority is claimed) or within nine months from PCT international filing date if no priority is claimed.

iii) At the end of eighteen months from the priority date or international filing date of application, it is published in the PCT Pamphlet.

iv) Preliminary examination is to be requested for before nineteen months from International filing date of priority date whichever is earlier from one of the six International Searching Authorities.

**National Phase**

After getting the search report and preliminary examination report (if opted for), the applicant has to file the National Phase Application in the designated countries he is interested in to enter the National Phase. The national application has to be filed before thirty one months if preliminary examination is not opted for and after thirty one months if preliminary examination is opted for. In the national phase, before the expiry of the specified period, the minimum documents, namely, specification, drawings (and translations if needed) details of international filing, Form 1A (as per patents act 1970) along with the prescribed fee are to be submitted.

Then the routine procedure for a normal national application, takes over with the only difference that the international filing date, the International Search Report and International Preliminary Examination Report are taken into account for granting the Patent.

## Lecture 10

## Commercialisation of IP-Licensing of Technologies and License Agreement

### License Agreement

Developers and owners of intellectual properties such as patents and trademarks may not wish to make utilize or commercialize( involving others) what they own for various reasons. If others wish to do so, a license agreement is a good vehicle. The detail and complexity of such agreements will vary with the property being licensed and the business in which the license will be utilized. For both licensor and licensee, the license agreement is a vital part of the business plan and therefore, all possible details and arrangements of the license agreement should be considered.

**ii) Licensed Property:** The licensed property may be technology, patents, patent applications, proprietary know-how, trademark, trade secrets or confidential information. The property being licensed should be meticulously defined in the intellectual property license to avoid conflicting interpretations.

**ii) Exclusive and Non Exclusive Licenses:** Licenses for intellectual property may be exclusive or non-exclusive. “Non-exclusive" means someone else might hold the same rights. "Exclusive" means no one else may hold those rights. Through an exclusive license, the licensor grants the right to use an intellectual property in a specified manner to one other user; this prohibits other users from using the same property for the duration of the license. A non-exclusive license also grants the right to use a given piece of intellectual property in a specified manner; however, the licensor can grant a non-exclusive license to several users simultaneously.

**iii) Grant of License:** The following aspects need to be addressed before a license agreement is made between licensee and licensor: Is the intellectual property license to be exclusive or non-exclusive? Do the contemplated arrangements include cross-licensing by which the parties grant each other licenses to their respective properties? Should there be a territorial limitation on the license, such as the right to use a trademark only in a certain city or state? Does the licensor wish to restrict how the licensed property will be used? Should the licensee have the right to assign the license or sublicense all or a portion of the licensed property?

**iv) Term of the License:** How long should the license last? Important factors to consider include: (a) the investment the licensee must make in order to use the licensed property; (b) the time required to develop a successful business with the licensed property; and (c) the possible appreciation or depreciation in the value of the licensed property over time.

**v) Changes and Improvements to the Licensed Property:** Is the licensee permitted to modify or improve the licensed property? If so, who owns the modifications or improvements? If the licensor makes changes or improvements, do these automatically fall under the license such that the licensee has rights to use them? Often intellectual property licenses do not adequately address these issues.

**vi) Royalties:** The royalty involves an agreement whereby an owner of a technological intellectual property (the licensor) allows another party (the licensee) to use, modify, and/or resell that property in exchange for a compensation (consideration). The compensation may take the form of a (i) lump sum royalty, (ii) royalty based on volume of production (called running royalty), or (iii) right to use licensee's technology (called cross licensing). Royalties may be paid in a lump sum or over time for the use of the patented invention to the licensor by the licensee. They may be a sum certain or based on a calculation, for example, as percentage of sales. Royalties might be adjusted downward periodically if the licensed property will decline in value over time, as may be the case with an expiring patent or know-how that eventually becomes public knowledge. Similarly, if the licensor continues to develop new property that comes under the license for the benefit of the licensee, the royalty formula agreed upon might yield higher payments to the licensor. In the case of patents related to food, drug or medicines, the royalty reserved to the patentee under a license shall not exceed 4 per cent of the net ex-factory sale price in bulk of the patented article.

**vii) Reports:** If royalty payments are based on a formula, the licensor will want adequate accounting and reporting requirements in the license agreement, along with an obligation of the licensee to maintain records. License agreements often contain audit provisions with cost shifting based on the outcome.

**viii) Infringement Matters:** Consider the extent to which the licensor will warrant that the licensed property does not infringe on the rights of others. All warranties and disclaimers should be set forth in detail. In addition, will the licensor be obligated to take action against infringers, or will such action be optional? Should the licensee have the obligation to provide notice of infringement to the licensor? If there is a successful challenge to the licensor's ownership of the licensed property, are the royalties payable reduced? Should the parties have a right to terminate the license?

**ix) Confidentiality:** This is very important, especially if trade secrets or confidential proprietary information are included in the licensed property. A designated key employee within the licensee's organization will be responsible for limiting dissemination of such information, assuming control of its return and safeguarding, and reporting on the same to the licensor.

**x) Rights and Obligations upon Termination:** Will there be materials to be returned to the licensor? Should there be a non-competition agreement for a period of time after termination?

**xi) Miscellaneous:** Final matters such as choice of law, dispute resolution, no assignment, etc. must be considered and added. Although these matters are routinely included in well-written agreements, they require careful consideration and drafting, and may require negotiation.

**xii) Licensing Provisions:** Two types of licenses: compulsory licenses and license of rights. Compulsory licenses enabling another party to work the patent can be applied for any time after the expiry of three years from the date of sealing of the patent. In the area of food, drug, medicine or chemical, after the expiry of three years from the date of patent grant, they shall be endorsed with the word "License of Right". These enable any interested person as a matter of right to be entitled to work such patents.

**xiii) Use of Patented Inventions by the Government:** In order to ensure that scarcity of a patented article doesn't arise and lead to high prices, the government is vested with powers to make use of or exercise any patented invention merely for its own purpose.

**xiv) Appeals:** In all cases, appeals will be only with the High Court.

**Licensing Agreements and Commercialization of Plant Varieties in India**

On the basis of the national priorities and issues of food and nutritional security, Indian Council of Agricultural Research (ICAR) may decide to place a plant variety solely in the public domain or else it may be licensed for commercial use on exclusive or non-exclusive basis. However, registration and protection of all protectable varieties will be ensured under the PPV&FR Act before placing them in public or commercial domain.

**Commercialization of Plant Varieties**

i) ICAR may consider any proposal for the grant of exclusive license to a private / public seed agency for commercialization of its protected plant variety abroad. All such varieties of ICAR which have commercialization potential abroad, shall be assigned to Agro Technology Management Centre (ATMC) and licensed under suitable arrangements / agreement keeping in view the interest of Indian farmers and national priorities.

ii) Advance breeding material or parental lines shall not be transferred/ licensed on exclusive basis. These will first be registered with National Bureau of Plant Genetic Resources (NBPGR) before any material transfer/licensing agreement is entered into.

iii) Commercialization of an ICAR variety will be done by the same institution/zonal institute that have secured the PVP title. However, where more than one ICAR institutions are involved/interested in the commercialization of the same variety, or where they are given this specific responsibility in public interest by the ICAR, these institutions will mutually

settle the sharing arrangements.

iv) ICAR institutions will obtain assistance/advice of ATMC/ Zonal Technology Management Centre (ZTMC), if needed, particularly for any legal opinion or market information.

v) The parametric values of all successful licenses will be recorded in the institutional/zonal/ central databases.

vi) ATMC will evolve a suitable mechanism for quick disposal of plant variety licensing cases at different levels in ICAR.

**Licensing of Seed and Planting Material**

i) **Licensing:** As the ICAR technologies like seed and planting/propagating material have direct impact on the productivity and production in agriculture, their transfer on priority through licensing to various seed producers and distributors shall be facilitated.

ii) **Non-Exclusive Licenses:** ICAR will provide commercial licenses, preferably non-exclusive licenses, for the commercialization of seed/planting material of registered and protected ICAR varieties to any interested party such as the following:

a) Central and State Departments of Agriculture on national/state basis for wide dissemination, popularization and public distribution of seeds / planting materials for development and cooperation.

b) Public Seed Agencies – Central and State Seed Corporations for multiplication and distribution widely.

c) Private/Cooperative seed producers on regional basis for encouraging local multiplication and promoting use of specific varieties.

d) Other contracting parties including foreign clients in seed business who may be interested in commercializing ICAR seed/ planting materials in other countries. The terms and conditions of the license will include, among other things, securing protection of ICAR varieties in the respective countries by the foreign client.

**iii) Exclusive Licenses:** Exclusive licenses may be given after negotiations and on mutually agreed terms. In the license agreement for an exclusive license, a sub-licensing clause will be negotiated / incorporated so that a part of the license fee and/or royalty from sub-licenses given by the licensee is provided to ICAR. Also, negotiation will be undertaken for a time-line for re-negotiation of the license, if needed, which will be recorded in the agreement.

**iv) Compulsory Denomination:** The ICAR seed and planting/propagating material shall be licensed under only the registered denomination. The licensee will be required to print the same denomination on the label and to sell the seed/planting material essentially under that denomination. Subsequently, it shall also not be changed by the licensee or by any third party

with whom the licensee deals with in that seed.

**v) Use of ICAR Mark:** Along with the use of registered denomination, all license holders shall be required to use ICAR' s Collective Mark/Trade Mark on all packets of seed/propagules of the licensed seed. In this context, if the licensee is interested to simultaneously use its own trade name in the licensed seed, the same can also be agreed to.

**vi) Seed Quality Assurance:** ICAR would provide breeder seed and will lay down the condition before the licensee to maintain the seed quality and purity. However, it will not be held responsible for the quality of subsequent lots produced and sold by the licensee. Thus, the agreement with the licensee shall also have the following clauses:

a) Assurance clause that the licensee will maintain the seed quality and genetic purity of the plant variety licensed by ICAR.
b) Disclaimer clause that ICAR will not be held responsible for the seed quality/purity of the subsequent lots commercialized by the licensee.
c) Indemnity clause that the licensee indemnifies the licensor, ICAR from any legal consequences of his deals in subsequent lots of licensed seed / propagules.

**vii) Joint Ownership Cases:** Varieties for which ICAR has joint ownership with State Agricultural Universities (SAUs) or others, the joint owner will be given the first priority to use the variety for commercial purposes on mutually agreed terms. In the absence of any such request for a reasonable time period (6 months from grant of PVP title on the variety), the ICAR may award a non-exclusive license to any other contracting party including in the territory of business interest of the joint owner for dissemination of seed to the farmers of that area.

**Breeder Seed**

i) Depending upon the terms and conditions of the licence agreement, breeder seed will be supplied by concerned institutions only once or recurrently. Subsequent agreement may also be made with the licensee for making fresh supply of breeder seed.
ii) ICAR shall maintain seed purity and health of all their released/registered varieties. Concerned ICAR institution(s) and breeder(s) will maintain and supply the breeder seed of respective registered and protected plant varieties as per licence agreements.
iii) Breeder seed will be provided to the licensees under the terms and conditions that the licensee (seed agency/company producing commercial seed of ICAR varieties) will be responsible and liable for maintaining genetic purity of the seed/propagule and seed quality during the entire term of licence and the licensor will not bear any liability for spurious seed.
iv) ICAR shall have the right to monitor seed genetic purity of the licensee' s seed lots at the

cost of the licensee, which will be recorded in the licensing contract.

v) ICAR may provide consultancies on request to the licensees for technical opinion/ assistance/ advice to maintain the genetic purity and seed quality of seed / propagules.

vi) It will be clearly mentioned in the licensing contract as to whether the breeder seed will be given to the licensee on one time basis or on annual basis or on recurrent basis with defined periodicity. The quantity of breeder seed to be given in each case/situation will also be mentioned.

vii) A clause will be included in the license agreement to the effect that no plant variety license will be valid unless the licensee agrees to produce and distribute/sell quality seed in the respective zone mentioned in the license agreement on a regular basis “in sufficient quantities and at a reasonable price”.

viii) ICAR will use various ways and means to further provide the breeder seed of its licensed varieties in case of any Compulsory Licensing under the PVP law.

ix) Breeder seed of jointly owned plant varieties will be produced maintained and supplied as per mutually agreed terms between ICAR and the other co-owners of the variety.

**Licence Fee/Sale Price of Breeder Seed and Royalty**

The concerned ICAR institutions will determine the license fee and royalty and/or sale price of breeder seed either on a fixed basis, through negotiations with the licensee, or through an open bidding process as appropriate. Expert opinion and judgment together with the following points will be considered to fix the price/license fee.

i) Cost of seeking and maintaining the plant variety right of the variety to be licensed.

ii) Cost of production, handling and supply of breeder seed.

iii) Other institutional costs as appropriate.

The Institute Technology Management Unit (ITMUs) /ZTMCs may determine the licence fee and/or sale price of the breeder seed at the institute level with the necessary in-house expertise/experience or they may seek assistance from the ATMC. As no standard formulae are available or can be provided for all crops, categories and situations, the ITMC at the institute level will determine the licence fee and/ or sale price of the variety taking into account issues of food and nutritional security, if any, the considerations of “what the market can bear” and cost factors mentioned above. The decision of the ITMC, based on holistic assessment and judgment will be final. If the matter has been referred to the ZTMC/ ATMC, the same procedure will be followed there. For evolving the system of licensing of plant varieties, ATMC/ZTMCs with the help of crop-specific institutions and outside experts, will develop and disseminate model agreements/case studies of different sizes and dimensions for reference purposes.

**Research Exemption and Benefit Sharing**

There will be exemption for research use of all registered and protected plant varieties and registered genetic stocks of ICAR.

i) Within ICAR, all institutions shall register their elite parental genetic stocks at NBPGR. They will transfer all plant genetic material under Material Transfer Agreement (MTA) through the Bureau; and also deposit a referral seed sample along with passport data set at the National Gene Bank as a pre-requisite.

ii) ICAR will not impose any royalty payment for such breeding material maintained by private seed companies without registration and protection under the PPV&FR Act as is developed / derived from genetic stocks of ICAR institutions. However, the concerned seed company has to share the commercial benefits accrued using these breeding materials.

iii) Condition of any royalty payment will also not be imposed for materials used in All India Coordinated Research Projects/ Network Projects by SAUs and other partners with whom ICAR has standing MoUs. Rather, such cases will be addressed/settled on mutually agreed terms.

iv) In accordance with the provisions of the PPV&FR Act, ICAR may charge a royalty on seed sale of a protected variety which is developed by another agency/ company/ breeder by using its genetic material, which will be recurrently required for the commercial production of the protected variety.

v) ICAR will consider/discharge any liability of benefit sharing that may be fixed by the PPV&FR Authority. Concerned ITMUs/ZTMCs shall verify the relevant facts and make a detailed case to ATMC for the consideration/approval of the competent authority.

**Records and Confidential Information**

- Standard records of genetic stocks at the institution along with confidential records (codes) where applicable shall be maintained in signed and countersigned notebooks/registers. Suitable data sets will also be documented in the institutional/zonal/central database.
- All confidential information, such as codes, etc., will be kept safely and would not be revealed by individuals/institutions except through confidentiality agreements which will expressly mention the purpose for sharing such information and other terms and conditions.

**Infringements:** Concerned breeders/ other ICAR scientists will report all matters of infringement / suspected infringement of plant variety rights in their knowledge to the respective ITMUs / ZTMCs / ATMC. Concerned ITMUs/ZTMCs will handle the cases reported to them or other apprehended cases either on their own or with the assistance of ATMC. Further legal action, if required, will be taken up with the approval of competent authority.

**Monitoring and IP/Market Watch:** The commercialization of plant variety portfolio will be monitored by ITMUs / ZTMCs / ATMC. The relevant developments / matters of concern, etc. will be critically observed and addressed. ATMC/ZTMCs will develop a mechanism of market watch.

**Socio-Economic Impact:** ATMC will plan/organize/assign suitable impact assessment studies on socio-economic impact of the commercialized plant varieties/hybrids of ICAR in different crops and regions of the country.

**ICAR Guidelines on Licensing IP technologies in India**

**Central Database of IPR Enabled Technologies**

A central database of the IPR enabled technologies will be maintained at the ATMC. The concerned institutions/zonal institutes will make entries of all new cases in their respective datasets and they shall communicate a data set to the ZTMC/ATMC for linking with the zonal/central database. The entire ICAR IP database will be suitably inter-linked through intranet and they shall also update the status of IPR protection/ maintenance in the data set from time to time.

**Transfer of IPR Enabled Technologies**

Notwithstanding the fact that only a small proportion of protected IP generally meets with commercial success world-wide, the Agro-technology Management Centre (ATMC) and Zonal Agro-Technology Management Centre (ZTMC)/ Institute Technology Management Unit (ITMU) will make efforts for technology commercialization with the primary objective of technology transfer to end-users. Depending upon factors such as the nature of technology, public need or marketing prospects, scale of technology etc. a decision will be taken by the competent authority whether the technology will be placed in the public domain through open access, or it will be transferred to end-users through commercialization.

**Registration of Commercial Entities**

The ITMUs/ZTMCs/ATMC shall develop a system of registering industry/ enterprises/ cooperatives for technology transfer/commercialization of ICAR technologies.

i) Registration of area/discipline/zone-wise potential licensees from industry / enterprises / cooperatives will be undertaken by inviting applications through advertisement.
ii) The registered entities will be informed of the IPR enabled technologies available from time to time for transfer through commercialization.
iii) A nominal registration fee will be charged and the registration renewed annually.

**Disclosure/Advertisement of IP Enabled ICAR Technologies**

The ITMUs will disclose the salient features of technology ready for commercialization. The technology disclosure for commercialization will be made in a confidential agreement. The

ITMUs shall supply the catalogue/ information to the registered agencies on the technology developed giving its details/ specifications and potential benefits. The ITMUs/ZTMCs/ATMC will also advertise the IP enabled ICAR technologies available for commercialization by suitable means. The IPR enabled ICAR technologies ready for transfer / commercialization will also be given publicity through web portals of federation / chamber of commerce, such as Federation of Indian Chambers of Commerce and Industry (FICCI) or Confederation of Indian Industry (CII) and other organizations for wider reach to interested clients.

**Commercializing IPR Enabled Technologies**

The IPR enabled technologies will be transferred for commercial purposes with suitable understanding/agreement or contracts with the concerned parties. Specific terms of licensing can be negotiable. Commercialization will be undertaken either by ITMUs of the concerned institutions that have the requisite expertise and experience or the concerned ZTMCs/ATMC. Commercialization in foreign countries shall be undertaken by the ATMC.

**Cost and Pricing of Technology**

Broadly, the worth of an IPR enabled technology will be derived from the likely benefits that may accrue to its end-users. The worth can be best determined on the judgment of technical experts, producers of technology and business managers. As there is no standard method or formula for assessing the worth of a technology, costs and pricing in ICAR will be determined on a case-to-case basis. The ICAR institutions will determine the license fee and royalty and/or sale price of its IPR enabled technologies either on a fixed basis, through negotiations with the licensee, or through an open bidding process as appropriate. Expert opinion and judgment viewpoint together with the following points will be considered in determining the price/license fee.

i) Cost of IPR protection and maintenance.
ii) Cost of production and handling.
iii) Other institutional costs as appropriate.

The ITMU may determine the license fee and/or sale price of the technology at the institute level similar to that of the breeder seed. The life of an IPR enabled technology in the market will vary and so will its popularity and sales. The recurring royalties will be mainly based on these factors. Therefore, the modes of payment (license fee and/or royalty) will be on mutually agreed terms with the licensee, and flexible/determined on a case-to-case basis rather than rigid. The terms of commercialization may also be revised over time. In evolving the process, ATMC will also support studies for developing indicative models/case studies for valuation, costing and pricing of IPR enabled agricultural technologies of different fields.

Suitable models/case studies can be published as reference material.

**Licensing of Intellectual Property**

Licensing of IPR enabled ICAR technologies will encompass out-licensing. The framework for licensing will be developed/refined/evolved by ATMC/ ZTMCs/ ITMUs. Licenses will be case-specific non-exclusive or exclusive licenses. Appropriate joint commercialization agreements would also be entered into.

Normally, non-exclusive licenses will be executed for technologies such as inputs (e.g. bio-pesticides or bio-fertilizers) so that these can lead to their wider adoption and thereby maximize research benefits to farmers and other end users. For non-exclusive licenses, there will be flexibility in fixing the license fee.

When a technology is licensed through an open tendering/bidding process, it will normally be given to one licensee. But depending upon the licensee's manufacturing capacity and size of business, other interested parties from outside the territory of his business/interest may also be considered if the technology has to be rapidly and widely disseminated. Alternately, a sub-licensing clause will be incorporated, which may require the licensee to share a part of the license fee and/or royalty from any sub-licenses that he may enter into with that technology.

Exclusive license will also be issued when (i) an IPR enabled ICAR technology is to be commercialized in countries abroad, and (ii) the technology is to be disseminated in difficult areas offering low incentives. As exclusive licenses are preferential, commensurate license fee and/or royalty will be negotiated and settled on mutually agreed terms with the licensee.

Joint commercialization of IPR enabled ICAR technologies will be undertaken on mutually agreed terms with another commercial enterprise when a close scientific supervision of scaling up or product development is required or in any other appropriate situation.

The duration for which ICAR will issue licenses will also be negotiated with the Licensee and settled on mutually agreed terms.

The ATMC will empanel professional consultants and agencies having the necessary experience and proven track record at the national and zonal levels as License Managers for licensing the IPR enabled ICAR technologies. Their services will be utilized as and when required by ATMC/ZTMCs/ITMUs.

**Implementation of Licenses**

Transfer of IPR enabled technology by ATMC/ZTMCs/ITMUs and payments by the licensees will be in accordance with the terms and conditions, including the time limits recorded in the licensing contracts/ agreements. If required, the concerned scientists/ innovators will

demonstrate the technology on lab scale to the licensee under a confidentiality agreement.

**Use of ICAR knowledge/IP by Foreign Clients:** In cases of use of ICAR knowledge base by foreign clients for research and/or commercial purposes, all issues relating to contracting, target domain, pricing, payment and ownership of intellectual property will be pre-determined in a Memorandum of Agreement (MoA) signed by ICAR and the foreign client. The terms and conditions, and limitations of the Agreement with prospective foreign client will be set/ negotiated by ATMC/ICAR headquarters. Wherever required, Technology Managers / License Managers or IP Consultants may be engaged. Approval of the competent authority in the ICAR shall be essential to proceed for any agreement with foreign clients for commercialization.

**Monitoring and IP & Market Watch**

A mechanism of monitoring the licensing/commercialization activities in ICAR will be developed. This mechanism will include IP and market watch with a view to safeguard ICAR interests and to bring further refinement in their approach to commercialization.

**Types of Agreements**

**i) Collaboration Agreements**: While similar to teaming agreements, collaboration agreements are executed between institutions irrespective of whether sponsored funding is anticipated. They cover the same programmatic issues as teaming agreements. In addition, if collaborators from one institution will be using the facilities of the other institution, collaboration agreements may include the typical provisions of a Facility Use Agreement mentioned below. Collaboration agreements may also have fairly detailed intellectual property terms.

**ii) Intellectual Property (IP) Agreements:** These agreements are written to cover inventions or other discoveries that may result from a collaboration. The coverage of intellectual property (IP) agreements would be essentially the same for inventions as for copyrights. The basic issue covered is ownership of the intellectual property (i.e., who owns what, and under what conditions). Other items addressed would be license rights between the parties, and perhaps provisions on sharing costs and income related to the protection and licensing of IP.

**iii) Umbrella Agreement:** The All India coordinated research in SAUs is governed by the umbrella MoUs between ICAR and the respective SAUs. To sustain partnerships in *National Agricultural Research Systems (NARS)* under the evolving IPR regime, ICAR will review and modify the standing MoUs with SAUs to include sharing of IP on mutually agreed terms. Specific collaborative programmes under this umbrella will be covered as per respective Memoranda of Agreement (MoA).

**iv) Other Agreements Used in Formalizing Aspects of Collaborations**

As noted above, the following types of agreements may be collaborative in nature or they may be used to formalize aspects of collaborations. In other situations, these agreements are used solely to define non-collaborative business transactions.

**a) Data Sharing Plans:** These are sometimes a requirement of national program announcements. Essentially, they contain information concerning the means by which data developed under a sponsored project will be made available to others requesting access. While the data sharing plan is not, in and of itself, evidence of collaboration, it does open the possibility for new collaborations to be established based on the data having been shared.

**b) Material Transfer Agreements:** A material transfer agreement (MTA) covers situations in which one collaborator owns research materials such as a chemical compound or a biological substance, and has received a request from another collaborator for samples of the material. Frequently MTAs are not a reflection of a true collaboration, but rather a contractual relationship established for the sole purpose of obtaining a given research material. Whether a true research collaboration exists or not, the terms and conditions of the MTA are identical, primarily because they address institutional rights to intellectual property. The issues addressed are generally: (i) an acknowledgement that the provider retains ownership over the original material and any duplicates of the material created by the recipient, (ii) an agreement concerning who owns other materials created through the use of the material, and (iii) the responsibility for liability that may occur in the conduct of research using the material.

**c) Facility Use Agreements:** When a researcher from one institution wishes to use a piece of equipment or a laboratory at another institution, the latter will often require that a facility use agreement is executed. The provisions of such agreements would cover insurance and liability issues, the cost of access, the ownership of intellectual property, and any limitations or restrictions that may be imposed on the visiting researcher. Frequently, collaborators visit and work in one another's facilities for short periods of time. Institutions may find it difficult to balance the need to facilitate research by encouraging collaborations while at the same time ensuring that its facilities are held harmless from damages, and that the institution is protected from any liability caused by the visiting researcher in the conduct of the research.

***

Lecture 11: World Intellectual Property Organization (WIPO) -Indian Patent office

**World Intellectual Property Organization (WIPO)**

During the process of promoting the IPR into international stage, the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) cannot be left unrecognized. The predecessor to WIPO was the BIRPI (*Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle*, French acronym for *United International Bureaux for the Protection of Intellectual Property*), which had been established in 1893 to administer the Berne Convention for the Protection of Literary and Artistic Works and the Paris Convention for the Protection of Industrial Property. WIPO was formally created by the Convention Establishing the World Intellectual Property Organization, which entered into force on April 26, 1970. The World Intellectual Property Organization (WIPO) became one of the 17 specialized agencies of the United Nations in 1974. Thus, the WIPO administers and fosters the Paris Convention for the Protection of Industrial Property, the Patent Co-operation Treaty, the Berne and Rome Conventions on copyright and neighbouring rights and the Madrid Agreement on trade mark registration. The Agreement between the United Nations and the World Intellectual Property Organization notes that WIPO is responsible

> "for promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to the developing countries in order to accelerate economic, social and cultural development, subject to the competence and responsibilities of the United Nations and its organs, particularly the United Nations Conference on Trade and Development, the United Nations Development Programme and the United Nations Industrial Development Organization, as well as of the United Nations Educational, Scientific and Cultural Organization and of other agencies within the United Nations system."

The Agreement marked a transition for WIPO from the mandate it inherited in 1967 from BIRPI, to promote the protection of intellectual property, to one that involved the more complex task of promoting technology transfer and economic development. WIPO currently has 187 member states, administers 26 international treaties, and is headquartered in Geneva, Switzerland. At the same time, WIPO was in charge of more than 20 international conventions relating to the protection of intellectual property rights. WIPO has established WIPOnet, a global information network. The project seeks to link over 300 intellectual property offices (IP offices) in all WIPO Member States. In addition to providing a means of securing communication among all connected parties, WIPOnet is the foundation for WIPO's intellectual property services.

## Indian Patent Office

The **Indian Patent Office** is administered by the Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM). This is a subordinate office of the Government of India and administers the Indian law of Patents, Designs and Trade Marks.

## Patent administration

Trends in Indian patents, 1997–2013, The number of biotech patents has doubled in a decade.

The CGPDTM reports to the Department of Industrial Policy and Promotion (DIPP) under the Ministry of Commerce and Industry and has five main administrative sections:[9]

- Patent Office
- Designs Registry
- Trademarks Registry
- Geographical indications Registry
- Rajiv Gandhi National Institute of Intellectual Property Management (NIIPM)
- Patent Information System

The patent office is headquartered at Kolkata with branches in Chennai, New Delhi and Mumbai, but the office of the CGPDTM is in Mumbai. The office of the Patent Information System and National Institute for Intellectual Property Management is at Nagpur.[10] The Controller General (CG), who supervises the administration of the Patents Act, the Designs Act, and the Trade Marks Act, also advises the Government on matters relating to these subjects. O.P. Gupta is the current CG and took charge on 16 November 2015.[11]Under the office of CGPDTM, a Geographical Indications Registry has been established in Chennai to administer the Geographical Indications of Goods (Registration and Protection) Act, 1999.

The Indian Patent Office has 526 Patent Examiners, 97 Assistant Controllers, 42 Deputy Controllers, 1 Joint Controller, and 1 Senior Joint Controller, all of whom operate from four branches. Although the designations of the Controllers differ, all of them (with the exception of the Controller General) have equal authority in administering the Patents Act. An Indian Patent Examiner is mandated to search for prior art and for objections under any other ground as provided in the Patent's Act, then to report to the Controller, who has the power to either accept or reject Examiners' reports. Unlike the system at the USPTO /EPO/JPO, Examiners at IPO have only recommending power and the controllers are empowered by statute either to accept or refuse their recommendations. Examiners' reports to the Controller are not open to the public

unless courts allow it (section 144 of the Patents Act). A Parliamentary committee has recommended repealing S144

## Lecture 12. Geographical Registry -National Institute of Intellectual property Management- -*National* Research Centre on Plant *Biotechnology*

### Geographical Indications (GIs)

The term "Geographical Indications(GI)" in relation to goods means an indication which identifies such goods as agricultural goods, natural goods or manufactured goods as originating, or manufactured in the territory of a country, or a region or locality in that territory, where a given quality, distinctiveness, reputation or other characteristics of such goods is essentially attributable to its geographical origin and in case where such goods are manufactured goods, one of the activities of either the production or of processing or preparation of the goods concerned takes place in such territory, region or locality, as the case may be.

### Indian Law for the Protection of Geographical Indications

WTO Members and their nationals are increasingly recognizing that GIs are valuable as marketing tools in the global economy. The TRIPS Agreement is the, first multilateral agreement dealing with GIs. GIs are protected in accordance with national laws and under a wide range of concepts, such as laws against unfair competition, consumer protection laws, laws for the protection of certification marks or special laws for the protection of geographical indications. India, as a member of the World Trade Organization (WTO), enacted the **Geographical Indications of Goods (Registration and Protection) Act, 1999** which has come into force with effect from 15th September 2003. The Act is administered by the Controller General of Patents, Designs and Trade Marks who is the Registrar of Geographical Indications. The Geographical Indications Registry is located at Chennai in July 2001.

Unless a geographical indication is protected in the country of its origin, there is no obligation under the TRIPs Agreement for other countries to extend reciprocal protection. Nevertheless, it is difficult to get similar protection in other countries, even if the GIs are accorded protection within a country. This could be achieved through bilateral agreements. So, if India and the EU decide to include GIs in the trade and investment agreement that they are currently negotiating, they would be according protection to their GIs in each other's markets.

According to the Act, the term ‘geographical indication’, means an indication which identifies goods such as agricultural or manufactured goods as originating, or manufactured in a country, or a region, whose characteristics are essentially attributable to the geographical area. The features of the GI Act, 1999 include: Registration of GI in specified classes, Prohibition of registration of certain GI, compulsory advertisement of all accepted GI, provision of infringement, higher level of protection, GI prohibited for registration as Trade Mark, appeal provision, penalties and protection of homonymous GI. The Act provides for activities of processing in case of manufactured goods.

**National Institute of Intellectual Property Management**

The Rajiv Gandhi National Institute of Intellectual Property Management has been established at Nagpur as a National center of excellence for training, management, research, education in the field of Intellectual Property (IP) Rights. The main objectives of this institute is to cater to the need of training of Examiners of Patents, Designs, Trademarks and Geographical Indications, IP professionals, IP managers, imparting basic education to user communities, government functionaries and stake holders involved in creation, commercialization and management of intellectual property rights, facilitate research on IP related issues including preparation of study reports and policy analysis of relevance to Government. Apart from this, Rajiv Gandhi NIIPM address the needs of increasing the general awareness and understanding of Government officers and users of IP systems including in universities and other educational institutions. It will also conduct research in IP and prepare study reports and policy analysis papers on subject of current relevance for policy and lawmakers. The details of activities to be performed by Rajiv Gandhi NIIPM are given below.

Training: The felt need is to establish a superior institute for catering to the training needs of the technical personnel on IP in view of the growing complexity in the applications being received and to meet global standards in quality in examination. The newly recruited Examiners of IP needs to be given exhaustive induction training in all aspects of patent examination for a reasonable duration. Similarly, senior examiners other higher officials also need to be provided training to keep abreast with latest techniques, information as well global development in IP. Further, NIIPM will also impart training to scientists, R&D Organizations, Government Institutions, IP professionals such as lawyers, attorneys, and agents and IP managers, i.e., personnel within the industry who have responsibility for management of the IP within their

organization including other stake holders involved in creation, commercialization and management of intellectual property rights

Research: IPR research is an emerging area and the research activities and results are having wider scope in terms of their impact on the people in the country. Intellectual Property Rights have gained a lot of recognition in the past few years in India mainly due to globalized economy, economic activity in India being on a healthy growth path and the efforts made by the Government to create enabling milieu by way of modernizing the IPR infrastructure as well as implementing various programmes for creation of awareness among the professionals as well as general public. Most research that is going on as of now are based on individual initiatives or sponsored research by corporation, which arguably have a very limited scope. The academic or research activities also require quality human resources to man the research positions as well as financial and technical resources in order to conduct any meaningful in depth, multidisciplinary and/or mature research in the field of Intellectual Property. This gap has been recognized by the government and therefore, it is proposed to include research activities as part of the activities of Rajiv Gandhi NIIPM in the field of IP on a number of socio-economic parameters, strata of the society, technological fields, R & D trends, etc

Education: The institutes providing IP education are very limited in the country. Therefore, Rajiv Gandhi NIIPM aims to introduce IP education in its curriculum as one of the activities. Accordingly, it has been proposed that the Institute will start three months diploma course, six months and one year Post Graduate Diploma course in Intellectual Property Law. It is also proposed to involve certain Universities or tie-up with them so as to develop the course content and also to make effective use of their resources particularly, Human Resources. The Institute also aims at making tailored made IP programmes for specific kind of users in order to suit their requirements. In addition to this, the Rajiv Gandhi NIIPM is also to organize IP Awareness/campaign in the country in collaboration with IP Offices, Government Organizations and R & D Institutions.

Policy Advice :The policy advice which is a result of IP research as well as deliberations or discussions by experts in IP law and multidisciplinary experts is important not only for the government but also to the industry, especially SMEs, Universities, etc. in the country. Further, researched factual information is also expected to instill confidence among various groups of population in order to understand the background, necessity, national and international

ramifications, short term and long term effects of any existing or proposed legislation, rules or practices.

**National Research Centre on Plant Biotechnology**

National Research Centre on Plant Biotechnology (NRCPB) is a premiere research institution of the Indian Council of Agricultural Research (ICAR). National Research Centre on Plant Biotechnology has been entrusted with the responsibility of developing new tools and techniques and to deliver breakthrough in biotechnology for crop improvement. With a humble beginning and a few dedicated scientists, the centre could successfully deliver varieties such as Pusa Jai Kisan, which is one of the top three mustard varieties released by the ICAR till date.

Lecture 13. World Trade Organization (WTO) - Globalization -Trade related Intellectual Property Rights(TRIPS) and agreement

**Genesis of General Agreement on Tariffs and Trade (GATT)**

The General Agreement on Tariffs and Trade (GATT) has its origin in the Anglo-American design for the post second world war reconstruction in 1947. The objective of GATT was to provide a frame work for rule based multi - national trading system, as well as a process within which trade liberalization can result with non-discrimination, reciprocity and transparency. It has set out to correct several aberrations that crept into the International Trade, which were distorting the free flow of goods and services from one country to another. Its purpose was the "substantial reduction of tariffs and other trade barriers and the elimination of preferences, on a reciprocal and mutually advantageous basis." It was negotiated 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).

At a conference in the Palais des Nations, Geneva, Switzerland, representatives of 23 countries met in 1947 and established two key pillars of the post war world trading system. First, they created a legal framework for commercial policy by finalizing the text of the GATT. Second, they negotiated numerous bilateral agreements to reduce import tariffs, the benefits of which were extended to other GATT parties through the unconditional Most - Favored Nation (MFN) clause. GATT was signed in October 1947, took effect in 1948, and lasted until 1994; it was replaced by the World Trade Organization in 1995. It was a treaty entered into by 146 countries of 191 member countries of the United Nations, of which 30 are developed, 86 are developing and 30 are least developed nations. India was the founding member of this organization. The mechanism envisaged by GATT to promote trade liberalization is the so called “rounds” system. The process periodically gathers the contracting parties together to agree on a package of trade measures. Table 1 lists the number of such contracting parties (countries) involved in the negotiations under GATT and the value of trade covered.

**Table 1 GATT Trade Rounds**

| Rounds / Places | Start | Dura-tion | Count-ries | Subjects covered | Achievements |
|---|---|---|---|---|---|
| I – Havana, Cuba | April 1947 | 7 months | 23 | Tariffs | Signing of GATT, 45,000 tariff concessions affecting $10 billion of trade |

| | | | | | |
|---|---|---|---|---|---|
| II - Annecy, France | April 1949 | 5 months | 13 | Tariffs | Countries exchanged some 5,000 tariff concessions |
| III - Torquay, Devon, England | Septem-ber 1950 | 8 months | 38 | Tariffs | Countries exchanged some 8,700 tariff concessions, cutting the 1948 tariff levels by 25% |
| IV - Geneva II | January 1956 | 5 months | 26 | Tariffs, admission of Japan | $2.5 billion in tariff reductions |
| V - (Douglas) Dillon, Geneva | Septem-ber, 1960 | 11 months | 26 | Tariffs | Tariff concessions worth $4.9 billion of world trade |
| VI – Kennedy Round, Geneva, Switzerland | May 1964 | 37 months | 62 | Tariffs, Anti-dumping | Tariff concessions worth $40 billion of world trade |
| VII-Tokyo, Japan | September 1973 | 74 months | 102 | Tariffs, non-tariff measures, framework agreements | Tariff reductions worth more than $300 billion dollars achieved |
| VIII - Punta del Este, Uruguay | September 1986 | 87 months | 123 | Tariffs, non-tariff measures, rules, services, intellectual property, dispute settlement, textiles, agriculture, creation of WTO, etc | The round led to the creation of WTO, and extended the range of trade negotiations, leading to major reductions in tariffs (about 40%) and agricultural subsidies, an agreement to allow full access for textiles and clothing from developing countries, and an extension of intellectual property rights. |

| | | | | | |
|---|---|---|---|---|---|
| IX - Doha, Qatar | November 2001 | ? | 159 | Tariffs, non-tariff measures, agriculture, labor standards, environment, competition, investment, transparency, patents etc | The round has not yet concluded. Bali Package signed on the 7th December 2013. |

### Uruguay Round: 1986–94

The Uruguay round aimed at expanding the competence of the GATT to important new areas such as services, capital, intellectual property, textiles, and agriculture. It was also the first set of multilateral trade negotiations in which developing countries had played an active role. Agriculture was exempted from previous agreements as it was given special status in the areas of import quotas and export subsidies. However, by the time of the Uruguay round, many countries considered the exception of agriculture to be sufficiently glaring that they refused to sign a new deal without some movement on agricultural products. These fourteen countries came to be known as the "Cairns Group", and included mostly small and medium sized agricultural exporters such as Australia, Brazil, Canada, Indonesia, and New Zealand. The round was launched in Punta del Este, Uruguay in September 1986, followed by negotiations in Geneva, Brussels, Washington, D.C., and Tokyo, with the 20 agreements finally being signed in Marrakesh, Morocco—the Marrakesh Agreement—in April 1994.

The Uruguay Round has been the most complicated of all GATT rounds held so far with 123 countries having negotiated as 16 negotiated groups. The outcome of this round which was long drawn (1986-94) was the creation of World Trade Organization (WTO). This round brought the following sweeping changes in the regime of world trade and intellectual property:

- **Agreement on Agriculture (AoA):** The AoA continues to be the most substantial trade liberalization agreement in agricultural products in the history of trade negotiations. The goals of the agreement were to improve market access for agricultural products, reduce domestic support of agriculture in the form of price-distorting subsidies and quotas, eliminate over time export subsidies on agricultural products and to harmonize to the extent possible sanitary and phyto-sanitary measures between member countries.
- The Agreement establishing the World Trade Organization (WTO)

- Goods and investment — the Multilateral Agreements on Trade in Goods including the GATT 1994 and the Trade Related Investment Measures (TRIMs)
- Services — the General Agreement on Trade in Services
- Intellectual property — the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement) including Trade in Counterfeit Goods
- Dispute Settlement
- Reviews of governments' trade policies

**b) World Intellectual Property Organization (WIPO)**

During the process of promoting the IPR into international stage, the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) cannot be left unrecognized. The predecessor to WIPO was the BIRPI (*Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle*, French acronym for *United International Bureaux for the Protection of Intellectual Property*), which had been established in 1893 to administer the Berne Convention for the Protection of Literary and Artistic Works and the Paris Convention for the Protection of Industrial Property. WIPO was formally created by the Convention Establishing the World Intellectual Property Organization, which entered into force on April 26, 1970. The World Intellectual Property Organization (WIPO) became one of the 17 specialized agencies of the United Nations in 1974. Thus, the WIPO administers and fosters the Paris Convention for the Protection of Industrial Property, the Patent Co-operation Treaty, the Berne and Rome Conventions on copyright and neighbouring rights and the Madrid Agreement on trade mark registration. The Agreement between the United Nations and the World Intellectual Property Organization notes that WIPO is responsible

> "for promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to the developing countries in order to accelerate economic, social and cultural development, subject to the competence and responsibilities of the United Nations and its organs, particularly the United Nations Conference on Trade and Development, the United Nations Development Programme and the United Nations Industrial Development Organization, as well as of the United Nations Educational, Scientific and Cultural Organization and of other agencies within the United Nations system."

The Agreement marked a transition for WIPO from the mandate it inherited in 1967 from BIRPI, to promote the protection of intellectual property, to one that involved the more complex task of promoting technology transfer and economic development. WIPO currently has 187 member states, administers 26 international treaties, and is headquartered in Geneva,

Switzerland. At the same time, WIPO was in charge of more than 20 international conventions relating to the protection of intellectual property rights. WIPO has established WIPOnet, a global information network. The project seeks to link over 300 intellectual property offices (IP offices) in all WIPO Member States. In addition to providing a means of securing communication among all connected parties, WIPOnet is the foundation for WIPO's intellectual property services.

**c) World Trade Organization (WTO)**

The WTO's predecessor, the General Agreement on Tariffs and Trade (GATT), was established after World War II in the wake of other new multilateral institutions dedicated to international economic cooperation – notably the Bretton Woods institutions known as the World Bank and the International Monetary Fund. A comparable international institution for trade, named the International Trade Organization (ITO) was negotiated. The ITO was to be a United Nations specialized agency and would address not only trade barriers but other issues indirectly related to trade, including employment, investment, restrictive business practices, and commodity agreements. But the ITO treaty was not approved by the U.S. and a few other signatories and never went into effect. In the absence of an international organization for trade, the GATT would over the years "transform itself" into a *de facto* international organization.

The World Trade Organization (WTO) was established on the completion of the Uruguay Round (UR) of negotiations of the General Agreement on Tariffs and Trade (GATT). WTO is an organization that intends to supervise and liberalize international trade. The organization officially commenced on 1 January 1995 under the Marrakech Agreement, replacing the GATT. The organization deals with regulation of trade between participating countries by providing a framework for negotiating and formalizing 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. Most of the issues that the WTO focuses on derive from previous trade negotiations, especially from the Uruguay Round (1986–1994).

The organization is attempting to complete negotiations on the Doha Development Round, at the fourth ministerial conference in Doha, Qatar in November 2001 with an explicit focus on making globalization more inclusive and helping the world's poor, particularly by slashing barriers and subsidies in farming. The conflict between free trade on industrial goods and services but retention of protectionism on farm subsidies to domestic agricultural sector (requested by developed countries) and the substantiation of the international liberalization of fair trade on agricultural products (requested by developing countries) remain the major

obstacles. These points of contention have hindered any progress to launch new WTO negotiations beyond the Doha Development Round. As a result of this impasse, there has been an increasing number of bilateral Free Trade Agreements (FTA) signed. According to a European Union statement, "The 2008 Ministerial meeting broke down over a disagreement between exporters of agricultural bulk commodities and countries with large numbers of subsistence farmers on the precise terms of a 'special safeguard measure' to protect farmers from surges in imports. As of June 2012, the future of the Doha Round remained uncertain: the work programme lists 21 subjects in which the original deadline of 1 January 2005 was missed, and the round is still incomplete. As of July 2012, there were various negotiation groups in the WTO system for the current agricultural trade negotiation which is in the condition of stalemate. A Trade Facilitation Agreement (TFA) known as the Bali Package was reached by all members on 7 December 2013, the first comprehensive agreement in the organization's history.

**Functions:** The most important functions of the WTO are:

- to oversee the implementation, administration and operation of the covered agreements; and
- to provide a forum for negotiations and for settling disputes.

Also, it is the WTO's duty to review and propagate the national trade policies, and to ensure the coherence and transparency of trade policies through surveillance in global economic policy-making. WTOs additional functions are listed below:

(i) The WTO shall facilitate the implementation, administration and operation and further the objectives of this Agreement and of the Multilateral Trade Agreements.

(ii) The WTO shall provide the forum for negotiations among its members concerning their multilateral trade relations in matters dealt with under the Agreement.

(iii) The WTO shall administer the Understanding on Rules and Procedures Governing the Settlement of Disputes.

(iv) The WTO shall administer Trade Policy Review Mechanism.

(v) In order to achieve greater coherence in global economic policy making, the WTO shall cooperate with the International Monetary Fund (IMF) and with the International Bank for Reconstruction and Development (IBRD) and its affiliated agencies.

As globalization proceeds in today's society, the necessity of an International Organization to manage the trading systems has been of vital importance. As the trade volume increases, issues such as protectionism, trade barriers, subsidies, violation of intellectual property arise due to the differences in the trading rules of every nation. The World Trade Organization serves as the mediator between the nations when such problems arise. The WTO

is also a center of economic research and analysis: regular assessments of the global trade picture in its annual publications and research reports on specific topics are produced by the organization. Finally, the WTO cooperates closely with the two components of the Bretton Woods system, the IMF and the World Bank.

**Principles of the Trading System**

The WTO establishes a framework for trade policies; it does not specify outcomes. That is, it is concerned with setting the rules of the trade policy games. Five principles are very importance in understanding both the pre-1994 GATT and the WTO:

**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 favorably 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 etc. 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 materialize.

**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 valves:** 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. There are three types of provision in this direction:

- articles allowing for the use of trade measures to attain non-economic objectives;
- articles aimed at ensuring "fair competition"; members must not use environmental protection measures as a means of disguising protectionist policies; and
- provisions permitting intervention in trade for economic reasons.

Exceptions to the MFN principle also allow for preferential treatment of developing countries, regional free trade areas and customs unions.

**iv) Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS)**

The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) was adopted under the framework of the WTO in 1993. The agreement provides many principles and systems to other country's legal system for promoting intellectual property system into the integration process. TRIPS agreement achieved the goal to link international trade with people's intellectual property rights. And the result is that it not only to expand intellectual property protection to the outside of the traditional areas of trade, but also penetrate into the technical trade and service trade, etc. all aspects of international trade, and accelerate the international trade into a new trade pattern.

**a) Inclusion of TRIPS in WTO:** The precursor to the WTO was the GATT which sought to address issues related to international trade in goods. The operation of the GATT over the years resulted in lowering of tariffs in general in international trade. As a result, increasingly, other domestic policies of nations came into focus of the trading nations. The developed countries like the United States started facing increasing competition in manufactured exports from Newly Industrializing Countries (NICs) of Asia. For intellectual property issues in general, the negotiators were required to "clarify GATT provisions and elaborate as appropriate new rules and disciplines" in order to reduce distortions and impediments to international trade. As technology became more important in goods and commodities, having higher proportion of invention and design (intellectual creativity) in their value, IPR became important in international trade. As a result, in the Uruguay Round negotiations, the IPRs dominated the discussions.

The inclusion of TRIPS was the culmination of an intense lobbying effort by the United States, supported by the European Union, Japan and other developed nations. Campaigns of

unilateral economic encouragement under the Generalized System of Preferences and Coercion under Section 301 of the Trade Act played an important role in defeating competing policy positions that were favoured by developing countries, most notably Korea and Brazil, but also including Thailand, India and Caribbean Basin states. In turn, the United States' strategy of linking trade policy to intellectual property standards can be traced back to the entrepreneurship of senior management at Pfizer in the early 1980s, who mobilized corporations in the United States and made maximizing intellectual property privileges, the number one priority of trade policy in the United States (Braithwaite and Drahos, 2000, Chapter 7).

As the ratification of TRIPS is a compulsory requirement of WTO membership, any country seeking to obtain easy access to the numerous international markets opened by the WTO must enact the strict intellectual property laws mandated by TRIPS. For this reason, TRIPS is the most important multilateral instrument for the globalization of intellectual property laws. States like Russia and China that were very unlikely to join the Berne Convention have found the prospect of WTO membership a powerful enticement. Furthermore, unlike other agreements on intellectual property, TRIPS has a powerful enforcement mechanism. States can be disciplined through the WTO's dispute settlement mechanism.

**b) Intellectual Property Rights (IPR):** According to the World Intellectual Property Organization (WIPO), intellectual property refers to creations of the mind, inventions, literary and artistic works, symbols, names, images and designs used in commerce.

Broadly, intellectual property is divided into two categories. The first category covers industrial property, which includes patents, industrial designs and trademarks which have industrial applications. The other refers to copyright laws which are applied to such things as literary, dramatic and artistic works; rights relating to performing artists, the production of phonograms; and rights of broadcasters in their radio and television programmes. Intellectual property (IP) rights as a term can be collectively used for multiple protection of different aspects of an inventive work as given below:

viii) Patents including the protection of new varieties of plants
ix) Copyrights and related rights (i.e., the rights of performers, producers of sound recordings and broadcasting organizations)
x) Trademarks, including service marks
xi) Registered (industrial) design
xii) Layout-designs (topographies) of Integrated Circuits (IC)
xiii) Geographical indications including appellations of origin, and
xiv) Undisclosed information, including trade secrets and test data

The **Agreement on Trade-Related Aspects of Intellectual Property Rights** sets down minimum standards for many forms of intellectual property regulation as applied to nationals of other WTO Members. The TRIPS agreement introduced intellectual property law into the international trading system for the first time and remains the most comprehensive international agreement on intellectual property to date. TRIPS also specify 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.

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 content producers including performers, producers of sound recordings and broadcasting organizations; geographical indications, including appellations of origin; industrial designs; integrated circuit layout - designs; patents; new
plant varieties; trademarks; trade dress; and undisclosed or confidential information.

**c) The Requirements of TRIPS:** TRIPS requires member states to provide strong protection for intellectual property rights. For example, under TRIPS:

- Patents must be granted for "inventions" in all "fields of technology" provided they meet all other patentability requirements (although exceptions for certain public interests are allowed (Article 27.2 and 27.3) and must be enforceable for at least 20 years (Article 33).
- Exceptions to exclusive rights must be limited, provided that a normal exploitation of the work (Article 13) and normal exploitation of the patent (Article 30) is not in conflict.
- Legitimate interests of third parties have to be taken into account by patent rights (Article 30).
- Copyright terms must extend at least 20 years, unless based on the life of the author. (Article 12 and 14).
- Copyright must be granted automatically, and not based upon any "formality," such as registrations, as specified in the Berne Convention. (Article 9).
- Computer programs must be regarded as "literary works" under copyright law and receive the same terms of protection.

- National exceptions to copyright (such as "fair use" in the United States) are constrained by the Berne three-step test.
- No unreasonable prejudice to the legitimate interests of the right holders of computer programs and patents is allowed.
- In each state, intellectual property laws may not offer any benefits to local citizens which are not available to citizens of other TRIPS signatories under the principle of national treatment (with certain limited exceptions, Article 3 and 5). TRIPS also has a most favored nation (MFN) clause.

Many of the TRIPS provisions on copyright were copied from the Berne Convention for the Protection of Literary and Artistic Works and many of its trademark and patent provisions were modeled on the Paris Convention for the Protection of Industrial Property.

**d) Links among TRIPS, WTO and WIPO:** Intellectual Property Rights (IPRs) at a multilateral level have their genesis in the Paris Convention for the Protection of Industrial Property in 1883 which protected industrial property, i.e., Patents and trademarks and the Berne Convention for the Protection of Literary and Artistic Works in 1886 for copyrights and related rights. World Intellectual Property Organization (WIPO) which began its work in 1967 taking over from the Bureau for the Protection of Intellectual Property that had been working since 1893, is the international agency under the United Nations that administers the work of these conventions. The WIPO administers many other international conventions on IPRs also.

While the IPR Conventions and treaties create the international standards in protection of IPRs which are to be followed by the member countries, substantive trade related disciplines on IPRs under these international conventions have been adopted by reference into the WTO through the TRIPS Agreement. This means that the Agreement provides rules for trade and investment in ideas and creativity by incorporating standards laid down in certain exact provisions of the major IPR conventions. The WTO provides that “intellectual property” should be protected when trade is involved. Thus, through the TRIPS, the WTO makes it mandatory for all its member countries to follow basic minimum standards of IPR provided for under TRIPS and bring about a degree of harmonization of domestic laws in this field.

**e) TRIPS plus Provisions in Free Tree Agreements (FTAs):** IPRs are territorial rights and can be acquired in the territory of the country having an IPR law. That is, IPR acquired in one country cannot be enforced in another country. The TRIPS Agreement lays down only certain minimum standards of protection and enforcement of IPRs by its Members through enactment of such national laws and regulations. The TRIPS Agreement, however, allows Members to have higher levels of protection than the minimum standards laid down in it, thus leaving the

flexibility to Members to have 'TRIPS plus' laws and regulations. The developed countries are moving toward higher, enhanced standards of IPR protection to evolve TRIPS-plus regime. These higher standards now appear in various Free Trade Agreements (FTA) and the developed countries are negotiating and entering into with their trading partners. Since these provisions go beyond minimum standards established under TRIPS, they may take away the flexibilities (for example the ability to issue compulsory licenses for medicines required in public health emergencies) that exist in the TRIPS Agreement. These countries negotiate rules and commitments in bilateral, sub regional and regional agreements that go beyond the multilateral level in WTO.

By entering into FTAs with the developed countries, developing countries have some advantages in tariff reductions on agricultural, clothing and other products. In return, developed countries seek better market access and investment opportunities for products and services of their interest. In addition, developed countries also seek to raise the minimum levels of protection for IPRs as they have a comparative advantage in technology products and services. At the same time, developing countries find it difficult to put forward the issues of their concern through the FTA negotiations including the harmonization of TRIPS and UN Convention on Biological Diversity (CBD), access to medicines, and protection against the bio-piracy of their biological genetic resources, farmers' rights and associated traditional knowledge, ability of their farmers to continue their subsistence and livelihood related farming practices and getting the same level of protection for their geographical indications as for wines and spirits of developed countries. As a consequence, FTAs create an imbalanced set of rights and obligations in favour of developed countries by ratcheting up the levels of IPR protection.

While it can be argued that there is no bar on developing countries in walking away from unequal agreements, it can also be argued that owing to unequal negotiating strengths, many bilateral agreements do turn out to be unequal. If the immediate need to benefit from reduced tariffs, etc. is high then a developing country can be guided into making concessions in areas of longer term impact such as IPRs.

**f) Implementation of TRIPS in Developing Countries**

The obligations under TRIPS apply equally to all member states, however developing countries were allowed extra time to implement the applicable changes to their national laws, in two tiers of transition according to their level of development. The transition period for developing countries expired in 2005. The transition period for least developed countries to implement TRIPS was extended to 2013, and until 1 January 2016 for pharmaceutical patents, with the possibility of further extension.

**Lecture 14. International Union for the protection of New Varieties of plants (UPOV)**

The TRIPS of WTO recognizes the creation of Intellectual Property Rights (IPR) as essential for the development of mankind. IPR is the property created by the human intellect which can be incorporated in tangible objects and reproducible in different locations. The types of IPR are copy rights, trademarks, patents, geographical indications, industrial designs, Integrated circuits and Trade secrets. IPRs confer legal ownership to the person or a business of a discovery or an invention attached to a particular product or process, which prohibits others from unauthorized use. Among the listed IPR's, the main concern is on patents, as India being a member of WTO, needs to provide for protection of plant varieties (PPV) either through patents or by an effective *sui generic* system or a combination there of and thus the whole issue of plant variety protection (PVP) (Plant Breeders Rights – PBR) became an intensely debatable subject.

The adoption of IPRs in agriculture has a recent origin, but in the USA, the Plant Patent Act was enacted in 1930. This Act, however, covered only asexually propagated plants (plants not normally sown from seeds), and was thus aimed at excluding the major food species and so prevented the emergence of grain monopolies. The European plant breeders pushed for Plant Breeders' Rights (PBRs), which were more comprehensive in the coverage of varieties to be granted legal protection. The origins of this movement for Intellectual Property Protection (IPP) for agricultural products go back to the late 19$^{th}$ century with the growth in the European seed trade and the development of breeders' associations, which was followed by various seed control systems and attempts to provide Plant Variety Protection (PVP).

In the early part of the 20$^{th}$ century, the potential benefit of systematic plant breeding to society and lack of an effective protection and reward system were felt and this led to the formation of the Inter Governmental International Union for the Protection of New Varieties of Plants commonly known as UPOV (based on its initials in French – (Union Internationale pour la Protection des Obtentions Végétales) with mostly developed countries as member states, after an International Convention in Paris in 1961. The UPOV is an intergovernmental organization with headquarters in Geneva (Switzerland). Belgium, France, the Federal Republic of Germany (FRG), Italy and the Netherlands were the original signatories on 2 December 1961. UPOV came into force only in August 1968 after the UK, FRG and the Netherlands had ratified it.

A striking feature about the membership is the high proportion of countries with relatively low shares of their economically active population in agriculture. At the end of 1999, only seven had more than 25 per cent of their workforce in agriculture and just two, China and Kenya, exceed 50 per cent. Most of the early members of UPOV have less than 5 per cent of their economically active population engaged in agriculture. There seems to be a strong

correspondence between adoption of IPP in agriculture and low shares of economically active population in this sector.

The convention has undergone revisions in 1972, 1978 and 1991 and has as on today, there are 53 member states. The purpose of the UPOV convention is to ensure Plant Breeders' Right (PBR) by making available to them an exclusive property right on new plant varieties in order to provide incentive to the development of agriculture and to safeguard the interests of plant breeders. To be eligible for protection, varieties have to be (i) distinct from existing commonly known varieties, (ii) sufficiently uniform, and (iii) stable and new in the sense that they must not have been commercialized.

UPOV '78 did not limit the farmers' rights and kept the rights of plant breeders within levels supported by some developing countries. Under the UPOV '78, the breeder could produce a new plant variety and had a monopoly via marketing right sale of seed. But the system allowed two important exemptions. One, the breeder's exemption, which allowed other plant breeders to use the protected variety for breeding purposes and the other one was that of the farmer's rights. The farmers were allowed to use seeds from their harvest to plant the next crop, even if the seed was protected by the PBR.

While the first two amendments of UPOV, in 1972 and 1978, kept the basic structure almost unchanged, the last amendment in 1991 introduced far reaching changes to the structure of protection, significantly strengthening PBRs. The more significant of these are the restrictions on the reuse of seeds, which could have implications for the farming communities using the protected varieties; in addition, the inclusion of Essentially Derived Varieties (EDVs) affects the ability of breeders to freely use protected varieties for research. Thus, UPOV '91, urged upon the WTO by the USA, contains an extensive protection for plant breeders to the prejudice of farmers' rights and severely restricts the scope of other breeders to innovate around protected varieties (the breeders' exemption), thereby disturbingly affecting the food security and equity goals of developing countries on the whole. The breeder's exemption was almost done away with in the UPOV '91 making way for royalty payments to the PBR holder from the breeders, if their new variety bears some resemblance to the protected variety even if the new variety has been bred for different characters. Besides, farmers cannot use farm saved seeds from protected varieties, without paying compensation. The methods of compensation are being currently discussed in various fora in Europe and the issue is a bone of contention between farmers and breeders.

The UPOV '91 raises the alarm that unfavourable regimes could be imposed on unwilling developing countries by incorporating the obligations of UPOV '91 into the WTO

agreement, making them enforceable under the WTO dispute settlement system, when they were not negotiated in the Uruguay Round to include them in the WTO. The response of some developing countries to these developments in the UPOV Convention has been the adoption of alternative *sui generis* options for the protection of plant varieties. The major differences in the protection between the UPOV '61 and Plant Patent Regime are given in Table 2.

**Table 2 Protection under UPOV '61 and Plant Patent Regime**

| S.No. | UPOV '61 | Plant Patent Regime |
|---|---|---|
| 1. | Plant breeders can obtain protection for discoveries | Patents only for inventions |
| 2. | Criteria for protection: (i) Novelty, (ii) Distinct, (iii) Homogeneity, and (iv) Stability | Criteria for protection: (i) Novelty, (ii) Inventive step involved, and (iii) Industrial Applicability |
| 3. | Forfeiture of rights if a protected variety loses its essential expressions of characteristics | No corresponding provision |
| 4. | Submitting of propagating material to the national authority designated for the purpose necessary in most laws | No such requirement |
| 5. | Initially covered a small canvas | Specified exceptions |
| 6. | Flexibility in favour of users | Rigid application to secure rights to patentee |
| | (i) "farmers' privilege" | (i) dilution of "farmers' privilege" |
| | (ii) "breeders' exemption | (ii) introduction of EDVs to curb research exemption |

Note: The essential structure of UPOV '61 remained almost unchanged till 1991 when major amendments were carried out.

**Lecture 15. National Biodiversity Authority(NBA) & Convention on Biological diversity (CBD)**

**Lecture 16. Biosafety - Bioethics - Biosafety International protocols**

**Lecture 17. Moral issues in patenting of biotechnological invention**

**Convention on Biological Diversity**

Plant Genetic Resources (PGRs) are the foundation for the development of a food and nutritionally secure society. Over 90 percent of plant species for food and agriculture are located in the economically developing parts of the world namely, the Asian, African, Latin American and the Far East Islands. In a reversal of the normal economic pattern in the world, the richest nations are poor in plant genetic resources. Although the growth of applied sciences and modern technologies is seen as an opportunity to improve the living standards of human beings, concerns have been increasing to also protect the traditional gene rich resources and the indigenous wisdom. PGRs were treated as the 'heritage of mankind' and were shared freely among nations, till the concerns for conservation of biological diversity were raised by the Convention on Biological Diversity (CBD), which came into force in 1993.

The Convention on Biological Diversity (CBD) has expressly provided for the rights of indigenous communities (Article 8 (i) of the CBD), and the International Undertaking on Plant Genetic Resources (IUPGR) has provided defined farmers' rights (CBD 1994, FAO 1983) *inter alia* affirm that "the past, present and future contributions of farmers in conserving, improving and making available the genetic resources is the basis of farmer's rights". The CBD, known informally as the Biodiversity Convention, is a multilateral treaty which has three main goals:

iv) conservation of biological diversity (or biodiversity);
v) sustainable use of its components; and
vi) 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. 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. The year 2010 was the International Year of Biodiversity.

The convention recognized for the first time in international law that the conservation of biological diversity is "a common concern of humankind" and is an integral part of the

development process. The agreement covers all ecosystems, species, and genetic resources. It links traditional conservation efforts to the economic goal of using biological resources sustainably. It sets principles for the fair and equitable sharing of the benefits arising from the use of genetic resources, notably those destined for commercial use. It also covers the rapidly expanding field of biotechnology through its Cartagena Protocol on Bio-safety, addressing technology development and transfer, benefit-sharing and bio-safety issues. Importantly, the Convention is legally binding: countries that join it ('Parties') are obliged to implement its provisions. The convention reminds decision-makers that natural resources are not infinite and sets out a philosophy of sustainable use. While past conservation efforts were aimed at protecting particular species and habitats, the Convention recognizes that ecosystems, species and genes must be used for the benefit of humans.

The safety and regulatory concerns associated with transgenic crops is a contentious issue because many lack the regulatory frameworks and technical capacity necessary to evaluate these crops and the conflicting claims surrounding them. There is less scientific consensus on the environmental hazards associated with transgenic crops. Regulatory procedures should be strengthened and rationalized to ensure that the environment and public health are protected and that the process is transparent, predictable and science-based. Appropriate regulation is essential to command the trust of both consumers and producers, but duplicative or obstructionist regulation is costly and should be avoided.

**Cartagena Protocol on Bio-safety:** Convention on Biological Diversity adopted a supplementary agreement known as the Cartagena Protocol on Bio-safety on 29$^{th}$ January 2000. [Cartagena is in Colombia]. The protocol became international law in September 2003 and has since been ratified by more than 100 countries excluding USA. India has acceded to the Bio-safety Protocol on 17$^{th}$ January 2003.

**Scope:** The Protocol seeks to protect from the potential risks posed by Living Modified Organisms (LMOs) resulting from modern biotechnology intended for direct use for food, feed or processing. It incorporates procedure for import of LMOs with respect to Food, Feed and Product.

**Risk Assessment and Risk Management Framework and Capacity Building:** Risk management measures include food labeling, conditions on marketing approvals, post marketing

monitoring and development of methods to detect or identify foods derived from modern biotechnology.

**Salient features** of the protocol are:

**i) Precautionary principle:** The Cartagena Protocol reaffirms the 'Precautionary principle' in decision procedures, risk assessment and risk management in the context of the protocol. The precautionary principle is similar to the idea of 'safety first'. When applied to new technologies, it means holding back from using a new technology until there is conclusive evidence that it will do no harm. Critics of GM technology say it is too early to say this conclusive evidence exists.

**ii) Advance Informed Agreement (AIA):** It establishes an advance informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. The objective is to allow a receiving country to assess potential risks to biological diversity and human health from such transfers.

**iii) Traceability:** Protocol calls for provision of detailed information for handling, packaging and transportation, and clear identification of LMOs. Importer of LMOs should be able to trace back the original exporter.

**iv) Liability and Redress:** The term "liability" is normally associated with the obligation under the applicable law to provide for compensation for damage resulting from an action for which that person is deemed to be responsible. Liability and redress in the context of the Protocol concerns the question of what would happen if the trans-boundary movement of living modified organisms (LMOs) has caused damage. Negotiators were unable to reach any consensus regarding the details of a liability regime under the Protocol.

**v) Bio-safety Clearing-House [BCH]:** The Bio-safety Clearing-House was established by the Protocol to facilitate the exchange of information on living modified organisms and to assist countries in the implementation of the Protocol.

The issues dealt under Convention on Biological Diversity of 2010 include:

- Measures and incentives for the conservation and sustainable use of biological diversity.
- Regulated access to genetic resources and traditional knowledge, including Prior Informed Consent of the party providing resources.
- Sharing, in a fair and equitable way, the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the

Contracting Party providing such resources (governments and/or local communities that provided the traditional knowledge or biodiversity resources utilized).

- Access to and transfer of technology, including biotechnology, to the governments and/or local communities that provided traditional knowledge and/or biodiversity resources.
- Technical and scientific cooperation.
- Coordination of a global directory of taxonomic expertise (Global Taxonomy Initiative).
- Impact assessment.
- Education and public awareness.
- Provision of financial resources.
- National reporting on efforts to implement treaty commitments.

**Nagoya Protocol**

At the 2010, 10th Conference of Parties (COP) to the Convention on Biological Diversity in October in Nagoya, Japan, the Nagoya Protocol was adopted. On 22 December 2010, the UN declared the period from 2011 to 2020 as the UN-Decade on Biodiversity. They, hence, followed a recommendation of the CBD signatories during COP10 at Nagoya in October 2010. The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization 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 thereby contributing to the conservation and sustainable use of biodiversity. The Protocol was adopted on 29 October 2010 in Nagoya, Aichi Province, Japan, and will enter into force on 12 October 2014. It has been ratified by 53 states and the European Union.

**Relevance:** The Nagoya Protocol is intended to create greater legal certainty and transparency for both providers and users of genetic resources by:

- establishing more predictable conditions for access to genetic resources; and
- helping to ensure benefit-sharing when genetic resources leave the contracting party providing the genetic resources.

By helping to ensure benefit-sharing, the Nagoya Protocol creates incentives to conserve and sustainably use genetic resources, and therefore enhances the contribution of biodiversity to development and human well-being.

**Scope:** The Nagoya Protocol applies to genetic resources that are covered by the CBD, and to the benefits arising from their utilization. It also covers traditional knowledge (TK) associated with genetic resources that are covered by the CBD and the benefits arising from its utilization.

**International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)**

Popularly known as the **International Seed Treaty**, it is a comprehensive international agreement in harmony with the Convention on Biological Diversity, which aims at guaranteeing food security through the conservation, exchange and sustainable use of the world's plant genetic resources for food and agriculture (PGRFA), as well as the fair and equitable benefit sharing arising from its use. It also recognizes Farmers' Rights: to freely access genetic resources, unrestricted by intellectual property rights; to be involved in relevant policy discussions and decision making; and to use, save, sell and exchange seeds, subject to national laws. However, as Regine Anderson of the farmers' rights project, among others, including Olivier De Schutter, the UN Special Rapporteur on the Right to Food, argue the interpretation and realization of farmers' rights is weak and is not the same across all countries. Without a consistent, strong international focus on the realizing the rights of farmers who conserve and sustainably use PGRFA to save, use, exchange and sell seeds saved on-farm, genetic variety of crops and related agricultural biodiversity will suffer. India, for example, includes an interpretation of farmers' rights in its Plant Variety Protection and Farmers' Rights Act, allowing farmers a restricted right to save and sell seed they have produced on-farm as they always have, even if it contains genes from a protected variety.

The treaty has implemented a Multilateral System (MLS) of access and benefit sharing, among those countries that ratify the treaty, for a list of 64 of some of the most important food and forage crops essential for food security and interdependence.

The treaty was negotiated by the Food and Agriculture Organization (FAO) of the United Nation’s Commission on Genetic Resources for Food and Agriculture (CGRFA) and since 2006 has its own Governing Body under the aegis of the FAO. Composed of representatives of all Contracting Parties, its basic function is to promote the full implementation of the Treaty, including the provision of policy guidance on the implementation of the Treaty. The Governing Body elects its Chairperson and Vice-Chairpersons, in conformity with its Rules of Procedure. They are collectively referred to as "the Bureau".

Some believe the treaty could be an example of responsible global governance for ensuring that plant genetic resources essential for present and future food security can be kept accessible to all farmers and in the public domain.

- The Governing Body met for the first time in Madrid in June 2006.
- The Second Session of the Governing Body was held in Rome in October/November 2007. This meeting discussed the implementation of Farmers' Rights, financial rules; the funding strategy, relationship with the Global Crop Diversity Trust; and implementation of the Multilateral System (MLS) for access and benefit-sharing, among other issues.
- The Third Session of the Governing Body was held in Tunis in June 2009. This meeting continued the unfinished business of the previous meeting and discussed, among other issues, funding strategy, compliance, sustainable use, the implementation of Farmers' Rights, relationship with the Global Crop Diversity Trust and the CGRFA, implementation of the Multilateral System (MLS) for access and benefit-sharing.
- The Fourth Session of the Governing Body was held in Bali, Indonesia in March 2011. Prior to the Governing Body meeting, Ministers adopted the Bali Declaration on the Treaty that commits them to engage in further enhancing Treaty implementation to help meet the challenges of agricultural biodiversity erosion, food insecurity, extreme poverty and the effects of climate change. The relationship of the Treaty with the CGRFA, the CBD's Nagoya Protocol, the Global Crop Diversity Trust and Biodiversity International were also included in resolutions.
- The Fifth Session of the Governing Body was held in Muscat, Oman in September 2013. The Fifth Session achieved: a good resolution on Farmers' Rights (FRs), which renewed the commitment of governments to implement Farmers' Rights; commitments to review and change the Multi Lateral Access and Benefit Sharing mechanism (MLS), to prevent pillaging of the System by patents on native traits, for example; and a request to the Secretary to report on relevant discussions that relate to Farmers' Rights within other UN fora including the Committee on World Food Security.

**Negotiations and Entry into Force:** The treaty was under negotiation for 7 years. A previous voluntary agreement, the International Undertaking on Plant Genetic Resources for Food and Agriculture (IU), was adopted in 1983. However, the IU was reliant on the principle of genetic resources being the common heritage of humanity. The Convention on Biological Diversity

(CBD) (1993) brought genetic resources under the jurisdiction and sovereignty of national governments. However, the CBD recognized the special and distinctive nature of agricultural genetic resources: they were international - crossing countries and continents - their conservation and sustainable use requires distinctive solutions and they were important internationally for food security. Subsequently, the IU was renegotiated, to bring it in harmony with the CBD, and was renamed as a treaty.

The treaty was approved during the FAO Conference (31st Session resolution 3/2001) on 3 November 2001, with 116 votes and 2 abstentions (USA and Japan). The treaty was opened for signatures until 4 November 2002 by all members of FAO or any state member of the United Nations or of the International Atomic Energy Agency. 77 countries and the European Union had signed the treaty by that date. Having reached the required number of instruments in order for the treaty to enter into force (40) on 31 March 2004, on which date 13 instruments (including the European Union) were deposited with the Director-General of FAO, the date of entry into force was on 29 June 2004.

**Discussion:** Plant genetic resources are essential to a sustainable agriculture and food security. FAO estimates humans have used some 10,000 species for food throughout history. However, only about 120 cultivated species provide around 90 per cent of food requirements and 4 species (Maize, Wheat, Rice and Potatoes) provide about 60 per cent of human dietary energy for the world's population. A large number of these crop varieties developed by farmers over millennia, which form an important part of agricultural biodiversity, more than 75 per cent have been lost in the past 100 years. Some fear that corporate financial interests might prevent safeguarding of livelihoods, promotion of food security, biodiversity-rich farming under control of local communities, and implementation of Farmers' Rights. Some of the points raised are:

- to what extent will intellectual property rights be allowed on genetic resources in the MLS, within treaty rules: some argue an agreement aiming at open access to genetic resources for food and agriculture should not allow restrictive property rights, and the treaty says in Article 12.3.d that *"Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System"*;

- to what extent will farmers and communities be allowed to freely use, exchange, sell and breed the seeds, and what enforcement procedures will be used by national governments to ensure principles of Farmers' Rights will be respected;
- Dispute settlement mechanism under the Third Party Beneficiary and the role of FAO.
- The first group of 11 projects funded by the treaty was announced during the Third Session of the Governing Body in Tunis in June 2009. The projects were funded according to criteria established by the Governing Body including regional balance: 5 from Latin America, 5 from Africa and 1 from Asia. The ranking of the projects was done by a Group of Experts nominated by the 7 regional representatives of the Bureau and the final approval was done by the Bureau on behalf of the Governing Body.
- while the whole Brassica family (Cruciferae) including all its sub-species and varieties is in the MLS, the total number of food crops and forages and their relatives included in the treaty is very limited. Soya, sugar cane, oil palm and groundnut are among important crops missing from the list.

The treaty came into force on 29 June 2004 at which time there were more than 54 ratifications by countries. From the entry into force, countries that previously signed are allowed to ratify the treaty, while countries that did not sign the treaty before it came into force can also accede to it. The instrument of ratification has to be deposited with the Director-General of FAO.

**National Biodiversity Authority (NBA)**

NBA is a statutory autonomous body under the Ministry of Environment and Forests, Government of India established in 2003 to implement the provisions under the National Biological Diversity Act, 2002, after India signed Convention on Biological Diversity (CBD) in 1992. In 2012, NBA organized the first ever National Biodiversity Congress (NBC) at Thiruvananthapuram, Kerala. On this occasion, National Biodiversity Students' Congress was also held. The International Treaty on Plant Genetic Resources (ITPGR) recognized the rights of farmers to save, use and exchange and sell farm saved seeds or propagating material. The Biological Diversity Act (2002) mandates implementation of the Act through decentralized system with the NBA focusing on advising the Central Government on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of benefits arising out of the utilization of biological resources; and advising the State Governments in the

selection of areas of biodiversity importance as heritage sites and measures for the management of such heritage sites.

The State Biodiversity Boards (SBBs) focus on advising the State Governments, subject to any guidelines issued by the Central Government, on matters relating to the conservation of biodiversity, sustainable use of its components and equitable sharing of the benefits arising out of the utilization of biological resources. The SSBs also regulate, by granting of approvals or otherwise requests for commercial utilization or bio-survey and bio-utilization of any biological resource by Indians. The local level Biodiversity Management Committees (BMCs) are responsible for promoting conservation, sustainable use and documentation of biological diversity including preservation of habitats, conservation of land races, folk varieties and cultivars, domesticated stocks and breeds of animals and microorganisms and chronicling of knowledge relating to biological diversity.

**Status of India's Biodiversity:** India is one of the 17-mega biodiversity countries of the world. With only 2.4 per cent of the land area, India already accounts for 7-8 per cent of the recorded species of the world. Over 46,000 species of plants and 81,000 species of animals have been recorded in the country so far by the Botanical Survey of India and the Zoological Survey of India, respectively. India is an acknowledged centre of crop diversity, and harbors many wild relatives and breeds of domesticated animals and fish besides millions of microbial diversity, insects and other species.

**Implementation Structures of Biodiversity Act, 2002**

The NBA with its headquarters in Chennai, Tamil Nadu, delivers its mandate through a structure that comprises of the Authority, Secretariat, SBBs, BMCs and Expert Committees. Since its establishment, NBA has supported creation of SBBs in 28 States and, facilitated establishment of around 32,131 BMCs. The Act and the Rules are implemented in India through a decentralized system. A three tiered structure has been established under the Act at the national, state and local levels.

- At the local level, the Biodiversity Management Committees (BMCs) are to be established by institutions of local self-government for implementation of specific provisions of the Act and Rules.
- At the state level, the State Biodiversity Boards (SBBs) are established to deal with all matters relating to implementation of the Act and the Rules.

- At the national level, the National Biodiversity Authority (NBA) is established to deal with all matters relating to implementation of the Act and the Rules. Each of these structure are required to be connected for decision making processes on various issues, including on issues of access and benefit sharing (ABS).

**Checking of Biopiracy under the Act: In order to** check misappropriation of Indian biological resources, the Act provides that access to Indian biological resources and associated knowledge are subject to terms and conditions which secure equitable sharing of benefits. Further, it would be required to obtain the approval of the National Biodiversity Authority before seeking any IPR based on biological material and associated knowledge obtained from India.

**Provision of Exemptions under the Legislation**

v) Exemption to local people and communities of the area for free access to use biological resources within India

vi) Exemptions to growers and cultivators of biodiversity and to Vaids and Hakims to use biological resources

vii) Exemption through notification of normally traded commodities from the purview of the Act only when used as commodity

viii) Exemption for collaborative research through government sponsored or government approved institutions subject to overall policy guidelines and approval of the Central Government and conforms to the central government guidelines.

**Benefit Claims**

- The benefit claimers are conservers of biological resources, creators and holders of knowledge and information relating to the uses of biological resources.
- The benefits could include monetary and non-monetary components. Examples could include grant of joint ownership of IPRs, transfer of technology, association of Indian Scientists in R&D, setting up of venture capital fund, etc.
- Under Rule 22 (6) of the Biological Diversity Rules, 2004, the BMCs' main function is to prepare the People's Biodiversity Register (PBRs). These registers are used, where available, to identify the BMCs where from the biological resources are accessed and benefits will be provided to the Local Biodiversity Funds (LBFs) maintained by BMCs.
- In cases where specific individuals or group of individuals are identified, the monetary benefits will be paid directly to the Local Biodiversity Fund to be used by the BMCs.