Course : PGDIPR-04

Vardhaman Mahaveer Open University, Kota

Patents

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Vardhaman Mahaveer Open University, Kota
Patents

Unit 1
Patents:
(Nature, Meaning, Objectives and Conceptual Aspects)

Objectives

After going through this unit, you will be able to appreciate the nature, meaning, objectives and conceptual aspects of patents. Patents are covered under IPR and it is an authoritative tool for protecting inventions. IPR initiatives are developing fast all over the world. Patent system has received importance in R & D sector. Patent rights play an important role in global economy. Patents give legal rights to patent owners for their inventions for tenure of twenty years. Patents are technical as well as legal i.e. "Techno-legal".

Structure:

1.1 Introduction

IPR is established for protecting intellectual products developed by human mind. Patent filing is gaining momentum all over the world. In fact, patent system is an age old concept for protecting the rights of inventors by a national agency for a specified period. Patent system was developed for the purpose of recognition of the innovator and to reward him for his valuable contribution of innovative ideas, by means of a formal system, to encourage technical developments and fair practices in a competitive age.

The practice started by issuing the "Open Letters" and users have been granted permission to access these documents. The term Open Letters is derived from the Latin term "Literate Patentees". Patent system was introduced in the advent of 15th century in Italy. In 500 BC, in the Greek city of Sybaris (located in what is now known as southern Italy), "encouragement was held out to all who should discover any new refinement in luxury, the profits arising from which were secured to the inventor by patent for the space of a year." In this way the first patent known to be granted was to a Florentine architect, Filippo Brunelleschi in the Republic of Florence, and he received a three year patent. Awarded an industrial patent (the first person to do so) for a barge with hoisting gear which was used to carry marble along the Arno River in 1421. Patents in the modern sense originated in 1474, when the Republic of Venice enacted a decree by which new and inventive devices, have to be communicated to the Republic in order to obtain the right to prevent others from using them (Patents Ordinance). It was also recorded that in England, earliest patents were given to John of Utynam in 1449 for "stained glass" for twenty years monopoly.

Subsequently, England followed the "Statute of Monopolies" in 1623 under King James I, who declared that patents could only be granted for "projects of new invention". During the reign of Queen Anne (1702–1714), lawyers of the English Court demanded that a written description of the invention must be submitted (Intellectual Property Office, UK, 2006). In United States, during the so-called colonial period and Articles of Confederation years (1778–1789), several states adopted patent systems of their own. The first Congress adopted a Patent

Act, in 1790, and the first patent was issued under this Act on July 31, 1790 (to Samuel Hopkins of Vermont for a potash production technique).

1.2 Statutes on Patents Developed in Various Countries

Following table provides the chronological development of patent system all over the world:

Statutes on patents developed in different countries

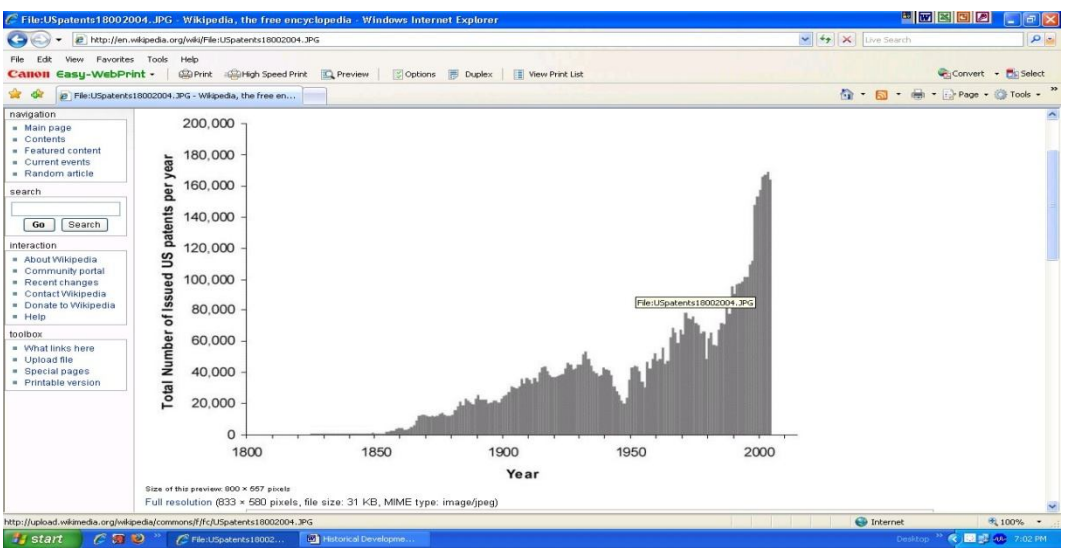
Country	**Year**
USA	1790
France	1791
Netherlands	1809
Austria	1810
Russia	1812
Bavaria	1812
Prussia	1815
Sweden	1826
Spain	1826
Canada	1826
Mexico	1832
Texas	1839
Brazil	1840
Chile	1646
Great Britain	1852
India	1856
Italy	1859

Germany	1877

Patent system changed its form with the industrial revolution followed by subsequent changes such as; advances in science and technology, international trade practices and invention-based commercial benefits in the society. This situation saw setting up of various patent conventions like Paris Convention Treaty (PCT) 1883. The internationalization of commerce in late 19th century developed filing of patent applications in each country where the inventor wants to exclude others from practicing the invention. This gave motivation for development of international treaty of patent applicants. In 1883, the Paris Convention for protection of Industrial Property granted the benefit, that an applicant of a patent in one member state can file applications for patents in all other member states within one year of original filing date and right will be given to the claimed invention as of the priority date established by the first filing.

In view of growing importance of patents, the Paris Convention was revised many times and included over 173 members as on 2nd August 2008. The Convention handles all forms of IP. India is one of the member countries.

The screenshot of growth of patents filed from 1850 to 2000 is given below, which indicates a steady growth.



1.3 History of Patent Literature

Simmons (1996) pointed out that the patent system was established by industrialized countries during the period of Industrial Revolution. This system was developed to provide incentives for development of technology and information to next generation of inventors. Patents rights are given to protect the manufacturing method, usage and sale of invention claimed in the patent. Patentee has the right to license, reassign or sell the rights conferred by the patent and protect the invention from infringement, unauthorized manufacture, use or sale of the product. Patents are granted by national governments and have effect only within the granting state.

The mid of 20th century has witnessed a sharp increase in research and development as well as internationalization of technology-based industries. This resulted change in patent literature which emerged as the core literature of technology. In this process, number of countries publishing the patent documents increased. The former communist and the Third world countries enacted patent laws. The number of patent issuing authorities increased. Further enactment of new patent laws by other countries in response to IP provisions of the GATT (General Agreement on Tariffs and Trade) established the World Trade Organization (WTO) and North American Free Trade Agreement (NAFTA).

Later, individual countries developed their own patent laws and procedures for protecting IP. The growth in filing of patent applications led to increase in the number of patent offices between 1964 and 1979. Patent applications were examined and only those found worthy were declared as granted patent. In 1940‟s most of the published patent documents were granted patents. However since 1990‟s, unexamined patent applications started getting published. Until 1970‟s all patents were effective only in the country in which they were issued, but in 1990‟s there were several types of international patent applications like European Patent which provides rights by European Patent Organization (EPO), which is a group of 17 European countries. Later, Eurasian Patent Convention was established in 1994 by 11 former member states of Soviet Union. Two regional organizations covering few African nations were granted patents by the African Intellectual Property Organization (OAPI) for 14 French speaking countries and also to the African Regional Industrial Property Organization (ARIPO) for 11 English speaking countries.

1.4 Milestones in the Development of Patent Literature

An attempt is being made to provide significant landmarks in the process of development of patent literature.

Table Milestones in development of patent literature

Year	Country or Authority	Development
1964	The Netherlands	First principle examining office to switch to universal publication and differed examination
1968	FRG (Germany)	Switched to universal publication
1971	Japan	Switched to universal publication, and increased the output @1,00,000/yr
1979	European Patent Office (EPO)	Single patent office covering multiple countries
1979	World Intellectual Property Organization (WIPO)	Single application for multiple countries and regional offices, increased the share of English Languages Documents
1980	United States	Periodic maintenance payments for granted patents, for 1980 December onwards
1995	United States	Switch to 20 year term from file date

It is commonly believed that patent literature is a major information resource which describes new technologies and new concepts. Patent literature is different from any other information source as the information disclosed in this literature is not published elsewhere. It provides valuable Current Awareness Service for researchers, R & D managers, technologists, and forecasters to enable them to predict as well as formulate corporate policies and strategies. The major

advantage of patent literature is to indicate gaps in the area of research where inventor or assignee can put efforts to innovate their new ideas.

1.5 Innovation

Innovation implies novel and accepted changes in the society. Innovations are fundamental not only to technological and economic development but also to the cultural development at large and there are different types of innovations like technological or technical, service innovation, financial innovations, managerial innovations, organizational innovations, marketing and distribution innovations, cultural innovations etc. Out of these, technical and technological inventions or innovations (which can be divided in to product and process) are patentable and the rest are non-patentable innovations, (only supporting technologies used may be patentable). Innovation is related to a change in ideas, practices, or objects involving some degree of novelty or any creation based on human ingenuity, success in applications etc.

1.6 Meaning of Patents

WIPO defined patent as "It is an exclusive right granted for an invention may be product or process which gives new way of preparing and providing solution to a problem". It protects novel inventions and manufacturing processes for duration of 20 years. It is a territorial protection and can be sold or licensed. Patent protection implies that inventions cannot be commercially made, used, distributed or sold without the patent owner's consent. A patent owner has rights to decide who may or may not use the protected invention for the period in which the invention is protected. Patent provides incentive to the creator for his invention. Filing of patent application to patent office is mandatory. A patent is granted by a national patent office or regional patent office on the basis of application. Every country has its own patent office and its own patent law for the protection of innovative ideas. Rights given by the patents are monopoly rights which prevent others from making, using or selling the creator's invention for a specified period of time. Patents are issued for inventions which are solutions to specific problems in the field of technology. Invention may be related to a product or a process. In order to get a patent for an invention, the invention has to be

patentable (Novel, non-obvious, inventive step, utility etc) and application must be filed in the patent office. In brief "Patents reward disclosure rather than secrecy". Patent document is published as an application and later granted by the patent office as a patent. Patents are granted for the inventions related to process, products, apparatus and industrial applications.

A patent is an agreement between an inventor and a country. The agreement permits the owner to exclude others from making, using or selling the claimed invention. Patent is a monopoly right to the exclusive use of an invention, granted to the inventor or his assignee. This right is granted only for a limited period called "term of Patent". (During the term of patent, it must be kept alive by payment of renewal fees).

A patent is an exclusive right granted for an invention, which is a product or a process that provides a new way of doing something, or offers a new technical solution to a problem. Patents give legal recognition to the owners of new inventions, providing them with the authority to stop others benefiting from their intellectual and financial investment. In fact, patent is an exclusive right for using an invention or innovation within a fixed period (usually 20 years). In exchange for this right, patents are published to share the knowledge with everyone so that new markets and technologies can evolve. A few facts about patent are stated below:

- A patent is an exclusive right, granted by a government, to an inventor in exchange for the inventor disclosing his invention to society.
- A patent may be defined as "a grant by the state of exclusive rights for a limited time in respect of a new and useful invention". (These rights are generally limited to territory of the state granting the patent, so that an inventor wishing protection in a number of countries must obtain separate patents in all of them.)
- Patent rights are limited and considered as the sole rights for excluding others from making, using and selling the invention. (Since, government gives the rights; they are effective only in the area controlled by that government.)
- If the inventor desires protection in any other countries, he must apply for a patent in each of those countries as well. (to minimize the costs of filings in each country, the Patent Cooperation Treaty (PCT) provides for the filing of an "international" patent application by the inventor to his national patent office in order to obtain protection in selected countries, which are the members of the treaty)

- The patent, in law, is a property right and it can be given away, inherited, sold, licensed and even can be abandoned.
- There is no world patent but only world application.
- Patents are unique sources of information, and failure to include them in literature search can cost an organization heavily.

EPO defined patent as "A patent is a legal title granting its holder the exclusive rights to make use of an invention for a limited area and time by stopping others from, among other things, making, using, or selling it without authorization". (http://www.epo.org/). It should be borne in mind that a patent is a negative right. A patent only provides the right to take legal action for infringement. It does not check for such infringement - it is up to the patent owner to ensure there are no infringements of the right.

In general, patent is a right granted by the government to an inventor due to which, inventor gets right to exclude others from making, selling, using or importing invention for sale (the invention claimed in the patent deed) for a certain fixed period, provided maintenance fees are paid. Currently there are 198 patent offices worldwide. Patents are the most important intellectual property in industrial technology domain. There are over 32 million patents published worldwide and over half a million applications are added every year. Around 25000 patents are published per week in the world of which 50% are new.

1.7 Nature of Patents

Grandstand (1999) presents typical nature of patents as economical and technological products of the human intellect.

1) Patent is a legal right with a possible economic value. A patent does not directly allow the holder to exclusively sell or even manufacture the invention. It is a negative right, a right to exclude others.
2) Patent can be seen as a socio-economic contract between an inventor (IPR holder) and society.
3) Patent rights are important as competitive means for the protection and commercial exploitation of new technologies.
4) Patent information is important as means for technology and competitor intelligence.

5) Patent rights are national in the sense that they refer only to the country that granted them and they must be applied for, in each country of interest.
6) There is no world patent or international patent.
7) A patent right is violated or infringed if someone exploits the invention commercially.
8) Patents are territorial e.g. an Indian patent has no force in other countries as well as patents filed in other countries use no force in India.
9) Patentable subject matter covered in patent gives new concepts, inventive step and has industrial applications.

1.8 Benefits of Patents

By and large, it is observed over a period of time that patents provide the following benefits:

- Provide a monopoly right to the exclusive use of an invention.
- Provide the owner with a right to take legal action to prevent other people exploiting the invention – i.e. it is a negative right and requires active policing to ensure protection.
- Overseas protection is through international conventions like European Community, Patent Co-operation Treaty.

In addition there are some other points regarding patents to take note of:

- It is not possible to guarantee that a patent is valid even when granted. It is always open to challenge**.**
- A patent places the invention in public domain. So it may not be a preferred business option. Secrecy may be more lucrative
- Access to patent information can give interesting insights into the activities of competitors etc.

1.9 Need for Patents

It is clearly realized that in recent days, intensity and complexity of technology competition has led to emergence of new ways of extracting information required for better decision-making in different organizational levels. Following are the factors that indicate the need of patents in research areas:

- Patents are excellent source of technical and legal information.

- More than 80 % of information in patents is not published elsewhere.
- Rewards to inventors for invention by granting protection
- If patents are commercially exploited, substantial benefits to the inventors or their assignees are gained.
- Patents give enforceable exclusive legal rights to the inventors for a limited period of time to reap monetary benefits out of the invention.
- The rights awarded to the inventors are enforceable against anybody within the jurisdiction of the Government.
- Patents play an important role in development of technology by helping in planning research and excluding the chances of repetitions.
- Patents play an important role in transfer of technology, which in turn results in economic growth.
- Patents are used to identify experts in a particular area.
- Patents are used to find out which companies are working in a particular area.

1.10 Possible Beneficiaries of Patents

- Researchers.
- Industries.
- Business organizations.
- Consultants and planners.
- Patent attorneys and agents.
- Society.

A **researcher** (from R & D, S & T organizations, universities and the industries) makes use of patents:

- To avoid duplication of research.
- To assess the state of the art before initiating a research project.
- To find ready solutions to technical problems in an ongoing research.
- To be updated with developments in the technology field.

Industries rely on the patents:

- To improve existing technology to produce newer, better and cheaper products.
- To find ready solutions to technological problems.
- To increase production and productivity.
- To identify suitable technologies for transfer.

- To evaluate alternative technologies.

Business organizations need to refer patents:

- To identify new products for marketing, licensing and distribution.
- To locate patent owner.
- To identify competitors.
- To avoid infringement problems.
- To locate areas of investment.

Consultants and planners require patents:

- To assess a technology for viability.
- Technology forecasting by identifying trend of inventions.
- To advise industry on issues relating to the technology.
- To find out future technologies.

Patent attorneys and agents make use of patents:

- To ascertain patentability, application of patent and opposition.
- Revocation under the patent law.
- Patent drafting.

Society largely benefits to gain:

- Newer, better, cheaper products available to the society.
- After expiry of the term of patent, the invention is available to public without any legal problem.

1.11 Special Features of Patent Information

Increase in patent filings and volume of patents, the effective retrieval and analysis of patent information has become an essential skill in business and R & D areas. These features are covered by which are as follows:

1) **Broadness**: Worldwide, well over 30 million patents have been published to date and millions are currently in force. Some patents contain well over 200 pages of technical information. In special areas of technology, like genetic sequences, there are now documents running to thousands of pages.

2) **Only source**: Patent documents contain information that is not divulged in any other form of literature. A study in the US Patent and Trademark Office shows that as much as 80% of the technologies disclosed in the US patent documents are reportedly not disclosed in non-patent literature.

3) **Detailed description**: The text of a patent document has to contain a full and practical description of the invention, clear enough to enable an expert in that field to recreate that invention. These make patents an invaluable information source, especially for those involved in R&D.

4) **Uniform structure**: Patent documents have a fairly uniform structure. The uniform structure of patent documents makes their reading, as one gets accustomed to it, generally easier, which is not the case with published articles where the reader has to familiarize himself with the style and mental process which differs from author to author.

5) **Concise information**: Technical information in patent documents is very brief and useful. Unlike other sources that their main notes are scattered among rather redundant statements, patent documents are well handy to find the information required.

6) **Easy access**: Full text of many patent documents is easily accessible via internet. This is an important advantage of patent information over other sources of technical information.

7) **Low cost**: Full and free access too many published patent documents is easily possible through Internet.

8) **Standard classification**: The International Patent Classification (IPC) has been established by Inter-Governmental Agreement and is now applicable by at least 50 patent offices. The IPC subdivides technology into 8 sections, 120 classes, 628 subclasses and more than 96000 fields called "groups" or "subgroups". Each group is described in a few words and identified by a "Classification Symbol" consisting of numbers and letters.

9) **Several searching approaches**: There are several possible approaches for searching and retrieving patent information, including different searches by using
   (i) filing or publication number,
   (ii) references found in a patent document,
   (iii) the bibliographic data,
   (iv) The International Patent Classification,
   (v) Well chosen keywords, and
   (vi) Combination of the mentioned strategies.

Given the immense amount of patents‟ information, the best and most precise way for gaining required information is through IPC-based searches.

1.12 Patentability Requirements:

In patents, the subject matter that can be protected by patents is more important. These subjects are called as “Patentable” subject matter. The prerequisites for patent filing are:

- **Novelty:** Novelty is newness, and while filing patent, the subject matter covered in it must satisfy the condition of newness in it, and should also not be known in the public domain. Public domain refers to all things that are available and accessible to the public. The invention must never have been made public in any way, anywhere in the world before the date of the application being filed (the “Priority Date”).
- **Utility**: Utility means the material to be patented should have commercial use or application. Utility is easily resolved in inventions involved in areas of science. A patent can only be granted if the invention is capable of being made or used in some kind of industry. This means it must take the practical form of an apparatus, a device or a product, or be an industrial process or method of operation.
- **Non obviousness**: It means that the invention for which patent protection is sought is just an obvious development for people skilled in the art, and then patent protection is not provided. Non-obvious to someone familiar in a similar field - must involve an inventive step, but this may be small, or may appear obvious to you, but not to everyone.
- **Inventive step**: an intermediary step developed which increases the productivity of the process.

Prerequisites for Patenting:

A technical invention fulfilling minimal requirements in respect of the following criteria is considered for the patentability.

1) It is novel to the world.
2) It is industrially applicable or useful.

3) It is non-obvious to the "average person skilled in the art" (professional practitioners).
4) The invention must exceed a certain minimum inventive step.

The minimum level of patentability requirements may vary across nations as well across the patent examiners.

Pressman (2004) suggested four legal requirements for obtaining a utility patent:

1) Statutory Class: The invention should fit in to one of the five classes viz. Process (method), machine, and article of manufacture, composition or a new use.
2) Utility: The invention must properly be regarded as a useful one.
3) Novelty: The invention must properly be regarded as novel.
4) Un-obviousness: The invention must be properly regarded as unobvious from the standpoint of someone who has ordinary skills in the specific technology involved in the invention (provide one or more new and unexpected results).

As per Indian Patent Act 1970, art, processes, methods or manner of manufacture, machine, apparatus, can be patented.

1.13 Non-patentable aspects

These are certain aspects which are excluded from patenting and these are enumerated as follows:

- Discoveries.
- Scientific theory.
- Mathematical model.
- Aesthetic creation.
- Computer programs - may be protected by copyright and may be patentable in certain specific instances and in few countries.
- Encouraging offensive, immoral or antisocial behavior.
- Medical procedure or method for diagnosis.
- Variety of animal, plant or biological processes. (Some plant varieties can be protected in certain circumstances).
- Anything contrary to law or morality or injurious to public health.
- Rearrangement or duplication of the devices.
- Method of agriculture or horticulture.

1.14 Types of Patents:

Thorough glance at the patents literature reveals that there are three types of patents covered-

1) **Utility Patents**: This is a main type of patent and covers inventions that function in a unique manner to produce utilitarian results e.g. new drugs, manufacturing process, new bacteria that can be made by humans. To get utility patent, one has to file a patent application disclosing the invention to public, indicating how to make and use the invention. It has a 20 years patent term from the date of filing.
2) **Design Patents**: A design patent covers unique, ornamental, visible shape, surface ornament, and an article or objects e.g. a lamp, a building, a computer case which has a truly unique shape. It has a 14 years patent term from the date of issuance.
3) **Plant Patents**: A plant patent covers asexually reproducible plants (Using grafts and cuttings) like flowers. Sexually reproducible plants (use pollination) can be monopolized under the plant variety Protection Act. Both sexually and asexually reproducible plants can now also be monopolized by utility patent. . It has a 20 years patent term from the date of filing.

Summary

A patent is a set of exclusive rights granted by a sovereign state to an inventor or assignee for a limited period of time in exchange for detailed public disclosure of an invention. An invention is a solution to a specific technological problem and is a product or a process. Patents are a form of intellectual property.

The procedure for granting patents, requirements placed on the patentee, and the extent of the exclusive rights vary widely between countries according to national laws and international agreements. Typically, however, a granted patent application must include one or more claims that define the invention. A patent may include many claims, each of which defines a specific property right. These claims must meet relevant patentability requirements, such as novelty, usefulness, and non-obviousness. The exclusive right granted to a patentee in most countries is the right to prevent others, or at least to try to prevent others, from commercially

making, using, selling, importing, or distributing a patented invention without permission.

Under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights, patents should be available in WTO member states for any invention, in all fields of technology, and the term of protection available should be a minimum of twenty years. Nevertheless, there are variations on what is patentable subject matter from country to country.

In modern usage, the term patent usually refers to the right granted to anyone who invents any new, useful, and non-obvious process, machine, article of manufacture, or composition of matter. Some other types of intellectual property rights are also called patents in some jurisdictions: rights are called design patents in the US, plant breeders' rights are sometimes called plant patents, and utility models and Gebrauchsmuster are sometimes called petty patents or innovation patents.

The additional qualification *utility patent* is sometimes used (primarily in the US) to distinguish the primary meaning from these other types of patents. Particular species of patents for inventions include biological patents, business method patents, chemical patents and software patents.

1.16 Self-Assessment Test

1) Discuss the origin and development of patents.
2) Explain the nature and meaning of patent.
3) What are the major objectives behind patent protection?
4) Mention the conceptual aspects regarding patent protection.
5) What are the different types of patents? Explain.
6) What are the requirements for an invention to qualify as a patent?

1.17 Further readings

1) http://www.wipo.int/
2) Indian Patents Act, 1970
3) Science and Law Journals and News Papers.

Unit 2
The Law relating to Patents in India (The Patents Act, 1970) Application, Objectives and Scope

Objectives

Inventive activity is supposed to result in innovation, which further leads to technological advancement, industrial development and economic welfare. This is possible through local working of inventions. When it comes to patented pharmaceutical drugs, law relating to patent becomes more crucial for it is concerned with health issues. Historically, patents in England have been granted with an intention to encourage local application of the invention through industrial establishment. In recent years, particularly after TRIPS, tremendous growth in patent activity has been seen. Local working of patents has been the most efficient way of transfer of technology which itself is one of the primary objectives of the patent system. However, it is noticed that these patents are not necessarily worked locally. This units aims to examine the law relating to patent, its implementation and feasibility in India. This unit argues that, though there are favourable conditions for investment, patents are not worked in India on a commercial scale. The present trend of non-working of patents in India indicates that patenting is attractive merely due to the high economic gains from the large Indian market, and patented products are often imported with no actual transfer of technology. It also shows that the present patent system has deviated from its ultimate objective of socio-economic welfare.

Structure:

2.1 Introduction

In the early days, patent privileges were issued to ensure the application of inventions in local industries and to establish new industries. Patent monopoly was used as a public tool to fulfil the government's social, economic and political objectives, such as increasing foreign trade, introducing new technologies, developing new industries and maximizing employment. In England, introduction of a new industry and local working were the primary requirements of the royal grant. The ultimate objective of the English monopoly privileges was to create a self-sufficient economy by importing new industries and technology from other nations. This royal policy of granting special privileges worked as a catalyst in the development of the state. The policy of encouraging the industrial growth through the grant of monopoly rights was also present in the 1624 Statute of Monopolies. In the later period, the patent system underwent a sea change and many aspects of the original patent system, which had a tremendous impact on development of industry, appeared to be missing or were ineffective in the modern patent system. The enormous technological growth and change in international trade policy resulted in the formulation of TRIPS Agreement, which mandated member states to change their domestic laws accordingly. During the pre-TRIPS period, patents were exclusively governed by national jurisdiction, subject to local laws framed according to the local needs and national developmental goals. There were differences among the nations in the levels of protection and fields of technology covered by patent, owing to divergent goals, values, history, culture, tradition and political climate of each country. These differences caused problems for the

developed countries in patenting of inventions in foreign countries. Therefore, TRIPS came into existence. TRIPS mandate provided for certain minimum levels of IP protection to be met by the member countries.

India as a signatory to the TRIPS, complied with the requirements under it, by amending the Patent Act, 1970, from time to time. The new Patent Act has spurred tremendous growth in patenting activity. However, this patenting growth could give rise to transfer of technology and ultimately socio-economic welfare, only if the patents are worked locally on a commercial scale. Local working of patents is possible only when there is adequate infrastructure and a favourable environment for industrial investment. This paper aims at examining the legal framework of local working of patents, its implementation and the feasibility of working patents locally in India.

2.2 Importance of Law relating to patent

Manufacture of the patented product or application of the patented process in a local industry is generally called as 'local working of patent'. It is claimed that the local production of patented inventions would decrease transport costs, cut dependence on foreign suppliers, provide local jobs, increase expertise, cause transfer of technology and lead to innovation. It is also affirmed that it will help the nations achieve economic autonomy and sustainable development. Local working may be achieved by direct investment, joint venture or by issue of exclusive or non-exclusive licences. In the words of Michael Halewood:

'Local working refers to the condition some countries impose on patentees that their patented product or process must be used or produced in the patent granting country. This condition has the effect of forcing foreign patentees to situate production facilities within the patent granting country. Such transfers of technology are desirable from the patent granting country's point of view because they contribute to a variety of public policy goals such as employment creation, industrial and technological capacity building, national balance of payments, and economic independence.'

In the contemporary era, technology is among the most important determinants of economic development and its transfer and dissemination is

essential for developing countries. Technology transfer is the process of sharing of skills, knowledge, technologies, methods of manufacture, samples of manufacture and facilities between governments and other institutions. It ensures that scientific and technological developments are accessible to a wider range of users who can then further develop and exploit the technology for new products, inventions, processes, applications, materials or services (Articles 7 & 8 of TRIPS). New technologies improve standard of living, create new jobs and facilitate change in the fabric of economy. Economic growth is largely based on advancement in technology and increase in job-oriented expertise. The success of businesses mostly depends upon the capacity of renewal and innovation. Technological and economic development worldwide leans heavily on new and competitive products and promotes general welfare. In most of the industries, intellectual property rights, especially patents, and their exploitation in the local industries, play a key role in the development and commercialization of new products. Patents are of vital importance to facilitate the transfer of technology, directly by stimulating the introduction of foreign technology and indirectly by making available the technological information through patent documents. 'The principal way in whom patients may contribute directly to the transfer of technology to developing countries is through the exploitation of the patented technology in the patent granting country by the foreign patent holder himself or with his consent by third parties. The former mainly takes place in the form of FDI (foreign direct investment) or joint ventures, while the latter chiefly occurs through a licensing arrangement.' Thus, local working has an unequivocal role in transfer of technology and socio-economic welfare of the state, which itself is the ultimate objective of the patent privilege.

2.3 History of Patents and Local Working

During the middle ages, patent letters were issued by the Crown to encourage tradesmen and industrialists to migrate to England to reinforce the realm's lagging industrial development and industrial attainments. The Venetian statute, framed in 1337 for the protection of the new industry, was also aimed at industrial development. The first monopoly privilege, granted by the Crown to a foreigner Henry Smyth in the form of Letters Patent for the production of Normandy glass,

was on the condition of (a) bringing the foreign trade of manufacturing Normandy glass to England, (b) benefiting the realm by lowering the price and (c) training Englishmen in its production. There were patents validly enforced even in case of a trade that was in use earlier but at that time out of use in the realm, with the purpose of re-establishing the industry. The status of 'inventor' was accorded to the patentee, as he was the first to establish or re-establish his respective trade, unless he took away the trade of others. The expression 'establish new trade and industry' was equated with the 'new invention', such newness being limited to the territory of the state. It was an incentive to import and establish (or re-establish) rather than to invent.10 Section 6 of the Statute of Monopolies, 1624, demonstrated clearly that 'the statute was an instrument of economic policy; rather than being motivated by the desire to do justice to the inventor; it was meant to encourage industry, employment and growth. The patentee's consideration for the grant was that he would put the invention to use'.

The statement of Holt C J and Pollex Fen in *Edge Berry* v *Stephens* is reminiscent of the patent policy of Statute of Monopolies:

'If the invention be new in England, a patent may be granted, though the thing was practised beyond the sea before; for the statute speaks of new manufactures within this realm; so that if they be new here, it is within the statute; for the Act intended to encourage new devices useful to the kingdom, and whether learned by travel or by study, it is the same thing.'

This affirms that the objective of the royal policy in granting patent monopoly was to introduce and establish new industries in the realm. The ultimate objectives of the Statute were to encourage industrial activity, employment and economic growth, rather than to reward the 'true and first inventor'. The Statute stated that monopolies are contrary to the 'ancient and fundamental laws' of the realm and exempted patent monopolies by virtue of a privilege based on their contribution to the public good. Local manufacturing of products was believed to be beneficial for transfer of technology and economic upliftment of the state. Therefore, it was a primary and fundamental obligation on patentees to produce the patented articles within the territory and it always remained the precondition for grant of patents. However, failure to work has always been considered a prima facie 'abuse' of the patent privilege. In this era, though the patents cannot be granted merely for establishing or re-establishing an industry, for the reason that

the circumstances which were in existence at that time, are not in existence today. However, the ultimate objective of the patent system remains the same, i.e. technological advancement and economic welfare.

2.4 Local Working under Paris Convention

The Paris Convention, under Article 5A (2), allows the member countries to take legislative measures providing for the grant of compulsory licences to prevent abuses, namely, failure to work or insufficient working, which might result from the exclusive rights conferred by a patent for invention. What amounts to 'failure to work' was not provided and the member states were free to define it. However Article 5A (4) did provide a timeline before the ground of failure to work or insufficient work could be evoked to grant a compulsory licence

Since it is recognized that the immediate working of an invention in all countries is impossible, Article 5A sought to strike a balance between these conflicting interests. The failure to work an invention cannot result in forfeiture of the patent, except in cases where the grant of a compulsory licence would not have been sufficient to prevent the abuse, and then also, only pursuant to a proceeding instituted after the expiry of two years' period following the grant of the first compulsory licence. However the compulsory licence under this provision shall not be granted if the patent holder is able to justify his inaction through legitimate reasons, for example, economic, legal or technical obstacles that caused the invention impossible to work, or work more intensively in the country. The grant of compulsory licence for nonworking or insufficient working must be nonexclusive and non-transferable and should be coupled with a share in profits earned from the compulsory licence. The patent owner should also retain the right to grant other non-exclusive licences and/or to work the invention himself. These limitations are imposed in order to prevent a compulsory licensee from acquiring a stronger position in the market than is warranted by the purpose of the compulsory licence, that is to say, to ensure sufficient local working of the invention.

2.5 Local Working under TRIPS Agreement

There is no express provision in the TRIPS Agreement regarding local working of patents; however, there are provisions which are incorporated by reference and some can be inferred from the objectives and principles.

Nevertheless, the US - Brazil patent dispute that ended undecided due to the withdrawal of complaint by US raised the issue of validity of the local working provisions in domestic laws of the member states.

Article 2.1 of the TRIPS Agreement incorporates Article 5A of the Paris Convention thereby making it obligatory for the WTO member states to comply with the relevant requirements under Paris Convention. Article 2.2 of the TRIPS Agreement further provides that 'Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.' Incorporation of these pre-existing WTO administered treaties into the TRIPS Agreement suggests that, TRIPS is 'an addition' and not a 'replacement' to the earlier conventions.

Article 27.1 of the TRIPS Agreement is regarding the subject matter of patent and extends the protection to the patented goods irrespective of the place of invention, the place of production and the field of technology. The expression 'patents shall be available and patent rights enjoyable without discrimination' along with 'whether products are imported or locally produced' imply that the patentee may either import the goods from other countries or may produce the goods locally. However this provision does not confer any absolute right in favour of the patent holder to import the patented goods from other countries.

A patent is not a goal in itself, rather it is a right created by the state as a means to achieve a larger social goal. Therefore, the state imposes certain restrictions on exercise of such rights in the form of exceptions so as to achieve the desired goal and also to prevent their abuse. The exceptions provided under Articles 65.4 and 70.8 are relating to the extension of patent protection to the products in the fields of pharmaceutical, agricultural and chemical technology for which there was limited or no protection in some countries prior to TRIPS; while non-patentable inventions are mentioned in Article 27.3. However, these provisions do not speak about law relating to patents, and therefore it is argued that Article 27.1 is only subject to the enumerated provisions and the law relating to patent is contrary to Article 27.1 of the TRIPS Agreement, while at the same time, one should bear in mind that there is no express provision which prohibits member states from requiring local working of patents after the grant of patent. On the contrary, Article 5(A) of the Paris Convention, which is incorporated into the

TRIPS Agreement by virtue of Article 2, authorizes the member states to adopt legislative measures like compulsory licence to prevent abuses such as failure to work. These two provisions appear to be contradictory and have created confusion about the legal validity of law relating to patent of patents under TRIPS. Nevertheless, the existence of provisions relating to exceptions under Article 30 and 31 suggest that Article 27.1 is not an absolute rule. Therefore Article 27.1 cannot be interpreted in isolation; rather it should be interpreted after considering other relevant provisions in the text of TRIPS in order to draw the right conclusion. Further, if Article 27.1 is considered as an absolute rule, Article 5(A) of the Paris Convention and Article 30 and 31 of the TRIPS Agreement would become meaningless. The mandate of Article 27.1 is thus qualified and subject to other provisions.

A right created under the law cannot be interpreted by ignoring the exceptions under the law and the ultimate goals for which it was created. The International Court of Justice asserts that the disputed provisions of a treaty should be interpreted in the context of treaty as a whole including objects and purposes. And if the text is ambiguous and unclear, the preparatory works, like the official record of negotiations, etc., shall be resorted to, in clarifying the intentions of a treaty or any other instrument. Therefore, interpreting Article 27.1 in isolation, ignoring the mandate of Article 5A of Paris Convention and Articles 7, 8, 30 and 31 of the TRIPS Agreement would be contrary to the principles of interpretation.

Article 5.1 of the Doha Declaration further provides that 'In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.' The objectives and principles of TRIPS Agreement are incorporated under Articles 7 and 8 wherein Article 7 provides that the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to the social and economic welfare and to a balance of rights and obligations. The principles of the TRIPS Agreement under Article 8.2 affirm the importance of technological innovation and of the transfer and dissemination of technology, which in turn require local working of patents. The failure to work the patent is

treated as abuse of patent monopoly and such abuse of intellectual property rights may adversely affect the international transfer of technology. Article 27.1 and Articles 30 and 31 should be interpreted in the light of the contents of Articles 7 and 8 of the TRIPS Agreement and hence it may be concluded that the local working provision is perfectly within the purview of TRIPS Agreement.

The TRIPS Ministerial Conference held at Doha in 2001 adopted the Doha Declaration to clarify the scope of TRIPS reaffirming the flexibility of TRIPS member states in circumventing patent rights for better access to essential medicines, stating that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. It also affirmed that the agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. Consequently, the member states could issue compulsory licences when access to medicine is restricted due to local non-working of patented invention or importation of patented goods from other countries. The Doha Declaration further affirmed that each member was free to determine the grounds of compulsory licences.

Thus Article 31 of the TRIPS Agreement regulates authorization of third parties to use patents without the consent of patent holder i.e. compulsory licensing. It does not limit the grounds upon which compulsory licences may be granted, however, it requires certain minimum obligations to be fulfilled while granting of compulsory licence. Accordingly, the member states may provide for 'local non-working of patents' as a ground of compulsory licence or 'licence of rights', subject to the requirements under Article 31 of the TRIPS Agreement.

A patent holder is required to ensure that the patented inventions shall meet the reasonable expectations of society (Article 7 of TRIPS). In case the patent holder fails to fulfil such expectations even after the expiry of a reasonable period, without any reasons, such a failure needs to be addressed in order to prevent the abuse of monopoly through non-use or local non-working. Furthermore, in such an event, the state has every right to protect its interests by allowing third parties to manufacture the patented products. Therefore, while Article 27.1 of the TRIPS Agreement is a general rule, Article 30 and 31 (compulsory licence) of the TRIPS agreement and Article 5A (2) of the Paris Convention are exceptions to it.

In another argument it may be claimed that the patent is a privilege granted by the state in the form of contract and local working is a reciprocal requirement of the contract. Hence, legislative measures requiring local working of patent along with the remedy of compulsory licence and revocation of patent available under Article 5A of Paris Convention and Article 31 of the TRIPS Agreement are perfectly justified.

Article 27.1 of the TRIPS Agreement together with Article 5A of the Paris Convention imply that patents are available and patent rights may be enjoyed by the patentee by producing the goods locally or by importing from the another countries; however, if there are no legitimate reasons for local non-working, he shall start local production at a reasonable extent, not later than four years from the application or three years from the grant of patent, whichever expires later. The period of three/four years as mentioned above is a reasonable period required for setting up an industrial unit and start actual production and not merely for importation from other countries.

2.6 Importation of Patented Goods and Law relating to patent

Article 5A of the Paris Convention which is incorporated in the TRIPS Agreement by virtue of

Article 2 provides for local working of patented inventions. However, it does not define 'local working' and leaves it for the member states to define it. This leads to conflicting interpretations about what constitutes 'local working' and whether mere 'importation' of patented goods would satisfy the law relating to patent.

The key argument underlying the provisions requiring the working of an invention in the country where the patent was issued is one of promoting industrialization of that country. The patents should be used to introduce new technology into the country, for which the patent system has emerged. G H C Bodenhausen, former Director of the Bureau for the International Protection of Industrial Property (BIRPI), while describing law relating to patent under the 1967 revision of the Paris Convention, observed that:

'The member states are also free to define what they understand by 'failure to work'. Normally, working a patent will be understood to mean working it industrially, namely, by manufacture of the patented product, or industrial application of a patented process. Thus, importation or sale of the patented article, or of the article manufactured by a patented process, will not normally be regarded as 'working' the patent.'

If the importation of patented goods is considered sufficient to meet the requirements of local working, failure to work the invention could have been addressed by 'parallel imports' using the provisions relating to international exhaustion under Article 6 of the TRIPS Agreement and there would not have been any need of incorporating separate provisions of Article 5A of the Paris Convention in the TRIPS Agreement. Incorporation of such an independent and separate provision into the TRIPS Agreement indicates that the framers of Paris Convention and the TRIPS Agreement intended 'local working' to mean 'local manufacturing 'in the country where the invention is patented which is to be enforced through issuance of compulsory licences and not merely parallel imports.

International Exhaustion Principle (Article 6 of TRIPS) may be invoked to import patented drugs from other countries so as to ensure availability and affordability of patented drugs, however, import of drugs from other countries may not always be an effective and adequate remedy to control the price of drugs and supply, as it always depends upon various factors such as, the taxing structure, capacity to manufacture, quality of drugs, cost of production, etc.

This principle may be invoked only when the quality drugs are available in other countries at lower prices. Therefore, though the provision of parallel imports is one of the remedies available to address shortage of drugs, drug prices and issues concerning the public health, it may not be effective in all cases, particularly in developing countries which themselves have domestic capacity to produce quality goods at much lower prices as compared to developed countries. The provision relating to local working has been incorporated with the wide objective of socioeconomic welfare, i.e. to ensure transfer of technology and industrial progress in addition to availability and affordability of patented goods. Such a provision is more effective particularly, in the developing countries such as India, China, Brazil, etc., having a strong industrial set up with capacity to produce quality drugs at cheaper rate.

If the importation of patented goods is considered sufficient to meet the law relating to patent, it would diminish the paramount objective behind incorporating the local working provision and the patent system itself. Let one assume for the sake of argument, that the importation of goods is sufficient to fulfil the local working of invention. According to Article 5A of the Paris Convention, the patentee is bound to work the invention only after the expiration of the specified period, and is excused from this duty if there are legitimate reasons for non-working. If this interpretation is accepted, the patent holder would be entitled to exploit unrestricted and absolute monopoly over the invention for the initial three to four years and even thereafter, if he has reasons for nonworking. If this were the case, international exhaustion provision would have been the proper and sufficient remedy for addressing the failure to work and there would not be any need for provision in the form of compulsory licence as in Article 5A of Paris Convention. The inadequacy of the provision relating to parallel imports as seen above and incorporation of local working provision indicates that mere importing of patented goods without local manufacturing would not be sufficient to comply with the local working condition and it requires local manufacturing of patented products to a reasonable extent in addition to the importation. It also indicates that both of the remedies are available for the member countries and may be invoked simultaneously and independently.

It may be argued that the manufacture of a product in the country where the invention is patented may not be feasible owing to inadequate infrastructure and high production cost. It may further be argued that the local applicant for a compulsory licence does not have sufficient technical and economic capability to exploit the patent. In the former case, the patent holder can opt for issuing licences to local manufacturers instead of investing huge capital; rather this is the primary demand of the local working provision. However, in the later case where it is not at all feasible to work the patent either by direct production or by issuing licences, the issue of compulsory licence may be decided on individual merits under Article 31(a).

It may also be argued that local working is not possible in all the cases as all inventions may not prove economically efficient due to lack of demand/market or interest; in such cases the patent holder cannot be burdened by requiring the local working of invention. However, such a scenario fall sunder the exception to work

an invention if there are legitimate reasons. Furthermore, a demand for compulsory licence from local manufacturers is expected only when the invention is economically efficient since the grant of such licence is also subject to payment of royalty. Therefore, the question of burden and inconvenience to the patentee does not arise in case of the law relating to patent.

2.7 Indian Patent Regime and the Law relating to patent

The Indian Patent Act, 1970 (hereinafter the Patent Act) under Chapter XVI (Sections 82-99), provides for certain obligations on patentees, proposed to ensure local working of the patent and avoid misuse of monopoly by mere import the product. Section 83 of the Patent Act stipulates the cardinal principles of patent privilege. It provides that the patents are granted to encourage inventions and to ensure that these inventions are worked in India on a commercial scale and not merely for benefitting from the monopoly. The protection and enforcement of patent rights should contribute to the promotion of technological innovation and to the mutual advantage of producers and users of the technological knowledge. The Act also intends that patents granted do not impede protection of public health and nutrition and act as instruments to promote public interest especially in sectors of vital importance for socio-economic and technological development of India. It further lays down that the patentee or his assignee shall not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Finally, it states that patents are granted to make the patented invention available at reasonably affordable prices to the public. This provision reiterates the fundamental objectives of the patent system and attempts to prevent the abuse of patent. Such abuses are restrained under Section 84 of the Patent Act.
According to Section 84(1) of the Patent Act, any interested person may, after the expiration of three years from the date of the grant of a patent, apply for the grant of compulsory licence on the grounds that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at reasonably affordable price or that the patented invention is not worked in India. As per the Section 84(7) of the Patent Act, the 'reasonable requirements of the public' shall be deemed not to have

been satisfied if *inter alia* the patented invention is not being worked in the territory of India on a commercial scale to the fullest extent that is reasonably practicable or if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article. Though there are three different grounds provided for issuing of compulsory licence, all are aimed to ensure that the patents are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable. Furthermore, under Section 85 of the Patent Act, 1970, a patent may be revoked if the patent holder fails to comply with the requirements under Section 84(1). These provisions clearly reflect the policy objective of the patent system. The Indian Patent Act has imposed a duty on the Controller of Patents to ensure the local working of patents. Under Section 146 of the Patent Act, the Controller may require the patentees to furnish to him information/statements regarding the working of patented invention on commercial scale in India. If any person refuses or fails to furnish such information to the Controller, he shall be punishable with fine which may extend to ten lakh rupees or if knowingly submits false information, he shall be punished with imprisonment which may extend to six months or fine or both (Section 122 of the Act). The Controller of Patents may also publish periodically, the information submitted under Section 146 of the Patent Act.

In the compulsory licence case of Natco Pharma, the Controller General of Patents approved the legality of these provisions holding that, 'When the Article 27(I) of TRIPS Agreement is read with the aforementioned provisions of TRIPS Agreement and the Paris Convention, it follows that importation of a patented invention shall not result in forfeiture of a patent. However, a reasonable fetter on the patent rights in the form of a compulsory licence is very well within the purview of the Paris Convention and TRIPS Agreement, when there is an abuse of patent rights. It is this flexibility that the Parliament have invoked in Chapter XVI of the Patents Act, 1970 by incorporating a provision for grant of compulsory licence upon failure to work the invention within the territory of India.'

Though there are various provisions requiring the patentee to submit information regarding local working of patents, there has been no mention about local working of patented inventions in the annual reports of the Controller of Patents till 2007. The data regarding the local working of patents provided in the

annual reports for the year 2007 to 2009 is based merely on the information provided by the patentees and reveals that, only 3499 patents were working commercially out of 29688 patents in force in 2007-08 while only 4752 patents were working commercially out of 30822 patents in force in 2008-09 (ref. 25). It indicates that about 85 – 90 per cent patent holders either failed to work the invention on a commercial scale in India or failed to submit the information regarding working of invention. In either case, it is breach of the duty under the Patent Act and the patent holder is liable for action of compulsory licence, revocation or/and fine.

In spite of having severe liability under the Indian Patent Act for non-working of patents, the situation of local working of patented inventions is miserable. Primarily, it is the duty of the Controller of Patents to implement these provisions. Nevertheless, it is only twice or thrice that such information was called for while no action has been yet taken against those who have not submitted such information.

Recently, the Indian Patent office, for the first time after implementation of TRIPS, issued a public notice dated 24 December 2009, directing all the patentees and licensees to furnish information working of patents, as prescribed by the law. However, there is not much information on whether any action has been taken on those who have not provided such information. Only one compulsory licence has been granted by the Patent Office in the patent history of India for failure to work the invention locally. In *Natco Pharma Ltd* v *Bayer Corporation*, the Controller General of Patents, after being satisfied with the claim of the applicant Natco Pharma Ltd, granted compulsory licence to manufacture and market the anti-cancer drug Nexavar proposed to be sold by Natco at a rate of Rs 8880/- for a dose of one month as against Rs 2,80,428/- by the German pharmaceutical giant, Bayer Corporation. However, the order of Controller of Patents is based on three grounds viz., reasonable requirements of the public with respect to the patented invention are not satisfied, the patented invention is not available to public at reasonably affordable price and that the patented invention is not worked in India. The Controller of patents held that 'working' does not mean 'importation' and 'worked in the territory of India' implies manufactured in India to a reasonable extent.

A report by Basheer that surveyed the top-selling drugs in India for the period 2007-2010 concluded that the pharmaceutical companies in India were not

serious about the local working provisions of the Patent Act. The provisions of law have been breached either by non-filing of the local working information, or by filing incomplete information. The information provided is often either not available, or inadequate to show whether the product is imported or produced locally. Although the study undertaken and the conclusions drawn are of very limited nature due to lack of adequate information on local working of patents owing to so called 'confidentiality' of third party information, stringent requirements and rigid approach of the Indian Patent Office in disclosure of information; the findings are enough to show the pharmaceutical companies' disregard towards their duties under the Patent Act, 1970. The information about the working of patents provided by the patent holder under Form 27 is of utmost importance; rather it can be the basis for grant of compulsory licence under Section 84(1) of the Patent Act, 1970. Non-availability of the information relating to working of patent on commercial scale in India is a basic obstacle in claiming compulsory licence under Section 84(1). The provision of 'licences of rights' (Sections 87 – 89) which existed under the Patent Act, (prior to amendment in 2002) perhaps would have been more appropriate in these circumstances.

Import of pharmaceutical drugs is likely to have an adverse impact on public access to medicine. The quality of imported drugs, unreliable suppliers, the high production costs and transportation costs, scarcity of drugs and shortage of supply are matters of concern in the importation of drugs. Local production of drugs is an attractive solution for such problems. Local production ensures price reduction, increases supply and competition and, consequently, ensures better access to medicines. It also brings self-sufficiency in medicines, cuts dependence on foreign suppliers, increases domestic expertise in the production of medicines for key local diseases, increases transfer of technology and knowledge, increases employment, opens a new export market and improves foreign exchange flows. 'India has low development costs, complex synthesis capabilities, growing experience with good manufacturing practice (GMP) compliance and a large local market in which to gain experience. India is also known for having a large number of strong chemists, many with Ph.D.s from the U.S. and Europe, providing rapid, and creative, process development'. India is the most viable place for production of quality drugs at comparatively lower cost. However, the pharmaceutical companies have failed to

follow the law relating to patents, thereby affecting access to medicine which is a derivative of the right to health.

Under the belief that price is the primary barrier to accessing effective drugs in developing countries, the international community has actively pressed for more competitive, efficient and transparent drug-procurement practices for lowering of prices, by encouraging more producers, increasing drug supply and driving prices down. Nevertheless, public access to medicine has remained one of the most pressing global public health concerns in developing countries.

With regard to the role of patents in transfer of technology, it is seen that the technology transferred to developing countries through patents, accounts for less than 2 per cent of the total technology transferred. The technology transferred through the FDI or joint venture is negligible, as almost none of the foreign owned patents are exploited in developed countries. This is because a majority of the patented inventions have not been used by patent owners in most developing countries.

2.8 Problems in Local Working of Patents

Local working condition requires the patentee to manufacture the patented product or product of patented process in the country where the patent has been granted. This needs initial capital investment, technological support, adequate infrastructure, cost effective labour and favourable environment. Inadequate infrastructure, such as shortage of water and electricity, shortage of skilled and non-skilled labour, bad condition of roads, lack of transport facilities and inadequate technological support are factors that may hamper production and also affect the cost and quality of product. Among other factors, political and social instability, lack of political will, indifferent public attitude, inapt tax structure, electricity costs, transport costs, cost of raw material, instability of foreign exchange, availability of market, market growth and the regulatory framework of that State are crucial in the smooth functioning and progress of the industry. Local working of patent would not be feasible in a country where these factors are not favourable.

In case patents have been granted in multiple countries for the same invention, it may not be possible for the patentee to establish separate industrial

units in all such countries due to administrative and financial reasons. In such cases, licensing to local firms is a better option for the patentee. However, the patentee may not get a local firm, which is economically and technologically capable of working the patent. The local working of the patent cannot be forced when it is not feasible.

In particular cases, bulk production of patented goods from an existing plant and importing the goods to the country of patent grant may be more convenient for the patentee, rather than to establish a new industrial unit. It saves the start-up costs, manpower, maintenance cost, administrative expenses and other infrastructural expenses, including electricity, water, etc. The price of imported products might be lower than the locally manufactured products. This happens particularly, when the market is very small in that country or the demand for the product is very low. The patentee shall not be subjected to a compulsory licence when there are legitimate reasons for his inaction or local non-working.

Where it is evident that the patentee prefers importing from other countries even when all factors are favourable for the establishment of an industrial unit, compulsory licensing is justified as an essential remedy to prevent misuse of monopoly. Such an action may result from the intention to earn higher profits by creating shortage and selling at higher rate, even without investing any capital.

The patentees may take a defense that it is not feasible to work the patent in India. Now the question is whether the industrial infrastructure and other conditions necessary for industrial investment are favorable for local working of patents in India. Answer to this question, to some extent, is case specific and to be answered on merits of each case. However, the general industrial conditions necessary for the establishment of an industrial unit and the feasibility to work the invention in a broad sense are common for all cases. The following few paragraphs are focused on the industrial policy and investment climate in India.

2.9 Availability and Affordability of Pharmaceutical Drugs in India

Indian drug industry has witnessed a significant growth in the last two decades and is now recognized as one of the leading global players in the manufacture of pharmaceuticals. It is ranked at the top in making generics at low prices worldwide, with wide ranging capabilities in the complex field of

technology, quality and the vast range of medicines that are manufactured. India's pharmaceutical industry is now the third largest in the world in terms of volume and 14th in terms of value. India tops the world in exporting generic medicines worth US$ 11 billion and currently the Indian pharmaceutical industry is one of the worlds' most developed industries. India has been supplying life-saving drugs at affordable cost to a number of developing countries and least developed countries and today, it is recognized as the pharmacy of choice of the developing world. However, high quality medicines within India appear to be overpriced, unaffordable and inaccessible, driving many patients to misery. Often Indians have to pay comparatively significant amounts of their wages, or borrow money, for purchase of medicines. Also, the majority of medicines used are not accessible through public health outlets and, have to be borne as out-of-pocket expense.32 According to an estimate, about 25 lakh people in India suffer from cancer and most of them are not financially capable of affording the high cost of anti-cancer medicines. Further, India reportedly has the highest number of HIV/AIDS patients in the entire South Asian region.

A look at the recent restructuring of ownership in the pharmaceutical sector shows that many strategic alliances are being forged by some large Indian players. For instance, during the last few years, six leading Indian companies, namely Matrix Labs, Dabur Pharma, Ranbaxy Laboratories, Shanta Biotech, Orchid Chemicals, Piramal Healthcare, were taken over by Mylan Inc, Fresenius Kabi, Daiichi Sankyo, Sanofi Aventis, Hospira, and Abbot Laboratories, respectively. The Department of Industrial Policy and Promotion (DIPP) while commenting on this trend warned that, 'Most of these companies are export oriented. There is a concern that their [Indian generic drug manufacturing companies'] takeover by multinationals will further orient them away from the Indian market, thus reducing domestic availability of the drugs being produced by them. This may weaken competition leading to headroom for increase in domestic drug prices' thereby worsening both, the availability and the affordability of pharmaceutical products. Furthermore, these foreign companies are taking over domestic drug companies in other countries also. For example, Sanofi Aventis took over Medley in Brazil and Zantiva in the Czech Republic, GSK took over BMS in Egypt and Pakistan. If this trend of takeover continues, it may establish hegemony of bigger companies, allowing them to dictate the prices of those drugs critical for addressing public

health concerns. Such monopoly is also likely to weaken the Government's ability to address such challenges through compulsory licensing measures. If large Indian generic companies with the capability to manufacture drugs based upon compulsory licensing are themselves taken over, then the regime of affordable and accessible drugs would be in serious jeopardy. Another consequence would be that such large Indian pharmaceutical companies, if taken over by foreign companies, may not be willing to apply for a compulsory licence, even if eligible, for obvious reasons. With the recent acquisitions of Indian pharmaceutical companies by overseas firms, there is a well justified concern that it may lead to the reduced local availability of patented drugs and an increase in prices, including those of generics.

2.10 Initiatives to Attract FDI and Impact on Local Working

The Indian government launched its market oriented economic reforms through its liberal investment policy in 1991. Since its inception, promotion of foreign direct investment (FDI) has been an integral part of India's economic policy and it has proved to be very effective in attracting FDI inflow. Efforts have continually been made to progressively rationalize it further, so as to encourage and facilitate FDI. Presently most of the FDI activities are covered under the automatic approval route and the FDI limit has been raised to 100 per cent for activities in Special Economic Zones (SEZs). Also, it has been raised considerably in other parts. Huge human capital, size of the market, market growth rate, cheap labour cost, lower country risk and political stability are the factors that attract FDI in India. India, the second fastest developing country in the world, with transparent, liberal and efficient investment norms and strong market potential, offers abundant opportunities for FDI and has emerged as the second most attractive FDI destination globally.

However the status of local working of patents in India is far from satisfactory. The rat race of inventors to file patent applications throughout the world appears to be merely for acquiring control over the market. Due to the potential threat of losing novelty, patent applications are frequently filed without properly evaluating the economic viability of the invention. Therefore, the patents

which are not worked locally or whose local working is interrupted, should be subjected to compulsory licensing and, subsequently, to revocation, except in cases where local working is not feasible.

2.11 Summary

The concept of patent has emerged as a concession conferred by the State for transfer of technology, innovation and industrialization. Industrial development, economic welfare and technological advancement are the prime objectives of the patenting system and these objectives cannot be achieved without local working of patents. Therefore, a patent right is always coupled with a reciprocal duty to work the invention in the local industry.

Tremendous growth has been seen in patent applications and grants in India, particularly, during the post-TRIPS period, although most of the patents are owned by inventors of foreign origin. However, these patents are not worked in India on a commercial scale. The huge patenting activity without local working is does not serve the purpose of society; particularly in the field of pharmaceuticals. It seems the patent holders are using Indian market only for economic gain with no actual benefits in the form of transfer of technology from inventive activity. The increased rate of patent grants has not achieved the desired aim and, hence, it appears that the new Indian patent regime has not been able to stimulate innovation and foster industrial growth in real sense. The time has come to reconsider the patent system in the light of original objectives for which the patent system was designed. Otherwise, it will continue to facilitate the exploitation by multinational corporations.

The Patent Act provides remedies, including compulsory licence, revocation and fine, if the patent holder fails to comply with the provisions of law relating to local working of patent. However, these remedies are rarely enforced. The 'Controller' of patents needs to take his role of 'monitoring' patents more seriously rather than merely 'registering' patents. These provisions have become lifeless and, hence, there is a need to revive the mechanism for monitoring the local working of patents.

The unavailability of information about working or non-working of patents and unfavourable and rigid approach of Patent Office towards disclosure of such

information is a major obstacle in claiming compulsory licence. The authors propose a revival of the 'licences of rights' provision which was in existence under Sections 87, 88 and 89 of the Patent Act, 1970 prior to amendment in 2005 with necessary modifications, which would be helpful in this regard. The Controller of Patents should enlist those patents in force, which are not working locally on a commercial scale, or are susceptible to compulsory licence/ licences of rights. Such patents should be endorsed with 'licences of rights' and the list published periodically on the official website with complete details, so that interested persons may apply for compulsory licence/licences of rights.

The problem of non-feasibility in working the patent has not been addressed by the Patent Act, 1970. All the inventions cannot be forcibly worked; there may be legitimate reasons such as economic, legal or technical obstacles causing the invention impossible to work, or work more intensively in the country where it is patented. Therefore the Indian Patent Act, 1970 should be amended to this effect.

Patenting of an invention is not an end in itself; rather it is a means to achieve the gigantic social goal. The Indian state has achieved the technical goal of harmonizing the patent system with TRIPS. However, it appears to have failed to achieve the ultimate goal of patent system, i.e. socio-economic welfare. India needs to stress upon the local working of patents and to implement the provisions relating to compulsory licence in cases where patent monopoly is abused affecting availability and affordability of drugs or unreasonably restrains trade or adversely affects the international transfer of technology or affects the commercial or industrial development in the country of sectors of vital interest provided, there are no legitimate reasons for failure to work. The conflicting provisions under Article 27.1 of TRIPS Agreement and Article 5A of the Paris Convention have created confusion about the legality of law relating to patent. Therefore, the Article 27.1 needs to be amended to the effect that it is subject to Article 30 and 31 of TRIPS Agreement and Article 5A of the Paris Convention. The Indian State should act to further strengthen infrastructure facilities and other determinants of FDI, so as to attract more FDI in India. It should also support the local inventors in converting their invention into innovation. What has been done is a mere formality and what needs to be done is a real, honest and visionary effort towards development through the available resources and new channels.

2.12 Self-Assessment Test

1. Explain the importance of Law relating to patent.
2. Explain the concept, importnce of Patented Goods and Law relating to patent.
3. Discuss the Indian Patent Regime and the Law relating to patent.
4. Discuss the problems in law relating to patent in India.

2.13 Further Readings

1. TRIPS Agreement, 1995
2. Paris Convention for the Protection of Industrial Property, 1883
3. The Patents Act, 1970

Unit 3
International Legal Regime relating to Patent: Paris Convention (Patent Cooperation Treaty)

Objectives

Obtaining international patent protection for an invention can present a significant financial commitment, especially for small or early-stage companies, entrepreneurial ventures, not-for-profit organizations (such as universities and charitable organizations), and independent inventors. Such entities usually have to conserve their financial resources while striving to build, maintain, protect, and expand their intellectual property (IP). The cost of procuring a national or regional patent, from the initial drafting of the application through prosecution of the patent application, allowance, issuance, and post-issuance maintenance of the patent, can easily run from US$30,000 to US$50,000 in legal and patent-office fees. Should patent protection for an invention be sought in more than one country, the costs of international patent procurement can multiply accordingly. Since the costs associated with obtaining patent protection are so significant, IP protection strategies that delay, consolidate, or minimize costs are advantageous.

Structure:

3.1 Introduction

The Patent Cooperation Treaty (PCT) is an important IP protection tool that can be used to confront the financial challenges associated with international patent protection. By facilitating the filing in any number of PCT member countries of parallel patent applications, a PCT patent application offers a valuable means of managing, delaying, or consolidating the costs of international patent protection for a given invention. The PCT can buy time to strategically evaluate the overall potential value of an invention, that is, provide time within which to make an informed decision as to how to best proceed.

The challenge of managing the costs of protecting IP so that the IP becomes a commercial asset—and not a financial liability—is one that is faced universally by technology managers. An enterprise that has developed (or acquired) IP must decide at the outset whether that IP is worth protecting with a patent. The costs and benefits of patent protection must be carefully analyzed. Although a discussion of such a cost-benefit analysis is beyond the scope of this chapter, it is worth noting here that a granted patent generally "protects" the subject IP only to the extent that it confers to the patent owner the right to enforce the patent, that is, to exclude others from making the invention, using it, importing it, and so forth. In conducting a cost-benefit analysis, an enterprise may decide that the total expected value of a particular piece of IP simply does not merit the expense of obtaining a patent and enforcing the rights the patent confers.

The patent applicant (or IP owner) must determine the merits of the invention, the commercial demand for the product or process provided by the

invention, the likelihood of its success in the marketplace, and whether protection should be sought in a particular country. The applicant must also determine, preferably with the advice of a patent attorney, patent agent, or other professional with expertise in patent law, the likelihood that the patent application would succeed in the patent office of a particular country or region and whether that national patent office would decide that the invention meets its requirements for patentability and, thereby, grant a patent.

Ideally, these analyses are conducted prior to selecting specific countries in which to file patent applications. Thus, any strategy that extends the time limit for filing a patent application in a country, while preserving the priority (first filing) date for the application, potentially gives the patent owner more time for analysis and decision-making before making the financial commitment to seek patent protection abroad.

For patent owners and other entities with a proprietary interest in the subject matter to be patented, but without large budgets for patent portfolio development (for example, not-for-profit organizations, universities, regional technology incubators, and agricultural cooperatives), extending the time limit for filing a patent application can provide a much-needed opportunity to stimulate investment and technology transfer. The extended time period afforded by filing an international PCT application, as described below, is increasingly recognized by developing countries as an opportunity to publicly promulgate an invention with "patent pending" status, to identify and negotiate with potential corporate sponsors, investors, licensees, and others involved in technology development and commercialization and to stimulate further domestic inventive and related technological activities.

3.2 Advantages and Disadvantages of PCT

The Patent Cooperation Treaty (PCT) provides a convenient and cost effective way for patent applicants to pursue patent protection simultaneously in several different countries. The benefit to patent applicants of proceeding internationally via the PCT route is illustrated by the extent to which they have adopted the PCT as their preferred route for pursuing international protection. Unfortunately, the success of the PCT might also prove its downfall, as rules

change to assist Offices cope with the huge increase in work load brought about by increased PCT usage. This paper discusses the advantages of the PCT route for international patent protection relative to separate national filings, and discusses some problems with the PCT system for applicants, as well as problems for third parties.

The advantages of the PCT system for applicants are well known to all. One of the primary advantages of pursuing international patent protection via the PCT route is that a single filing with a single Receiving Office within 12 months of the filing of a priority application can be considered to comply with the 12 month Paris Convention deadline in all countries which are members of the PCT. This is achieved by filing a single specification, filling out a single PCT Request form and providing a single certified copy of the priority application. Where the Receiving Office is also the office where the priority application was filed, the priority document can be supplied by crossing a box on the PCT Request form.

An important advantage to applicants in filing a PCT application is that this effect can be achieved upon payment of a single modest fee, rather than paying separate filing fees in each of the designated countries. While these national fees will need to be paid when national phase entry is confirmed, the fact that the payment of these filing fees is deferred is a substantial advantage for applicants.

By deferring the payment of national filing fees, the PCT applicant is also able to defer making a decision on the countries where patent protection will ultimately be pursued. This deferral period, which is generally 18 months, allows the patent applicant to assess suitable markets for the invention, and to assess the merits and likely commercial success of the invention.

When a PCT application is filed the applicant is issued an International Search Report (ISR) which, if well conducted, provides the applicant with a useful indication of the prior art against which the invention will be assessed. As this International Search Report is issued prior to international publication, the applicant is afforded an opportunity to withdraw the application on receipt of an unfavourable ISR prior to publication of details of the invention. Under the enhanced international search and preliminary examination system to be implemented next year, the ISR will be accompanied by a Written Opinion on

patentability. The applicant is also permitted an opportunity under Article 19 to amend the claims of the application to avoid prior art cited in the ISR.

Since it is possible to pursue one or more national filings in parallel to the PCT application it is possible for an applicant to obtain multi searches simultaneously, thereby obtaining a better assessment of the prior art against which the invention will be judged. This parallel processing is often used in countries where applicants have a choice of International Searching Authority, such as in the United States.

Another benefit of the PCT to patent applicants is that they can arrange for an international type search under Article 15(5) of the PCT even prior to the filing of the international application. If a PCT application is subsequently filed, the applicant may receive a reduction in the search fee component of the international application fee as a result of the earlier search.

Under the PCT the applicant also has the opportunity to file a Demand for International Preliminary Examination, which may be accompanied by amendments to the description and claims. Until recently, one of the main incentives for filing the Demand was the reward of a 10-month extension of the national phase entry deadline. This incentive no longer exists. While the filing of the Demand could result in the issuance of a clear International Preliminary Examination Report (IPER), the International Preliminary Examiner generally issues a Written Opinion drawing attention to any perceived deficiencies in the application.

Where a Written Opinion issues the applicant has the flexibility to adopt a number of strategies for response, depending on the content of the Written Opinion and the particular circumstances of the applicant. For example, where the objections raised relate to clear matters of novelty and clarity, the applicant may respond by proposing amendments that remove these deficiencies, thereby allowing the International Preliminary Examiner to issue a clear report. Such a clear report may be important for an individual inventor or a start-up company that needs to rely on investors for the protection of the invention and its subsequent exploitation. It may also be important where the applicant wishes to seek patent protection in developing countries or other designating countries that rely on PCT reports in deciding whether or not to grant patents.

Where the objections raised in a Written Opinion relate to matters of inventive step the applicant may choose not to respond to the Written Opinion and allow the IPER to issue in the form of the Written Opinion. This would allow the applicant to address the inventive step issues separately before each national office, and in accordance with national inventive step law and practice. Another situation where an applicant might not respond to a Written Opinion is where the applicant has concerns that the International Preliminary Examiner may not be readily persuaded to remove his objections. In this case the filing of a response may result in the issuance of an IPER with rejections which are more detailed and more substantiated than the rejection of the first Written Opinion. Since a report of this nature may interfere with the applicant's chances of obtaining broad protection in a number of countries which place reliance on the IPER, an applicant may choose not to risk arguing an objection with an International Examiner. For most applicants though, the International Preliminary Examination procedure provides an opportunity to address patentability issues with a single Examiner, usually in their own country, language and time zone. In fact, where International Preliminary Examination results in a clear report, it is likely that prosecution of the national phase application in that country will proceed on a similar basis. In Australia, it is usual for the Australian national phase application to be given to the Examiner who performed the International Preliminary Examination.

Further flexibility is provided to the PCT applicant when the national phase entry deadline approaches. If the applicant requires further time to raise funds or assess the potential of the invention the applicant can take the step of withdrawing the priority claim. Of course the applicant will only take this step if unaware of any relevant intervening publications. Withdrawal of the priority claim provides a further 12 months before national phase must be entered. Some applicants also commence the national phase processing procedure in some countries prior to withdrawal of the priority claim thereby providing a further 12 months for national phase entry on a non-convention basis within the next 12 months.

Despite the enormous advantages associated with pursuing international patent protection via the PCT route, and while a number of proposals to amend the PCT are due to come into effect next year, there are still problems with the PCT.

One of the main problems with the PCT is that it does not specifically provide for top-up searching, or allow applicants to request searches from more

than one International Searching Authority. Since the ISR is prepared prior to publication, there is the potential for additional relevant patent applications to be published subsequent to the preparation of the ISR. Since there is always the potential for different patent applications covering the same inventions to be filed in similar time frames, it will always be necessary for a top-up search to be completed. If this is not included as part of the PCT procedure, then it must be performed by the national offices. It must also be acknowledged that it is unlikely that a single search will identify all prior art relevant to a particular invention. This is illustrated by the frequency with which prior art is revealed by searching conducted by national offices post national phase entry.

Further problems with the PCT for applicants appear to have been introduced with the enhanced international search and preliminary examination system due to commence next year. Under the new system the applicant may have no opportunity to enter into a dialogue with the searcher or examiner to formally contest an adverse patentability finding of the ISA, even if a Demand is subsequently filed. According to the new procedure there is no opportunity to formally respond to the Written Opinion on patentability issued by the International Searching Authority. If a Demand is filed, this report is treated as the first Written Opinion for the purposes of International Preliminary Examination, and the new procedure appears to allow the IPEA to immediately issue an IPER without any dialogue with the applicant. With the 10 month extension of national phase entry on filing a Demand removed, and the prospect of gaining little value from a Demand under the new system high, there is a strong possibility that the number preliminary examinations performed by IPEAs will decrease substantially. This is an unfortunate outcome for the PCT itself, as well as for national offices. While the workload in the IPEA may be reduced in the short term, overall the amount of examination work being done on each family of patent applications by national offices will increase substantially.

A further problem with the PCT is the lack of quality control in relation to international searches and IPE. A poor search or poor examination can have disastrous consequences for the applicant, and can increase the workload at the national offices, or alternatively, result in the grant of overly broad patents. This is problematic for both the applicant and for third parties.

The PCT presents significant problems for third parties. One of the major problems is the length of time it allows between filing a priority application and commencing national phase processing. Although the international application and ISR are published at 18 months, there is a further 18 months before an applicant needs to commit to national phase in any particular country. This provides a long period of uncertainty for third parties. This problem is exacerbated by the lack of any central searchable database that provides third parties with information regarding national phase entry.

Another significant problem for the PCT is that it only allows the filing of a single specification. Until there is harmonisation of the requirements of a specification and interpretation (as in the draft SPLT), problems will be created for the patentee by insisting on a single specification to suit all national requirements. Although the applicant is generally afforded an opportunity to file amendments before the national offices to bring the specification into better conformity with local practice and to maximise the ability to enforce protection in that jurisdiction, the result must necessarily be a compromise.

Despite these problems with the PCT it is hoped that the international patent community will work towards the implementation of changes which will make the PCT more user friendly for applicants, more useful for national offices and less problematic for third parties.

3.3 Approaches to International Patent Protection

There are three basic approaches to procuring international patent protection on an invention. The first approach, and the most expensive, is to file (usually on the same day) separate patent applications in the national patent office of each country or region in which protection is sought. The drawback of this approach is that legal and filing fees for each country begin to accrue as soon as the application is filed.

The second approach for filing internationally is to file a patent application in accordance with the Paris Convention for the Protection of Industrial Property. Taking this route, the applicant files a patent application in a single Paris Convention member country (usually required to be the country of residence of at least one of the inventors), which establishes a first or *priority filing date* for the

application. The applicant can then delay filing in other Paris Convention countries for up to 12 months after the priority filing date. Member countries of the Paris Convention agree to recognize the priority date of a patent application filed in one member country and to give the benefit of that priority date to corresponding applications in all member countries. This approach delays the costs associated with international patent procurement for one year. Procurement costs initially accrue in the country of first filing, and then, up to one year later, the costs associated with filing applications in the other Paris Convention countries begin to accrue

The third and least-expensive approach, which is the primary focus of this chapter, is to file a single "international" application under the auspices of the PCT. Of the three approaches, filing a PCT patent application is, financially and strategically, the most advantageous for managing, delaying, or consolidating the costs of international patent procurement. Filing a PCT patent application allows the applicant to delay, for up to 18 months after the filing the application or in most cases, for up to 30 months after the filing of the first (priority) application, strategic decisions about which countries to pursue patent protection in. The delay provides a significant advantage, since it allows the applicant more time to evaluate the commercial strength and viability of the invention prior to filing national-phase patent applications in the countries in which patent protection is sought.

3.4 The Patent Cooperation Treaty (PCT)

The Patent Cooperation Treaty (PCT) is a cooperative agreement entered into by more than 130 countries (called PCT contracting states) with the purpose of bringing international conformity to the filing and preliminary evaluation of patent applications,[8] both simplifying and making more economical the process of seeking patent protection in other countries. An applicant does not apply for an "international" patent by filing an application under the PCT. The World Intellectual Property Organization (WIPO), which administers the processing of PCT applications, does not grant international patents. Instead, the PCT filing process produces a single patent application that has been vetted for compliance with filing formalities and that has undergone a preliminary search and evaluation.

This single application can then be transmitted to the national patent offices of as many PCT member countries as the applicant chooses, for filing as a *national-phase* application in that country. The PCT thus streamlines and consolidates the process of seeking patent protection in more than one country into a single series of steps and a single set of preliminary requirements (see Section 4).

Filing international applications with the PCT is becoming increasingly popular. In January 2005, the one millionth PCT application was filed, with the doubling time for numbers of applications filed having gone from 22 years (for the first half million applications) to just 4 years (for the next half million applications).

3.5 Non-PCT member countries

More than one hundred countries, however, are *not* members of the PCT, including a number of countries in Asia (for example, Cambodia, Nepal, Pakistan, Thailand), South America (for example, Bolivia, Chile, Guyana, Paraguay, Peru, Suriname, Uruguay, Venezuela), Central America (for example, Panama), the Middle East (for example, Iran, Iraq, Jordan, Kuwait, Lebanon, Saudi Arabia, Yemen), and Africa (for example, Ethiopia, Rwanda, Somalia). To obtain patent protection in non-member countries, a patent application must generally be filed directly with the national (or regional) patent office. Since patent protection involves complex questions of law, the applicant is well-advised to consult with patent counsel familiar with local patent law, international Paris Convention patent practice, and international PCT patent practice *before* filing a patent application, especially if applicants are either residents of non-PCT contracting states or inventions were made in non-PCT contracting states. For example, if all of the applicants on a patent application are residents or nationals of non-PCT countries, then an application filed with the PCT is generally denied an international PCT filing date.

In general, if the application is first filed in a country that is not a member of the PCT but *is* a member of the Paris Convention, then the applicant will be *ineligible* to file a PCT application but may choose to file additional applications in the national patent offices of other Paris Convention member

countries within 12 months of the filing (priority) date of the first application (Section 2, second approach, above).

If the application is first filed in a country that is not a member of the PCT or the Paris Convention, then the applicant will be *ineligible* to file a PCT application, or an application under the Paris Convention in Paris Convention member countries, within 12 months of the filing (priority) date of the first application. The applicant will be obliged to file a separate patent application (usually on the same day) in the national patent office of each country or region in which protection is sought (Section 2, first approach, above).

3.6 Costs associated with filing a PCT patent application

Filing a PCT patent application entails paying a single set of filing fees, as opposed to multiple filing fees for each country in which patent protection is sought. Currently, PCT filing fees are approximately US$1100 for filing an application (with a fee reduction for filing electronically online or via other electronic media), from US$200 to US$2100 for a search of prior art publications (depending on which international searching authority performs the search), and a nominal transmittal fee (around US$300) charged by the PCT receiving office. The applicant can also elect to file a *demand* (request) for international preliminary examination of the application, which entails an additional fee of approximately US$600 to US$750.

3.7 PCT filing consolidates and delays patent prosecution costs

Filing a patent application under the PCT consolidates or eliminates the duplication of costs associated with multiple filings in multiple countries and enables the applicant to submit a single patent application in a single language and in a format that conforms to the requirements of all the national patent (or regional) offices of PCT contracting states. The added burden and expense of translating the application and of filing it in a particular format for a particular national patent office is thus avoided.

During the *international phase* of its pendency, a PCT application undergoes a preliminary evaluation that comprises an international search for prior art publications, a written opinion and a preliminary report on patentability, and optionally, a preliminary examination and a second, more detailed, report on patentability. The applicant can then choose to transmit the uniform application and accompanying evaluation documents to the national patent offices of as many PCT contracting states as desired, in which the application enters the national phase of the patent procurement process.

By far, the most expensive aspect of international patent procurement is the national-phase cost, which includes the fees paid to each national patent office for entrance into the national phase and during the patent prosecution process, the legal fees of local attorneys or agents to obtain a national patent, and the fees to the national patent office to maintain the granted patent in force. Filing under the PCT enables costs associated with the national phase to be deferred, in most cases for up to 30 months from the priority (first filing) date, while an international patent-protection strategy is formulated and decisions are made about which countries to seek protection in.

3.8 The role of WIPO in the Patent Cooperation Treaty

WIPO, an international organization based in Geneva, Switzerland, is the administrative body that oversees the filing of international applications under the PCT. The International Bureau of WIPO administers the international phase of the PCT application process, prior to entrance into the national phase of countries in which patent protection is sought. WIPO receives and stores PCT applications, along with their associated files of patent search and examination documents and correspondence. WIPO examines each application for its adherence to filing formalities (such as the required format for the patent application, accompanying administrative filing papers, and fees paid). Based on this initial examination, the applicant may be required to correct any formal defects to bring the application into conformity with the PCT format accepted by patent offices in the member states. The carrying out of these procedures reduces the costs of patent procurement at an early stage. Formalities defects in the PCT application that are identified during the international phase can be rectified before the application

reaches the national patent offices and enters the national phase of the patent examination and procurement process. Thus, separate formalities rejections by national patent offices in which patent protection is sought can be avoided.

WIPO is responsible for publishing PCT applications and accompanying information about them, which can be accessed worldwide via the Internet at the WIPO Web site. WIPO oversees translation of portions of the PCT application and associated documents into English or French, also available on the Internet, and can provide the national patent offices of contracting states with application documents.

3.9 Options and Steps for Filing under the PCT

Alternative 1: File an international PCT application that complies with PCT formality requirements and pay one set of fees.

An international patent application can be filed under the PCT if at least one of the inventors of the invention is a resident of a PCT contracting state. Applicants can generally file an international PCT application with the national patent office of their country of residence, with the national office acting as a receiving office for the PCT. Under some circumstances, the PCT application can be filed directly with WIPO in Geneva.

The WIPO Web site provides detailed guides to PCT filing requirements, as well as a guide to PCT time limits and a PCT time-limit calculator to assist applicants in computation of essential time limits for filing applications and for submissions of other required documents. Time limits under the PCT are measured from the priority date of the application. The priority date is defined in PCT Article 2(xi) as follows:

(xi) "priority date," for the purposes of computing time limits, means:

(a) where the international application contains a priority claim under Article 8 [of the PCT], the filing date of the application whose priority is so claimed;

(b) where the international application contains several priority claims under Article 8, the filing date of the earliest application whose priority is so claimed;

(c) where the international application does not contain any priority claim under Article 8, the international filing date of such application

The time limits are based on the earliest priority date of the PCT application and include:

- time limit for submission of the priority document on which the priority date of the PCT application is based
- earliest potential date for international publication of the PCT application, which is usually 18 months after the priority date
- time limit for a demand for international preliminary examination
- time limit for entry of the application into the national/regional phase

Alternative 2: File a national application first and then a PCT application within 12 months

Once a PCT application is filed, the applicant has up to 18 months to delay before deciding to enter the national phase and file national applications in one or more PCT contracting states (Figure 2). To delay even further the time between the first filing (priority) date of an application and entry into the national phase, the applicant has the option of filing a national application first, and then, up to 12 months later, filing a PCT application claiming priority to the national application. Laws of individual PCT contracting states generally require that if an applicant desires to file a patent application and the invention was made in a particular state, then either a national patent application must be filed in that state (and generally, a foreign filing license obtained) before the application is filed as a national application in other states, or an international PCT application must be filed directly with a PCT receiving office.

During the 12-month period following the filing of the priority application, the applicant can choose to file one or more additional national applications, as new refinements or embodiments of the invention are developed. A PCT application must be filed no later than 12 months after the filing date of the first application, however, to claim benefit of that earliest application's priority date.

The PCT application, however, can incorporate the disclosures of, and claim priority to, all the national applications directed to that invention that were filed during the previous 12-month period. The disclosure and claims of the PCT application may therefore differ from those of the priority application(s) preceding it in the *patent family*. The PCT application can also include new disclosure

pertaining to the invention (for example, a description of new embodiments of the invention) or new claims that were not set forth in any of the priority applications. However, to obtain benefit of an earlier priority date, a new claim included in the PCT application must be supported by the disclosure of the priority application filed on that date.

After filing the PCT application, the applicant has, as described above, up to 18 months to delay before deciding to enter the national phase and to file national-phase applications in separate PCT member countries. Hence, the applicant can delay for 12 months plus 18 months, or in most cases up to 30 months, after the filing of the initial priority application before entering the national phase in a desired PCT contracting state. In the meantime, the applicant can use this delay to advantage, and take the time to evaluate the merits of seeking protection in specific countries and to delay the assessment and accrual of patent prosecution fees in multiple countries.

Hence, with this approach:

- A *national* patent application is filed in the patent office of a PCT contracting state (member country), establishing the priority (first filing) date. This national application is sometimes referred to the *priority application*.
- Within 12 months after the priority date, a PCT application is filed and enters the *international phase*.
- Within 18 months of PCT filing, or within 30 months of the priority date, the PCT application enters the *national phase* of selected PCT member countries.

3.10 Summary

Filing a patent application under the PCT enables the applicant to delay strategic decisions about where to pursue patent protection by:

- consolidating patent prosecution costs: single-application format, language, and set of fees
- providing the applicant with preliminary feedback regarding patentability of the invention
- providing the applicant with the opportunity to present arguments for patentability, to amend claims, and to strengthen the application prior to filing with national patent offices

- enabling the applicant to delay filing the application in individual national patent offices for up to 30 months after the first (priority) filing date
- delaying prosecution costs of filing applications in multiple countries
- streamlining the process of filing applications in multiple countries

Delaying international patent prosecution provides more time to determine:

- the value of IP to applicant or owner
- the strength of commercial demand abroad
- which claims in a patent application are likely to be patentable
- which countries are most attractive for pursuing patent protection
- the likelihood of obtaining a patent grant in target countries.

3.11 Self-Assessment Test

1.` What are the Advantages and Disadvantages of PCT?
2. What are the Approaches to International Patent Protection?
3. What are the Costs associated with filing a PCT patent application?
4. What is the role of WIPO in the Patent Cooperation Treaty?
5. What are the options and Steps for Filing under the PCT?

3.12 Further Readings

1. Paris Convention.
2. Patent Cooperation Treaty.
3. Various articles and journals relating to the same.

Unit 4
Role of TRIPS and WTO in Patent protection

Objectives

The TRIPs agreement, together with the 1968 Stockholm Conference that adopted the revised Berne and Paris Conventions and created the World Intellectual Property Organization (WIPO), is undoubtedly the most significant milestone in the development of intellectual property in the twentieth century. Its scope is in fact much broader than that of any previous international agreement, covering not only all areas already protected under extant agreements, but also giving new life to treaties that failed and protecting for the first time rights that did not benefit from any multilateral protection. In addition, the TRIPs agreement enshrined detailed rules on one of the most difficult and, for rights holders, painful aspects of intellectual property rights' enforcement.

Structure:

4.1 Introduction

The Uruguay Round of multilateral trade negotiations resulted in the adoption of the Agreement Establishing the World Trade Organization (WTO Agreement) on April 15, 1994 in Marrakech. The TRIPs agreement was contained in the Annex to the WTO agreement, which entered into force on January 1, 1995. Built upon the foundations laid by the Paris Convention and the Berne Convention, the TRIPs agreement is an unprecedented international agreement in terms of its coverage, scope, specificities and enforceability.

As regards geographic coverage, the TRIPs agreement is binding on all WTO members. Compliance with its provisions is a precondition of joining the WTO, which deals with the rules of trade between members at a global level. Although intellectual property rights (IPRs) and their effects on trade have been advocated for a long time, the TRIPs agreement is the first international instrument to focus on trade-related aspects of IPRs. In view of the different levels of 'preparedness' among members to implement the TRIPs agreement under national laws, the TRIPs agreement sets out certain periods of time after the entry into force of the WTO Agreement before members are obliged to implement the TRIPs agreement. Different periods were prescribed for developed countries (January 1, 1996), developing countries (five years from the date on which the TRIPs agreement becomes mandatory for developed countries) and least-developed countries (ten years from the date on which the TRIPs agreement becomes mandatory for developed countries). The targeted date for least-developed countries, which was January 1, 2006, has proved to be too ambitious, and was extended further to July 1, 2013.

In the area of patents, the TRIPs agreement established the standards concerning the availability, scope and use of patent rights. They include: (i) basic standards for patentability and a limited list of exceptions to patentable subject matter; (ii) in terms of the availability of patents and the enjoyment of rights, no discrimination as to the field of technology, the place of invention and whether products are imported or locally produced; (iii) rights conferred by a patent and exceptions to the rights; (iv) conditions concerning the disclosure of the invention in a patent application; (v) compulsory licenses; (vi) availability of judicial review

process for any decision to revoke or forfeit a patent; (vii) the term of protection and (viii) the burden of proof in deciding whether a product was obtained by a patented process. Setting international standards on a number of issues is an extraordinary result achieved by the TRIPs agreement. However, the controversy as such has not disappeared with the adoption of the TRIPs agreement. Re-examination of provisions with respect to patents is under way.

Among all the provisions of the WTO agreement, the one relating to Trade Related Intellectual Property Rights (TRIPs) has possibly been the most widely debated in the country. There are very good reasons why this has been so. First, because provisions in TRIPs relate to the country's Patent Laws and has a very serious bearing on major areas of the country's well-being – health, agriculture, research, etc. Second, because India has been particularly fortunate among all developing countries in having a very liberal Patents regime since 1970 that promoted the country's interests. Third, because in the initial stages of the "Uruguay Round" of negotiations under the aegis of the then General Agreement on Tariffs and Trade (GATT), which finally led to the formation of the World Trade Organisation (WTO), India had been extremely vocal in opposing the inclusion of Patent laws in the negotiations. While the Uruguay Round was initiated in 1986, it was only in 1989 that India did a sudden volte face and succumbed to pressure from the US and European countries by agreeing to include TRIPs in the negotiating agenda. Many, today, feel that if India had not succumbed in that crucial phase of the negotiations, the TRIPs agreement itself may never have seen the light of day.

4.2 TRIPs Agreement and Amendments to the Indian Patents Act 1970

India became signatory to the Agreement on Trade Related aspects of Intellectual Property Rights (TRIPs) of the World Trade Organization in 1995 along with other developing countries with a hope that TRIPs regime will result in free flow of trade, investment and technical know- how among the member countries by removing barriers that exists in the form of differences in the standards of intellectual property.

The unaltered earlier Indian patent regime under 1970 Indian Patents Act differed in many ways from that of the TRIPs agreement. The Patents Act drastically restricted the rights of patent holders in fields linked to basic needs. This is due to the fact that the adoption of the Patents Act 1970 was based on a lengthy legislative process and careful consideration of the socio-economic impacts of the patents in sensitive fields such as health and food. Therefore India had to considerably alter its patent law.

In order to fully comply with the TRIPs provisions India amended the Patents Act 1970, three times. The first two amendments to the patent legislation took place in 1999 and 2002 mainly to accommodate issues like 'exclusive marketing rights' (EMRs) and to extend the patent protection for the 20 years respectively. In 2005, the Patents Act 1970 has been amended for the third time. Immediately after this amendment the scientific, technical and business communities geared up for intense debate.

4.3 The Patents (Amendment) Act, 1999

In compliance to the provision of transitional arrangement and protection of existing subject matter as per Articles 65 and 70 of TRIPs, India notified an amendment to the Patents Act, 1970, by proposing and introducing Exclusive Marketing Rights (EMR) provisions on 1st January 1995. However, this notification failed to receive assent of the Parliament and lapsed thereafter. Consequently, India was dragged to Dispute Settlement Body (DSB) by United States and European Union. On receiving the adverse judgment from DSB, India successfully enacted in the 1st Amendment introducing the EMR provision for a period of 5 years or till the product patent is granted or patent application is rejected, whichever is earlier and the mailbox procedure for patent applications claiming pharmaceutical and agro-chemical products retrospectively from 1st January 1995.

The main objective of the Patents (Amendment) Act 1999 is to remove exclusion of product patents in the area of food, medicine and drugs. According to the Government, this has been necessitated by India's obligations as a signatory to the WTO. However, by merely introducing new clauses for exclusive marketing rights associated with product patent applications in the area of pharmaceuticals

and agrochemicals as required by the TRIPs treaty without introducing new clauses for exclusion. The Patents Act 1970 had excluded large areas from patentability. The 1999 Act in contrast gives Exclusive Marketing Rights (EMRs) merely on the basis of foreign patents obtained after 1 January 1995 without any scrutiny on the basis of impact on public health, public morality or the public interest.

The Patents (Amendment) Act, 1999 specified four pre-conditions to be met by an EMR applicant: (a) the applicant must hold a valid patent on pharmaceutical product granted after January 1, 1995 in any of the WTO member countries; (b) the applicant should have marketing rights in the member countries; (c) a product patent application should already have been made in India, and (d) marketing approval of the same product should have been granted in India. The first three conditions were as per the stipulation of TRIPs agreement. The fourth clause was incorporated to meet the Indian drug regulatory approval. The other important change made was the removal of restriction on residents to apply for patents outside India. In the Patents Act (1970) it was obligatory for residents (section 39) to seek prior permission before applying for patent outside India.

This Act sought to provide stronger patent protection for foreign pharmaceuticals and to create stronger domestic research capabilities. For example, an Indian company (Ranbaxy Lab, Inc.) signed a $ 90 million dollar joint venture with Eli Lilly & Co. to collaborate for pharmaceutical research and development. These Indian patent laws could allow the Indian pharmaceutical industry to modernize its pharmaceutical industry and compete with the developed world.

4.4 Software Patentability

Section 3(k) of the Patents (Amendment) Act, 2005 excluded "a computer program per se" from the scope of patentability. This exclusion met with conflicting interpretations at the patent office, with some examiners granting patents to software combined with hardware or software with a demonstrable technical application of some sort. The 2004 Ordinance therefore qualified this exclusion by stating that software with a "technical application" to industry or when "combined with hardware" would be patentable. Owing to vigorous

opposition from the free software movement, this provision was removed from the 2005 Act. The earlier position under the Patents Act, 1970 that a computer program per se is not patentable now prevails. Interestingly enough, a draft of a recent manual of the Patent Office that attempts to lay down guidelines to interpret the Act arrives at a conclusion that is similar to what the Ordinance provision sought to achieve. It notes:

The statute excludes from patentability the software per se. The inventions relating to the application of the computer program or software is [sic] held patentable under the Indian Patent Act, 1970 when claimed in combination of hardware and software components of a computer which provide a "technical advancement" over the prior art. It is necessary for the applicant to describe the "technical contribution" to the prior art when the invention involves software. The technical problem, which needs to be solved by the invention, should be sufficiently described as to how the hardware is controlled by the software to overcome the previously described problem. The "technical character" of the invention should be brought out clearly in the claims.[42]

4.5 Distinguishing Features of Patents (Amendment) Act 2005

'New Invention'

The Patents Amendment Act, defines the term 'new invention' as "any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art".

It appears that the intent behind this provision is to define a 'novelty' standard - which, along with 'non-obviousness' (or 'inventive step') and 'utility' ('industrial applicability'), are the three prerequisites for 'patentability'.

However, a term such as 'new invention' raises the question of what an 'invention' is in the first place. Section 2(j) defines an invention as "a new product or process involving an inventive step and capable of industrial application". Since 'new' is already a part of the term 'invention', introducing a term such as 'new invention' to define a novelty standard is circular and makes for shoddy drafting.

A clearer way of doing this would have been to define the term 'new' as found in the term 'invention'.

The 'new invention' definition suffers from yet another infirmity. While it appears to endorse an 'absolute' novelty ground, the Act still retains a 'relative' novelty ground in section 25. Section 25 stipulates that a patent application can be opposed on the ground that the invention was "publicly known or publicly used in India before the priority date of that claim". To this extent, the ground for opposition is based on 'relative novelty', i.e. the invention should be known or used in India, whether or not it is so known or used in any other part of the world. The new definition under the 2005 Act however provides for 'absolute' novelty - in order to qualify as a 'new invention', the said invention should not have "been anticipated by publication in any document or used in the country or elsewhere in the world".

Consider an application for invention X in India, where the said invention had already been used in China at some earlier point in time. It would appear that such application could be refused by the patent office on the ground that the invention had been used in China and is not therefore a 'new invention'. However, at the stage of opposition, a third party cannot take up this ground under section 25, since the invention had never been publicly used in India before the priority date of the claim. This difference in standard seems odd, given that an interested third party is more likely to be aware of a foreign use of the invention in question than an Indian patent examiner.

The 'Inventive Step'

The 2005 Act makes a critical change to the earlier 'non-obviousness' or 'inventive step' test. The definition now reads:

'inventive step' means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to the person skilled in the art.

As can be seen from this definition, while the fundamental yardstick for measuring an 'inventive step' remains that which is "not obvious to a person skilled in the art", a requirement that the invention involve a 'technical advance' or have an 'economic significance' of some sort has been added

This change in the standard seems odd, given that the very purpose of the 'inventive step' criterion is to determine whether an invention sufficiently advances the technical arts so as to warrant an exclusive right. This is no doubt achieved in an optimal manner by the simple test of whether the invention, though novel, is non-obvious to a person skilled in the art. By itself, the non-obviousness test is a difficult one to apply - additional criteria such as 'technical advance' and 'economic significance' only further the complexity. Contrary to suggestions by some commentators, the addition of 'technical advance' or 'economic significance' to the 'non obviousness' test does not dilute the 'inventive step' requirement - on the contrary, it is susceptible to being interpreted in a manner that renders it more onerous to satisfy.

Further, 'economic significance' seems to be more of a 'utility' or 'industrial applicability' standard. By including such a criterion within a 'non-obviousness' or 'inventive step' standard, the Act creates considerable uncertainty. A commentator observes: "It interferes with the time-tested principles of patents law, and in that process has created a new definition that can lead to lose interpretations."

Pharmaceutical Substances

The introduction of a new definition for "pharmaceutical substance" under Section 2(t a) of the Patents Act, as amended, defines a pharmaceutical substance as "any new entity involving one or more inventive steps".

If the real objective of the definition was to narrow the scope of patenting of pharmaceutical products, it falls far short of meeting this objective. In fact, the existing definition opens the door for frivolous claims aplenty in this area. It has been argued for instance that the term 'chemical' should have been inserted so that the definition would be 'any new chemical entity'. That this suggestion has considerable merit can be seen from the manner in which the Food and Drug Administration (FDA) deals with this issue. According to the FDA, new chemical entity (NCE) or a new molecular entity (NME) means a drug that contains no active moiety that has been approved by FDA in any other application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act. An active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other non covalent derivative (such as a complex, chelate,

or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.

The 'New Use' Exclusion

Section 3(d) of the Patents Act, 1970 excluded a "new use for a known substance" from the ambit of 'invention'. The 2005 Act has expanded on this exception by providing that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance" would not be patentable. It then states that salts, esters, ethers, polymorphs, metabolites, etc. shall be considered as the same substance unless they "differ significantly in properties with regard to efficacy".

The introduction of a new definition for the term 'substance' through the explanation above would make for some nuanced interpretative battles. If, for example, X1 is a polymorphic form of X, then would a showing of increased efficacy for X1 change it to a new substance? In short, at what point would a showing of increased efficacy change a 'new form' of an existing substance to a new substance altogether?

In order to answer this question, one has to first address the issue of what exactly the term 'efficacy' means. Would this term be construed in a manner similar to how a drug approval agency would construe it?

It is interesting to note in this connection that this provision in the 2005 Act, which finds no parallel in any other patent legislation in the world, has been copied from a European Directive dealing with drug safety regulation.

As one can well appreciate, blindly transposing a provision that operates within the context of a drug regulatory regime to a patent regime can pose problems. For one, it makes it more likely that the term 'efficacy' would be construed in a drug-regulatory sense - consequently, the requirement would be a difficult one for most patent applicants to satisfy. Pharmaceutical companies generally file patent applications at the initial stage of discovery of a drug; it is only much later in the development process that clinical studies (phase III) are conducted to gather information pertaining to the therapeutic efficacy of the drug. The requirement of information on 'efficacy' at the stage of filing a patent application is therefore an onerous one.

If, on the other hand, the term 'efficacy' were to be construed in a liberal manner to include even a general hint of an added advantage in using the new form, it is possible that a good number of formulations would qualify as new substances upon the showing of an increased efficacy.

The amended section 3(d) appears to be limited to only new forms that demonstrate an increase in known efficacy. It does not, therefore, apply to a case where the new form is found to have a completely different use (and not just an increased efficacy vis-à-vis the known use). If the intention behind this provision is to heighten the obviousness standard and weed out frivolous and fairly obvious patents, this seems a rather illogical result, as a new use for a new form is certainly more inventive than a mere showing of an increase in known efficacy.

4.6 Pre-Grant and Post-Grant Opposition

The Patents Act, 1970 is endowed with a fairly robust pre-grant opposition mechanism. It provides for several grounds on which a patent could be opposed including the lack of novelty, inventive step or utility (the traditional patentability criteria) or that the claimed invention does not fall within eligible subject matter or that the specification does not disclose the source or geographical origin of biological material used for the invention.

The 2005 Act has introduced a post-grant opposition mechanism for the first time. Within a year of the patent being granted, a 'person interested' can challenge the issued patent on grounds that are identical to the grounds available at the pre-grant opposition stage. The key difference between the pre-grant and the post-grant opposition mechanism appears to be that while 'any person' could challenge at the pre-grant stage, the challenger has to be a 'person interested' at the post-grant stage. "Any person" has been interpreted to cover potential generic competitors as well as social action groups representing interests of patients suffering from various diseases like cancer and AIDS.

India is one of the few systems to provide pre-grant as well as post-grant opposition proceedings. Interestingly, most advanced countries do not follow pre-grant opposition proceedings.

A competitor who fails to challenge a patent application at the pre-grant/post grant stage has a further opportunity - he or she can seek revocation of the patent

under section 64 of the Patents Act. Here again, the grounds that could be cited for revocation (whether by a direct petition to the Controller or as a counter-claim during infringement proceedings) are broadly similar to that available at the pre-grant and post-grant stage. This combination of a pre-grant opposition mechanism, a post-grant opposition mechanism and a revocation mechanism makes the regime a very effective one for filtering out frivolous claims.

4.7 Compulsory Licensing Regime

India's compulsory licensing provisions are the broadest and most comprehensive of all the world's patent systems. Section 92 of the India Patents Act, 1970 (2005) allows the grant of compulsory licenses on notification of the Indian government "in circumstances of national emergency or […] extreme urgency or in case of public non-commercial use." Moreover, Section 92A of the Act creates a new avenue for compulsory licensing that permits the manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity to address public health problems. However, the grounds upon which compulsory licenses may be granted go far beyond national emergency, extreme urgent situations, and public health crises. For example, non-availability of the patented invention "at a reasonably affordable price" and the failure to work the invention in the territory of India can also be invoked to justify a compulsory license (Section 84).

This is one area where there have been major changes, both substantive and procedural.

Automatic Compulsory Licenses for Mailbox Applications

The biggest substantive change has been the addition of a new ground for compulsory licensing. As is well known, India amended the Patents Act in 1999 to provide that applications claiming pharmaceutical inventions would be accepted and put away in a mailbox, to be examined in 2005. These applications are commonly referred to as 'mailbox applications'. This amendment was in pursuance of a TRIPs obligation aimed at preserving the novelty of pharmaceutical inventions in those developing and least developed country (LDC) members that did not grant product patents for pharmaceutical inventions in 1995. By virtue of this 'mailbox facility', applications would be judged for 'novelty' on the basis of

the filing date and not with reference to 2005, the year in which product patents were first incorporated into the patent regime.

The Act provides that in the case of those mailbox applications that result in the grant of a patent, an automatic compulsory licence would issue to those generic companies that made a 'significant investment' and were 'producing and marketing' a drug covered by the mailbox application prior to 2005. Such licence is subject to a payment of a 'reasonable royalty'. However, no specific yardstick is provided to determine 'reasonableness' and this term is likely to lead to disputes in coming years. Perhaps one will have to go by the broad criteria in section 90 of the Act - that while computing the royalty payable, one shall have regard to "the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors".

It will be interesting to see how this new provision pans out in the years to come. It is reminiscent of the 'licence of right' provisions under the earlier patent regime.

Inventions pertaining to food and medicine were subjected to an automatic endorsement (i.e. they were deemed to be so endorsed) with a 'licence of right' after a period of three years from the date of sealing of the patent. In other words, any person interested in working the patented invention, endorsed with a 'licence of right' could have a licence as of right, without needing to establish any specific grounds for it.

Compulsory Licences for Exports

In order to incorporate what is commonly referred to as the Paragraph 6 Decision, the Ordinance introduced section 92A, which provides for compulsory licences to enable exports of pharmaceutical products to those countries with no manufacturing capacity of their own. Unfortunately, this suffered from a handicap - the provision required that the exporter obtain a compulsory licence from the importing country as well. In the process, the provision failed to cater to those situations where there was no patent in such importing country and no requirement for obtaining a compulsory licence there. The 2005 Act therefore seeks to rectify this by adding that an exporter can resort to section 92A where the importing country "has by notification or otherwise allowed importation of the patented pharmaceutical products from India".

Procedural Changes

The general compulsory licensing procedure under Chapter XVI states that in most cases, a compulsory licensing application can be entertained only if negotiations towards a voluntary licence have not borne fruit within a reasonable time period. In order to prevent patentees from dragging on voluntary negotiations to the detriment of applicants, the Act caps a 'reasonable' period of negotiations at six months.

4.8 Government Use

Most patent regimes provide that, under certain circumstances, government is entitled to use an existing patent (commonly referred to as 'government use' provisions).Indian law also provides for a mechanism allowing the government to use the patented invention under certain circumstances. This is more or less in sync with TRIPs requirements, and the law provides adequate remuneration to the patentee in each case— considering the economic value of the use of the patent— and stipulates that the government notify patentees of the use as soon as practicable, except in cases of emergency. There is one more specific provision, dealing with medicines, that allows the government to import patented drugs or medicines "for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government" or designated under the Patents Act.

The 2005 Act expands the scope of 'government use' provisions in some respects and reduces it in others. Thus, sub-clause (iv) has been added to section 2(h) of the old act to include any 'institution wholly or substantially financed by the Government' within the ambit of a 'government undertaking' that can avail itself of a patent under the 'government use' provisions spelt out in Chapter XVII. However, the Council for Scientific and Industrial Research (CSIR), a premier science research institution, was excluded from the ambit of the term 'government undertaking'. This, perhaps, was in recognition of the fact that CSIR has been patenting extensively and is a private player in several respects.

Government use is another effective means to curb abuse of patents. It allows the government or its authorised agent to use the patents without the authorisation of the patent holder. Generally, the government can take over the

patent invention without seeking a licence or to negotiate. This practice is available in most common law countries, especially in the US and the UK. In the UK, it is known as 'in the service of Crown.' In the US, it permits the government or its authorised person to use any patents on the ground of public use. The patent holder can sue the government only for compensation and no injunction remedy is available under the US law. The advantage of government use is that it can bypass most of the procedural hurdles of the compulsory licence. However, the purpose of government use is restricted to non-commercial use. A country like India, with a public sector pharmaceutical industry, should strengthen the government use provisions in its Patents Act.

The TRIPs provision on the government use is mentioned in Article 31(b) as public non-commercial use. It permits skipping requirements of voluntary licence and negotiating requirements. An important issue often raised is that when government use is non-commercial use, whether it is possible to sell through private channels. The answer is in the affirmative and government can recover the cost of production and distribution from non-commercial use. The affordability of drugs can be ensured through a strong government use provision. (Indian context)

The Patents Act provides three types of government use. Firstly, a patent is granted in India with a condition that government can import the medicines for the distribution of drugs in public sector hospitals or any other hospitals to be notified in the gazette. Secondly, government or authorised persons can use a patent against a royalty payment. Thirdly, the central government can acquire a patent after paying compensation. Government can exercise these powers at any time. However, the main lacuna is that the patented article under the Act can be sold only for non-commercial use. This restriction may have far reaching effect, because the courts may restrict the sales of medicines to public sector hospitals only. Further, the Act provides room for challenging the government decision to use or acquire the invention in the High Courts. It means the patentee can delay such use and the government has to prove need before the court. Using the TRIPs flexibility, the government should have opted for administrative review. The government has also failed to use the TRIPs flexibility with regard to removing injunction as a remedy in the case of government use.

Parallel Imports

One of the areas where there has been considerable debate has been the impact of TRIPs on public health. The concern has been that the product patent regime mandated by TRIPs will make, even life-saving drugs, particularly for diseases of the developing world unaffordable to its vast populations. Even though the Doha Declaration has once again reconfirmed that public health concerns will supersede commercial interests, the mechanism for remedying the problem of availability and accessibility of patented drugs have not been addressed. The conduit for achieving these is supposedly through the compulsory license route. However very few developing countries have the technical capability to produce modern drugs even if they have no patent hurdles. The way out would be to make compulsory licenses valid for imports of the patented goods in addition to manufacture. Alternatively, permitting imports from the cheapest source in the world will ensure availability of the needed drugs at the lowest possible cost. That is where parallel imports come in.

Parallel imports are imports of goods produced under protection of a trademark, patent or copyright in one market, imported into a second market without the authorization of the local owner of the intellectual property. Article 6 of the TRIPs recognizes the possibility of legally allowing parallel imports from the territory where it has been licenced, based on the principle of 'exhaustion of rights', which means, that, once the patent holder is has exercised his patent rights, they are considered to be exhausted. Once the goods are put in the market, he has no further rights to control the use or release of these products.

The earlier section 107A (b) provided that it was not an infringement to import a patented product provided such import was from an exporter who was "duly authorised by the patentee to sell or distribute the product". The 2005 Act now makes such import easier by dispensing with the authorization required from the patentee - it only requires that the exporter of such patented product be "duly authorised under the law to produce and sell or distribute the product". Under this amended provision, it would appear that an Indian pharmaceutical company could set up base in Bangladesh to manufacture and export medicines to India. In the absence of a patent in Bangladesh and/or any other law barring manufacture/exports, such company would presumably be 'duly authorised' under the laws of Bangladesh to 'sell or distribute the product'.

The provision therefore is extremely broad in scope and may contravene TRIPs. Article 6 of TRIPs agreement states in pertinent part that "…nothing in this agreement shall be used to address the issue of the exhaustion of intellectual property rights".

The meaning of Article 6 is made clear by Article 5(d) of the Doha Declaration which states: "The effect of the provisions in the TRIPs agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge ..."

However, the above hypothetical example of an Indian company setting up base in Bangladesh does not involve an 'exhaustion'. There is no first sale of the patented drug by the patentee - rather the drug is manufactured and then exported by a third party. In short, the very essence of an exclusive right to import mandated under Article 28 of TRIPs is affected.

4.9 Is Indian patent law TRIPs complaint?

The TRIPs agreement basically deals with countries which are developed, developing & less developed. Being the developed countries, USA, UK, Canada actually incorporated most of the TRIPs provisions but countries like India, Singapore, Bangladesh could not do the same because of its socio-economic conditions. Some countries have had much less amicable reactions to TRIPs. South Africa and Brazil stand out with regard to the health issue. Both countries have successfully attempted to chart out a new course, which goes much beyond what would have been deemed acceptable under TRIPs until recently. This is remarkable because both legal regimes were challenged and the challenge was abandoned in each case. But in reality, the patent law which was a model for other developing countries like Argentina, Mexico, Egypt, Brazil and Chile, has been replaced by the Indian Patents Act, 1999, which is modeled on the basis of the TRIPs (Trade-Related Aspects of Intellectual Property Rights) text. This amendment seeks to implement the obligations that India has taken in the field of patents by signing the TRIPs agreement. The bill generally aims at making the 1970 Patents Act as TRIPs compliant as possible.

The Patents Act, 1970 was amended again in 2002 and 2005. The Patents (Third Amendment) Act, 2005, extended product patents to products from all

industry sectors, including pharmaceuticals. It also set the term of patent protection to 20 years to meet the TRIPs deadline for January 1, 2005. This closed the option of reverse engineering that largely contributed to the growth of the Indian pharmaceutical industry. It will not be possible to produce the patented product by adopting a different process. Some safeguard measures and flexibilities contained in the TRIPs agreement were introduced in the patent system to protect public health, such as the Commissions on TRIPs that included leading senior former government officials and experts as members and held public consultations that recollected the views of experts, NGOs, industry associations and government officials. The reports produced by the People's Commissions studied the debates in parliament on amendments to the Patents Act, 1970 and provided specific suggestions on changes to ensure the amended Act would prioritize the national interest and access to medicines.

The TRIPs agreement has widened the scope, duration, and strength of patent protection. India actually complied with some major provisions of the TRIPs agreement, i.e. Article 27.1, Article 33, and Article 31. But provisions like Section 3(d) directly go into conflict with the TRIPs agreement. This is because the Section 3 (d) of the Patents Act narrowly defines 'new use' doctrine and excluded from patentability the new use of an old substance with intention of preventing 'ever-greening' of patents.

The law relating to computer software has been clarified. Although software per se is not patentable, software configured to achieve a particular technical result may be. Previous practice was to grant patents only to software coupled with hardware. Methods of treating plants are now patentable, although processes for treating human beings and animals are not. Micro-organisms are now patentable, whereas previously all forms of life had been excluded.

The present scenario is not altogether as disappointing as it was in the 1970s or 1990s; the scenario is better than it was before. The new amendment of the Indian Patent Act gave a crystal clear view of India's progressive attitude and intention to enter in the arena of advancement. Since the amendment the Global Economic Competition welcomes India as a nation having huge prospect for investment. The Information era urges before India to wipe out the evils of social dilemma in regard to granting Patent right India must also take the convenient means to eradicate the lacunas in its Patent law (e.g., Section 3(d) of the Indian Patent Act)

to cope up with the progress of other nations and achieve the tag of Developed Nation.

The Indian Patent System has geared up to provide a level playing ground for all stake holders. The recent amendments have brought the national IP Laws close to the TRIPs norms which were the real need to change the scenario prevailed in regard to Patent rights. The 40 years old system of limited term process patents for pharmaceutical products is getting abolished by virtue of the new Amendment. Multinational Companies are looking at the Indian market more seriously which will boost up Indian economy and progress. The patent law attempts to put India in compliance with its TRIPs obligations. In the process, it sets aside some of the most salient elements of the current legal regime which, together with other instruments such as the Drugs Price Control Order, have generally served well the interests of the country and its inhabitants. It is likely to bring about a legal regime that is less favourable from the point of view of access to drugs for the people of this country. Further, TRIPs cannot be implemented in isolation. India has a number of other international obligations, in particular in the field of human rights. As interpreted by UN human rights organs, the right to health requires that countries progressively take positive steps towards facilitating access. Dismantling the 1970 regime may constitute a violation of India's obligations under the covenant on economic, social and cultural rights.

4.10 Summary

The major changes introduced in the Indian Patent Act that were required to India’s obligations to international agreements and treaties. The new Patents Act (Patents

Amendment Act 2005) has created a strong patent system in India. Overall the present Act has increased the scope of patenting and provides stringent safeguards to the patentee. The new Act would play a major role in creating a technology driven market. Firms would increasingly try to create monopoly based on their patented technology. Indian firms primarily those that are in high technology areas would face increasing pressure, as patented products would enter the market.

The pharmaceutical sector would face the maximum impact. On one hand newer drugs would enter the market, on the other hand drug prices are expected to rise as generic drugs for drugs patented post 1995 would have to withdrawn. A patented drug provides the firm holding the said patent on it a monopoly and thus it can demand a very high price for the drug. It would be difficult for Indian firms to control the market. Mailbox' filing shows the intention of foreign firms to bring in patented products in pharmaceuticals in the Indian market.

One of the ways for Indian firms would be to increase their own R&D and innovation activity to create patented products in pharmaceuticals. Patent trends show Indian firms are trying to become innovative firms. Product patents in pharmaceuticals were also obtained in the USPTO. However, it should be noted that through incremental modification of their products, changing dosage intensity and including minor features such as inert ingredients and the form, colour etc. it is possible to get product patents in pharmaceuticals in the USPTO. This may not be possible in the IPO, as patents would be granted only for any 'new entity' involving one or more inventive steps.

Indian firms can also gain advantage through compulsory license. The amendment now gives the option of exporting drugs to a country, which makes a request for a generic drug. The only condition would be that the country where it can be exported should have no or insufficient manufacturing facility.

The major changes made in the Indian Patent Act would have significant impact. The market would increasingly become technology driven. Indian firms would have to compete in the new scenario. The new Act provides little scope for firms to infringe upon products that are protected by patents.

Finally, the extent of the flexibility that is built into the TRIPs agreement is not clearly defined. Many provisions in the new patents regime are likely to be challenged in the near future since their compliance with TRIPs remains an open issue. This lack of clarity has to be resolved and, therefore, the system can benefit from the judicial analysis by unravelling the meaning of its new patent law.

4.11 Self- Assessment Test

1. What is the effect of TRIPs Agreement on the Amendments to the Indian Patents Act 1970?

2. What is Software Patentability?
3. What are the Distinguishing Features of Patents (Amendment) Act 2005?
4. Is Indian patent law TRIPs complaint?
5. Explain the role of TRIPS and WTO in Patent protection.

4.12 Further Readings

1. WTO Agreement.
2. TRIPS Agreement.
3. Patents Act, 1970 (with all the amendments)

Unit 5
Patentable and Non Patentable Inventions

Objectives

Patent is a set of exclusive rights granted by a state to an inventor or his assignee for a fixed period of time in exchange for the disclosure of the invention. It refers to a grant of some privilege, property, or authority made by a government or the sovereign of the country to one or more individuals. The instrument by which it made is known as Patent. An invention is the creation of intellect applied to capital and labour to produce something new and useful. Such creation becomes the exclusive property of the inventor on the grant of patent.

Structure:

5.1 Introduction

The procedure for granting patent, the requirements placed on the patentee and the extent of exclusive rights vary between countries according to the national laws and international agreements. Typically, however a patent application must include one or more claims defining the invention which must be Novel, Inventive and Useful. In many countries certain subject areas are excluded from patents such

as business methods and mental acts. A patent is a negative right which grants exclusive rights to a patentee to prevent or exclude others from making, using, selling, offering to sell or importing the invention. The patent law recognises the exclusive right of a patentee to gain commercial advantage out of his invention. This is to encourage the investors to invest their creative faculties, knowing that their invention would be protected by law and no one else would be able to copy their inventions for certain period during which the respective investors would have exclusive rights.

5.2 Patentable subject-matter

Patentable, statutory or patent-eligible subject matter is a subject matter which is susceptible of patent protection. The laws or patent practices of many countries provide that certain subject-matter is excluded from patentability, even if the invention is novel and non-obvious. Together with novelty, inventive step or non-obviousness, utility, and industrial applicability, the question of whether a particular subject matter is patentable is one of the substantive requirements for patentability. The subject-matter which is regarded as patentable as a matter of policy, and correspondingly the subject-matter which is excluded from patentability as a matter of policy, depends on the national legislation or international treaty.

Inventions

Section 2(1) (j) of India's patent statute now defines an "invention" as "a new product or process involving an inventive step and capable of industrial application." This language was implemented via the Patents (Amendment) Act, 2002, so as to expressly incorporate the TRIPS-mandated "inventive step" criteria of patentability into the definition of an invention. The prior version of the statute omitted the inventive step criterion and defined "invention" in a more complicated manner as encompassing:

Any new and useful—

(i) art, process, method or manner of manufacture;

(ii) machine, apparatus or other article;

(iii) substance produced by manufacture, and includes any new and useful improvement of any of them, and an alleged invention. India's new definition of an invention as "a new product or process involving an inventive step and capable of industrial application" also compresses the categories of potentially patentable subject matter to simply "products and processes," in accordance with TRIPs. In contrast with U.S. patent law, the new Indian definition of an invention Omits "discoveries." This is consistent with the European approach, which expressly excludes "discoveries" from patentability.

A 'new invention' refers to an invention or technology which has not been anticipated by publication in any document or used, in the country or elsewhere in the world before the date of filing of patent application with the complete specification. In other words, the subject matter has not fallen in public domain or that it does not form part of the state of the art.

According to Section 2 (1)(ac), which explains, "capable of industrial application, in relation to an invention means that the invention is capable of being made or used in any kind of industry".

The interpretation of the words "capable of industrial application" is also subject to judicial scrutiny. An invention, in order to be patentable, must be capable of being made or used in some kind of industry. Hence, 'industry' should be understood in its broadest sense as including any useful practical activity as distinct from purely intellectual or aesthetic activity, and does not necessarily imply the use of a machine or the manufacture of an article.

An 'invention' within the meaning of the Act is an invention for a manner of new manufacture that is in some way associated with trade and commerce, meaning traffic in goods, i.e. exchange of commodities for money or other commodities.

The entire definition is dependent on or associated with the word 'manufacture' which denotes: (i) either a thing made which is useful for its own sake and vendible as such, or (ii) means an engine or instrument to be employed either in the making of some previously known article or in some useful propose or extending to new process to be carried on by known implements or elements acting upon known substances and ultimately producing some other known substance, but producing it in a cheaper or more expeditious manner, or of a better or more useful kind.

'Invention' includes both products and processes. In the case of a product patent, the article or apparatus itself, which is the end product, qualifies for a patent protection. In the case of process patent, the patent protection is limited to a particular process through which the end product is attained. Section 5 introduced the process patent and product patent distinction in providing that no patent shall be granted in respect of claims for substances intended for use as food or as medicine or as drug, but claims for the methods or processes of manufacture of these substances shall be patentable. With the omission of section 5, such distinction is of limited relevance.

The term invention means 'to find out something or discover something not found or discovered by any one before'. An invention is understood based on how the three of its subjective constituents, i.e. novelty, inventive step, and industrial application are understood. The subject matter should involve an invention over what is old. Anything that is in the knowledge of the public or is disclosed to the public cannot be regarded as an invention under the Act. An invention need not be a complicated advancement in technology. Even a simple invention, so long as it is novel or new, would be an invention. An improvement can also be an invention.

It is normally expected that the patentee would specify in the specification the distinguishing features of his application which improve upon the existing level of knowledge and show how such an improvement will constitute an invention. The definition of the term 'invention' does not expressly include an improvement or a modification. However, the Patents Act covers improvements that amount to a patentable invention. To qualify as an invention, an improvement must by itself satisfy the test of patentability. An improvement or modification of an earlier patent may qualify for a patent as a patent of addition. 'Improvement' is not a term of art, and can have wider or narrower meanings according to context.

A new product or a process could also mean a new improvement over an existing product or a process. Every improvement cannot qualify for a patent, but improvements on the prior art so long as it satisfies the prerequisites of patentability, can qualify as a patentable invention. Mere workshop improvements, devoid of ingenuity, will not qualify for a patent. The application of a known mechanism which had already been used for all practical purposes and the mere collection of more than one integer not involving the exercise of any inventive faculty do not qualify for the grant of a patent. A combination of known integers

will qualify for a patent if it can be shown that the improvement was not hitherto known, and that such improvement was new and useful.

A greater degree of control in performance can qualify for an improvement, but such a change in the absence of performance of a new function will not be treated as an invention. Superior utility, comparative excellence, efficient production and qualitative improvement of the product should be taken into account in determining whether an improvement amounts to a patentable invention.

Process Patents and Product Patents

Patents for pharmaceutical substances have been a subject matter of special interest in India. Modern pharmaceutical industry, which is popularly identified with the allopathic form of medicine, blossomed and flourished as a result the therapeutic revolution of the twentieth century. With the increase in the production and development of new drugs, the pharmaceutical industry became an industry based on R&D. Eventually dominance in the pharmaceutical industry came to be a direct consequence of the R&D efforts put in by the pharmaceutical companies. As the cost of research and development of new drugs involved exceptional professional expertise and burgeoning R&D expenditure, not all pharmaceutical companies could participate in the development and promotion of new drugs. This eventually demarcated the players in the industry into two broad categories: (1) the brand name companies which are usually multinational in their operation and are involved in extensive R&D for the promotion of new drugs and (2) the generic companies which in comparison are smaller in size and which manufacture bulk drugs not covered by a patent or whose patent rights have expired.

The pharmaceutical industry relies heavily on patent protection as the cost of R&D of a new drug is excessively high compared to the relative low cost of imitating the same drug. The peculiar nature of pharmaceutical industry had put its entire focus on patent protection for the new drugs developed by the brand name companies. The success in the pharmaceutical industry is now associated with not only the ability to frequently come out with new drugs, but also the feasibility of obtaining patent protection for these new drugs.

The fact that pharmaceuticals were inevitably regarded as a part of public health, led many countries to provide for special regulations for them. India granted

product patents for ordinary inventions allowed only process patents for pharmaceutical substances till 2005. Section 5 of Patents Act 1970 offered only a process patent for food, medicine or drug substances and specifically excluded product patents for the same.

This enabled Indian manufacturers to make copies of drugs patented elsewhere by finding out the constituents through reverse engineering. It is believed that the distinction between a product patent and a process patent was instrumental to the success of the pharmaceutical industry in India.

The Patents (Amendment) Act of 2005 came into force with retrospective effect from 1 January 2005, introduced product patents for pharmaceutical substances.

For the first time since 1972, India's patents regime once again recognizes the potential patentability of pharmaceutical products. Section 4 of the Patents (Amendment) Act, 2005, the cornerstone provision for bringing India's patents law into compliance with TRIPS, repealed the pre-existing statutory prohibition on the patenting of claims directed to "substances intended for use, or capable of being used, as food or as medicine or drug, or . . . relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds)."

Patentability of Biotechnological Inventions

In the field of biotechnology, inventions may be made with respect to the following:

(a) Living entity of natural origin (like animal, plant, human beings including parts thereof);

(b) Living entity of artificial origin (like micro-organism, vaccines, transgenic animals and plants etc);

(c) Biological materials (like DNA, plasmids, genes, vector, tissues, cells, replicons etc); and

(d) Biological processes (like process relating to living entities, process relating to biological materials, methods of treatment of human or animal body, essentially biological process).

As in the case of an invention in any other field of technology, the three prerequisites of patentability, i.e., novelty, inventive step and industrial

application, have to be satisfied for the grant of a patent for a biotechnological invention. The application of these standards has lead to differing practices between countries.

According to section 3(j), patents shall not be granted for 'plants and 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'. The above section is modeled on article 27.3(b) of the TRIPS Agreement. Section 3(j) of the Patents Act deals with three broad classes, which are: 'microorganisms', 'essentially biological processes' and 'plants and animals'.

Micro-organisms

Microbiological inventions generally involve the use of new strain of microorganism to produce a new compound or to produce a known compound more efficiently. The new organism may have been found in nature or may have been produced in the laboratory by artificially induced random mutation or more specific techniques such as genetic engineering.

If the microorganism produces a novel product, such as a new antibiotic of which the structure has been determined or which can be characterized by a 'fingerprint claim' then the novel product may be claimed as any other new chemical compound and subject to the requirements of a sufficient description, may be granted patent. If the end product is already known, process protection is available, but this protection is weak and it would be preferable to patent the new organism itself.

Most patent laws do not deal with the question of whether or not a new living strain of microorganism is itself-patentable, but the UK Patent Act 1977 and EPC do not exclude the possibility. Plant and animal varieties are excluded from protection as is any biological process for their production, but not excluded is a microbiological process or the product of such a process, which may of course be a microorganism. Most of the countries including India did not grant patents for microorganisms per se. The TRIPs agreement makes it obligatory for all WTO members, after the end of applicable transition period, to grant patents for microorganisms. If the microorganism is one, which occurs in nature, it will be necessary to claim it in the form of an isolated strain, in order to avoid possible

novelty objections. The term microorganism is interpreted broadly so as to include not only bacteria and fungi but also viruses and animal and plant cells.

In USA, in spite of the precedent of the Pasteur patent, it had become the practice of the patent office to refuse claims to living system as not being patentable subject matter. In 1980 however, the Supreme Court decided in the famous *Chakrabarthy's* case, that a new strain of bacteria produced artificially (by bacterial recombination) was patentable invention. Although, Chakrabarthy's bacteria did not produce a useful product they had the useful property that could feed on and disperse, oil slicks. Since the product, which would be sold, would be the bacterial strain itself, it was particularly important in this case to obtain per se claim to the microorganism.

Section 3(j) of the Indian Patents Act allows for patents for micro-organisms. It is worded in the form of an exception to an exception. The permissibility of patenting micro-organisms was considered in *Dimminaco AG v. Controller of patents and designs*, a case which involved an invention relating to a process for preparation of infectious Bursitis vaccine for protecting poultry. The Assistant Controller of Patents and Designs rejected the application on the ground that it did not constitute an invention under section 2(1) (j) of the Patents Act, holding that the process of preparing the vaccine which contains a living virus cannot be considered as 'manufacture' under the old definition of invention. On an appeal preferred under section 116 of the Patents Act to the Calcutta High Court, the court took into account the practice of the Patent Office in granting patents for end products containing living virus and quashed the order of the Controller and directed the reconsideration of the patent application.

The above case was decided under the provisions of the Patents Act before the Patents (Amendment) Act 2002 came into force. The said Amendment introduces section 3(j) which allows patents for micro-organisms.
Indian Patents Act has defined invention to mean a new product or process involving an inventive step and capable of industrial application. The Act gives a list of exclusions, which states that, "Plants and animals in whole or any part thereof other than microorganisms cannot be patented". So microorganisms are patentable in India, provided they satisfy the criteria of patentability. But the Act has not defined what constitutes microorganisms. The judiciary, while dealing with the catena of cases, has made an attempt to define microorganism

In *Green Peace Ltd v. Plant Genetic Systems N.V.*, the Technical Board of Appeal of the European Patent Office has attempted definition of microorganisms. It states: "…….Microorganisms includes not only bacteria and yeasts, but also fungi, algae, protozoa, human, animal and plant cells, i.e. all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a laboratory. Plasmids and viruses are also contained to fall under these inventions".

5.3 Exceptions to Patentability

Apart from satisfying the three prerequisites of novelty, inventive step and industrial application, to qualify for a patent, an invention should not be excluded from the categories mentioned in sections 3 and 4. These sections contain a list of inventions that are not patentable. The list includes matters which are incapable of being the subject of legal monopoly, matters excluded by policy and matters which are protected by other forms of intellectual property rights.

Frivolous inventions and inventions contrary to natural laws

Any invention which is frivolous or which claims anything obviously contrary to well established natural laws is not patentable. An invention that lacks utility because it serves no purpose or use is called a frivolous invention. It was held in *Indian Vacuum Brake Co. Ltd. v. E.S. Luard*, that patent for making in one-piece articles which were formerly prepared in two or more pieces could not be called to be a valid patent and was frivolous. Mere usefulness is not sufficient to support the patent.

Recently there has been a flood gate of frivolous patents in the pharmaceutical sector. Section 3(d) of the Indian Patents Act is an attempt to stop such frivolous patents.

Inventions contrary to public order or morality

Inventions whose primary or intended use or commercial exploitation is contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment are not patentable. The phrase 'serious prejudice to human, animal or plant life or health or to the environment'

was introduced to accommodate and clarify the expanding meaning of the words 'public order or morality'. The jurisprudence of the EPO interpreting the scope and meaning of the words 'public order or morality' will be relevant as this provision is similar to art 53(a) of the EPC.

Discovery not an Invention

Generally an idea or a discovery cannot be a subject matter of a patent. A practical application of an idea or a discovery can, however, qualify for a patent. Such a discovery will be patentable even though the practical application of the discovery is inherent in the discovery itself or becomes obvious once the discovery is made. Such a patent should claim the practical application of the discovery as an invention. A method of identifying diamonds by means of photographic records of their X-ray diffraction patterns (topograms) was held to be a patentable invention. Thus, mere discoveries or ideas cannot be the subject matter of a patent, but discoveries or ideas which have a technical aspect or make a technical contribution will be patentable.

Inventions Pertaining to Known Substances etc

Section 3(d) includes a category of inventions pertaining to known substances and known processes that are not patentable. The mere discovery of a new form of a known substance which does not enhance the known efficacy of that substance is not patentable. Similarly, the mere discovery of any new property or new use for a known substance or of a 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, shall not be a subject matter of a patent.

Invention Pertaining to Mere Admixture or Arrangement

Section 3 (e) of the Indian Patent Act 1970 provides that "a substance obtained by a mere admixture resulting only in the aggregation the properties of the components thereof or a process for production such substance" is not patentable.

By "mere mixture of known ingredients" is meant a mixture exhibiting only the aggregate of the known properties of the ingredients. Not only must the ingredients be known, but the property that makes the ingredients useful for the purpose of the invention must also be known. If the result achieved by the

invention is more than might be expected from a mere mixture, the invention is patentable.

It is possible that a substance is not excluded from being a mere admixture merely on the basis that the physical form of an ingredient has been changed, for example, sweet formed from a mixture of sugar and cellulose which has been turned hard by boiling. In order to overcome the Section 3(e) barrier, a patentee is required to prove that the combination of the known substances has resulted in a synergism wherein the combination displays properties that are not displayed individually by each component.

A mixture of different kinds of medicines, forming a cocktail of drugs, to cure multiple diseases will not be a patentable invention. For instance, a composition of two drugs, i.e., Paracetamol and Ibuprofen for curing fever and pain or a process of preparation thereof, will not be patentable as the composition is a mere admixture of two drug components resulting in an aggregation of analgesic and anti-inflammatory actions of their respective components.

Method of Testing

Section 3(g) in relation to method of testing now stands omitted in the Patents Act. Consequently, a method of testing can now be a subject matter of a patent. A method of testing which could be applied to the improvement or control of manufacture could qualify for a patent in the United Kingdom.

Method of agriculture or horticulture

A method of agriculture or horticulture cannot be the subject matter of a patent under the Patents Act. Tracing history, we find that the Indian policy was based on the concept that plant varieties and seeds were the common heritage of mankind. Though there was an increase in the rate of growth in agriculture, the State could not meet the rising demand for the food. The need for attaining self-sufficiency in food led to the pursuit of the green revolution. During the colonial period, food production was on the decline. Land reforms had a great impact on the agrarian structure. The rise of the modern technology culminated in agriculture research. This formed the foundation of technological farming. The vision of our forefathers was towards alleviation of poverty. This could be done only by attaining self-sufficiency in food production which could be obtained only by

excluding methods of agriculture from protection. Large population of the country derives their livelihood from agriculture. Agriculture is the back bone of India's economy. Small and marginal farmers predominate agriculture. The main aim of excluding methods of agriculture from protection was to alleviate poverty and also to ensure that there would be self-sufficiency in food sector.

Methods of Medical Treatment of Human and Animals

Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free from disease or to increase their economic value cannot be a subject matter of patent. A method of medical treatment for an ailment is not a patent eligible subject-matter. A process consisting of the use of a known compound for treating a human being medically has never been held to be patentable because courts have consistently expressed the opinion that a process for medical treatment of human beings is not a proper subject for a patent monopoly.

Plants and Animal Varieties

Plants and animals, in whole or in their parts, are excluded from patent protection.

Seeds, varieties and species are also included under the section 3(j). The section also excludes 'essentially biological processes'. However, micro-organisms can be a patentable invention. Plant varieties are protected by a sui generis system under the Protection of Plant Varieties and Farmers' Right Act 2001.

Business Method, Computer Program etc.

A mathematical or business method or a computer program per se or algorithms is not patentable under the Patents Act. In India, patent protection is not afforded to business methods and computer programs though Article 27 of the TRIPs agreement does not exclude them from patentability. Computer programs are excluded from patent protection as they are protected as a literary work under the Copyright Act 1957.

Though patent for a computer program per se is not patentable, a claim expressed as a computer arranged to produce a particular result, and computer

programs which have the effect of controlling computers to operate in a particular way may be the subject matter of a patent. The prevailing view is that where the subject matter as claimed makes a technical contribution to the known art, the patentability should not be denied merely on the ground that a computer program was involved in its implementation.

Literary, dramatic, musical or artistic work etc

The subject-matter of a literary, dramatic, musical or artistic work is protectable under the Copyright Act. The protection is for the original expression of the idea and not for the idea. Moreover, the requirements for obtaining a patent protection cannot be satisfied in the case of the above works.

A copyright infringement action may be clubbed along with a suit for infringement of a patent if both the issues flow from a common set of actions.

Scheme or Rule

A scheme does not amount to a manner of manufacture as it is a mere idea. Here too, an exception is entertained with regard to those ideas which could have a practical effect. Every invention should have begun as an idea. An invention may lie in an idea or in the way in which the idea is carried out or both. Such an idea must either suggest a new way of making something or it should show a new way of producing a new article.

Presentation of Information

Section 3(n) of Patents Act excludes a presentation of information from the ambit of patent protection.

An invention in order to obtain patent protection should have a technical result. In Marker/Beattie, the invention consisted of an apparatus for and a method of learning how to play a keyboard instrument, with numbers corresponding to notes on a sheet of music appearing on the keys too. The patent application was for a marker to be laid on a musical keyboard to facilitate learning music. The technical feature claimed was the marking of the keys. Patentability was ruled out by Article 52(2) (c) and (d), EPC. Since the key markings were merely known technical features, the contribution made by the claimed invention to the working of the teaching apparatus lay solely in the content of the information displayed, not in the apparatus itself it was held to be not patentable.

Topography of integrated circuits

Topography of integrated circuits cannot be the subject matter of a patent protection. Topographies or lay-out designs of Integrated circuits are protected by the Semiconductor Integrated Circuits Layout- Design Act, 2000.

Traditional Knowledge

An invention which is a part of traditional knowledge cannot be the subject matter of a patent. Similarly, an aggregation or duplication of known properties of traditionally known component or components is also excluded from patent protection. An invention based on traditional knowledge may be opposed or revoked under the Patents Act on the ground that the invention is anticipated. Clause 19 of the Doha Declaration provides that the Council for TRIPs shall review the implementation of the TRIPs agreement and examine, among other things, the relationship between the TRIPs agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments.

Inventions Relating to Atomic Energy

Section 4 prohibits the grant of patents for inventions relating to atomic energy. It is widely accepted that countries can provide for security exceptions for the protection of essential security interests relating to fissionable material. Even if a patent is granted for an invention relating to atomic energy, the same may be revoked under section 65 of the Patents Act. The provision relating to atomic energy inventions are contained in section 20 of the Atomic Energy Act 1962.

5.4 Conditions for patentability

Inventions can be as simple as a paperclip or as complicated as a robot but they must meet certain conditions of patentability before they can be patented. An invention must meet several requirements to be eligible for patent protection. These include, in particular, that the claimed invention: (1) consists of patentable subject matter; (2) is new (novelty requirement), it could be a new concept or idea or solution to an existing problem or completely a new method/process/device/utility; (3) involves an inventive step (non-obviousness

requirement); (4) is capable of industrial application (utility requirement); and (5) is disclosed in a clear and complete manner in the patent application (disclosure requirement).

Novelty and Anticipation

The concept of novelty in intellectual property jurisprudence lays down that only what is new at the time of the filing of the application for a patent is patentable. Patent eligible subject-matter is granted a patent if the subject-matter is novel, non-obvious and is capable of industrial application. Of these requirements, novelty is of core value.

Patentability always depends on novelty. The court in *AT&T Knowledge Ventures LP, re* observed that patentability cannot be put into a watertight compartment completely separate from novelty.

The Indian Patents (Amendment) Act, 2005 defines a "new invention" as any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of the application with the complete specification. Novelty and anticipation are determined by reference to the language of the claim of the patent application. Under Section 64 of the Indian Patents Act 1970 a patent shall be revoked "where it is not novel". The Patents (Amendment) Act, 2005, section 23 states that after an application for patent has been published and before the grant of a patent, the grant of patent may be opposed on the ground of novelty.

In *Bombay Agarwal Co. v. Ramachand Diwanchand*, a Division Bench of the Nagpur High Court held that in cases of patents, the court must see whether there was novelty in the process, whether the subject-matter of patent is proper and whether there is utility. By the subject-matter of patent, was meant the exact advance upon the existing knowledge which the patentee claims. It was further held that the patent can be defeated if it is not "a new manufacture or improvement, thereby, indicating that manufacture it was being indulged in by others prior to the date of the patent."

Australian Courts have laid down that the test for determining whether an invention lacks novelty is the "reverse infringement test" as set out in *Meyers Taylor Pvt. Ltd. v. VicarrIndustries Ltd*., where Aickin J. stated: "The basic test for anticipation or want of novelty is the same as that for infringement and generally

one can properly ask oneself whether the alleged anticipation would, if the patent were valid, constitute an infringement".

The Patents Act requires an invention to be new. An invention is regarded as new if it has not fallen in public domain or if it does not form part of the state of the art. The ambit of the term 'the state of the art' would include every matter in the public domain available in any part of the world before the date of filing the patent application. As per the definition in s 2(1) (l), when an invention or technology is anticipated by publication in any document or used in any part of the world, a patent will not be granted as the information disclosed forms a part of the state of the art. It would appear that the standard of absolute novelty introduced by s 2(1) (l) may be employed in determining lack of novelty under s 64(1) (e) of the Patents Act. But s 64(1) (e) prescribes a different standard of novelty.

The difficulty imposed by the introduction of the absolute standard of novelty is that it attempts to replace the existing relative standards of novelty contained in s 64(1) (e), albeit inconclusively. To start with, the definition of 'new invention' is not used anywhere in the Patents Act. The standard of novelty under the Patents Act based on which a patent can be revoked for lack of novelty is prescribed in s 64(1) (e), which is a relative standard. It restricts the novelty search to 'what was publicly known or publicly used in India'. However, the standard of novelty with regard to published documents is an absolute standard as it covers 'what was published in India or elsewhere'.

It is submitted that in understanding novelty, courts should try to avoid subjective judgments and should adopt the principle of 'objective novelty'. British courts have followed the principle of 'absolute novelty' which requires novelty to be decided against all the information available at the priority date of the invention. This concept of worldwide novelty disregards the place where the information is available and the manner and form in which it is made available. The standard of absolute novelty avoids subjectivity and most questions of degree.

Novelty refers to a characteristic of the invention of being new, i.e., the invention does not form a part of the state of the art. As one of the prerequisites for the grant of a patent, i.e., a condition that needs to be satisfied before the grant, it casts a duty on the Patent Office to verify whether the invention has been anticipated. The Patents Act provides for an examiner to search for anticipation by previous publication or by prior claim and empowers the Controller to refuse an

application where the invention is anticipated. An opponent may oppose an application for a patent or a granted patent on the ground of lack of novelty. The absence of novelty, as on the priority date of claim, can be a ground for revocation of the patent which may be exercised any time during the life of a patent. Thus, novelty remains an essential feature of an invention throughout the life of the patent.

In determining novelty, the following three steps may be considered: (i) what is the invention about, (ii) what is the information disclosed by the prior art? and (iii) is the invention new?

The first step is to identify the invention. The manner in which an invention is defined should also be considered. The second step will involve the determination of the information disclosed by prior art. For this to be done, it is necessary to first find out what material forms a part of the state of the art. The state of art will mean a body of information restricted by a point of time. It pertains to the material known before the date of filing of the patent application with the complete specification. Once the material is ascertained, the nature of information disclosed can be found out. The third step will involve a determination as to whether the invention is new, i e, whether the invention is excluded from the state of the art.

The State of the Art

The recent introduction of the expression 'the state of the art' into the Patents Act imports a larger concept than the idea conveyed by anticipation that existed in the Act. The state of art refers to all the information which is in the public domain. To form a part of the state of the art there is no need for the information to be put to actual use. The mere fact that it was available and was capable of being used by the public is sufficient. The possibility of accessing the information by a person will determine whether it formed a part of the state of the art, even if 'the public has not recognized their potential or taken advantage of them.

Priority Date

Section 2(1) (l) states that the date at which the novelty is to be assessed is the date of filing of the patent application with the complete specification, i.e. the

priority date. Section 11 of the Patents Act enumerates the principles for ascertaining the priority dates of claims of a complete specification. The state of the art includes information that is in the public domain before the priority date. Though the priority date is usually the date of filing the patent application, there are instances where the priority date is calculated from a previous date. Under the Patents Act, a patent may be held to be invalid due to the applicant's own acts and disclosures which destroy novelty. Thus priority date is relevant not only for assessing novelty but also for exploiting the invention without jeopardizing any potential patent.

Prior Publication

Section 64(1) (e) states that an invention that is published in India or elsewhere in any document will lack novelty. The section implies that such publication will make the invention available to the public. An invention is not made available to the public merely by a published statement of its existence, unless the method of working is so self-evident as to require no further explanation. This would mean that the person of ordinary knowledge of the subject would at once perceive and understand and be able to practically apply the discovery without the necessity of making further experiments. This would also imply that the information given by the prior publication must, for the purpose of practical utility, be equal to that given by the subsequent patent.

Prior publication usually refers to publication in any document made anywhere in the world. It would include documents in foreign language published in a foreign country. Thus, a foreign specification posted in a noticeable part of the Patent Office library where members' search for information was held to be prior publication. Even a document communicated to a single member will constitute prior publication to the public if there was no bar on that person to further disseminate the information contained in the document.

Publicly known or publicly used

Section 64(1) (e) states that an invention will lack novelty if it is publicly known or publicly used in India. The ambit of the above section is limited to knowledge or use within India. However, the definition of 'new invention' expands the scope of public use beyond India. It covers any invention or

technology 'used in the country or elsewhere in the world'. There is a need for clarification with regard to how s 64(1) (e) will be interpreted in the light of the introduction of the expression 'new invention' is s 2(1) (l).
Public knowledge need not mean widespread use to the knowledge by the public.

To satisfy the requirement of being publicly known as used in clause (e) and (f) of s 64(1), it is not necessary that it should be widely used to the knowledge of the consumer public. All that is required is that 'it is known to the persons who are engaged in the pursuit of knowledge of the patented product or process either as men of science or men of commerce or consumers.

A mere publication will not be sufficient to show that an invention is publicly known. A matter may be publicly known even if it is not published in a document, if, for instance, it is publicly used. An invention may be publicly known by oral disclosure, written disclosure by document or by public use. The date of knowledge or use by any person other than the patentee is the date before the invention and not the date before the grant of the patent. To what extent knowledge anticipates an invention is a question of fact which will depend upon the facts and circumstances of each case.
Where the invention claimed was a new product, dealing with that product by way of trade, whether by buying it or selling it with a view to profit or making it for the purposes of sale, will constitute 'public use' as stated by the House of Lords in *BristolMyers Co (johnson's) Application*:

The right of a trader to go on dealing by way of trade in any man-made substance, in which he had dealt before, without impediment by a monopoly in that substance granted to any other person, was not dependent upon his knowledge of its composition or how it could be made. If he had in fact dealt in that substance he had 'used' it; his ignorance of these matters was irrelevant to the question of his use. Nor was his right to go on dealing in it dependent upon his disclosure to the public the composition of the product or the means of making it, or giving to the public the means of finding that out for themselves.

An invention may not be considered as new if it was put to prior public use. Though the Patents Act makes prior secret use in India a separate ground for revocation, it excludes secret use for the purpose of determining lack of novelty. The purpose of s 64(1) (e) is to protect prior users. A person who is already manufacturing an article or has previously manufactured it, or had put it into use,

should not be stopped from doing what he had done before. The grant of a patent should be curtailed where it can result in prohibiting prior users of the article from continuing to use such an article. This would be the case even if the prior user did so in complete ignorance of the scientific technology involved in the invention. The protection will be available to him even if he had manufactured the article by chance and later found out that it had particular advantages or was useful for particular purposes. If another person invents a process for manufacturing the same thing, the latter person will not be entitled to stop the prior user from doing what he was doing before.

Anticipation

The Patents Act, 1970, under section 29 to section 34 lays down the provisions governing anticipation in various forms for an invention.

In an application for grant of patent, the specification pertaining to the invention is required to be given. And each claim of the specification is given a priority date. If the invention as claimed in complete specification is noted to have been published before the priority date, then it is a case of anticipation by prior publication. But such an invention is deemed not to have been anticipated by prior publication, if the patentee or the applicant proves that the matter was obtained and published without consent and upon learning of such publication, the application for grant of patent was made as soon as practicable thereafter.

The above does not apply in case the invention has been commercially worked for the purpose of reasonable trial by patentee or applicant himself or through his authorized representative, before the priority date of the claim.

If subsequent to the disclosures made by an unauthorized applicant, the invention is used or published, the invention claimed in the specification is deemed not to have been anticipated.

Anticipation by previous communication to Government

An invention claimed in complete specification, if communicated to government or its authorized representative in response to any communication for investigating or doing anything relating to the invention is deemed to have not been anticipated.

Anticipation by public display etc.

The authorized display or use of invention at any industrial or other exhibition promoted by the Central Government notification through its Official Gazette or the subsequent publication of any description of the invention does not cause the invention to have been anticipated. Also the unauthorized use of invention after such public display will not result in the invention being treated as anticipated, provided that the application for grant of patent must be made not later than twelve months after opening of the exhibition.

The description of the invention in a paper read by the true and first inventor before a learned society or published with his consent in the transactions of such society will not cause the invention to have been anticipated provided the application for the patent is made by the true and first inventor or a authorized representative not later than twelve months after the reading or publication of the paper.

Anticipation by public working etc.

An invention claimed in the complete specification is deemed to have not been anticipated, if the invention has been publicly worked in India within one year before the priority date of the relevant claim of the specification, provided such working was effected for the purpose of reasonable trial only and the nature of invention made it necessary that the working for that purpose should be effected in public.

Anticipation by use and publication after provisional specification

An invention described by provisional specification is not refused grant of patent or the patent having been granted is not revoked or invalidated solely by the reason of that the matter described in such specification was used in India, or published in India or elsewhere at any time after the date of filing of that specification.

Inventive step/non-obviousness

Non-obviousness/inventive step measures the technical accomplishment reflected in an invention. It attempts to measure an even more abstract quality than novelty and utility. Non-obviousness asks whether an invention is an adequate technical advancement to merit the award of a patent. Even if an invention is new and useful, it does not deserve a patent if it represents merely a trivial step forward

in the art. The objective of the patent system is the advancement of science. It aims to protect those, which would not be obvious to anyone skilled in the art if they had put their mind to it. It is regarded as the final gatekeeper of the patent system.

The philosophy underlying the concept of inventive step is similar to that in novelty. By granting monopoly over an obvious thing, the public should not be prevented from doing anything that is merely an obvious extension or workshop variation of what was already known.

The Patents Act defines an invention to mean a new product or process involving an inventive step and capable of industrial application. Section 2(1) (ja) defines inventive step as follows:

'inventive step' means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.

5.5 Summary

In practice, several issues remain open. Law cannot be static. It has to be modified to meet the requirements of the fast changing environment. Similarly, science is also not static and changes are taking place at a very fast pace. Since patent is related to science & technology, the patent legislations cannot also be static. This is based on the fact that our country possesses the highly capable intellectuals and natural wealth, and that too in plenty. Combining these two valuable strengths/assets, we could have become a country holding valuable IPRs which would have helped economical and industrial development of the country even faster. India should have been proactive instead of reactive. Time is still not lost. India can still initiate appropriate action in this direction in the coming years and achieve benefits from the Intellectual Property System, especially Patent system.

5.6 Self- Assessment Test

1. Give examples of patentable subject-matter with relevant sections of Patents Act, 1970 and case laws.
2. Give all the Exceptions to Patentability as mentioned in Patents Act, 1970 and various case laws.

3. What are the different conditions for patentability?
4. Mention the various sections in Patents Act, 1970 which talks about the patentable and non-patentable invention. Also explain the same.

5.7 Further Readings

1. Patents Act, 1970
2. TRIPS Agreement
3. Case laws stated above

Unit 6
Rights of Inventor and Patentee

Objectives

Intellectual property rights have come to occupy an increasingly important place in the world today. The expression 'intellectual property' itself connotes a string of rights available for the protection and exploitation of technology to its maximum potential. Intellectual property law is generally understood in two categories: *industrial property* which concerns patents, trademarks, designs etc. and *copyrights* which concerns literary and artistic works. The major goals of any intellectual property system are safeguarding the rights of an inventor in his invention and facilitating economic and social growth by providing an impetus to the advancement of science and technology.

Structure:

6.1 Introduction

Patents in some form or the other have been recognised since times immemorial. The strict literal meaning of the word *patent* is '*open to the public, readily visible or intelligible*'. '*Patent'* has its origin in the term 'Letters Patent' which meant open letters (as distinguished from closed letters) through which the Crown conferred certain rights and privileges on one or more individuals in the

kingdom. The history of patents and patent laws is generally traced to Italy, to a Venetian Statute of 1474 which was issued by the Republic of Florence. The state issued a decree by which *new* and *inventive* devices, once they had been put into practice, had to be communicated to the Republic in order to obtain legal protection against potential infringers.

A patent is a form of *industrial property.* A patent may be broadly described as a monopoly right conferred by the state to an inventor to industrially and commercially exploit his invention at the cost of making a complete disclosure of the details of his invention. In the Indian context, patent means the grant of some privilege, property or authority made by the Government to one or more individuals. Statutorily, patent has been defined under the Patent Act, 1970 as '*a patent granted under the Act*'.

6.2 Objects of patent law

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) outlines its objectives as follows:

"The protection and enforcement of intellectual property rights should 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."

Thus, it is clear that the entire IP system, including patent law, is ordered to ensure four broad objectives:

i. *promotion of technological innovation;*
ii. *the transfer and dissemination of technology;*
iii. *the advantage of consumers and inventors;*
iv. *in a manner conducive to social and economic welfare.*

The object of *patent law* has been succinctly stated by the apex court in *Bishawanath Prasad Radhey Shyam v. Hindustan Metal Industries* case as: '*[T]he object of patent law is to encourage scientific research, new technology and industrial progress. Grant of exclusive privilege to own, use or sell the method or the product patented for a limited period stimulates mew inventions of commercial utility. The price of the grant of monopoly is the disclosure of the invention at the*

Patent Office, which after expiry of the fixed period of monopoly, passes into the public domain.'

The Court of England, too, in *Chiron Corporation v. Organ on Technical Ltd.* has justified the patent system in pragmatic words stating:

'*... it is generally accepted that the opportunity of acquiring monopoly rights in an invention stimulates technical progress in at least four ways. First it encourages research and invention; secondly, it induces an inventor to disclose his discoveries instead of keeping them a secret; thirdly, it offers a reward for the expense of developing inventions to the state at which they are commercially practical and, fourthly, it provides an inducement to invest capital in new lines of production which might not appear profitable if many competing producers embark on them simultaneously...*'

It is clear from the above that the patent system has lofty objectives. If operated towards securing the goals outlined above, it is clear that the system shall benefit all stakeholders- be it society, inventors or governments. However the system is not without its detractors. The opposition to the grant of patent was succinctly summarized by *The Economist* as:

'*...inflames cupidity, excites fraud...begets disputes and quarrels, betwixt inventors, provokes endless lawsuits, makes men ruin themselves for the sake of getting the getting privilege of a patent, which merely fosters a delusion of greediness.*'

Stringent opposition to grant of patent rights is seen in developing countries, especially with regard to patenting pharmaceutical products. Inspite of the cogent arguments that may be advanced for discarding the patent system, no other system has yet been envisaged that adequately compensates acts of genius while at the same time ensures that the interests of society are not jeopardized. Dutton has suggested the following arguments for retaining and improving the patent system:

1. *The contract theory*: Temporary protection granted in reward for knowledge of new inventions
2. *The reward theory*: Inventors should be rewarded for making useful inventions and the law must be used to guarantee this reward so that inventors can receive sufficient recompense for their ingenuity.
3. *The incentive theory*: By constructing a framework whereby the invention is rewarded, this will act as an incentive to make new inventions and to invest the

necessary time and capital. This is a forward-looking approach in contrast to the latter which is retrospective.

4. *The natural law/moral rights theory*: Individuals have a right of property in their own ideas and this right should be protected from being usurped or stolen by others.

6.3 Benefits conferred upon the patentee

The patent law recognizes the exclusive right of a patentee to gain commercial advantage out of his invention. This is to encourage inventors to invest their creative facilities, knowing that their inventions would be protected by law and accordingly no one else would be able to copy their inventions for certain period (generally 20 years) during which the inventor would have exclusive rights.

Once a patent is granted, certain monopolistic rights are conferred upon the patentee, as an incentive for disclosing his invention to the public. These monopoly rights, generally for a period of 20 years, are *assignable* thus enabling the patentee to *licence* invention thereby maximizing his profit.

Article 28 of the TRIPS Agreement provides these exclusive rights as follows:

'Article 28: Rights Conferred:

1. *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.

2. *Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.'*

Section 48 of the Patent Act, 1970 which embodies Article 28 above, provides the follows exclusive rights to the patentees:

'***48. Rights of patentees****:*

1) Subject to the other provisions contained in this Act, a patent granted before the commencement of this Act, shall confer on the patentee the exclusive right by himself, his agents or licensees to make, use, exercise, sell or distribute the invention in India.

2) Subject to the other provisions contained in this Act and the conditions specified in Section 47, a patent granted after the commencement of this Act shall confer upon the patentee:

a) where the patent is for an article or substance, the exclusive right by himself, his agents or licensees to make, use, exercise, sell or distribute such article or substance in India;

b) where a patent is for a method or process of manufacturing an article or substance, the exclusive right by himself, his agents or licensees to use or exercise the method or process in India.'

Jeremy Bentham strongly argued that as an invention involved a great deal of time, money and effort and included a large element of risk, the exclusive use of the invention must be reserved for a period of time so that it could be exploited and thereafter used for the general increase of knowledge and wealth.

In *Asahi, Kanei Kogyo* Lord Oliver expressed the underlying objective of patent law as encouraging improvements and innovation by conferring the benefit of a monopoly for a defined period on the inventor so that he may make known his invention to the public. Another purpose equally stimulating is that companies would be willing to take risk and expend much money and efforts in the developments of scientific and technical research.

Patents have a special significance to inventors especially in the pharmaceutical industry. It is estimated that on an average more than $45 billion are spent yearly on R&D. Moreover, average R&D expenditures per company have grown at a rate of close to 300% per year. It is also submitted in spite of huge investments incurred; very few drugs are actually commercially produced. In the course of the R&D process, more than 8,000 compounds are tested on average, of which only one is developed into a potent and safe drug. Patents granted to

pharmaceutical products encourage more extensive and comprehensive research in that area. The monopoly rights conferred by the patent system provide the necessary incentive for pharma companies to invest their resources in R&D.

Thus, patents provide the necessary incentive for inventors to undertake capital intensive projects knowing that they will receive have the exclusive rights to profit from their inventions once they secure patents in respect of the inventions.

6.4 Benefits conferred upon the society

Through patents, monopoly rights are conferred upon inventors. Inventors alone have the right to make, sell, licence the patented invention. Many consider this as detrimental to the interests of society as patentees have the discretion of charging their own prices for their products. Further, they might refuse to sell their patented products in certain areas depriving people of the benefits of their inventions. While these misgivings might to true to an extent, it s seen that that society's interests are *protected* rather than *derided* by the patent system. *Firstly*, all inventions for which patents are granted are accompanied by an enabling disclosure, i.e. all details required to reproduce the invention are provided. As the details of the invention fall into the *public domain*, competing inventors can use this information as a base and improve upon the same, thus automatically providing for higher quality goods and increasing the choice of the consumers in the market. *Secondly*, although the grant of the patent confers the exclusive right to make, sell, licence the patented right etc., it is clearly provided that the use of the invention for research or teaching purposes shall not be considered as a violation of the patentee's rights.

Article 30 of the TRIPS Agreement provides for *limited exceptions* to the rights conferred upon a patentee:

'*Members 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 the third parties.*'

Section 47 of the Indian Patent Act, 1970, which embodies this *limited exception* clause, provides that the grant of a patent is subject to certain conditions:

'47. Grant of patents to be subject to certain conditions:

The grant of a patent under this Act shall be subject to the condition that -

1. any machine, apparatus or other article in respect of which the patent is granted or any article made by using a process in respect of which the patent is granted, may be imported or made by or on behalf of the Government for the purpose merely of its own use;
2. any process in respect of which the patent is granted may be used by or on behalf of the Government for the purpose merely of its own use;
3. any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils; and
4. *in the case of a patent in respect of any medicine or drug, the medicine or drug may be imported by the Government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the Official Gazette.*'

Thus it is clear that notwithstanding the fact that patents confer certain exclusive privileges, the grant of patents itself is subrogated to the interests of society. This is of special significance in the pharma industry, where patents provide the fine balance between the incentives to innovate and safeguarding the interests of society. In the absence of sufficient safeguards to patentee's rights, the pharmaceutical companies would not produce, let alone disclose scientific formulations, which would not only stem scientific progress but also deny the few who have access to patented products their right to enjoy them.

From the above it is clear that it is society's best interest that genuine innovations should be protected and rewarded without stifling further innovation. The best illustration of how a patent benefits the public by encouraging disclosure in return for a period of exclusivity is the plain-paper copier (the "Xerox machine"). Before the invention of that copier, copies had to be made using expensive and messy systems like photography, heat-sensitive paper, or

mimeographs and ditto machines. That changed when a patent attorney came up with an electrostatic copying method. Because the patent attorney was the first to invent the technique, he received a patent giving him the exclusive right to practice the invention for 17 years (under the law at that time). By the time the patent expired, Xerox was an established company, and companies like IBM and Canon joined Xerox in building and marketing plain-paper copiers.

6.5 Benefits conferred upon the government

Intellectual property is based on liberal, democratic principles. Any person, exercising *mental effort* may claim it and no political system dare destroy it. Shri Kamal Nath, the Union Minister for Commerce and Industry has observed: '*Intellectual property is the foundation of a knowledge based economy and is becoming increasingly important not only for creation of wealth, but for providing employment and improved standard of living for the masses.*'

Thus, it clear that the benefits of the patent system are not restricted to the inventors and consumers alone. The government too is a considerable stakeholder in patent system, being a key role-player in the patent policy.

One of the reasons for the tremendous and rapid advance in industrial power in the United States from the 19th century was the liberal patent laws, the number of patens exceeding the million mark in 1911 itself. As of today it is estimated that the US and EU together hold 97% of all patents worldwide, and multinational corporations account for 90% of all product and technology patents.

The purpose of an invention is to protect and encourage fair competition in the field of technology so as to transform inventions or creations into real and productive forces as quickly as possible. A country's market economy is dependent on the successful working of its patent system.

6.6 Patents--Balance of competing interests for the benefit of all

It is clear that any patent system involves the balancing of competing interests. While companies on the one hand would seek to extend their monopoly rights over patents, thereby maximizing their profits from the same, society would require that these monopolies be destroyed, leading to more competitors entering

the market thereby reducing prices of the patented product. In reality however, such a conflict of interest should not arise. As the application for a patent is accompanied by the complete *enabling disclosure* of the invention, competitors often use this information to produce improved products and patent them. Their improved products being also accompanied by enabling disclosure, provides the necessary base for further improvements. Thus consumers benefit as the patent system automatically leads to an increased choice in the market and companies benefit as they can focus their energies on providing new and improved products rather than diverting their resources to ascertain the nature of existing inventions.

The Act itself balances the 'competing interests' of society. It envisages that in certain exigent situations, there might be a conflict between the interests of society and the rights of the patentee. Recognizing the most basic principle of *sales popular est. supreme lax*, the Act provides, *inter alia,* for the grant of '*compulsory licenses*'. Section 92 of the Act reads:

"*If the Central Government is satisfied, in respect of any patent in circumstances of* ***national emergency*** *or in* ***circumstances of extreme urgency*** *or in case of* ***public non-commercial use****, then it is necessary that compulsory licenses should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the official Gazette..."*

Thus, through the compulsory licensing regime, the rights of the patentee are waived and the Central Government may license the patent as it sees fit. However, even in this exigency, the Act reserves the right of the patentee to secure adequate compensation, thus ensuring that the rights of the patentee are protected as well. S.89 (b) of the Act which considers '*General principles applicable for the grant of compulsory licences*' states:

"*…the interests of any person for the time being working or developing an invention in the territory of India under the protection of a patent are not unfairly prejudiced*"

S. 90(ii) of the Act states:

"*…the Controller shall endeavour to secure--*

(iii) "*that the royalty and other remuneration if any reserved to the patentee or other person beneficially entitled to the patent is reasonable having regard to the nature of the invention, the expenditure incurred by the patentee in making the*

invention or in developing it and obtaining a patent and keeping it in force and other relevant factors"

Further, S. 92 of the Act which deals with granting compulsory licenses in special circumstances states:

"*in settling terms and conditions of license granted under this section the Controller shall endeavour to secure that the articles manufactured under the patent shall be ... consistent with the patentees deriving a reasonable advantage from their patent rights*"

Similar provisions are seen when the government acquires the patent. It is clear from the above that the Act not only recognizes the right of the patentee in securing a "*reasonable advantage*" from the patented product but also considers *remuneration* to the patentee in case compulsory licenses are granted. Generally it is seen that it has been a practice of all nations that whenever a compulsory license have been granted, some amount of compensation has always been paid to the patentee.

Thus it can be seen that there is an equanimity maintained through the patent system. Whenever the monopoly rights conferred upon the patentee are usurped, care is taken to ensure that the rights of the patentee are not '*unfairly prejudiced*' in addition compensation is paid to the patentee for such '*infringement'* of his rights.

The Act also contains general principles applicable to the working of all patented inventions. It is provided that in exercising powers concerning grant of compulsory licences, regard should *inter alia* be had to encourage innovations and to secure that inventions are worked in India on a commercial scale, and to the fullest extent reasonably practicable without undue delay; and not to encourage a patentee to merely import the patented article, but to see that patent rights contribute to technological innovation, and to transfer and to disseminate technology for the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare and to ensure that the benefit of the patented invention is available at a reasonably affordable prices to the public and for grant of compulsory licences in respect of patents for the reasonable requirements of the public.

6.7 Summary

The ultimate goal of any intellectual property system is the advancement of science and technology as a means of securing overall social and economic development. By conferring exclusive rights on inventors, the true goals of any intellectual property system are actually the advancement of science and technology. It is expected that if additional rights are conferred upon inventors, it would induce further inventions, enabling giant strides in the development of technology, ultimately benefiting society.

Thus it can be seen from the above that the intellectual property law by protecting the rights of an inventor in his invention actually ensures the progress and growth of science and technology as a means of securing economic and social development.

6.8 Self-Assessment Test

1. What are the objects of patent law viz-a-viz rights of an inventor and patentee?
2. What are the benefits conferred upon the patentee?
3. What are the benefits conferred upon the society by patenting an invention?
4. What are the benefits conferred upon the government by patenting an invention?
5. Explain the phrase- "Patents--Balance of competing interests for the benefit of all"

6.9 Further readings

1. TRIPS Agreement.
2. Indian Patents Act, 1970
3. All the case laws mentioned above.

Unit 7
Procedure for Obtaining Patent, Opposition, Grant and Sealing

Objectives

The objective of this unit is to make you aware of the procedure for obtaining patent, opposition, grant and sealing. The unit would be dealing from the very initial step of filing an application for obtaining the patent, and then would also be telling you about the kind of oppositions which can be brought forward (pre-grant and post-grant) and finally about the granting of the patent followed by the seal.

Structure:

7.1 Introduction

After filing the application for the grant of patent, a request for examination is required to be made for examination of the application by the Indian Patent

Office. After the First Examination Report is issued, the Applicant is given an opportunity to meet the objections raised in the report. The Applicant has to comply with the requirements within 12 months from the issuance of the First Examination Report. If the requirements of the first examination report are not complied with within the prescribed period of 12 months, then the application is treated to have been abandoned by the applicant. After the removal of objections and compliance of requirements, the patent is granted and notified in the Patent Office Journal. The process of the grant of patent in India can also be understood from the following flow chart:

7.2 The Application

Filing an application is typically the first step towards procuring a patent in India. Indian practice follows the single inventive concept meaning that one application should be filed for each invention or inventive concept. A process and product for manufacturing that product is considered as one invention. However subsequent methods of using the product are treated as a separate invention.

The true and first inventor, his or her assignee and/or legal representative of any deceased person who immediately before his or her death was entitled to make such application can make the application for grant of patent for an invention in India. In the U.S. only individuals are eligible for filing an application, whereas the Courts in India have confirmed that a firm can apply for a patent as an assignee.

Ordinary Application

An application for patent without any claim for priority made under any convention and without reference to any other application is referred to as an ordinary application. Every ordinary application is required to be filed in duplicate in Form –1 with the concerned Patent Office. The territorial jurisdiction of the Patent Office is based upon whether any of the following falls within the territory of that Patent Office:

a. Place of residence, domicile or business of the applicant (or of the first mentioned applicant in case of joint applicants);
b. Place from where the invention actually originated; or

c. Address for service in India as given in the application when the applicant has no place of residence, domicile or business in India.

Every application is required to specify that the applicant is in possession of the invention and shall also state the name and address of the first and true inventor. A patent application must be accompanied by the following documents.

(a) Provisional or Complete Specification in Form 2 and drawings if any;
(b) Statement and Undertaking regarding foreign filing details in respect of the same or substantially same invention in Form 3;
(c) Declaration as to inventor ship in Form 5 (in case application is filed with the complete specification);
(d) Priority document (in case of convention application);
(e) Power of Attorney, if application is made through a patent agent; and
(f) Proof of right if the application is made by the assignee. Proof of right can be filed by way of separate assignment deed or by incorporating in the body of the application by endorsement in Form 1. In case the legal representative makes application, "death certificate" of the deceased would be treated as the proof of right.

The fee for filing the application (Rs. 1000/- for natural person and Rs. 4000/- for other than natural person) can be paid within one month of filing and the aforesaid proof of right can be filed within three months of the application. Further, the cost is also depended on the number of claims, priority dates and the number of pages of the complete specification.

International/PCT Application

An international application filed in accordance with the Patent Cooperation Treaty (PCT) is known as a PCT International application. A PCT international application designating India, if filed with the Controller of Patents in India within 31 months from its international date of filing, is referred as a PCT National Phase application and is treated as if the application were filed under the Act. The filing date of the national phase application shall be the international filing date accorded under the PCT. Every PCT national phase application shall be accompanied by a complete specification. The title, description, drawings, abstract and claims filed with the application are treated as the complete specification by the Patent Office. The time limit prescribed for entering into the national phase is thirty-one months

from the priority date, but an application could be examined or processed at any time before this time limit if an express request to the Patent Office is made. Usually, the Patent Office commences the processing and examination of the application only after the thirty-one month period has lapsed. Unlike U.S. and certain other countries, national phase entry cannot be postponed and the non-compliance of the requirements would cause the application to be treated as abandoned.

Convention Application

A convention country is any country which is a signatory or a party to an international or bi-lateral treaty or convention or arrangement to which India is a signatory or party whereby privileges granted to their citizens are likewise granted to Indian citizens. In order to claim convention status, an applicant should file the application in the Indian Patent Office within a period of twelve months from the date of filing a similar application in the convention country. The applicant will not be entitled to any benefit of provisions as no retrospective effect can be claimed for an application filed in a country before declaring it as a convention country. The convention application should include:

(a) A complete specification;

(b) Specify the date and the convention country in which the application was made; and

(c) State that no application for protection in respect of that invention has been made in a convention country before that date.

If two or more applications have been made with respect of inventions in more than one convention country, and the inventions are related to constitute one invention, one application may be made within a period of twelve months from the date on which the earlier or earliest of such applications was made. If any of the documents filed are in a foreign language, the Controller may request the translation of the document verified by affidavit or otherwise to his satisfaction.

Application for Addition

A Patent of Addition enables the applicant to apply for an improvement or modifications made on the invention disclosed in the complete specification. The

improvement must be something more than a mere workshop improvement. The term for a Patent of Addition shall not exceed the term of a regular patent, and shall not be granted prior to the date of grant of a patent for the main invention. A Patent of Addition cannot be questioned on the ground that the invention ought to have been the subject of an independent patent.

The complete specification for a Patent of Addition shall include specific reference to the number of the main patent or the application number of the main patent as the case may be. The applicant for a Patent of Addition must also make a statement to the effect that the invention comprises an improvement in or a modification of the invention claimed in the specification of the main patent granted or applied for.

Divisional Application

A divisional application is an application divided out of parent application. A divisional application is preferred when the applicant claims more than one invention and the law does not permit multiple patents in one invention. Applicants, at their own request, before the grant of patent, divide the application and file two or more applications as desired for the invention. The main objective of the divisional application is to meet the official objections raised by the Controller on the question of an application disclosing more than one invention. It is not clear as to whether the applicant may file a divisional from another divisional while maintaining the priority claim to the original application. The complete specification for a divisional application should not include any matter not disclosed in the complete specification of the first application.

Specification

A Specification is should accompany an application for patent. A patent specification is a technical and legal document susceptible to interpretation by court of law. The main function of a specification is to convey to the public what the patentee considers to be invention. The specification shall be filed in Form 2 and the Act facilitates the filing of provisional specification and awards a time span of twelve months to file complete specification.

Provisional Specification

The main objective of filing a provision specification is to obtain priority over any other person who is likely to apply for the same invention developed concurrently in any other part of the world. A provisional specification shall contain a description of the invention along with a title and is not replaced by the complete specification but is regarded as an independent document. A complete specification, not being a convention or PCT application, can be converted into a provisional application within twelve months from the date of filing of the application by the Controller upon request of the applicant.

Complete Specification

The main objective of complete specification is that it should enable a person skilled in the art to make the invention. The Manual on Patent Procedures, 2005 specifies that a complete specification should contain:

1. Title
2. Field of Invention
3. State of art in the field
4. Object of invention
5. Statement of Invention
6. Detailed description of the invention with reference to the drawings
7. Scope and ambit of the invention
8. Claims, and
9. Abstract

The specification must sufficiently and fairly describe the invention in a manner that allows one of skill in the art to practice the invention. A specification that fails to do so may render the patent invalid and may provide grounds for revoking the patent. The applicant has a duty to state things clearly and the language used in describing an invention depends upon the class of persons skilled in the art who may act upon and reply upon the specification.

The original filed specification must be complete because the statute prohibits amending the specification if it would lead to extension of the claims. If an amendment to the specification is made and admitted, then it is construed as part of the full specification

Claims

If the objective of the specification is to convey to the public what the invention is, the primary purpose of the claims is to state the extent of monopoly that the patentee is seeking. A claim is a statement of technical facts expressed in legal terms by defining the scope of the invention sought to be protected. The specification is usually followed by claims which should be succinct and clear and must relate to one invention. What is not claimed in the claims will be regarded as being disclaimed. Though there are no statutory limitations with regard to the number of claims, the claims in excess of ten are subject to additional fees. The principal claim or the first claim essentially defines the novel features of the invention whereas the optional features may be claimed through subsidiary claims. The subsidiary claims may include independent or dependent claims and each claim is evaluated on its own merit.

Duty to Disclose

A patent applicant in India has the duty to disclose information regarding corresponding applications filed in other countries. At the time of filing a patent application in India, the applicant must file a Form 3 under Section 8 of the Patents Act, 1970 dealing with the duty of the applicant to disclose the information.

The Applicant has the following obligations under Section 8:

(1) File Form 3 with information regarding corresponding applications at the time of filing the Indian application or within 6 months from the date of filing the application in India. This applies to PCT National Phase Applications as well;

(2) Undertake to keep the Controller of Patents informed of every other application filed outside India subsequent to the filing of the Indian application; and

(3) At any time during the prosecution of the application in India, if the Controller of Patents (read Examiner) requires, furnish details regarding the prosecution of corresponding applications in other countries.

The second and the third obligations are the trickiest and most difficult to comply with. In the event an applicant to fails to comply with these obligations, it can be a ground for opposition under Section 25 (h) of the Patents Act, 1970.

Often Examiners ask applicants to submit the search and examination reports of corresponding foreign applications. This can become an onerous task if the applicant has filed patent applications in numerous countries.

Foreign Filing License

A foreign filing license must be obtained from the Patent Controller if an Indian resident makes or even causes to make a foreign patent application without filing a corresponding Indian patent application 6 weeks prior to filing the foreign application. This provision does not apply to a patent application filed outside India by a person not resident in India.

The implication of the provisions on foreign filing licenses, which as per the Indian patents law is referred to as a 'written permit', is that when a first filing of a patent application is effected outside India by an assignee company resident in India or with inventors resident in India, a foreign filing license must be obtained. The expressions 'resident in India' and 'makes or causes to be made' make this provision extend to applications naming inventors resident in India. In practically terms, the Patent Office will make a determination of this based on the nationality of the inventors as well as the permanent residential address of the inventor as shown in the patent application. An assignee will be considered as resident in India if the applicant company has a registered office in India or a place of business.

The Controller issues a 'written permit' within 3 months from the date of filing Form 25. However, in the past the Patent Office has issued the permit as soon as within 48 hours of making a request.

The liabilities and penalties for not complying with the foreign filing license include:

(a) Refusing to grant a patent in India for the same invention (the invention in respect of which a foreign application was made without a foreign filing license or without filing a corresponding application 6 weeks prior to the filing of the foreign application);

(b) Fine\;and/or

(c) Imprisonment up to 2 years.

7.3 Filing of the Application

An application is usually filed at the appropriate Patent Office based on residence or principal place of business or from the place where the invention

originated. The applicant however can withdraw the application at any time after filing application but before the grant of a patent.

7.4 Publication

Upon receiving the application, the Patent Office accords the application an application number and applications corresponding to international applications designating India shall constitute a different series. All applications which have not been abandoned or withdrawn are published in the Patent Official Journal within 18 months from the date of filing or priority date, whichever is earlier. The applicant is permitted to request early publication from the Controller using Form 9. The public shall have access to the details of the application only from the date of publication. If the patent is for a biological material, the depository institution will make the biological material available to public.

The application shall not be published if a secrecy direction is given or if the application has been abandoned. The publication shall include the details such as the date of application, the application number, the name and address of the inventor and the abstract of the invention. Once the application is published, the applicant will be entitled to like privileges as that of the patentee from the date of publication except for the ability to institute infringement proceedings.

7.5 Request for Examination

The application shall be taken up for examination only when a request for the examination has been filed using Form 18.The request can be made by either the applicant or by any other interested person. A request for examination (RFE) can be filed by either the applicant or by interested person within a period of 48 months from the date of priority or date of filing, whichever is earlier.

The application is deemed to have been withdrawn on the non-submission of request for examination within the prescribed period. Usually, a RFE is filed along with the application for patent so as to accelerate the examination process. If the application was bound by any secrecy direction, the applicant can make a request for examination within 48 months from the date of application or from the

date of priority or within six months from the date of revocation of the secrecy direction, whichever is earlier.

7.6 Pre-grant Opposition/Representation

The Ayyangar Committee recommended the inclusion of both pre grant and post grant oppositions, but the Patents Act, 1970 when enacted contained only pre-grant (post-acceptance) opposition. The Patents Act, 1970 changed the *locus standi* of an opponent and mandated that the opponent must be an 'interested person'as against the 1911 Act that enabled 'any person' to file a notice of opposition to grant of patent. It is the Controller of Patents or the Court that ascertains whether an opponent is 'an interested person'. An opposition or representation shall be filed at appropriate office with a statement and evidence along with a request for hearing. The representation can be filed after the publication of the application under section 11A of the Act until the grant of patent. The opposition or representation shall be considered only along with the request of examination. Section 25 of the Act, elaborates on the grounds to oppose a patent application.

Wrongful Obtaining: A person can oppose a patent application or a patent if the applicant/patentee or the person under or through whom he claims has wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims. However, "obtained" does not necessarily mean fraud or misappropriation, rather the only rider attached with obtaining is "wrongful." Thus, if a person obtains the invention wrongfully, by whatsoever means, it will fall within the ambit of section 25(1) (a). In such a case, the Controller, may, on request made by the opponent in the prescribed manner, direct the application to proceed in the name of the opponent with the benefit of priority date attached to the application.

Prior Publication: A prior publication will be considered only if the invention as claimed has been published before the priority date of the claim in any specification filed in pursuance of an application for a patent made in India on or after January 1, 1912 or in India or elsewhere, in any of other document. However, the opposition under this ground will succeed only if the prior publication constitutes anticipation as envisaged under the Act itself.

Prior Claiming: Prior claiming occurs when invention claimed in any one claim of the complete specification has been published on or after the priority date of the applicant's claim. However, mere comprehension of the subject matter of a claim in the cited specification will not be considered prior claiming. The opponent has to establish that the subject matter of a claim in the applicant's specification forms the subject matter of a distinct claim in the cited specification.

Prior Public Knowledge or Public Use: If the invention so far as claimed in any claim of the complete specification was publicly known or publicly used in India before the priority date of that claim, the invention can be opposed on the ground of prior public knowledge or public use. An invention relating to a process shall be deemed to have been publicly known or publicly used in India before the priority date of the claim if the product made by that claim has already been imported into India for commercialization. However, secret use shall not be considered as prior public knowledge or public use within the meaning of this section.

Obviousness or Lack of Inventive Step: An application can also be opposed if the invention as claimed is *obvious and doesn't involve any inventive step* with reference to any document having the effect of anticipating the invention under sec. 25(1) (b). Inventive step has been further defined in sec. 2(1)(ja) of 1970 Act as a *feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.* Another important provision of the law that has a direct bearing on this ground of opposition is Section 3(d) of the Act. This Section is the most widely used to support patent oppositions in India. As an example, generic pharmaceutical companies rely on Section 3(d) r/w Section 2(1) (ja) to oppose pharmaceutical patent applications filed through the WTO Mail Box system.

Claim not a Patentable Invention: If an invention falls under a statutory excluded category (non-statutory subject matter), it will not be considered as an invention patentable under the Patents Act, 1970 and hence can be opposed

Invention not sufficiently and clearly described: If the complete specification doesn't sufficiently and clearly describe the invention or the methods by which it is to be performed, it can be opposed. The 'sufficiency' of description refers to enabling the best mode requirement as per section 10 of the Patents Act,

1970. It is pertinent to note that India's patents law mandate a 'best mode' requirement.

Failure to Disclose Information Regarding Foreign Application: This ground has recently provided the most common basis for filing patent oppositions in India. Section 8 of the Patents Act, 1970 makes it obligatory on the part of the applicant for a patent to submit details of all corresponding patent applications to the Controller of Patents. Further, the applicant is also under an obligation to keep the Controller informed of the status of such corresponding applications until the grant of the Indian patent. Such information must be submitted within 6 months from the date of attending to a prosecution step with respect of an overseas application. In other words, an applicant for a patent in India must submit information relating to developments in corresponding applications that are pending in all other countries within 6 months from the date of such a development.

Conventional Application Time-Barred: In the case of a convention application, if the application was not made within twelve months from the date of the first application for protection for the invention made in a convention country by the applicant or a person from whom he derives title, the application can be opposed.

Non-disclosure of Origin of Biological Material: A patent application can be opposed on the ground that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention.

Prior Knowledge in Local or Indigenous Community: The provision concerning mandatory disclosure of the source of biological materials in an Indian patent application was only recently adopted. If the invention claimed in a patent application relates to the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere, the patent application can be opposed.

7.7 Examination

After filing a request for examination, the application is taken up for examination and the Indian Patent Office follows a deferred examination system.

The application will be examined to check whether it complies with the requirement of the Act and whether there are any lawful grounds for objection to the grant of patent. A search is then conducted for prior publications and prior claims. The Indian Patent Office usually proceeds with the examination of an application in the following order:

1. Understanding the invention;
2. Assessment of patentability of the subject matter;
3. Assessment of sufficiency of disclosure;
4. Check for unity of invention;
5. Appraisal of Industrial Applicable;
6. Classification of the invention;
7. Determination of the priority of each claim;
8. Novelty search;
9. Determination of the inventive step; and
10. Judgment and validity of the claim.

Search and Investigation

The patent examiner is required to conduct a search for anticipation by previous publications and by prior claims. Chapter VI of the Patents Act, 1970, beginning with Section 29, lists the laws on anticipation/ and novelty and its exceptions. Novelty, according to the Indian practice, is judged according to an absolute novelty standard for both publications and public disclosures/use which includes "documents in foreign languages disclosed in any format in any country". In addition, India has a 12 month grace period for filing a patent application after a public display at an exhibition which is specifically approved by the government. As noted above, the exceptions to anticipation are similar to those in the U.S., except that there is no 12 month grace period for an inventor's publication and/or public use. The patent examiner on completion of the search and investigation is required to report to the Controller. But the examination and investigation alone does not warrant the validity of the patent.

First Examination Report

Upon receiving a request for examination (RFE), the Controller shall task an examiner with preparing a First Examination Report (FER). The examiner has to prepare the FER within about one month and not more than three months from the date of application. The Controller shall dispose of the examiner's report ordinarily within a month from the date of receipt. The FER, along with application and specification, shall be sent to the applicant within a period of six months from the date of request for examination or from the date of publication, whichever is later and an intimation of such examination is to be made to the 'interested person' if he or she had filed RFE.

Putting Application in Order for Grant

If certain objections are stated in the report of the examiner, the applicant has a time span of twelve months to put the application in order for grant. The applicant has the option of either amending the application or complete specification as the case may be or by raising arguments. If the applicant is not able to comply within the time stipulated, the application is deemed to have been abandoned.

7.8 Intimation for Grant

Once the application is put in order for grant, intimation to the effect that the application is found to be in order for grant subject to pre grant proceedings are sent to the patent applicant.

7.9 Grant

Upon meeting all of the requirements described above, the patent shall be granted as expeditiously as possible provided the Controller does not refuse the application by virtue of his or her inherent powers. The specification and other documents shall be open to the public for examination after the Controller has published the fact of grant. The patent shall be valid for a period of twenty years and the date of patent shall be the date of application. A patent certificate is usually issued within seven days from the date of grant.

7.10 Publication of Grant

After the grant of patent, the Controller shall publish the fact that patent has been granted and the application, specification and other documents shall be open for public inspection.

7.11 Post Grant Opposition

One of the substantive changes brought out by the Patents (Amendment) Act, 2005 is the Post Grant Opposition proceedings. With the introduction of Post Grant Opposition proceedings, India may be the only country which provides for both pre-grant opposition and post-grant opposition. The grounds for post-grant opposition are similar to those for pre-grant opposition. Only a person interested may give notice of opposition within one year from the date of publication of the grant. The notice of opposition shall be made in Form 7 and shall send to the Controller in duplicate. A post-grant opposition has more procedural nuances than a pre-grant opposition. Some of the steps are explained below.

Notice of Opposition & Written Statement: A Notice of Opposition can be made at any time after the grant of a patent but within one year of the date of publication of grant of a patent. It should be made in Form 7 and should be sent to the Controller of Patents in duplicate at the appropriate office. The Opponent is required to file a Written Statement and supporting evidence along with the Notice of Opposition.

Constitution of Opposition Board: The Controller, on receipt of the Notice of Opposition constitutes an Opposition Board. The Opposition Board consists of three members; of them one shall be nominated as the Chairman. The Examiner who examined the patent application shall not be member of the Board. Typically, the Controller appoints a Deputy Controller of Patents or an Assistant Controller of Patents as the Chairman of the Opposition Board and 2 Senior Examiners as its members.

Reply Statement and Evidence by Patentee: The Patentee, if he desires to contest the opposition, must submit with the Controller a Reply Statement and evidence in support of his case. This must be done within 2 months from the date of receipt of a copy of the Written Statement and the Opponent's evidence. A copy of the Reply Statement and evidence must be served on the Opponent.

Filling of Reply Evidence by Opponent: Within one month of receipt of Reply Statement and evidence, the Opponent can file further Reply Evidence strictly confined to the evidence relied on by the Patentee. The parties can file additional evidence, apart from those mentioned above after taking leave of the Controller. However, the Controller has discretion to grant or refuse the permission.

Hearing: The parties will get an opportunity to be heard by the Controller before a final decision is rendered. Generally, upon completion of the submission of evidence, the Controller notifies the parties of the date of hearing. The parties, if willing to be heard, have to inform the Controller by way of a notice along with the prescribed fee.

THE FOLLOWING TABLE HIGHLIGHTS THE PROCEDURAL DIFFERENCES BETWEEN PRE-GRANT AND POST-GRANT OPPOSITIONS.

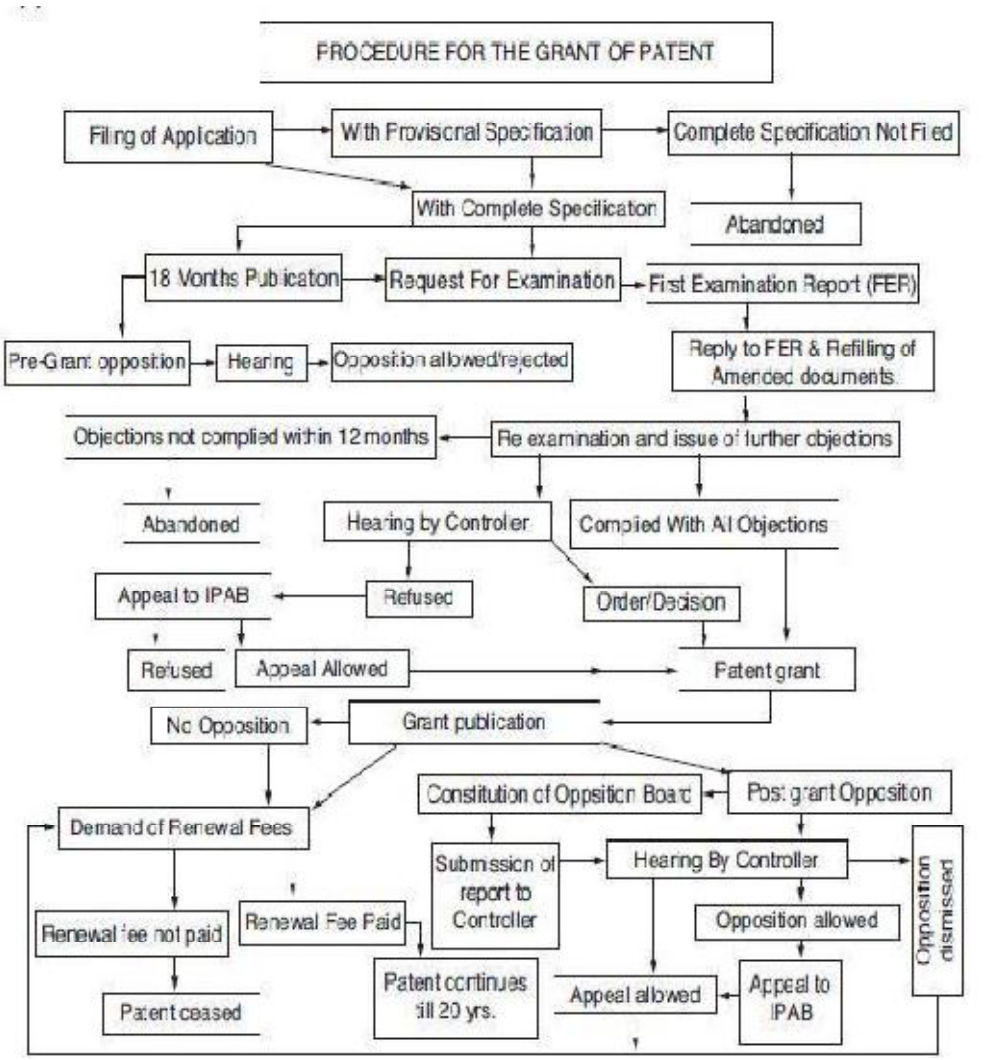
SL. No.	Issue	Pre Grant Opposition	Post Grant Opposition
1.	*Locus Standi*	Any person	Only person interested
2.	Opposition Board	Not constituted	Constituted
3.	Notice	Notice of Representation	Notice of opposition
4.	Examination of written statement and evidence	Done by controller	Done by Opposition Board
5.	Hearing	At the discretion of controller	At the discretion of parties
6.	Evidences	No reply evidence by opponent	Reply evidence by opponent
7.	Further evidence	No provision	With the leave of controller

In the near future, many provisions of the amended Indian patents law will come up for judicial scrutiny, including the provisions concerning opposition. Such scrutiny will bring greater clarity to the system.

7.12 Sealing

The applicant's claim to the patent is granted and sealed once the application is accepted, either without any opposition or after the applicant was adjudged the first inventor of the invention in an opposition. The date of the sealing of the patent is entered in the register maintained by the Patent Office.

7.13 Summary



7.14 Self-Assessment Test

1. Discuss the procedure for obtaining a patent.
2. Discuss the procedure for pre-grant opposition.
3. Discuss the procedure for post-grant opposition.
4. Show the whole process of obtaining a patent diagrammatically.
5. Mention the types of patent application and also explain each one of them.

7.15 Further Readings

1. Patents Act 1970
2. Patent Cooperation Treaty
3. TRIPS Agreement

Unit 8
The Role of Patent Office, Controller- Functions and Powers

Objectives

The Patent Office functions under the superintendence and control of the Controller General of Patents, Designs and Trade Marks (CGPDTM), Mumbai. The Office of CGPDTM is a sub-ordinate office under the Department of Industrial Policy and Promotion (DIPP), Ministry of Commerce & Industry, Government of India. The Patent Office discharges its statutory functions in accordance with the provisions of the Patents Act, 1970 (as amended) and corresponding Patents Rules, 2003 (as amended) and the Designs Act, 2000 and corresponding Designs Rules, 2001 (as amended), respectively.

Structure

8.1 Introduction

Grant of a patent confers upon the patentee, where the subject matter of the patent is 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, and where the subject matter of the patent is 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. Registration of a design confers upon the registered proprietor the exclusive right to apply a design to any article in any class in which the design is registered.

While patents can be granted by the Patent Office located at any location, i.e. Kolkata, Delhi, Chennai and Mumbai, only the Designs Wing of the Patent Office, Kolkata registers designs. Under the Patents Act, 1970, the statutory authority for grant of patents is the Controller General of Patents, Designs and Trade Marks (CGPDTM). CGPDTM also delegates his powers under the law to his subordinate officers e.g. Senior Joint Controller of Patents & Designs, Joint Controller of Patents & Designs, Deputy Controller of Patents & Designs, Assistant Controller of Patents & Designs (All Group 'A' officers).

The other statutory post under the Group A category is the Examiner of Patents & Designs. An Examiner examines patent and design applications and submits a report to the Controller. Examiners also assist the Controllers in all procedural, administrative and supervisory functions connected with various proceedings under the said Act and the Rules.

The Patent Office works from four locations viz. Delhi, Mumbai, Kolkata and Chennai. A patent application is required be filed in the appropriate office in accordance with rule 4 of the Patents Rules, 2003. Similarly, a design application can be filed at the Patent Office located at any of the above four locations.

Introduction of office automation and electronic processing of patent applications has resulted in a significant level of uniformity and transparency. Information, to the maximum possible extent, has been made available online to the public viz. information relating to patent applications, status of the applications, examination reports and other documents. Processing of a patent application is a multi-stage process, involving filing of an application, electronic

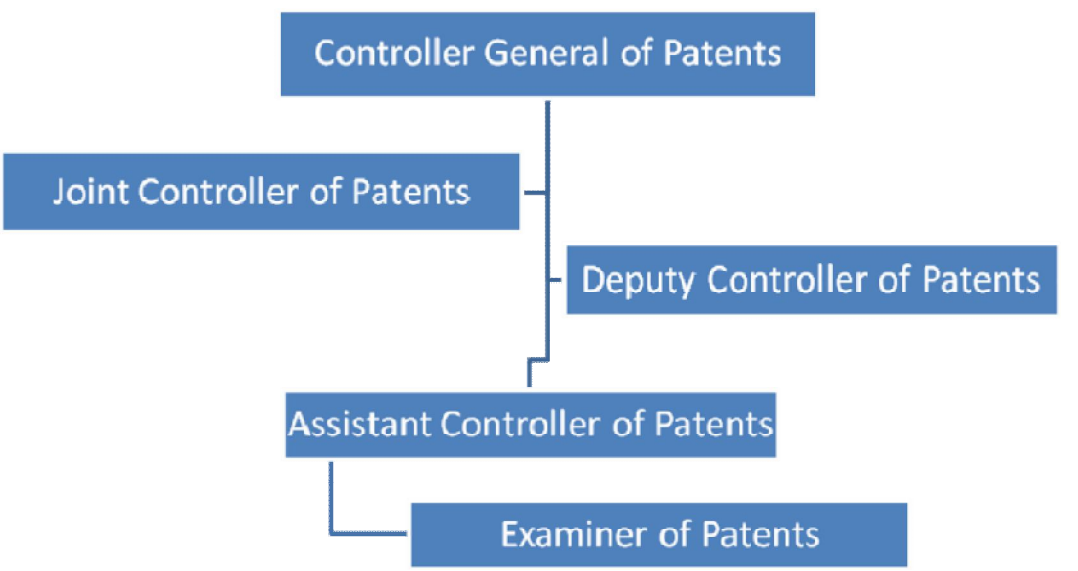
data processing, verification, screening and classification, publication, examination, pre-grant opposition, grant/refusal, etc.

The Official Journal of the Patent Office is published weekly on every Friday. The Journal contains the information mandated by the Act to be published. For Designs, such information is also published in the Official Journal. This office also has a website (www.ipindia.nic.in) which provides a comprehensive view of the organization and its activities. Patent Office also publishes an Annual Report which is placed before both Houses of the Parliament every year.

8.2 The Office of Controller of Patents

The Controller of Patents is the principal officer responsible for administering the patent system in India. The Controller is the overall supervisor of the four Patent Offices in Chennai, Delhi, Mumbai and Kolkata. Since the Controller also acts as the Registrar of Trademarks with the Head Office of Trade Marks in Mumbai the Controller of Patents functions from his office in Mumbai. Officially, the Head Office of Patents is in Kolkata (Calcutta) The Examiners of Patents appointed under the Patents Act and other officers of the Patent Office discharge their functions under the direction of the Controller. The hierarchy of the officers at the Patent Office is illustrated below:

8.3 Hierarchy of Officers in Patent Office



8.4 Powers of the Controller:

The Controller's powers, rights and duties include the following:

(a) To receive, acknowledge, accept, publish and examine a patent application, claim, description and specification, etc.

(b) to make search and investigate for anticipation by previous publication and by prior claim

(c) to consider the report of the examiners;

(d) to refuse application or require amended application, in certain cases

(e) to make orders respecting division of application

(f) to make orders respecting dating of applications

(g) to make orders regarding substitution of applicants

(h) to receive, hear and dispose of representation by way of opposition against the grant of patent

(i) to receive notice of opposition before the expiry of a period of one year from the date of publication of grant of a patent

(j) to constitute the Opposition Board to examine the notice of opposition and to submit recommendation to the Controller

(k) to consider the recommendation of the Opposition Board, hear the opponent and to make orders to maintain, amend or revoke the patent

(l) to order mention of inventors as such in patent provided the request or claim for such mention is made before the grant of patent

(m) to issue secrecy directions for prohibiting or restricting the publication of information with respect to the invention relevant for defence purposes as notified by the Central Government

(n) to revoke secrecy directions on being notified by the Central Government

(o) to issue written permit to a person resident in India to make an application outside India for the grant of a patent for an invention

(p) to grant patent

(q) upon grant, to publish the fact that the patent has been granted and the application, specification and other documents related thereto are open for public inspection

(r) to issue directions to the co-owners of a patent with regard to the sale or lease of the patent or any interest therein

(s) to grant patent for improvement or modification as a patent of addition

(t) to allow or refuse an application to amend an application for patent or specification or any documents related thereto

(u) to allow restoration of lapsed patent

(v) to receive, hear opposition in respect of application for surrender of patent and to order for revocation

(w) to carry out the directions of the Central Government in respect of grant of a patent for an invention relating to atomic energy

(x) to keep, control and manage the Register of Patents under the superintendence and directions of the Central Government

(y) to register assignments, transmission, mortgage, license or any other instruments creating an interest in a patent

(z) in any proceedings before him, to enjoy the rights and privileges of a civil court

(aa) to correct clerical errors, etc. in any patent or in any specification for a patent or any clerical error in any manner which is entered in the register

(bb) to receive evidence by way of affidavit or to take oral evidence and to allow any party to be cross examined on the contents of his affidavit

(cc) to grant compulsory licenses in respect of patented invention that has not worked in India or is not available to the public at a reasonably affordable price

(dd) to revoke the patent for non-working

(ee) to grant license for related patents

(ff) to grant compulsory license on the declaration of the Central Government of the circumstances of national emergency or of extreme urgency

(gg) to grant compulsory licenses for export of patented pharmaceutical products in certain exceptional circumstances

(hh) to appear and be heard in any proceedings before the Appellate Board in which the relief sought includes alteration or rectification of the register of patents or in which any question relating to the practice of patent office is raised or in any appeal to the Appellate Board from an order of the Controller

(ii) to maintain the register of patent agents

(jj) to remove the name of any from the register of patent agents

(kk) to refuse to deal with certain agents

(ll) to call for information from patentees as to the extent to which the patented invention has been commercially worked in India and/or other information related thereto

8.5 Intellectual Property Appellate Board

The Intellectual Property Appellate Board (IPAB) was established on September 15, 2003 by the Central Government under the provisions of section 83 of the Trade Marks Act, 1999. The Patents Act, 1970 (as amended in 2002) provided for designation of IPAB as the Appellate Board for the purposes of the Patents Act, 1970. The Ministry of Commerce and Industry, Government of India recently announced the appointment of a Technical Member on the IPAB effective as of April 2, 2007. The IPAB is headquartered in Chennai and also conducts hearings on rotation in Chennai, Delhi, Mumbai, Kolkata and Ahmadabad.

8.6 Powers and Jurisdiction of the Appellate Board:

As of April 2, 2007, the Appellate Board is empowered to receive, hear and dispose of all appeals from any order or decision of the Controller and all cases pertaining to the revocation of a patent, other than through a counter-claim in a suit for infringement. The Appellate Board may proceed with the matter either *de novo* or from the stage at which it was transferred on appeal. The jurisdiction to hear patent infringement cases continues with the High Courts.

8.7 The Powers and Duties of Patent Office's Officers and Employees

Group 'A' Gazetted

1. **Controller General of Patents, Designs, and Trade Marks (CGPDTM) -** The Controller General of Patents, Designs, and Trade Marks administers the laws relating to Patents, Designs, Trade Marks & Geographical Indications of Goods in India. CGPDTM heads the Patent Office, Trade Marks Registry, Geographical Indications Registry, the Patent Information System (PIS) & the Rajiv Gandhi National Institute of Intellectual Property Management (RGNIIPM).
2. **Senior Joint Controller of Patents & Designs**

3. **Joint Controller of Patents & Designs**
4. **Deputy Controller of Patents & Designs**
5. **Assistant Controller of Patents & Designs**

They have delegated powers to carry out the functions as 'Controller' under the Patents Act, 1970 (as amended).

6. **Examiner of Patents & Designs**- Examiners primarily examine each application under Section 12 of the Patents Act, 1970 (as amended) according to their field of specialization and report to the Controller about its patentability under the Patent Act, conducting search for anticipation under Section 13 of the Patents Act, 1970 (as amended), IPC classification of patent applications, preparation of detailed examination reports, consideration of observation/submissions and proposed amendments, can act as chairman/member of opposition board, assisting Controllers in opposition matters, administrative supervision of staff working under them etc.

7. **Hindi Officer-**To ensure accurate translation from English to Hindi and vice versa of various rules and regulations etc., and ensuring the implementation of the Official Language Policy of the Government of India and other instructions issued from time to time related thereto.

Group 'B' Gazetted

8. **Administrative Officer-**He is entrusted the responsibility for handling matters relating to establishment including maintenance of service records of officers and staff and looking after general administration and any other work assigned in this regard.

9. **Assistant Library and Information Officer**- He is the in-charge of Library and responsible for maintenance of books, records& journals. He also handles the work relating to procurement of books and supervises the Library & Information Assistant.

Group 'B' Non-Gazetted

10. **Office Superintendent-**An Office Superintendent looks after establishment, accounts and general sections of the office. Their duties include supervision of the work of Upper Division Clerks and Lower Division Clerks of their sections like maintenance of service records of officers and staff, preparations of all kind of bills, preparation of budget, pay bills, purchase land maintenance of records of stationery, purchase of furniture, promotions, recruitments, maintenance of rosters, preparations of confidential reports forms, housekeeping etc.

11. **Library and Information Assistant-**He is responsible for maintenance of books, records& journals and assists the Assistant Library & Information Officer.

12. **Stenographer Grade-I-**To take dictation from the officer in charge prepares notes during hearing and submits the typed documents.

13. **Junior Hindi Translator-**To carry out the translation works from Hindi to English and vice-versa.

Group 'C'

14. **Photography Assistant**- To carry out the work of photocopying of documents and day to day maintenance of machines.

15. **Stenographer Grade-II**- To take dictation from the officer in charge, take notes during hearing and submit the typed documents.

16. **Upper Division Clerk**- Upper Division Clerks are posted in different section like Technical Sections, Accounts, Administrations, and Records etc. Their duties include preparing salary bills, maintaining all type of bills, PF of employees and other clerical work and putting the case to their Section in charge.

17. **Lower Division Clerk**- Lower Division Clerks are posted in different section like Technical Sections, Accounts, Administrations, and Records etc. Their duties include preparing salary bills, maintaining all type of bills, PF of employees and other clerical work and putting the case to their superiors and section in charge.

18. **Hindi Typist**- To carry out the typing work of Hindi Section and report to Hindi Officer/Jr. Hindi Translator.

19. **Data Entry Operator**- To attend various typing and other data entry and processing related jobs, to attend any other work assigned to them by the Head of Office/Officers in this regard.

20. **Multi-Tasking Staff**- Physical maintenance of records of the Section, general cleanliness & upkeep of the Section/Unit, carrying of files & other papers within the building, photocopying, sending of FAX etc, other non-clerical work in the Section/Unit, assisting in routine office work like diary, dispatch etc. including on computer, delivering of dak (outside the building), watch & ward duties, opening and closing of rooms, cleaning of rooms, dusting of furniture etc., cleaning of building, fixtures etc, work related to his ITI qualifications, if exits, upkeep of parks, lawns, potted plants etc.

Note: Posts mentioned at Serial No. (2) to (20) may require to carry-out any other work assigned to them by the higher authority from time to time

8.8 The Procedure Followed In the Decision Making Process, Including Channels of Supervision and Accountability

Applications for patents are serially numbered and kept confidential till 18 months from the date of filing, unless requested by the applicants to the contrary, by way of early publication. The examination of the application is carried out pursuant to the filing of a request for examination and the examination report contains objections, if any, that are communicated to the applicant or his authorized agent. Replies to the objections, when filed, are re-examined according to the provisions of law. The applicants are to comply with the objections within twelve months from the date of first examination report. The applicants are given an opportunity to be heard in case of dispute for appropriate adjudication. The decisions of the Controller are appealable. After complying with the office objections, the patents are granted as certificates, registered and notified in the official journal of the Patent Office.

Patents are required to be renewed by paying renewal fees to keep them in force, failing which the patents are ceased. Necessary changes in the proprietorship of the patent in terms of licensing, assignment, if any should be registered. The Register of Patents can be seen online. A lapsed patent can be restored by making an application in the prescribed form along with fee and on subsequent payment of other fees.

Request for information

A person may request for specific information on patents under section 153 read with rule 134 along with prescribed fee, which is supplied to him accordingly.

Patent Cooperation Treaty

The office also has a PCT section which deals with PCT international applications for filing abroad by the nationals and acts as a receiving office for filing of PCT international applications.

International Searching Authority / International Preliminary Examining Authority

The Indian Patent Office is recognized as an International Searching Authority (ISA) and International Preliminary Examining Authority (IPEA) under the PCT and has started functioning as an ISA/IPEA with effect from 15th October 201

Patent Agents

The office also deals with the registration of Patent Agents. A degree holder in science/technology/ engineering from any Indian university or equivalent may apply to appear in an examination conducted by the office of CGPDTM and qualify to make themselves eligible for registration. These registered patent agents assist and deal with applications on behalf of the applicants before the Patent Office.

Decision making power

The final decision on an application for patent or design as to whether the applicant would be granted a patent or allowed to register the design resides with the Controller. Similarly, for any other proceedings under the Act in both Patents & Designs, the Controller is the ultimate authority to decide allow ability or otherwise of the same. An application for a patent or a design or any proceeding is routinely diarized with appropriate records of number and date and put up to the Examiner by the Support Staff with office notes stating the facts. The Examiner examines the documents under the provision of the law and gives his report to the Controller. The report of the Examiner is based on his findings after due process of examination as specified in the law. The Examiner acts as a techno-legal person for examination of patent applications. Depending on his findings in the investigation, the final fate of an application with respect to the grant of the patent is determined. However, the Controller is also under the obligation to offer the applicants an opportunity for hearing before taking any adverse decision or refusing any application under the law. His decisions are also appealable under the law. .

8.9 The Norms Set By It for Discharge of Its Functions

The Patent Office discharges the functions and duties in accordance with the Patents Act, 1970. The Government of India invested on infrastructure, both physical and manpower during the past decade, establishing a strong intellectual property regime in the country. Due to improved infrastructure by way of increased human resources in specialized fields and fully air-conditioned state of the art integrated building with computerized environment at each place for the office, the Patent Office is now better equipped to handle increased number of applications in both Patents as well as Designs.

Norms of Initial Processing of a Patent Application

On receipt of a patent application, the Patent Office accords a date and serial number to it through the central server. PCT national phase Applications and non-PCT Applications are identified by separate serial numbers.

Patent applications and other documents filed through offline mode are digitized, verified, screened, classified and uploaded to the internal server of the Office. The said application and the documents relate thereto are arranged in a file wrapper and the bibliographic sheet is prepared and pasted on the file cover, so that the files move on for storing in the compactors.

All patent applications are screened for: (a) International Patent Classification (IPC), (b) Technical field of invention for allocation to an Examiner in the respective field and (c) Relevance to defence or atomic energy.

Norms of Comprehensive e-Filing Services for Patents

Indian Patent Office has developed a comprehensive e-filing system for Patents, wherein, in addition to online filing of New Applications, subsequent filing shave also been integrated. Applicants can register themselves as users and own personal folders in the IPO's environment. New and enhanced features of comprehensive e-filing services include:

- Web based filing system.
- Dual way login (Digital Signature as well as Password based) and password re-generation procedure.
- Provision for filing of all entries as per Schedule 1 of the Patents Rules, 2003.
- Proper Validations with IPO Patent database.
- Facility to upgrade/update the digital signatures.
- User Profile.
- Improved procedures to minimize transaction errors.

Norms of Request for Examination

On receipt of a request for examination, the Patent Office accords a date and serial RQ number to it through the central server.

An application for a patent is not examined unless the applicant or any other interested person makes a request for examination. The request is to be filed in Form 18 with the fee as prescribed in First Schedule.

A request for examination has to be made within forty-eight months from the date of priority of the application or from the date of filing of the application, whichever is

earlier. If no such request for examination is filed within the prescribed time limit, the application shall be treated as withdrawn by the applicant.

In a case where secrecy direction has been issued under Section 35, the request for examination may be made within six months from the date of revocation of the secrecy direction, or within forty-eight months from the date of filing or priority, whichever is later.

The Office will not examine an application unless it is published and a request for examination is filed. When a request for examination is filed by an interested person other than the applicant, the Examination Report is sent to the applicant only, and intimation is given to the interested person.

Norms of Reference for Examination as per Chronological Order

Once a request for examination is received, and the application is published under section 11-A, the application is taken up for Examination in the chronological order of filing of request for examination.

The patent application is referred to an Examiner by the Controller for conducting the formal as well as substantive examination as per the subject matter of the invention vis-à-vis the area of specialization of the Examiner.

Norms of Specialization

At present, the Patent Office has four examination groups based on the broad area of specialization viz.:

- Group 1: Chemistry and allied subjects.
- Group 2: Biotechnology, Microbiology and allied subjects.
- Group 3: Electrical, Electronics & related subject
- Group 4: Mechanical and other subjects.

On an application being referred to him by the Controller, the Examiner makes a report on the patentability as well as other matters to the Controller ordinarily within one month but not exceeding three months from the date of such reference.

Norms of Hearing

The applicant is required to comply with all the requirements imposed upon him by the Act as communicated through the FER (First Examination Report) or subsequent communication, at the earliest. However, if applicant fails to respond to the FER within twelve months from the date of issuance of the FER, the application is deemed

to have been abandoned under Section 21(1). A communication to that effect is sent to the applicant for information.

If the response/amendment filed by the applicant does not satisfy the requirements laid down by the Act, the Controller offers the applicant an opportunity of hearing in compliance of the Principles of Natural Justice and decides the case on merits.

Norms of Common Patent Number

The Patent is granted as expeditiously as possible when the application has not been refused by the Controller by virtue of any power vested in him by this Act, and the application has not been found to be in contravention of any of the provisions of the Act.

On the grant of patent, every patent is allotted a serial number through the electronic system on an all-India basis. A Certificate of Patent is generated in the prescribed format and an entry in the e-register is made simultaneously. In the present electronic system, the date of recordable of the patent in the Register of Patents is the same as the date of grant of the patent by the Controller.

Norms of Transparency and Uniformity

(i) Public Search Engine for Patent (IPAIRS Version 2.0)

The current version of search engine is basically a structured search i.e. interface providing pre-defined Indexed fields for searching in the database. This version has been improved over previous so as to provide:

- Increased no. of fields
- Combination of Search fields
- Inclusion of operators
- Distinct (non-repetitive) results
- Detailed information of Patents (01/01/1995 onwards)

(ii) Dynamic Utility

In order to enhance the transparency in the patent granting process, dynamic utilities have been launched to allow the public to see, on real time basis, the detail of:

(a) Expired patents.

- Patents that have expired, i.e. the 20 years term is over.
- Patents which have ceased to have effect by reason of failure to pay the renewal fee.

- Patents, according to their Number, Title & Technical/Scientific field, which have expired or have ceased to have effect by reason of failure to pay the renewal fee.

(b) Disposal of Patent application.

(c) RQ status of issued FERs.

(d) Dynamic FER view (jurisdiction and group-wise).

(e) Information u/s 146 (working of patents).

(f) Dynamic status of Patent applications as per the field of invention.

(iii) Indian Design Information Retrieval System

A search system has been developed for the public on the official website of the IPO (www.ipindia.nic.in) for retrieving the information about design applications.

(iv) Manuals and Guidelines

In order to establish uniform and consistent practice in the patent granting procedure, the Patent Office has issued:

(a) Manual of Patent Office Practice and Procedure.

(b) Guidelines for Examination of Biotechnology Applications for Patent.

(c) Guidelines for processing of Patent Applications relating to Traditional Knowledge and Biological Material.

Norms of Quality Management System (QMS)

The Patent Office has access to a comprehensive collection of patent and non-patent literature that covers the PCT minimum documentation. An Integrated Search platform (IPATS) is being developed to enable one click search through the vast collection of information. Professionally qualified and skilled Examiners are the assets of the Patent Office. IPO has established a Quality Management System (QMS) covering technical and administrative tasks of the office. Fully electronic processing system ensures speedy disposal and dissemination of information on real time basis.

The Indian Patent Office has identified the following yardsticks for determining the quality of our products and services:

- Reliability of our search reports,
- Consistency in our examination reports,
- Timeliness in delivering services,
- Correctness of data while providing patent information
- Real time dissemination of information
- Stakeholder satisfaction encouraging feedbacks and being responsive and
- Continuous improvement.

8.10 Summary

The Office of the Controller General of Patents & Designs administers the Patent Act, 1970 and the Rules made there under. Any reference to the "Central Government" in the Act or the Rules refers to the Government of India, typically represented by the Secretary, the Department of Commerce & Industry. The Office of the Controller General of Patents & Designs is also responsible for the administration of Trademarks and Geographical Indications. The Ministry of Industrial Policy & Promotion, through the Joint Secretary, has administrative and supervisory control over the office of the Controller General of Patents, Designs, Trade Marks and Geographical Indications. For the purposes of the Patents Act, 1970 and the Rules, the Controller General acts as the Controller of Patents. Further, the Act also provides for an Appellate Board to entertain and admit appeals arising out of the orders of the Controller of Patents and to exercise jurisdiction with respect to proceedings to revoke a patent other than through a counterclaim in a suit for infringement. An Intellectual Property Appellate Board (IPAB) was established under section 83 of the Trade Marks Act, 1999 to act as the Appellate Board for the purposes of the Patents Act, 1970.

8.11 Self-Assessment Test

1. Explain the hierarchy of Officers in Patent Office,
2. What are the powers of the Controller?
3. What are the powers and Jurisdiction of the Appellate Board?
4. What are the Powers and Duties of Patent Office's Officers and Employees?
5. What is the Procedure Followed in the Decision Making Process, Including Channels of Supervision and Accountability?

8.12 Further Readings

1. Patents Act, 1970
2. IPAIRS Version 2.0
3. Patent Rules, 2003
4. Designs Act, 2000
5. Designs Rules, 2001

Unit 9
Patents: The Working of Patent, Infringement and Remedies

Objectives

Intellectual property assets are touted as the cornerstone of competitiveness in international trade and are the driving factors behind socio-economic development in India. However, it is of prime importance that strong
IP laws be framed and complemented by an equally strong and substantive
Enforcement mechanism. This unit looks at the enforcement mechanism in
Place regarding Patent infringement in India.

The intellectual property system plays a pivotal role in framing industrial, trade and financial policies, for scientific and technological development of any country. The infringement of intellectual property rights (IPR) has become a bane and is a major hindrance for India's economic development. It is of prime importance that strong IP laws be framed and complemented by an equally strong and substantive enforcement mechanism. It is imperative to have strong and equitable IP enforcement because it gives impetus to innovation, encourages innovative technologies and provides financial incentives to the owners.

Structure

9.1 Introduction

The Patent Act of 1970 (IPA) provides for the enforcement of patents by way of suits for infringement. Post-WTO TRIPS Agreement, various methods have, however, been adopted by legislators in India to improve patent enforcement measures. The TRIPS Agreement has introduced several domestic enforcement mechanisms in an attempt to overcome the shortcomings of pre-existing international IP laws. The 2005 Amendment of the IPA was a significant breakthrough as it marked the beginning of a product patent regime in chemicals, food and drugs, and also some of the notable patent litigation between innovator companies and the Indian generic drug industry.

Before delving into the enforcement measures, it is pertinent to discuss activities amounting to infringement, the provision in the statute that exempts certain activities from infringement liability and the defences available in case of an infringement suit.

9.2 Infringing Activities

The IPA does not specifically define activities that constitute infringement of patent rights. Section 48, however, confers exclusive rights upon the patentee to exclude third parties from making, importing, using, offering for sale or selling the patented invention. It can therefore be concluded that violation of aforementioned monopoly rights would constitute infringement of a patent.

9.3 Non-Infringing Activities

Government Use

An invention can be used any time after the application for a patent is filed, or after the patent is granted by the 'Central Government' and by 'any person authorized by it'. The patented product may be imported or made by or on behalf of the government. Similarly, the patented process may be used by or on behalf of the government for its own use.

Research Exemption

Any person may use or make the patented invention merely for the purposes of experiment or research including and imparting instructions to students.

Supply of Patented Drugs to Health Institutions

A patented invention in respect of any medicine or drug may be imported by the Government for the purpose merely of its own use or for distributing in any dispensary, hospital or medical institution maintained by or on behalf of the government.

Use of Patented Invention on Foreign Vessels

Patent rights are not considered to be infringed where the foreign vessel/aircraft/land vehicle temporarily or accidentally comes to India and uses the invention in the body of the vessel/in machinery/tackle/apparatus/in its construction or working. However, this provision is applicable only to the foreign vessel/aircraft/land vehicle of those foreign countries that provides reciprocity to Indian vessel/aircraft/land vehicle.

The Bolar Exemption

The patented invention may be used, constructed, made, sold or imported for the reasons solely related to the development and submission of information to the regulatory authority of India or elsewhere. This provision particularly helps generic companies as they can use the patented drug for carrying out their bioequivalent studies and submit the result to the regulatory agencies for getting marketing approval. This would ultimately aid them in entering the market as soon as the product patent has expired.

Importation of Patented Products

Importation of patented products by any person from a person (who is duly authorized under the law to produce and sell or distribute the product) will not be considered as an infringement of patent rights.

9.4 Jurisdiction

A patent holder can file a suit for infringement in the District Court or High Court. However where counter-claims for revocation of the patent is made by the defendant, the suit along with the counterclaims are transferred to the High Court for a decision on the validity of the patent.

The IPA, however, is silent as to which courts will have the jurisdiction to hear the case. According to s 19 of the Civil Procedure Code 1908, the patentee can bring the suit for infringement in the court which has jurisdiction in the area where he/she resides or carries on a business or personally works for gain. The patentee can also bring the suit for infringement in a court which has jurisdiction in the area where the infringing activity took place.

The flip-side of the above provision is that there are more than 600 District Courts in India which virtually enables the patentee to do the any kind of *forum shopping*. Invariably, in an infringement case, the defendant would also challenge the validity of the patent which would lead to a transfer of the case to the High Court. Therefore, to avoid any delay, it is better to file the case in the High Court only. It is worth also noting that the suit for infringement can only be brought once the patent has been granted. However, if the court decides in favour of the patentee then he/she can claim damages for the infringement that was committed between the date of publication of the patent application and its grant.

The suit for infringement can also be initiated by the licensee. The licensee may call upon the patentee to initiate proceedings to prevent infringement of the patent. If the patentee does not take any action within two months, the licensee can institute proceedings for infringement in his/her own name.

The Indian Limitation Act governs the period of limitation for bringing a suit for infringement of a patent, which is three years from the date of infringement. Therefore, it is pertinent to note that the limitation period for the suit runs from the date of infringing act and not from the date of grant.

Another point worth noting is that if the patent has ceased to have an effect due to non-payment of the renewal fee, then the patentee will not be entitled to institute the proceedings for the infringement committed between the date on which patent ceased to have an effect and the date of publication of the application for restoration of the patent.

9.5 Burden of Proof

Where there is an alleged infringement of a patented invention that is in the form of a product, the burden of establishing that an infringement has occurred lies on the patentee. However, in the case of a process patent, the burden may shift to the defendant/infringer provided the patentee is able to prove to the court that through reasonable efforts he/she has not been able to determine the process which has been used by the defendant.

9.6 The Legal Interface of IPR

It is worth noting that all the IPR laws (excluding patent and designs laws) provide penal provisions to prevent infringement.

Administrative Remedy

If and when infringing goods are imported into Indian Territory, the IP owner can approach the Collector of Customs and prevent the entry of these goods into the Indian market. The IP owner must provide the name of the exporter, consignee, port of entry, name of the ship, etc to avail him/herself of this remedy.

Civil Remedy

To claim damages, the IP owner will have to pay a court fee on the damages claimed. The Chartered High Courts in India, namely, Bombay, Madras Calcutta and Delhi have different and liberal laws for the computation of the court fee.

The courts in India grant two types of injunctions.

A. Interim Injunctions

Interim injunctions are granted during the pendency of the case even before a full-fledged trial. This relief is granted by a summary procedure based on the admitted facts and by establishing:

1. a *prima facie* case where the burden of proof lies on the patentee to establish the patent violation. There are more chances of proving the *prima facie* case if the patent is sufficiently old; and
2. a balance of convenience in favour of the plaintiff as per the doctrine of relative hardships. The plaintiff would suffer irreparable loss if his/her prayer for a temporary injunction is not allowed.

Usually, in patent infringement cases, an interim injunction is not normally granted before a full-fledged trial. It is a kind of norm that whenever the patentee files a suit for infringement, the defendant/infringer counter-claims for invalidity. For example, in the case of *Novartis AG v Mehar Pharma* 2005 PTC 160 (para 28), as soon as the defendant counter-claims for invalidity it becomes difficult for the patentee to establish a *prima facie* case as a result of which the court does not grant any injunction against the defendant.

Under Indian law, there is no presumption of the validity of a recent patent. In the case of patents older than five years, the court may presume the validity of a patent. However, in the case of patents where a Certificate of Validity has been granted under s 130 of the IPA either by the High Court or by the Intellectual Property Appellate Board (IPAB), then the patentee can demand an interim injunction.

B. Permanent Injunctions

Permanent injunctions are granted after a full-fledged trial. In the event that the court concludes, after a full-fledged trial, that the plaintiff had unjustly obtained an interim injunction before trial, then the Court will direct the plaintiff to compensate the defendant for the losses that the defendant had suffered due to the subsistence of the injunction prior to the trial.

Relief of Delivery Up

Shortly after the initiation of a case, Indian courts usually grant an interim order for the preservation of suit properties to ensure that the available evidence is not destroyed by the infringer. Order XXXIX rule 7 of Civil Procedure Code empowers Indian courts to appoint a Commissioner to visit the defendant's premises and take inventory of the infringing articles that are present in the defendant's premises. Such orders are normally granted without notice to the infringer; this provision is similar to Anton Piller orders granted by English courts. The Commissioner will give notice of the inspection to the defendant just prior to the commencement of the search by the Commissioner.

Criminal Remedy

The Indian Penal Code provides for penal remedies against infringement of IPR. Criminal sanctions are warranted to ensure sufficient punishment and deterrence of wrongful activity. Criminal remedies against infringement of various forms of IPR are as follows:

- the filing of a criminal complaint before the chief judicial magistrate/chief metropolitan magistrate of the relevant jurisdiction;
- leading evidence with respect to infringement;
- the filing of application u/s 91/93 of the Criminal Procedure Code for the issue of search and seizure warrants;
- orders/directions issued by the court to the police for the search and seizure of infringing material or alternatively, a direction by the court to the police for investigation by lodging a First Information Report (FIR) and search and seizure under s 156 of the Criminal Procedure Code 1973; and
- the filing of a complaint/FIR with the police.

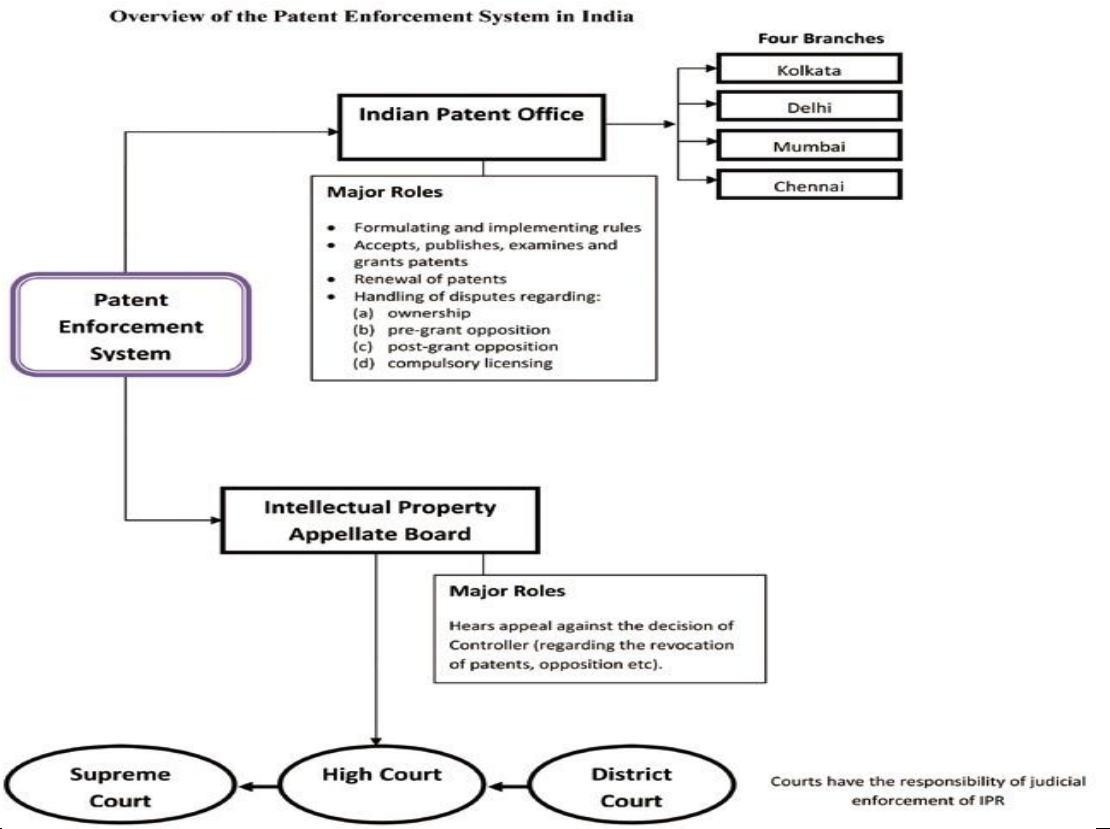
9.7 Remedies

The remedy that a court may grant in any suit for infringement includes an injunction and at the option of plaintiff, either damages or an account of profits. The court may also order that the goods which are found to be infringing and materials and implements the predominant use of which is in the creation of infringing goods shall be seized, forfeited or destroyed.

However damages or account of profits shall not be granted against the defendant who proves that at the date of infringement he or she was not aware and had no reasonable grounds for believing that the patent existed. It further provides that a person shall not be deemed to have been aware or to have had reasonable grounds for believing that a patent exists by reason of application to an article of words 'patent' or 'patented' or any other words implying that the article is patented unless the number of patent accompanies the word or words in question.

Further, if in an infringement proceeding it is found that any claim of the specification, being a claim in respect of which infringement is alleged, is valid, but that any other claim is invalid, the court may grant relief in respect of any valid claim which is infringed provided that the court shall not grant relief except by way of injunction (and not in the form of damages or account of profit.) However, if the plaintiff proves that the invalid claims were framed in good faith and with reasonable skills and knowledge then the court may, subject to its discretion, grant relief in the form of damages or account of profit.

The Indian judicial system has not provided for the constitution of Special Courts for hearing patent infringement matters. Hence, the Presiding Officers may not have expertise to pronounce on complicated questions involving state of the art technology. In such cases, the Patents Act provides for appointment of Scientific Advisors who will advise the court on questions of fact or give an opinion on technology that does not involve interpretation of laws. Unlike an expert who will have to be paid for by the parties calling the expert, the Scientific Advisor will be paid from the Consolidated Funds of India.



9.8 Parallel Proceedings

The IPA does not provide for provisions dealing with parallel proceedings. If a person has filed a petition for revocation of a patent in IPAB and then starts selling the (said patented) product in the market without patentee's permission, and the patentee sues for infringement in the High Court, the person can then defend him/herself by using a counter-claim for invalidity. The two cases would be pending – one in IPAB to determine

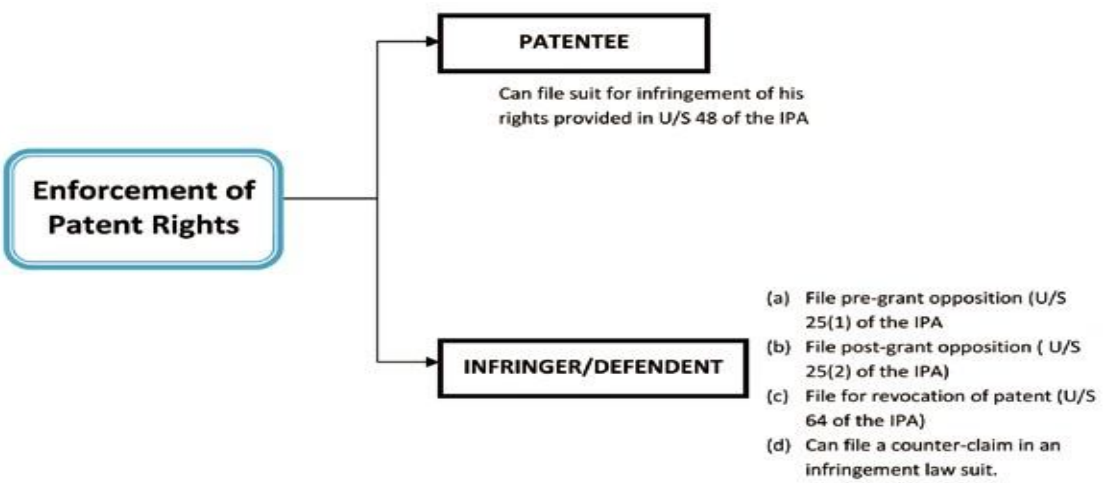
whether the patent is invalid and the other in the High Court where the case of both invalidity and infringement will be examined. The High Court may stay infringement proceedings until the final decision is reached by IPAB; however, it is totally at the discretion of the High Court.

9.9 Relief in Case of Groundless Threats of Infringement

Where any person (whether entitled to or interested in a patent or an application for patent or not) threatens another person with proceedings for infringement of a patent, the person aggrieved may bring a suit against him/her for the following relief:

1. a declaration that the threats are unjustifiable;
2. an injunction against the continuance of such threats; and
3. such damages as he/her has sustained thereby.

For the grant of an injunction, the burden of proof lies on the plaintiff to show that a *prima facie* case has been made out. IPAB is an administrative body that has the appellate jurisdiction over the decision of the Controller of Patents. However, IPAB has no statutory powers to trial infringement proceedings. Subject to s 117G of the IPA, all cases that are related to decisions or orders of the Controller which are pending in the High Court must be transferred to IPAB. When Novartis appealed against the decision of the Controller denying the grant of the patent covering a new form (beta crystalline form of imatinib mesylate) of the known drug imatinib mesylate in the High Court, the case was transferred to IPAB. In fact, it was the first case in India that was transferred from the High Court to the IPAB.



9.10 Detecting Patent Infringement

Determining patent infringement is very crucial for a company. A company may hold patents and may have products and/or processes in the market which may be protected by these patents. However, patenting an invention or a product is not the last stop. To reap complete benefits of patent system, these patents should be enforced by the company. Thus, the company should make sure that competitor s products and/or processes are not infringing on their patents and are not damaging the company s revenues, market share, and market position. The company should also make sure that none of its products and/or processes is infringing patents granted to others. This is important because, in one scenario the company may have a product and/or a process in the market which has breakthrough invention at its core and generates a significant amount of revenues for the company. However, if that product infringes on some patents, then the company may end up incurring significant financial losses in the litigation process due to the infringement.

Therefore, it is always advisable to keep a tab on competitor s patents and products. A direct way to determine patent infringement is to keep a market-watch for all products released in the market by a company in a technology domain, especially for competitors. All these products can then be closely examined to determine what features of these products read onto the inventions patented by the company. To facilitate this, the company can avail some patent analytic services to create a patent portfolio for the company, especially, if the company has a huge number of patents across various technological domains.

Secondly, the company should keep an eye on all the published patent applications of its potential competitors. This can be done by doing a patent-watch in the technology area and for the competitors to analyze patenting activity in the last 3-4 year. The portfolios generated using patent-watch help in anticipating the product that a competitor may be launching. A comparison with the company s patent portfolio may establish that some of these anticipated products may infringe on one or more of its patents. This gives an early idea about competitor s moves and helps the company prepare in advance to take further appropriate action. For example, to save litigation costs, the company may try to invalidate/oppose the patent/patent publication before hand, so that the competitor never launches the product in question.

9.11 Steps to Establish Infringement

Having detected that one of the patents of the company might be infringed by a competitor s product or process; a detailed analysis should be performed to establish patent infringement (special patent analytic service can be used for the same). The product or the process need not infringe all claims of a granted patent; in fact it is merely enough even if the product or process in question is found to infringe even a single claim of the granted patent. To perform this analysis, a complete description of all products or processes of a competitor, which will include all product brochures or promotional materials, web site pages, instructions or directions for use, advertisements, and product packaging, should be compared with patents that are being infringed. The infringement analysis may be depicted in the form of a claim chart, which highlights the features, of a competitor s product or process that read onto one or more claims of the patents granted to the company.

The usual strategy of a defendant will be to try to invalidate the patent in question and if the defendant succeeds in invalidating the patent, then the litigation suit will have to be withdrawn. Therefore, before filing a patent infringement suit, it is very essential to get an invalidation search conducted for the patents to evaluate the strength of the patents. It is advisable to establish validity of the patents before filing a patent infringement suit against a competitor, because, if a competitor succeeds in invalidating the patents in question, the company may incur significant legal costs and also market prestige, position, and market share will be at stake.

9.12 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 wilful 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.

9.13 Patent Infringement Disputes in India

Patent infringement disputes in India starts with a suit that a plaintiff files in the District Court, which is followed by a reply to the suit by the defendant. Subsequently, a hearing is held as per the Patent Rules 2003 in the District Court, taking into consideration evidences, scientific expert s testimony, statements of the witness etc. After considering the defences put by defendants the District Court decides the dispute and award the damages or prescribe the penalties, provided the infringement is found. If any of the plaintiff and the defendant are not satisfied, they can approach the High Court under Article 226/227 and further to the Supreme Court under Article 32,133,136,or 142.

In India only High Courts have the power to deal with matter of both infringement and invalidity simultaneously. A specialized forum is now been established as the Intellectual Property Appellate Board (IPAB). Provisions related to IPAB were introduced into the Act in 2002 and are enforced now. Also, all pending appeals from Indian High Courts under the Patents Act were to be transferred to the IPAB from April 2, 2007. The IPAB has its headquarters at Chennai and has sittings at Chennai, Mumbai, Delhi, Kolkata and Ahmadabad. The IPAB is the sole authority to exercise the powers and adjudicate proceedings arising from an appeal against an order or decision.

Also, all the cases pertaining to revocation of patent other than a counter-claim in a suit for infringement and rectification of register pending before the Indian High Court shall be transferred to the IPAB. In case of a counter-claim in a suit for infringement, the Indian High Court continues to be the competent authority to adjudicate on the matter. The IPAB also has exclusive jurisdiction on matters related to revocation of patent and rectification of register. The IPAB in its sole discretion may either proceed with the appeals afresh or from the stage where the proceedings were transferred to it.

9.14 Patent Claim Infringement

As described above, patent infringement may occur where the defendant has made, used, sold, or imported in India any invention that has been patented in India.

In India, no infringement action may be started until a patent has been granted. This right to obtain provisional damages requires a patent holder to show the following:

(1) The infringing activities occurred after the patent application was published;
(2) The patented claims are substantially identical to features of the process or the product infringing the patent; and
(3) The infringer had actual notice of the published patent application.
The Supreme Court of India has laid down the following guidelines to determine infringement of a patent, based on Biswanath Prasad Radhey Shyam v. Hindustan Metal Industries:
(1) Read the description and then the claims;
(2) Find out what is the prior art;
(3) What is the improvement over the prior art;
(4) List the broad features of the improvement;
(5) Compare the said broad features with the defendant s process or apparatus; and
(6) If the defendant s process or apparatus is either identical or comes within the scope of the plaintiff s process or apparatus, there is an infringement.

9.15 Injunction

Injunction is as an equitable remedy in the form of a court order, whereby a party is required to do, or to refrain from doing, certain acts. An injunction may be preliminary or permanent. A preliminary injunction is a provisional remedy granted to restrain activity of a defendant on a temporary basis until the Court can make a final decision after trial and a permanent injunction is one which is granted after the trial. Preliminary (temporary or interim) injunction and permanent injunction are provided under Order 39, Rule 1-2 of Code of Civil Procedure, 1908.
For the court to order an injunction, the plaintiff has to fulfil the following criteria:
(1) Establish his case only at a prima facie level, i.e., the plaintiff has to show that he has some possibility of success and that his claim is not vexatious;
(2) Demonstrate irreparable injury if a temporary injunction is not granted; and
(3) Demonstrate that the balance of convenience is in favour of the plaintiff (i.e. the plaintiff will be more disadvantaged because of the non-grant of the injunction that the defendant will be disadvantaged because of the grant of one).
Permanent injunction is granted only after the trial when the Court concludes that the defendants' product infringes the plaintiff's patent. In Dhanpat Seth & Others (plaintiffs/ patentee) Vs. Nil Kamal Plastic Crates Ltd (Defendants); the plaintiffs

solicited grant of permanent injunction restraining the defendant from infringing Indian Patent No. 195917, granted in their favour on July 11, 2005. As the case progressed the defendants successfully proved to the Court that the Kilta (patented article of the plaintiffs) is a mere imitation of traditional Kilta made by bamboos and has been in use since times immemorial. As a result, the Court not only rejected the plaintiffs request for permanent injunction but also revoked that granted Indian Patent No. 195917. Thus, the plaintiff was not able to establish the case at a prima facie level, as the patent in question was revoked.

9.16 Procedure Followed By Judges in Patent Infringement Cases in India

In India judges of District Courts, High Courts and Supreme Court deal with patent infringement cases. Described below are general methods used by Indian judges in deciding such type of cases:

METHODS ON JUDICIAL PROCEDURE

(1) Concerned parties, plaintiff and defendant, are notified in advance of the judicial rights and the judicial obligations they shall comply with during lawsuits.

(2) The parties are required to exchange the evidence before the trial begins. When the plaintiff accuses the defendant of infringement, the plaintiff is responsible for providing the proof. During trial, parties concerned are required to verify and cross-examine disputed facts and evidences. If the defendant is accused of infringing a process patent, then reversal of burden of proof is implemented. In other words, the party who is accused of infringement is responsible for providing evidences for the manufacture process of such product.

(3) Either of the plaintiff and the defendant may appeal to the Appellate board against the decision of the Controller and other matters within three months from the date of the decision.

(4) The plaintiff should bring the suit in the court within three years from the date of infringement (which is called the limitation period). The limitation period for the suit starts from the date of infringing act and not from the date of the grant of the patent. The limitation period is defined by the Section 40 of the Indian Limitations Act,

(5) Section 77 of the Patents Act, 1970 confers powers of a Civil Court on the Controller in following matters:

a. The Controller can summon and enforce the attendance of any person and examine him on oath;

b. Every party is entitled to know the nature of his opponent s case. The Controller can direct and obtain the documents from plaintiff for handing it to defendant or vice versa;

c. The Controller can receive evidence on affidavits from the plaintiff or defendant;

d. During the proceeding of suit some people are exempted from appearing in person. In such circumstances, the Controller is empowered to issue Commissions for the examination of witnesses or documents;

e. The Controller can award costs which are reasonable with regard to all the circumstances of the case;

f. The Controller can be requested to review his decision. This can be done by filling form 24 along with prescribed fee within one month from the date of decision;

g. The Controller can set aside an order passed in absence of any party at the hearing. However, the affected party should make a request to set aside an order. This can be done by filing form 24 along with the prescribed fee within one month from the date of communication; and

h. The Controller also has the power of taking oral evidence. He may also allow any party to be cross-examined on the contents of his affidavit. The Controller may also accept documentary evidence unaccompanied by an affidavit.

9.17 Facts Finding and Application of Substantive Law

(1) To make conclusions for infringement actions against patents, the courts generally adopt the following steps:

a. The protection scope of patent right are determined;

b. Relevant technical characteristics of products which are accused of infringing the patent is determined; and

c. The essential technical characteristics of the claims of the patent and that of the products accused of infringement are compared.

(2) The Courts may apply the Estoppel Principle in patent litigation. In other words, during prosecution, the contents abandoned by the patentee can no longer be used against the party accused of infringement.

(3) To calculate the amount of compensation for losses due to patent infringement, the court uses following methods:

a. The actual economic loss incurred to the patentee due to infringement is considered as the amount of compensation against such a loss;

b. The total profit obtained by the infringer through infringement is regarded as the amount of compensation against such a loss. The arithmetic formula could be expressed as: profit obtained from each piece of infringed product X total number of infringed products sold = infringement profit; and

c. A reasonable amount not less than the royalty of patent licensing is regarded as the amount of compensation against such a loss.

9.18 Summary

A patent granted to a person bestows exclusive right to the person to make, distribute, mortgage, or sell the invention in India. Patents are jurisdictional rights, and are therefore restricted to a country that grants the patent. Patents are analogous to Real-estate property. Both grant exclusive rights to the owner. Violation of the exclusive rights of a Real-estate property by someone who unlawfully uses an area of the real-estate property is called encroachment. Similarly, an encroachment upon the invention patented by the owner is called "infringement".

Patent infringement is the unauthorized making, using, offering for sale, selling any patented invention within India, or importing into India of any patented invention during the term of a patent. In India, Section 104 to section 114 of the Indian Patents Act 1970 provides guidelines relating to patent infringement.

Patent infringement occurs when a product infringes one or more patents. To determine patent infringement, firstly a product or a process is analyzed and compared with all relevant patents that may claim an invention similar to the product. Secondly, the product or the process is scrutinized to see if the product or the process reads on one or more patents and is substantially described by the claims of the one or more patents.

9.19 Self- Assessment Test

1. What are the remedies for patent infringement?
2. How we can detect patent infringement in India?
3. What are the steps to establish infringement?
4. What is the relief in case of groundless threats of infringement?
5. What is the procedure followed by judges in patent infringement cases in India?

9.20 Further Readings

1. Patents Act, 1970
2. Patents Rules, 2003
3. All the cases mentioned above

Unit 10
Patents: Revocation of Patents and Acquisition of Patent by Central Government and Compulsory Licensing

Objectives

The Intellectual Property regime of the Government of India underwent significant changes after India's accession to TRIPS in 1995. Amendments were made to the Patents Act and the Trade Marks Act. The Designs Act as well as the Geographical Indications Act was enacted. The focus on the IPR regime is now on consolidation as well as promoting a fair balance between IP protection and public interest. In this connection certain policy issues have been identified which will help in moving towards our development and technological goals while giving protection to intellectual property rights. These include the issue of compulsory licenses and acquisition of patent by central government. This unit deals with the subject of 'Compulsory Licensing of Patents'. The objective is to develop a predictable environment for use of such measures.

Structure

10.1 Introduction

Compulsory licensing is a system whereby the Government allows third parties (other than the patent holder) to produce and market a patented product or process without the consent of the patent owner. This mechanism enables timely intervention by the Government to achieve equilibrium between two objectives - rewarding inventions and in case of need, making them available to the public during the term of the patent. Through such an intervention mechanism, the Governments balances the rights of the patent holder with its obligations to ensure working of patents, availability of the products at a reasonable price, promotion and dissemination of technological invention and protection of public health and nutrition.

Compulsory Licensing (CL) has been an integral part of the patent regime since its inception. The introduction of patents in Venice in the fifteenth century was accompanied by a broad set of rules which included the state's right to issue a compulsory license. Article 5 A(2) of the Paris Convention of 1883 provides that "Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work." During the World Wars, compulsory licensing was resorted to for the sharing of aviation technology and the manufacture of penicillin.

Relatively more recent instances of compulsory licensing are indicated below. As will be seen, both developed and developing countries have issued compulsory licenses in the recent past.

10.2 Recent Instances of Compulsory Licensing

Internationally

1. ***United States of America*:** Compulsory Licenses which have been/are being issued fall into six categories. These include a) Mandatory compulsory licenses for

patents whose term was extended by GATT implementation b) Cases involving government use under 28 USC 1498 c) Cases involving the Bay Dohl Act and d) cases involving merger reviews e) cases involving non-merger remedies to anti-competitive practices and f) cases subsequent to the Supreme Court opinion in eBay versus Merc Exchange.

2. ***Canada*:** Canada, which had a special compulsory license regime for food and pharmaceuticals, issued 662 compulsory licenses between 1923 and 1993. Of these, 613 were issued after 1969, when the law was amended to provide for import of generics under a CL. This allowed for low prices of pharmaceuticals while encouraging the growth of the local generic drug industry. In 1993, CLs for pharmaceuticals were effectively abolished.

3. ***United Kingdom*:** Compulsory licensing has been used by the National Health Service in the past. It imported drugs, patented in the UK from countries where no pharmaceutical patent had been granted, on the ground of 'Crown use'. Such provisions continue to exist in British Law.

4. ***Italy*:** In 2006, the Italian Competition Authority issued a CL on antitrust grounds for production of an active ingredient for an anti-migraine drug. In 2007, it issued a CL for a drug to treat prostate enlargement and baldness on similar grounds.

5. ***Developing and Least Developed Countries*:** After the Doha Declaration on the TRIPS agreement and Public Health, about 52 countries have issued CLs. These include Brazil(2007 for an anti AIDS drug); Thailand(2006 and 2007 for anti AIDS drugs), Malaysia (2003 for Anti AIDS drugs), South Africa (Anti Aids Drug) Kenya (voluntary licenses issued in 2004 after threat of CL), and most recently Ecuador (April 2010 for an anti AIDS drug)

In India

No CLs have been issued in India under the amended Patents Act. In September 2007, three applications under section 92A of the Patents Act, 1970 were received for grant of compulsory license for the manufacture and export of patented drugs to countries which reportedly did not have manufacturing capacity nor had insufficient capacity. The process envisaged under the Act was initiated. However, the applicant subsequently withdrew his applications.

10.3 Compulsory Licensing Provisions in TRIPS

Compulsory licensing under TRIPS is covered under two Articles. Article 30, allows limited exceptions to be provided to the rights conferred under patents provided they do not "unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties." This broadly covers the possibility of issuing CLs. However, Article 31 is more pointed. While providing for "Other Use without authorization of Right Holder", it qualifies the circumstances of this use through twelve conditions. The stipulations of local requirement and the public non-commercial use/national emergency/extreme urgency clauses are not required to be applied whenever such licensing is aimed at addressing anti-competitive practices. While TRIPS restricts the issue of CLs for semi-conductor technologies to public non-commercial use or to remedy anti-competitive practices, it does not provide any other constraint on either the field of technology or the circumstances of issue. There is no restriction that such measures should be taken only to address public health concerns. The grounds on which a CL can be issued are not stipulated. The procedure to be followed for issuing CLs is also not specified, thus allowing for different procedures to be adopted for different circumstances. Thus, significant flexibility is provided to the member countries for the issue of a CL.

TRIPs also stipulate that 'the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization'. Remuneration is further discussed in Section XIV.

This unit explores the scope of compulsory licensing using the pharmaceutical industry as a basis. A similar approach can be adapted to any other sector where the issue of a compulsory license is found necessary.

10.4 National Pharmaceutical Policy

The National Pharmaceutical Policy 2002 recognizes the need to 'ensure abundant availability at reasonable prices of good quality essential pharmaceuticals of mass consumption'. The draft National Pharmaceutical Policy 2006 while acknowledging the explosive growth in this sector between 1990 and 2010, and the accompanying low cost of medicines notes, that concerns regarding the accessibility and affordability of medicines remain. It proposed a number of key objectives including a) ensuring availability of good quality medicines within the country at reasonable prices (b) improving accessibility of essential medicines for common man particularly the poorer

sections of the population. To address these issues, the draft policy proposed a slew of measures. These included enacting a new law to exercise more effective price control /monitoring of the prices of drugs, creating a National List of Essential Medicines consisting of 354 drugs, strengthening the drug regulatory system, limiting trade margins and negotiating prices for patented drugs. The draft policy has not yet been finalized. However, it made some pertinent observations on high prices and consequent low demand of cancer and aids drugs. These points, reproduced below, are relevant to the issue of the reasonable requirements of the public being met at reasonably affordable prices – part of the grounds for issue of CLs under the Indian Patents Act.

At any given point of time there are about 20 to 25 lakh people suffering from cancer in the country who are affected by various types of cancer. It is estimated that every year about 7 lakh people are detected with different types of cancer. Most of them are unable to afford the cost of expensive anti-cancer medicines. Going by a conservative estimate of average cost of anti-cancer medicines per patient as Rs 25,000 per annum, it would require medicines worth Rs 5,000 crore. As against this, the present turnover of this segment of medicines in India is estimated to be only Rs 150 crore. The big gap indicates the near non-accessibility of the medicines to a vast majority of the affected population mainly because of the high cost of these medicines.

India has the highest number of reported HIV/AIDS cases in the entire South Asian region. There are about 25 lakh people affected by HIV/AIDS in India, about 85% of the South Asian total. Presently, only those patients with a CD 4 below 200 per cu ml of blood are being treated. The number of patients being treated would be about 3 lakh. Further first generation drugs are being used which are gradually losing their effectiveness, requiring the use of second and third generation drugs. NACO purchases medicines and distributes them free of cost through its Centers and State Aids Control Societies. Lower prices for these medicines would allow greater coverage of affected patients.

10.5 Views of the Parliamentary Standing Committee

The Department Related Parliamentary Standing Committee on Health and Family Welfare presented its forty fifth reports on 'Issues Relating to the Availability of Generic, Generic Branded and Branded medicines, their formulations and therapeutic

efficacy and effectiveness' to the Parliament on 4th August 2010. Its report expressed its concern on the following issues:

a. The high prices of the newly patented medicines which were not being regulated by the NPPA and the need for bringing in more drugs under the ambit of the NPPA

b. Even in the case of the 74 drugs which were being regulated by the NPPA, the increasing incidence of unorthodox practices adopted by drug companies wherein regulated drugs were substituted with new ingredients in popular brands to avoid regulation.

c. The super profits being generated by some drug companies who price their products significantly above cost and the need to explore possibilities of capping profit margins for all medicines including those not covered by the DPCO.

d. The takeover of Indian drug companies by some foreign companies and the need to generate policy options to ' ensure that major Indian pharma companies remain in Indian hands '

The Prime Minister, Dr Manmohan Singh in his remarks at the Fortune Global Forum in New Delhi in October 2007 stated "We have affirmed our commitment to the protection of intellectual property rights. But, the global economy, the global community cannot afford the complete privatization of research, of knowledge generation, especially in fields like medicine. We need to evolve mechanisms that protect intellectual property and at the same time, address the needs of the poor".

10.6 The Pharmaceutical Sector

Over the past fifteen years, the pharmaceutical sector has witnessed significant growth. India is now recognized as the one of the leading global players in the manufacture of pharmaceuticals. India now ranks third in terms of volume of production (9.3% of the global share) and 14th in terms of value (1.5% of global share). India is now supplying affordable and high quality medicines to a number of DCs and LDCs and has become the pharmacy of choice to the developing world. Its costs are also amongst the lowest in the world. Annexed I details the sales, and export turnovers of the Indian Pharmaceutical industry between 1994-95 and 2008-09. This analysis raises some concerns. The gross sales turnover increased from Rs 14,200 crore in 1994-95 to Rs 75,500 crore in 2008-09. This has been accompanied by a more than proportionate

growth in exports. Pharma exports have risen from Rs 2512 crore in 94-95 to Rs 39,538 crore in 2008-09. During 2008-09, the export growth rate was 29% against the industry growth rate of only 8 %.

Though imports have been growing, the emphasis on exports has resulted in a significantly lower growth of domestic consumption when compared to exports during most years during this period. During 2008-09, domestic consumption in value terms fell from Rs 45,953 crore to Rs 44,579 crore.

This is despite the fact that India itself has a large unmet domestic demand for critical medicines. 65% of the Indian population still lacks access to essential medicines. Share of drugs in OPD expenses were estimated at 63 per cent by NSSO 60th Round (January 2004). NSSO in their Report on 61st Round indicated this expenditure having increased to 82 per cent. As per National Health Accounts, medicines accounted for 38-62 per cent of inpatient expenditure in rural and urban areas. With total household expenditure on health estimated at Rs 92,838 crore in 2004-05, at 60 per cent level, expenditure on medicines is estimated to cross Rs 50,000 crore.

This data appears to reinforce the issues raised by the Parliamentary Committee on the need to increase the availability and accessibility of drugs to the poor in the country

Given this background, the need for affordable and high quality medicines is critical for the sustainable growth of the Indian economy. In this context, three developments in the pharmaceutical sector in India have heightened the concerns being expressed. These are the enactment of the amendments to the Indian patents Act in 2005, the recent restructuring of ownership in the sector and the strategic alliances being forged by some large Indian players in this sector.

The enactment of the Patent Amendment act in 2005 allowed for the grant of product patents in the pharmaceutical sector. The first pharmaceutical product patent under the amended act was granted in 2006. While the bulk of essential drugs are still under the process patent regime, new formulations will steadily be issued product patents resulting in focusing of monopoly power among the patent holders.

Six reported cases where foreign companies have taken over Indian companies are provided in Table 1 below.

Table 1

Year	*Indian Co taken over*	*Foreign Company which took over*	*Country of origin*	*Take over amount US$ (mil)I*
Aug 2006	Matrix Lab	Myla n Inc	USA	736
April 2008	Dabur Pharma	Fresenius Kabi	Singapore	219
June 2008	Ranbaxy Laboratories	Daiichi Sankyo	Japan	4600
July 2008	Shanta Biotech	Sanofi Aventis	France	783
Dec 2009	Orchid Chemicals	Hospira	US	400
May 2010	Piramal Health Care	Abbot Laboratories	US	3720

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Most of these companies are export oriented. There is a concern that their takeover by multinationals will further orient them away from the Indian market, thus reducing domestic availability of the drugs being produced by them. This may weaken competition leading to headroom for increase in domestic drug prices. Data Base from the Centre for monitoring Indian Economy indicates that while the rate of growth of sales of the pharmaceutical companies declined during 2001-2009 (14.2 per cent annual) compared to their growth during 1988-2000 (19.5 per cent annual), their ratio of profit after tax to total income increased to 9.7 per cent (average of 2001-2009) from 4.9 per cent (average of 1988-2000). This may point to the worsening in both the availability and affordability of pharmaceutical products.

Additionally, the strategic alliances being forged by other foreign companies with Indian drug manufacturers for licensing and supply also alter the pharmaceutical landscape. These include alliances between GSK with Dr Reddys; Pfizer with three companies - Aurobindo, Strides Arcolab and Claris Life Sciences; Abbot with Cadilla Health Care and Astra Zeneca with Torrent. Further foreign companies are taking over domestic drug companies in other countries also. For e.g. Sanofi Aventis took over Medley in Brazil and Zantiva in the Czech Republic, GSK took over BMS in Egypt and Pakistan. It can thus be said, that there is a move towards consolidation in developing country markets

10.7 Concerns relating to drug prices and availability

The top 10 pharmaceutical companies by 2008-09 sales are listed below in Table 2. Their aggregate sales (including exports) represent nearly 39 % of the total industry sales

Table 2

Rs crore

Cipla	4807.67
Ranbaxy Laboratories:	4755.76
Dr. Reddy's Laboratories-	4394.90
Lupin	2934.25
Sun Pharmaceutical Inds.	2830.86
Aurobindo Pharma	2730.75
Cadila Healthcare	1765.40
Glaxosmithkline Pharmaceuticals	1668.08
Piramal Healthcare	1565.42
Wockhardt-	1448.87

After the recent takeover, three of these ten companies are multinationals. In 1998-99, only one of the top ten companies ranked by sales was a multinational company. There are increasing concerns that if such a takeover trend continues, an oligopolistic market may develop which may result in a few companies dictating prices of drugs critical for addressing public health concerns including fighting front line diseases like HIV/AIDS, Hepatitis C. Such a contingency while reinforcing the newly acquired monopoly patent power of the foreign companies may also weaken the government's ability to address such challenges through the issue of compulsory licenses. If large Indian generic companies with the capability to manufacture drugs based upon a CL (where they issued to them) are themselves taken over, then the regime of cheap and effective drugs may be threatened for four reasons:

a. The large Indian pharmaceutical companies, which have been taken over by foreign companies, may no longer be willing to apply for a Compulsory License even if eligible. Their deterrent threat is thus emasculated.

b. When government notifies a public emergency and recognizes the need for issue of a CL for a particular drug, adequately capable drug manufactures may not be available to come forward to apply for CL and work it at a reasonable cost.

c. There is a concern that foreign companies may utilize the marketing channels of the Indian companies they take over to sell higher cost patented drugs or branded generics rather than the cheaper generics that were being sold earlier. This may push up drug prices in general.

d. Some of the Indian companies taken over were recipients of substantial grants as well as tax concessions. Others were transferred or allowed to work patents owned by the CSIR at concessional prices. Thus a significant portion of their market value arose because of state support and they were catering to niche markets for relevant drugs. With their transfer to foreign control, they may no longer be interested in doing so.

10.8 Options available

In the event of any or all these concerns crystallizing, four possible responses are available with the Government of India. One is an immediate response and three are short term policy responses. These are:

a. If the circumstances so require; for example a public emergency like a pandemic , or whenever the demand for a critical drug is not being met, then a compulsory license can be issued promptly to a qualified company to produce such a drug or the government use provision invoked.

b. The first short term option is invoking the Competition Act 2002 to scrutinize whether the price or availability of a drug is a consequence of an anti-competitive agreement or a combination which has an adverse effect on competition; or the abuse of dominant position by a company and initiating suitable action .

c. The second short term option is to review the policy on foreign investment for pharmaceutical companies. Presently, investment up to 100% in the pharmaceutical sector is on the automatic route. This could be shifted to the government route so that proposals for mergers and acquisitions in this important sector could be scrutinized by the FIPB. This could be a way of monitoring whether new technology is being brought in by a foreign company while taking over an Indian company.

d. The third short term option is to expand the ambit of the National Pharmaceutical Pricing Authority and vest it with the power to regulate the prices of a larger number of drugs than the present 74.

The first option is a focused and sharp response – which can be invoked when a single critical drug is either unavailable per se or unavailable at reasonably affordable prices.

10.9 Provisions under TRIPS

Article 4 of 'The Declaration on the TRIPS Agreement and Public Health' adopted in Doha in November 2001 affirms that the TRIPS agreement does not and should not prevent member countries from taking measures to protect public health. Accordingly, it allows for interpretation and implementation of the TRIPS agreement in a manner supportive of the WTO's members right to protect public health and in particular, promote access of medicines to all. Article 6(b) of the Doha Declaration recognizes that the flexibilities of the TRIPS agreement include the right of each Member to grant compulsory licenses and the freedom to determine the grounds under which such licenses are granted. Article 6(c) recognizes the right of each Member to determine what constitutes a national emergency or other circumstances of extreme urgency.

These flexibilities have been incorporated in the Patents Act 1970 as amended in 2005 which is fully consistent with TRIPS. Chapter XVI of this Act entitled 'Working of Patents, Compulsory Licenses and Revocation' deals with the issue of Compulsory Licenses (CLs). Sections 84, 85, 91, 92, and 92A enumerate the various circumstances under which CLs may be issued. Chapter XVII contains provisions for use of inventions for the purposes of government and the acquisition of inventions by the Central Government. Chapter VIII of the Patent Rules 2003 as amended in 2006 provides for the modalities of issue and maintenance of Compulsory Licenses. Rule 97 discusses the action to be taken when a prima facie case has not been made out. Rule 98 enables a notice of opposition to the CL to be made out while Rule 100 provides for amendment to the terms of the CL.

Section 84(1) of the Act provides that at any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license. The earliest pharmaceutical product patents were granted in January 2006 under the amended Act. More than five years have elapsed since then. It is necessary that an objective framework for the issue and

maintenance of compulsory licenses be developed using the mandate provided by the law as the basis for the same.

10.10 Legal Provisions

Section 83, at the beginning of Chapter XVI unusually lists the "General principles applicable to working of patented inventions". These 'Directive Principles of Patent Policy' incorporate the philosophy of the patent frame work under Indian law. This Section is also the bedrock on which the edifice of compulsory licensing is built in the subsequent sections. It states as under:

Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely,—

(a) That patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;

(b) That they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;

(c) that the protection and enforcement of patent rights 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;

(d) that patents granted do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;

(e That patents granted do not in any way prohibit Central Government in taking measures to protect public health;

(f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

(g) That patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

This Section draws significantly from TRIPS. Section 83(c) is a replication of Article 7 of TRIPS – its Objectives. Section 83(d) draws from Article 8(1) of TRIPs – its Principles. Section 83(f) draws on Article 8(2) of TRIPS - the second part of the Principles.

Section 89 further specifies the objectives of a compulsory license. It states that "The powers of the Controller upon an application made under section 84 shall be exercised with a view to securing the following general purposes, that is to say,—

(a) that patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable;

(b) that the interests of any person for the time being working or developing an invention in the territory of India under the protection of a patent are not unfairly prejudiced.

Compulsory licensing is enabled under four sections of the Patents Act. These are Section 84 (general CLs to be issued by the Controller on application) , Section 91(issue of CL by the Controller for a related patent on application) , Section 92(issue of CL by the Controller based upon a notification by the Central Government of circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use) and Section 92 A(issue of CL by the Controller on application for manufacture and export of patented pharmaceutical product to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems). In addition, Chapter XVII provides for use of inventions for the purpose of government and acquisition of inventions by Central Government.

Under Section 92, the Controller can issue a CL on application only after the Central Government issues a special notification. Under 92A, he is required to act only after either issue of a CL by the importing country or on the basis of a suitable notification issued by that country. XI. Category I CLs

Under Section 92, the Central government can notify the need for issue of a CL on the following grounds

a. Circumstances of national emergency;
b. Circumstances of extreme urgency;
c. In case of public non-commercial use;

These grounds are identical to those mentioned in Article 31(b) of TRIPs which allows members to issue CLs. Section 92(3) clarifies en passant that such circumstances

could include public health crises, relating to Acquired Immune Deficiency Syndrome, Human Immune Deficiency Virus, tuberculosis, malaria or other epidemics. This is consistent with Para 5(c) of the Doha Declaration on TRIPS and Public Health which states that public health crises including those related to HIV/AIDS, tuberculosis, malaria and other epidemics can represent a national emergency or other circumstances of extreme urgency. The Patent Act however, does not in any way stipulate that the circumstances justifying issue of a CL are exclusively public health crises. The three circumstances mentioned in Para 42 above could occur in other sectors also.

Given the extremely diverse nature of these three grounds, one view is that it may not be feasible or even desirable to focus the scope of their application in a definitional sense. Another view is that it is necessary to clarify that these grounds can be used for promoting access to medicines like cancer and diabetes. Para 4 of the " Doha Declaration on the TRIPS agreement and Public Health" specifically clarifies that the TRIPS agreement does not and should not prevent Members from taking measures to protect public health. It further affirms the Members rights to protect public health and in particular to promote access to medicines for all. Thus chronic diseases can also be addressed though such provisions.

While granting a Category I license, the Controller should endeavor to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights. In contrast, while granting Category II licenses, the Controller is required to ensure that the patented articles are made available to the public at reasonably affordable prices while ensuring that the patented invention is worked to the fullest extent and with reasonable profit to him. Thus, the Controller appears to have a higher burden in the case of issue of Category I licenses in the matter of the price at which the patented article is made available to the public.

Under Section 92A, a compulsory license shall be issued for export of patented pharmaceutical products to a country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.

This provision mandates that the Controller shall issue a CL when its stipulations are met. Such a CL is restricted to pharmaceutical products which are defined separately under the explanation to the section as "any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use".

This Section mirrors the August 30 decision of the TRIPS Council. Article 31(f) of TRIPS provides that production under a compulsory license must be 'predominantly for the supply of the domestic market'. This restriction limited the quantity of exportable products, and inhibited the advantage of economies of scale being leveraged in the manufacture of such products. Acting on the mandate provided by paragraph 6 of the Doha Declaration, the TRIPS Council resolved on 30 August 2003 to waive the requirements of Article 31(f) till the proposed amendment (Article 30 bis) comes into force. The amendment puts in place a mechanism providing for a CL based export approval by the TRIPS Council on a drug by drug, case by case and country by country basis. Both the exporting and the importing countries are required to notify the TRIPS Council in advance.

The three applications received by the Indian patent office in September 2007 referred to in Para 11 above were for grant of CLs under this section. Since the corresponding CLs/notifications from the importing country could not be made available, the applications were withdrawn. A similar trend is seen internationally in invoking the August 30 decision. Only in one case has this decision been invoked over the last eight years. The additional burden of compliance with respect to the stipulations of the TRIPS Council in such cases appears to be a deterrent.

10.11 Central Government Use

Chapter XVII of the Patents Act provides for the Central Government using an invention for the purpose of government on payment of royalty. Section 100(1) specifies that the Central Government or any person authorised by it in writing may use the invention for the purpose of government. Section 99 defines the term purpose of government to mean "made, used, exercised or vended for the purposes of the Central Government, a State Government or a government undertaking." Such a definition caters to the needs of the Central Government, the State government as

well as both Central and State government undertakings. Since such making, using, exercising or vending is for the purposes of government and not by the government, Central Government can authorize third parties to manufacture products patented by others to fulfill government purpose. Thus the first part of Chapter XVII effectively allows for compulsory licensing of patents. This provision can also invoked at any time after the application for a patent has been file, thus making it stronger.

Section 100(6) clarifies that the right to make, use, exercise and vend an invention for the purposes of government under sub-section (1) shall include the right to sell on non-commercial basis, the goods which have been made in exercise of that right. The use of the words' sale on non-commercial basis' contrasted to the words 'use on non-commercial basis' in 92(3) appears to empower the government under this provision to manufacture or cause to manufacture patented products and sell them without profit. For example, in the case of pharmaceuticals, patients can be charged cost price for drugs provided to them through such an arrangement. Since general Government expenditure on health is only 25% of total health expenditure, it may be necessary to use all available channels for such distribution, including the private sector.

Section 102 provides for outright acquisition of a patent by the Central Government by notification, if it is satisfied that it is necessary to do so for a public purpose, subject to payment of compensation. Compensation may be determined by the High Court under Section 102.

10.12 Category II CLs

The essential element in Category II licenses is the ability of the applicant to prove that a) the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India. While conditions required to satisfy the first set of circumstances are amplified in Section 84(7), there is no guidance available in the Act for determining the existence of the second and third set of circumstances. However under Section 90, the Controller is required to secure on an endeavor basis compliance with a number of conditions.

Under Section 84(6) (ii) and (iii), the Controller is required to satisfy himself about the ability of the applicant to work the invention to the public advantage as well as the

capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;

10.13 Payment of Royalty

WHO-UNDP Guidelines for Non-Voluntary Use of Patent

These guidelines published in 2005 outline four different methods for payment of remuneration consistent with TRIPS. These are briefly described below.

The simplest is the method recommended in the 2001 UNDP HDR report which proposes a royalty rate of 4 percent of the price of the generic product. This can be increased or reduced by 2 percent depending upon other factors.

The Japanese Patent Office published guidelines in 1998 for setting royalties on government owned patents. These guidelines allow for a base royalty of 4 percent which can be increased or decreased within a band of 0 to 6 percent. In case the product licensed spans a number of patents, there is a provision to bias this percentage downwards for each patent depending upon its individual contribution to the composite patent.

The Canadian government in 2005 adopted royalty guidelines for compulsory licensing of patents for export to countries which lack the capacity to manufacture such medicines. These guidelines use a base rate of 4 percent of the generic sales price. This royalty rate is then biased downwards based upon the rank of the importing country in the UN Human Development Index. The lowest ranked country in the index will pay 0.02 percent, while the highest ranked country will pay 4percent.

The Tiered Royalty Method (TRM) is computed using as a base the price of the patented product in the high income country. The royalty rate of 4 percent applied on this rate is then biased downwards by the ratio of per capita incomes of the respective countries. For countries with a high burden of disease, the relative income per person with the disease could be used as the biasing factor.

In the case of Government use of a patent, the proviso to Section 100(3) of the Patents Act stipulates that in case of Central Government use of an invention the patentee shall be paid not more than adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent. However, any dispute on the amount paid can be referred to the High Court under Section 103.

Another view is that the amount paid must be including a reasonable solatium to the patentee, with the aim of not radically discomfiting him both economically and otherwise. It is thus argued that the amount paid should be significantly above the maximum royalty of 4% indicated in the TRM method. Under this view, an aggregate payment of about 10% of the generic sale price of the drug in the country where the CL is used is appropriate.

In Practice:

In April 2010, Ecuador used the tiered royalty method (TRM) to allow for royalty payments of 5% of the US price biased downwards by the ratio of per capita incomes for the CL issued by it for the manufacture of Ritonavir. Thailand in 2006 allowed a royalty fee of 0.5 percent of the sale value of the product in that country. Indonesia in 2004, allowed a royalty of 0.5% of the net selling value in that country.

10.14 Local working of the Patent

Article 84(4) of the Patents Act authorizes the Controller to grant a compulsory license if amongst other things, he is satisfied that the patented invention is not worked in the territory of India. He can also grant a compulsory license if he is satisfied that the reasonable requirements of the public with respect to the patented invention have not been met. Under Section 84(7) (e), one of the criteria for deciding the latter is ' if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article' . There are thus two independent grounds:

a. The invention is not worked in the territory of India at all.

b. The reasonable requirements of the public are not being met as the working of the patent in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by interested persons.

The issue which then arises is what the term 'working in the territory of India' means. Whether this implies that the product must be manufactured in the territory of India, or it can be taken to mean making available for local sale. Expectedly, there are opposing views in the matter.

Article 27(1) of TRIPS partially reads "… patents shall be available and patent rights enjoyable without discrimination as to ...whether products are imported or locally produced". This Article appears to mandate that so long as the patented product is

available in the market at an affordable cost, the use of the patent cannot be differentiated on the basis of its sourcing – whether it was manufactured within the country or imported from without. However, it has been argued that the exceptions provided in Articles 30 and 31 of TRIPS override the general stipulations in Article 27.It is further argued that Articles 7 and 8 of TRIPS which recognize the need to promote transfer of technology support provisions for local sourcing . Therefore local working stipulations are valid and enforceable.

Local Working requirements with a corresponding remedy of issue of a compulsory license for non-compliance find place in the laws of a number of countries – both developed and developing. Such provisions can be traced to the origin of the patent system. A number of countries have local working conditions in their patent laws. Brazil's Intellectual Property Law authorizes the government to issue a compulsory license if the patent owner does not manufacture the product in the territory of Brazil within three years of the grant of the patent. This provision was challenged by the US in a WTO dispute hearing in 2000.

Though the US subsequently withdrew its complaint, it reserved its rights to recommence the WTO complaint. However, it is noteworthy that during a Congressional hearing in Nov 2005, the US DHSS Secretary testified that he had effectively required the patent owners of Tamiflu to set up manufacturing facilities in the US so that the US would have access to Tamiflu if confronted with an avian flu pandemic.

The entire Chapter XVI on 'Working of Patents, Compulsory Licenses and Revocation' with sections 82 to 98 was substituted for the old Chapter XVI containing sections 82 to 94 by way of amendments to the Patent Act (Act 38 of 2002) with effect from 20/5/2003. Section 90(3) provides that Central Government may, in public interest, direct the Controller at any time to authorize any licensee in respect of a patent to import the patented article or an article or substance made by a patented process from abroad. Section 86 provides that the Controller may adjourn hearing of applications on this ground by up to 12 months if he is satisfied that adequate time was not available to the patentee to work the patent in the territory of India. Read together, these two sections appear to assert that the local working requirement implies manufacture within the territory of India.

10.15 Summary

Compulsory licenses are generally defined as *"authorizations permitting a third party to make, use, or sell a patented invention without the patent owner's consent."* Under Indian Patent Act, 1970, the provision with regard to compulsory licensing is specifically given under Chapter XVI. Internationally also, the provision of compulsory licensing is well-recognized. The inbuilt flexibility provided under TRIPS agreement also paved the way to grant of compulsory licensing. This is done while keeping in mind the interest of public at large.

Since compulsory licensing limits the right of exclusive ownership conferred by patents, it has long been controversial.[3] When it comes to implementation of compulsory licensing, there has been little consensus. Among the signatories of TRIPS, developed countries generally tend to view this provision with suspicion, while the developing countries consider it as an issue of prime importance. Recently, India granted its first compulsory license which triggered the debate as to position taken by India in the international scenario.

In March 2012, India granted its first compulsory license ever. The license was granted to Indian generic drug manufacturer Natco Pharma Ltd for Sorafenib tosylate, a cancer drug patented by Bayer. Non-governmental groups reportedly welcomed the decision.

10.16 Self-Assessment Test

1. What are therecent Instances of Compulsory Licensing?
2. Mention and explain the Compulsory Licensing Provisions in TRIPS?
3. What is National Pharmaceutical Policy? Discuss and Explain.
4. What are theviews of the Parliamentary Standing Committee?
5. Mention and explain the provisions under TRIPS regarding compulsory licensing?

10.17 Further Readings

1. Patents Act, 1970
2. TRIPS Agreement
3. Berne Convention.

Unit 11
Emerging Issues in Patent: Biotechnology, Life forms, Human Genome, and Relevant part of Biological Diversity Act, 2002 as to Plant Breeders Rights and Farmers Rights

Objectives

In recent years, biotechnology played a major role in advancing the agricultural research in India. Likewise, the farmers' rights and plant breeders' rights have received attention of the policy makers, research organizations and development agencies. The recombinant DNA based technology (e.g. genetically modified crops) and trait-genetic use restriction technologies (e.g., terminator, verminator and traitor genes) have been employed as a part of biotechnology by public and private institutions and genetically modified crops are available for commercial exploitation. Considering present social, economic and ethical situation in India, more periods would be necessary to avail advantages offered by the GATT/WTO agreement signed by the government although patent laws have been changed under TRIPS regime and quantitative restrictions for agricultural inputs have been removed.

Structure

11.1 Introduction

The intellectual property rights (IPR) refer to a group of laws intended to provide legal protection for an intellectual creation. Evolution of IPR laws is a continuous and complex issue but they provided incentives for technical and industrial development in Indian agriculture and served as effective tools for national economic growth. Also, grant of IPR and their proper enforcement encouraged fair trade and facilitated the access of consumers to quality products in several ways (e.g. safety to humans and animals, product's price, shelf life and degradation).

As per Trade-Related Intellectual Property Rights (TRIPS) Agreement of 1994 that India signed, IPR laws for patents, industrial designs, copyright, trademark, trade secrets, geographical indications and protection of plant breeders' rights are being executed. Patent is a protection granted by the government to an inventor for protecting his/her invention for a limited period, thus permitting the holder to control commercial use, sale or manufacture of the patented product or process which should be novel, unique, useful and ethical, should satisfy the technical tests of inventions, and is disclosed to the public. The ownership can remain with a founder agency, individual, community, public sector or a private company.

Similarly, "Defensive patents" can be used more effectively in order to prevent others from patenting the same products. Basically, IPR are catalytic in encouraging innovation but sometimes counter the public interest at large leading to piracy of the biological resources in the country. Therefore, international agreements are made. The Indian Patents Act, 1970 & Patent Rules 1972 work under the framework of the 1883 Paris Convention which is administered by the United Nations World Intellectual Property Organization (WIPO) to serve the public interests by balancing rights and obligations of the patent holder. This Act was revised through Patent Amendment Bill of 1995 and was presented in the Parliament in March 1999, after having incorporated the obligations of the World Trade Organization (WTO) treaty signed in December 1998 and was passed in July 2002. The recent version includes updated definitions of inventions, uniform patent protection for 20 years, safeguard of public interest and reserved powers to license the production and price fixing of the product. In case the

patent is broken, an Appellate Board takes the decision. The Seed Act, 1966, has also been legalized and came into effect in 2002 by which National Seed Board would replace Central Seed Committee, and Central Seed Certification Board will maintain a national seed register.

11.2 Biotechnology in Agriculture

In India, biotechnology research and development (R &D) is in progress particularly in crop improvement. The most promising benefit from genetic engineering is the use of recombinant DNA techniques. Because it is possible to break through natural species barriers systematically by moving genes from one species to another that do not combine in nature.

The genetically modified (GM) crops have been developed by using input traits (e.g. resistance to insect pests and plant diseases), output traits (e.g. delayed fruit ripening, better taste, nutritious, elimination of saturated fats in cooking oils, elimination of allergens, better delivery of necessary nutrients), agronomic traits (e.g. resistance to drought, salinity, acidity, flood, etc. and increase in crop yield). It takes a decade or more period to develop technology and perhaps one innovation in thousand becomes a successful commercial product or process.

For example, maize seeds with high protein quality (e.g. amino acids lysine and tryptophan), grass pea seeds with very low content of neurotoxin (e.g. *b*-N-oxalyamino-*L*-alanin), rice grains containing higher amount of βcarotene), mustard oil with low saturated fat, and other crops have been engineered by public and private institutions, and are in either advanced stage of development or field testing (Table 1).

The new trait-genetic use restriction technology (T-GURT) is being employed as a part of biotechnology by means of terminator, verminator and traitor genes. In this case, users have to rely upon the chemically dependent plants with proprietary 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.

Likewise, 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.

The medicinal properties of turmeric (*Curcuma domestica* Val.), tamarind (*Tamarindusindica* L.), neem (*Azadirachtaindica*Juss.) and several other plants are well known to Indians and therefore, Council of Scientific & Industrial Research (CSIR) could get back some of the patents previously claimed by developing countries. Following two examples explain the patent related technological progress.

Golden Rice

Rice (*Oryzasativa* L.) which is a staple food in many developing countries is consumed in milled form and lacks in provitaminA (β-carotene) and iron in its endosperm. This diet results in blindness and anemia in humans. Recently, the Swiss and German scientists developed GM rice containing snippets of DNA borrowed from bacterium *Erwiniauredovora* and daffodils that gives a grain a golden yellow hue and hence nicknamed as "Golden rice". This rice contains vitamin A equivalent to 300 g of cooked rice and 2-fold increase in iron content. Some genotypes with yellow endosperm also appear to contain Bcarotene levels comparable to those of Golden rice.

Efforts are therefore on to introduce β-carotene genes into indigenous varieties (e.g. IR-64, PusaBasmati, PR-114, ASD-16), and increase its bioavailability. Indian scientists have sequenced 6 million base pairs of chromosome II of rice for desired genotype for higher productivity and improved quality. Food Standards Agency is now proposing an isotope and trace elements analysis, which can reveal the geographic origin of rice by comparing the unique trace elements in it. Drought resistant rice is also being developed by the University of Hyderabad in association with Rockfeller Foundation of the USA by using molecular and genomic techniques. Recently, Indian rice in the foreign markets witnessed tough challenge as a consequence of the decision of the US Patent and Trademark Office (USPTO) because this office granted permission on 2 Sep 1997 under brand name "Texmati" to US-based Rice Tec. Inc. to sell it in the domestic and foreign markets with a label claiming the product to be superior or at least equivalent to Indian Basmati Therefore Government of India filed a petition in the USPTO and subsequently Rice Tec Inc surrendered four claims in

September 2000 and 11 more claims in August 2001. The Rice Tec Inc is presently selling *basmati* after developing its novel lines named BAS-867, RT-117, RT-112. The United Kingdom is allowing *basmati* only from India and Pakistan though it is patented as Texmati in the USA and as Jasmati in Thailand. Similarly, new high yielding, photoperiod-insensitive aromatic super fine rice strains (e.g. Pusa Sugandha-2, Pusa Sugandha-3, Pusa RH-10) bred at Indian Agricultural Research Institute, Delhi, will not be marketed internationally as *basmati* rice because of geographic indication specific to the region but simply as aromatic rice.

Some risks expressed are that genes from GM plants could be easily taken up by consumers when eaten and thus become a part of their own genetic makeup. However, experiments on animals fed with large quantities of DNA did not show survival of intact DNA in either stool or blood because after digestion, DNA gets fragmented into small pieces and thus fails to express. The doubt about transfer of antibiotic resistance gene from

GM food consumed by people into bacteria inhabiting human gut and making them resistant to antibiotics is baseless. The possibility of gene flow to close relatives of transgenic plants creating super weeds or causing gene transfer by pollination to other crops is very low because such genes would become diluted with successive generations. But if seeds remain dormant in the soil for several years, it will be difficult to eradicate them. In order to surpass this risk, the Indian Council for Agricultural Research (ICAR) is currently mapping the molecular fingerprints of *basmati* and profiles about 2000 released varieties and parental lines of hybrids and seeds containing genes for desirable traits. India has also participated to the International Rice Genome Sequencing Programme, which was conceived in 1997, and aims to sequence 10 Mb of chromosomes II of the total 30 Mb rice genomes over the next five years.

BT Cotton

Cotton (*Gossypium* spp.) is a major fibre crop for which >50% of total insecticide consumption is meant for this crop. The misuse of chemicals resulted in undesirable secondary effects. One of the probable remedy is to use GM cotton in which Cry 1A (b) and Cry 1 A (c) genes from a bacterium, *Bacillus thuringensis* (BT) are incorporated. By planting this cotton, it was expected to reduce 70-80% reduction in pesticide sprays, more photosynthetic efficiency and early maturity by 2-3 weeks with higher production and better cotton quality than non-Bt cotton. Limited field trials

were carried out on plots of 200 sq.m. in Karnataka, Maharashtra, Haryana and Tamil Nadu in 1997. The number of trial locations was increased to 40 in 1998 followed by additional 11 field trials in 1999. Presently, advanced field trials have been permitted under the supervision of the Department of Biotechnology (DBT). On 26 March 2002, Monsanto-Mahyco Biotech Ltd. (MMBL) got conditional sanction from the Genetic Engineering Approval Committee (GEAC) established under the Ministry of Environment and Forests for commercial cultivation of three hybrids (Mech-121, Mech-162, Mech-184) in spite of an on-going Supreme Court case by Research Foundation for Science, Technology and Ecology challenging the 1998 field trials and pointing irregularities, and violations of bio safety laws and guidelines in previous years and susceptibility of crop to pests and diseases. Similarly, ICAR claims that Bt cotton developed by its institutes is superior to Monsanto cotton because multiple pest resistant genes are incorporated in a single variety for which farmers need not to purchase seeds every year. Similarly, the National Botanical Research Institute at Lucknow and the University of Agricultural Sciences at Dharwad, are ready to transfer technology to produce indigenous Bt cotton which would be resistant to insect pests (*Helicoverpaarmigera, Spodopteralitura),* ecofriendly and cost effective. In order to test whether plants contain Bt genes, a simple and fast method known as Quickstix has been invented by ICAR.

Some risks, however, are evident such as, creation of a new or known toxin or allergen from Bt cotton, changes in surface properties that may affect interaction between species in any ecosystem, interference with reproduction and symbiotic relationship, and crossing the country or region's boundary by genes. A packet of 450 g of seeds of Bt cotton and non Bt refuge was sold in 2002 crop season for Rs 1400-1600 compared to Rs. 300-400 for conventional seeds. Planting refuge around the main plot is not relevant to Indian farming conditions because of fragmented holdings having several cotton genotypes in a single farm. The bollworms may develop resistance through natural selection towards Bt sprays. Lot of regulation is involved in releasing these hybrids such as, Institutional Bio safety Committee, Biotech Food Approval Committee, Review Committee on Genetic Manipulation, and Monitoring cum Evaluation Committee, State Biotech Coordination Committee, and National Bureau of Plant Genetic Resources.

Table 1— Major institutions engaged in biotechnology research and development for agricultural crops in India

Crop	Institution
Fruits	
Banana	Indian Agricultural Research Institute. (IARI), De
	Biotechnology Centre, Horticulture Department, Bangalore
	Indian Institute of Horticultural Research (IIHR), Bangal
	National Chemical Laboratory (NCL), Pune
Citrus	National Botanical Research Institute (NBRI), Lucknow
Mango	Biotechnology Centre, Horticulture Department, Bangalore
Muskmelon	University of Agricultural Sciences (UAS), Bangalore
Papaya	IARI, Delhi
Pineapple	Bhabha Atomic Research Centre (BARC), Mumbai
Spices	
Pepper/chillies	Rallis India Ltd., Delhi; Centre for DNA Printing Diagnostics, Bangalore
Cardamom	NCL, Pune
Turmeric	NCL, Pune
Ornamentals	
Bougainvillea	NBRI, Lucknow; NCL, Pune
Chrysanthemum	NBRI, Lucknow; NCL, Pune
Ferns	Baroda University, Baroda
Gladiolus	NBRI, Lucknow; NCL, Pune
Orchids	IIHR, Bangalore; NBRI, Lucknow
Commercial crops	
Cotton	Central Institute for Cotton Research (CICR), Nagpur Coimbatore
	Delhi University; Delhi; IARI, Delhi; NBRI, Luckn
	Dharwad University, Hubli; Maharashtra Hybrid Se

	Company Limited (MAHYCO), Mumbai
Sugarcane	Sugarcane Breeding Institute, Coimbatore
Vegetables	
Cabbage	IARI, Delhi; Tata Energy Research Institute (TERI), De Proagro-PGS India Ltd (PGIL), Delhi
Cauliflower	TERI, Delhi; PGIL, Delhi
Potato	PGIL, Delhi; IARI, Delhi; BARC, Mumbai; National Centr Plant Genome Research (NCPGR), Delhi; Central Ptato Research Institute (CPRI), Simla; Jawaha Nehru University (JNU), Delhi
Eggplant (Brinjal)	IARI, Delhi; TERI, Delhi; Delhi University, Delhi; PGIL, Delhi; MAHYCO, Mumbai
Tomato	PGIL, Delhi; IARI, Delhi; Delhi University, Delhi; JN Delhi; Indo-American Hybrid Seeds, Bangalore; Rallis Ir Ltd., Bangalore
Pulses	
Chickpea, Pigeon p	International Crops Research Institute for the Semi-A Tropics (ICRISAT), Hyderabad; IARI, Delhi; BARC, Mumb

Crop	Institution
Narcotics	
Tobacco	Central Tobacco Research Institute, Rajahmundry
Cereals	
Maize	MAHYCO, Mumbai; Vivekananda Parvatiya Kr Anusandhan Sansthan. (VPKAS), Almora
Paddy	Bose Institute, Kolkata; Delhi University, Delhi; Tamil N Agricultural University (TNAU), Coimbatore; IA Substation, Shillong;National Research Centre on P Biotechnology (NRCPB), Delhi; Directorate of Rice Resea

	(DRC), Hyderabad; M.S. Swaminathan Research Foundati (MSSRF), Chennai
Wheat	G B Pant University of Agriculture & Technology, Pantna Delhi University, Delhi
Oilseeds	
Groundnut	ICRISAT, Hyderabad
Mustard	IARI, Delhi; TERI, Delhi; Delhi University, Delhi; PG Delhi

11.3 Biodiversity

Diversity is deemed important for national food security by enhancing crop productivity and quality of the produce. India being a home of 45, 000 plant species an exchange between wild and cultivated plants is a continuous and dynamic process and acts as a gene flow. By this way, biodiversity is naturally maintained if human intervention is avoided. This system also helps to maintain and enhance genetic resources in farmers' fields. On the contrary, there are expected side effects and possible danger to our biodiversity by using transgenic crops because new gene is introduced in an agro-ecosystem irrespective of boundaries. Allowing IPR means loss in biodiversity conservation activities of peasant farmers because they retain best seeds of previous crop season and plant them as per family needs in highly variable environment taking all risks of natural calamities. This system assures farmers the minimum crop production and whole family survives on these food sources and thus forms a part of sustainable agriculture, which is today's need. Also, farmers are cultivating several plants since decades and help in maintaining biodiversity. For example, the bright red *Byadgi* chillies, the sour *Appimidi* mangoes and salt resistant *Kagga*strains of paddy in Karnataka, *Pattambi* paddy resistant to brown plant hopper in Kerala. Such local cultivars had been useful as parents in breeding programmes to incorporate their qualities. But through Green Revolution in late sixties, we have replaced land races and traditional varieties by high yielding hybrids resulting in at least 5% gene flow in self pollinated crops and up to 50% in cross pollinated crops. The recent technique of DNA fingerprinting of plant varieties would protect India'

genetic resources and can establish profiles of origin of the genetic material in the event of award or patent dispute.

The recent technique of DNA fingerprinting of plant varieties would be useful to protect India's genetic resources and to establish profiles of origin of the genetic material in the event of award or patent dispute.

At the 1992 UN Conference on Environment and Development, a Convention on Biological Diversity was agreed upon to promote both conservation and utilization at three levels, e.g. ecosystems, species and genes and international working groups on biodiversity are working on the following issues:

1. WIPO Committee on legal standards for patent protection for inventions in biotechnology.
2. Licensing related to IPR in biotechnology.
3. Administrative and procedural improvement in delivering patents.
4. Relationship between patents and other IPR such as, plant variety protection, trade secrets, geographical indications.
5. Moral and ethical concerns such as, inventions involving genetic alterations of plants and animals, preservation of environment, protection of animal and human health by introducing criteria such as, bio-safety, biodiversity, food security, sustainable agriculture etc.

As per Article 3 of the Indian Patents Act, 1970, any form of intellectual property in biodiversity is not recognized. But as per Article 27 of the TRIPS proposals, biodiversity cannot be excluded from IPR control. On the contrary, it extends patents or other IPR related to plant, animal and microorganisms. Being a signatory in the WTO agreement, government drafted an Indian Biodiversity Act through National Biodiversity Bill 2002, which would be introduced in the Parliament; a National Biodiversity Authority is being set up at Chennai in order to follow the guidelines of the WTO convention that India has ratified along with 175 other countries. Thus, patented biodiversity innovation available in the country enhanced the cooperation between Indian and foreign companies.

11.4 Plant Genetic Resources

Farmers' Rights

The plant genetic resources (PGR) always existed at the intra-species level in farms and forests, and as wild species. In reality, 80% of the cultivated area is covered by small farms characterized by interaction between a wide range of plant and animal species in diverse ecological zones. Farmers did efforts for improvement by crossing different cultivars, saving seeds from spontaneous mutation, and by collecting cultivated and uncultivated relatives of agricultural crops. These techniques proved to be useful to provide: (i) resistance or tolerance in plants to the attack of pests, diseases and environmental stress, (ii) specific culinary and nutritional qualities, (iii) raw material for agro-industries and biotechnology projects. But in recent years, genetic diversity declined sharply due to introduction of modern high yielding hybrids and synthetics, which do not always perform well in small farms, compared to local cultivars unless inputs are applied (e.g. fertilizers, pesticides, irrigation). When a farmer is unable to supply these inputs, he/she may face high risk of crop failure or low productivity. Under such financial crunch, farmers should be able to plant cultivars adapted to specific agro-climatic zones and socioeconomic situation (low or without inputs). After having studied the peasant farmers' fate, the Food and Agriculture Organization of United Nations (FAO) resolved in the conference held in 1989 that farmers should be allowed to derive benefits from the improved breeding and IPR through protection of farmers' rights. The new Farmers' Rights Bill has been proposed by central government through which National Gene Fund would be created and the National Bureau of Plant Genetic Resources has been established at Delhi where seeds of indigenous cultivars of all crops are stored in the Gene Bank.

11.5 Plant Varieties Rights or Plant Breeders' Rights

Several exotic plant species imported in India were crossed with local or improved cultivars to increase the crop production. These new cultivars having narrow genetic base have also been used extensively in breeding programmes resulting in the reduced level of variation within plant population. Last year, following the recommendation of the Parliamentary committee, Protection of Plant Varieties and Farmers' Rights Act 2001 was introduced to protect plant varieties either by patents or through an effective *sui generis* system or by any combination thereof. This Act provides legal rights to farmers to save, use, exchange or sell their seeds and stimulates plant breeders to improve crop performance. The authority registers new variety and ensures fair and

equitable benefit sharing or financial compensation. Since farmers play a vital role in conserving local ecotypes and can develop new strains through selection and breeding, they would have the same rights as any professional breeder. In order to avail the plant breeders' rights (PBR), varieties have to be genetically distinct from the existing ones, sufficiently homogeneous and stable, and must not have been commercialized. Plant breeders can use the exotic material for crossing with locals. For this purpose, breeding techniques of *in vitro* pollination, *in vitro* fertilization, *in vitro* mutagenesis, *in vitro* selection, exposing somaclonal variability for increasing diversity, adding or deleting selective plant genes etc., need to be encouraged. The 1991 revisions to the convention of the International Union for the Protection of New Varieties of Plants, 1961 (UPOV), extend PBR protection from the propagating part of the plant to all material derived from the protected variety to the extent that if a protected gene is found in another variety, whether by deliberate or accidental crossing or natural introgression, the patent holder can claim over the resulting variety. In India, private companies are making large investments in crop breeding programmes, particularly for creating GM crops due to global trend towards commercialization. By this way, they safeguard their investment through IPR for their inventions. But this system encourages monopoly resulting in higher cost of these seeds for each crop to be purchased each year by farmers.

11.6 IPR: Status and Repercussions

IPR has a substantial impact on biological diversity, plant genetic research and human welfare in long term. After having studied the status of the genetic resources and community rights, the World Food Summit organized by FAO in June 2002 cautioned about the use of GM crops. In India, the Ministry of Human Resources Development has embarked a campaign to educate public about IPR in the context of globalization and would host the global depository for microorganisms at the Institute of Microbial Technology, Chandigarh. Ownership of genes and need for patents is currently under ethical debate because exotic genes have entered into Indian crop varieties through conventional breeding and it would be difficult to trace their origins. Labelling of foods from GMC has been compulsory in developed countries but in Indian context, there is no public awareness on this issue. This implies to integrate the risks and opportunities associated with GM foods into general food supply of the country.

Constitution of food security norms will facilitate higher-level protection and codify provisions that already exist in the WTO agreement.

Bansal explained major steps involved in filing a patent in India. ThinkGen, a bio-information company based in Bangalore, has also an in-house IPR and patent cell. Total time for grant of patent is 5-6 years and is valid for five years from the date of sealing or seven years from the date of filing whichever is shorter. Since 1995, the Patent Facilitation Cell in the Department of Science & Technology, Delhi provides patent information to public. The Patent Information Office, Kolkata and its branches at Mumbai, Delhi and Chennai, provide guidance, awareness, on line patent search on Internet and issue application forms. At international level, Patent Cooperation Treaty (PCT) was concluded in 1970 and modified in 1984 with objective to facilitate filing of applications. India is also a member of PCT from December 1998. One can now file a single application for patents in several countries but each country gives grant individually. Krishnamurthy, and Varadachari&Joardar suggested certain steps considering the difficulties and prospects of IPR in biotechnology and proposed necessary amendments in the Articles 7, 8 (1 & 2), 27, 29 (1), 34 (1), 40 (1 & 2) for a middle course of action balancing TRIPS with our national interests. To facilitate the clearance of biotech products, the national task force of the Confederation of Indian Industry has proposed a single window agency at DBT as Indian companies have to go through elaborative and complex regulatory process for approvals. This task would include delivery of information, consultancies, resources, trademark and patent searches, legal advice, patent drafting, filing, copyright opinion, technology and business expertise. The Intellectual Property Management Division of CSIR organizes programmes on awareness and planned to have electronic database on Indian herbs, to translate ancient literature and provide this information to public through electronic media and publications. The Ministry of Commerce & Industry, Govt. of India, also established an Intellectual Property Training Institute at Nagpur (Maharashtra) in August 2002. Similarly, DST is associated with >50 countries by international collaborative agreements. While considering the Environment Protection Act 1994, India has taken up initial steps to set up the Traditional Knowledge Digital Library on traditional wealth, medicinal plants, etc. in a digital form in accordance with the international format to facilitate diffusion of information.

11.7 Future Needs

Multidisciplinary linkages within public and private institutions may be established. Such partnership has shown excellent results in the USA and China. This model can therefore be adopted in India. The government has now recognized the importance of IPR and need for motivation to transfer the technology for commercialization, to reward the innovators through encouragement for updating R & D, and for building competence on IPR and related issues. Some issues like cultivation of GM food crops including vegetables, oilseeds, fruits and cotton need to be studied from the point of view of additional benefits to farmers through value addition of pesticide residue free crops. This impact will be clear only after the transfer of biotechnology into fields and its large-scale adoption by farmers.

As India is facing a threat of rapidly growing human population and reduction in agricultural resource base, biotechnology must be judiciously deployed. The Government should ensure continued safe and effective testing before introducing GM crops, and regulatory network to inspire public awareness and confidence. Public debate and participatory approach on the impact of technology on environment, bio safety, sustainability and food security is essential if GM crops are to be accepted by the farmers and consumers. The World Food Summit organized by FAO in June 2002 recommended a temporary ban on GM crops after having studied the status of the genetic resources and community rights.

Protection is better *via* trusts rather than patent owners. This system would encourage, on community basis, an eco-friendly and economically viable growth in crop productivity and consequently in sustainable agriculture. Since there is provision in Article 253 of the constitution, recently the Parliament accorded the implementation of this system within its legal powers.

Available information on PGR and traditional plant products needs protection by the way of legislation and national policies for social and developmental benefits and for encouraging farmers and youth for biodiversity protection. Cultivars affecting socio-economic and ethical issues must be banned completely (e.g. terminator gene). In fact, foreign companies introduce exotic varieties with a narrow genetic base, and do not initiate production of local varieties. So, there should be patent protection through compulsory licensing but informal innovation (without IPR) may be allowed in needy research areas. On this basis, plant breeders should agree with farmers and development agencies if patented variety is used in R & D activity. At present, seed

companies are dominantly present in the Indian market. There is no mechanism to protect the innovations of farming communities and to compensate them if any new variety fails to germinate, it is not eco-friendly and its produce is hazardous to health. As such, any company releasing its variety must compensate farmers if economic loss is incurred from adopting such varieties. These guidelines are not available to share the benefit between development institutes and basic plant material donor. The Government and citizens should come together to protect the knowledge of our traditions from unethical perspectives. It is often difficult to check unscrupulous patenting on traditional knowledge and patenting of plants from their place of cultivation because documentation, validation and recognition of traditional knowledge, geographical indications, PGR etc. is lacking and the present Patent Act does not allow patenting of products *per se*.

For naturally occurring genes and for free exchange of germplasms, patent becomes illogical and hindrance because patents restrict creation of new varieties and access to a common pool of PGR. Any variety cannot be developed or maintained for local distribution by reshowing the seeds saved from the harvest of a protected variety without permission and without paying royalty. Adequate legislation to protect local cultivars, right of farmers over biological resources, biosafety, conservation of germplasms, development and preservation of value added products from plants, animals and micro-organisms, is urgently needed by incorporating the spirit of Article 22, 23, 24 of Section 3 of TRIPS chapter of the WTO/GATT agreement. Biopiracy is on increase day-by-day and difficult to check with present laws because patents are based on DNA sequences. The diversified legal system in transnational co-operation may also lead to colonial exploitation, which is often termed as “bio colonization”. Persons involved in unlawful affairs should be severely punished and heavy penalty should be levied upon them if they don’t respect laws or interpret laws in their favour.

Ex situ conservation of seeds has resulted in some loss of viability and characteristics. Therefore farmers should be encouraged to conserve traditional varieties on their farms. This system would create gene banks that may be diversified and established at least at district level so that plant material would be easily available to farmers who can develop their own varieties. As patented variety would restrict the flow of acceptable and adapted variety to farmers, domestic patent and IPR legislation should include provisions to maintain “Farmers’ privilege” in order to allow farmers to plant saved seeds in successive seasons. This system provides them the incentives for

biodiversity conservation. Indian economy is linked with import and export of essential goods. For example, export duty on cotton is being increased by Multifibre Agreement, which would affect industries and extension activity due to patent protection and policy of "Minimum Support Price". The Japanese rice is nearly eight times costly in the international market but the country imposed a prohibition on rice import to offer higher price to farmers. Indian government has to take necessary steps on these lines. Our export-import policy needs boost through export zones and by establishing Biotech Parks with primary processing facilities; marketing infrastructure and recent information on export rules. Of course, priority should be accorded to growers in economic consequences of marketing.

11.8 Summary

There is an urgent need of an alliance between: (i) private and public sectors, (ii) global giants and Indian firms, and (iii) industry and academia to improve existing technology, identify appropriate biotechnology for adaptation and transfer, to locate patent owners or competitors and fix the areas of investment. Moreover, huge potential of the biotech projects in agriculture cannot be tapped unless the industry changes its model from service to product. For example, China has been able to seek 9000 patents against only 3500 in India. The scope for IPR and patents should be envisaged in the forefront disciplines particularly the genetic engineering, though patents are relatively costly. Biotechnology is an advanced step in science but socio-cultural problems have to be considered as India has ancient basic ethics and religious customs. New research in these domains is welcome and public has to be adequately informed about the biotechnological progress.

Existing knowledge and new technology systems may be employed together in a decentralized and participatory approach for better development. Because formal (laboratory) and informal (farmers' fields) sectors may contribute substantially to maintain genetic and biological diversity otherwise erosion in biodiversity will continue until commercial agriculture through intensive practices will expand. There are political and economic issues pertaining extension of the IPR to plants and their

genetic components, and farmers' contribution to development and conservation of the genetic resources remained unrewarded.

Concerted and collaborative efforts have to be established in near future to ensure close linkages among all concerned so that green revolution is changed into evergreen revolution by means of genetic engineering and other biotechnology sciences and considered as a challenging tool and opportunity for improving the living standard of both urban and rural populations. These challenges are to be accepted with rigidity and commitment as there is enough scope to pursue the development and extension work in biotechnological subject matter.

11.9 Self-Assessment Test

1. Explain farmers' rights.
2. How is patent and Biotechnology in Agriculture related to each other?
3. How are Plant Genetic Resources protected in IPR?
4. What are Plant Varieties Rights or Plant Breeders' Rights?
5. What is the status and repercussions of IPR in biotechnology?

11.10 Further Readings

1. Patents Act, 1970
2. TRIPS Agreement
3. Patent Cooperation Treaty
4. Biological Diversity Act, 2002

Unit 12
Patent and Human Rights Issues
(The Viability of the Life Saving Drugs)

Objectives

The theory of human rights stems from the idea that all human beings are equal and all share certain rights. It can be argued that private intellectual property rights and their protection are being favoured over basic rights such as the right to life and health, the right to share in the benefits from scientific advancement and the right to development. The extent to which this is happening is perhaps most shocking in relation to the Aids epidemic. Patents give a few pharmaceutical companies a monopoly over life-saving medicines. This has enabled the companies to sell drugs at prices that are unaffordable for most people in the developing world. In crude terms, patents have enabled a few to put a price on life and it is too high for many of the world's poorest citizens. It is they who are bearing the cost of protecting monopoly profits, often with their lives. The right to patent pharmaceutical drugs is not a 'human right' but some governments and corporations are favoring the protection of patents over the protection of basic human rights.

Structure

12.1 Introduction

Intellectual property rights in the form of patents give a right of exploitation in information. They are monopoly rights that allow the rights holder to exclude others from using the resource. This ability to exclude others is what leads to a conflict in rights. The specific issue under discussion is whether there is a 'right' to have a patent for pharmaceutical drugs and if so what the nature of this right is and to look at how such patents conflict with basic human rights. Pharmaceutical patents give a monopoly right to the rights holder and put the control of life-saving drugs into private hands, which means high prices can be charged. Many commentators have referred to the pricing of Aids drugs by large pharmaceutical companies as putting a 'price on life' that is too high for many of the world's poorest citizens.

The facts surrounding the Aids epidemic are staggering. In sub-Saharan Africa 29.4 million people are infected with HIV and last year 2.4 million people died as a result of Aids. The cost of treatment can be over $10,000 per person per year but many African countries spend just $5 per person per year on healthcare. Some companies, under great public pressure, decreased the prices of their drugs in certain sub-Saharan countries to $1000, but this is still higher than the cost of generic drugs and too high for those poorest in the world. Patents allow multinational corporations to make large profits on the drugs they own at the expense of others who are often among the poorest people in the world. Poor people should not pay the penalty for protecting these markets. The Commission for Intellectual Property Rights said that private intellectual property rights should not take precedence over human rights. It is to be hoped that this will be followed. At present it can be said that the multinational companies that own the patents and the governments of certain rich countries are putting the right to make profits above the protection of fundamental human rights.

In recent years, the patentability of health-related innovations has become under debate world-wide. Billions of dollars are invested each year in pharmaceutical research, but the percentage of people who can afford potentially life-saving drugs remains minuscule. The consensus amongst the World Trade Organization (WTO) is that public health precedes intellectual property rights during national emergencies. However, the problem is not as simple as a mere question of morality. The development of drugs is costly for pharmaceutical companies, and without intellectual property law protection, the formula for the drugs can be easily duplicated and the drugs can be synthesized at a cheaper cost. Thus, intellectual properties laws often allow companies to monopolize the synthesis and sales of drugs. Unfortunately, this

exclusive right to manufacture and sell drugs provides the necessary monetary incentive for drug discovery.

In 2001, this problem of intellectual property right of technologies that affect public health was address by the WTO in the Doha Declaration on the TRIPs Agreement and Public Health. In the declaration, compulsory licensing of technology of intellectual property that is critical to the health of the public is granted in a time of national emergency. However, what constitutes an "emergency" rests in the hand of individual government. The TRIPS agreement, although hints at the problem of manufacturing the necessary drugs under compulsory licensing in developing countries that lack the sufficient resources, fails to consummate a proper solution. Many developing countries that lack the resources to synthesize drugs at a cheaper cost must depend on the original manufacturers who hold the patents. The TRIPs agreement further prevents developing countries from helping one another. Under it, a country has the right to copy these drugs, but does not have the right to export them. Developed countries that have the resources to synthesize these countries often have laws that allow the drugs to be patented and are thus the ones who hold the patents for these drugs.

The access to health-related technology especially in developing countries is a serious concern. In Africa, the AIDS epidemic is causing alarm world-wide. However, it is reported that only less that 0.1 percent of the people with HIV/AIDS have access to anti-viral drugs. Many developing countries have taken measures that put human rights over intellectual property rights. There are generally two ways in dealing with this issue. One of which is to completely eliminate patents on drugs. In China, any foreign or domestic technology concerning methods of diagnosing or treating diseases is prohibited.

However, due to its policies, companies are reluctant to enter the Chinese markets. In Brazil, since 1996, Brazil has cut the number of people dying of AIDS in half, by providing patented anti-retroviral drugs to 150,000 people free of charge. In India, one of the largest producers of pharmaceuticals in the world, the problem becomes increasingly complex in recent years. Until December 2005, India only allowed patents on methods to produce drugs, but not on the actual chemical composition of the drugs themselves. However after 2005, India changed its policy to allow drug patents in order to encourage more foreign companies to enter India and synthesize their drugs cheaper. The rationale for the new measure is to enable foreign companies

to take advantage of the cheaper production cost in order to lower the prices of drugs for the rest of the world.

The U.S. intellectual property laws protect the rights of small inventors and large corporations alike to guarantee "the first to invent" the exclusive right to the patent, regardless the order of the actual filing of the technology. These measures encourage fair competition and provide incentive for the development of novel ideas and products. In the U.S., The United States Patent and Trademark Office is a centralized governmental agency that handles all intellectual property related matters. The total number of U.S. patents averaged over 160,000 per year in 2005. As of 2006, the U.S. patent office has issues over 7 million patents. The U.S. patent laws do not include compulsory licensing. The implementation of a patent rests solely on the holder of the patent. For instance, a patent on a drug, which falls under the category of utility patent, once granted can be held for 20 years till it becomes public domain. Although America has the technology, U.S. corporations are reluctant to market in developing countries where often their products on in high demand due to their lack of intellectual property protection and widely practiced patent infringement, especially in countries where drug patents are not recognized. Patent laws in the U.S. not only affect the availability of drugs both domestically and globally. Domestically, despite innovations, according to the U.S. Congress, the domestic retail prescription prices have increased an average of 7.4 percent a year from 1993 to 2003, nearly tripling the average inflation rate of 2.5 percent. Without government interference, the costs of drugs are quickly increasing. Retail sales of prescription 1 drugs totalled $179.2 billion in 2003, up 10.7 percent over 2002 and over 4 times as much as the amount spent in 1990. On a global scale, from 1996 to 2000, the U.S. holds the number one spot for having the most overall percentage of medical-related patents in the world, amongst both developed and developing countries. On average, in the U.S., 63% of the patents are medical related, which bring to question the human rights issue concerning patenting of health-related technology. U.S. is also the world leader in medicinal research and drug discovery.

To solve the drug price inflation within the U.S, the Congress has taken initiative in recognizing that drug patents are different from other innovations. In 2005, congressional proposal H. R. 41 to change the way pharmaceuticals are patented was introduced in Congress. Under the new plan, new drugs would be sold at generic prices upon Food and Drug Administration's approval. New drugs, unlike other

innovations, will no longer be rewarded by net-profit from sales, but instead by Medical Innovation Prize Fund at a level of 0.5% of the U.S. gross domestic product, currently a $60 billion per year fund, that provide money to developers of new products based upon the actual impact on health outcomes over ten years. With the passing of this new law, the Congress sends out the message that no individual or company shall have the exclusive right to manufacture, sell, or use a biological product or drug in interstate commerce. It is too soon to tell whether this new measure will be enough to bring down drug prices. Even if the measure works domestically, it is unlikely to solve the problem on a global scale.

Recent year has brought a craze for patenting every novel idea and new technology. Although patents protect the rights of the inventors and encourage innovation, there are certain ideas that should not be patented. Potentially life-saving technologies should be separated from other types of innovations, and money-making should not be the only incentive for drug discovery. For many countries, medical technologies are already under the category of "un-patentable". The rights of human beings to life-saving products, for instance, should come before property rights. On an international level, the WTO's TRIPs agreement marks the first step taken by the world community to solve the issue of intellectual property and human right to health care in developing countries. The incentive for the development of such technology should be measured by lives-saved instead of the money made. With the Medical Innovation Prize Fund, U.S. has invented one way to separate saving lives from commerce. Within the U.S, the new legislation will allow those who could not previously afford them to use them. This will hopefully lead to more legislation that will eventually become an international law that prevents monopoly on drug manufacturing and retail. The number of people world-wide who have access to medicine is staggeringly low, and allowing patents on drugs, although increase the number of advancements in life-saving technologies, will decrease the number of people who has access to them. International efforts should focus on allocating monetary motivation to provide people to access drugs.

12.2 The nature of a right to a patent

Patents often collide with human rights and come off the better, as can be seen in relation to the current Aids epidemic. It has to be questioned whether they should be

able to come above human rights in this way. Put another way, the question that should be asked is whether there is a 'right' to get a patent and if so what is the nature of such a right.

Intellectual property rights are not mentioned specifically in the Universal Declaration of Human Rights, but property rights are. If intellectual property rights and, more specifically, the right to a patent, could come within the scope of property rights in the Universal Declaration, then that could give them the status of a human right. 'Property' is normally taken to mean tangible property, whereas intellectual property is an intangible form of property. Despite this, it could be that Article 17 of the Universal Declaration, which sets out a right to own property, could be read to include intellectual property as well.

One theory about intellectual property applies John Locke's arguments about a right to property. It is based on the idea that a person who labours upon resources adds value to the finished product by virtue of their labour and has a natural property right to the results of their labour, which the state has a duty to enforce. This can be applied to intellectual products, as they are the result of a person's intellectual labour. It is arguable that there should be a natural right for a creator to own what they produce.

It can be argued that the labour theory of property is not entirely suitable for application to intellectual property. Although intellectual labour is important in creating the value of the product, often more than one person may have contributed. This is especially so with patents for pharmaceutical drugs where many people and maybe different institutions will have been involved with the research and it might even be that some of the research was government funded. The labour theory does not provide a justification of why, when so many people have been involved, a right of ownership in the product should be granted to one person or institution, for example a single company.

Locke's theory was that everyone owned property in their own person, which included their labour. When they used their labour to give a resource value they had a natural right to the product of their labour. Patents for pharmaceutical drugs can be seen to be more of an investor's right rather than a creator's right, as it is usually the body that has invested money in the research which will get the patent rather than an individual whose labour produced the product. In this way a patent for a pharmaceutical drug is not a natural right in the same sense as a creator's right to the reward from his labour.

Companies argue that because they have invested time, money and resources into producing a drug, then this is analogous to a person using their labour to transform a resource and so they should be able to earn from what they have invested. In this way companies can further argue that as an extension of their right to property they also have a right to earn and make a profit from their investments. It is arguable that in the same way states should enforce the right to own property, they should enforce the right to make profits as a corollary of the right to property. Patents facilitate this by protecting ownership of the product. However, there is no specific right to a profit.

Robert Nozick makes an interesting interpretation of Locke's argument, focusing particularly on the idea that the acquisition of property rights by a person mixing their labour with resources held 'in common' is only legitimate if 'there is enough and as good left in common for others'. Nozick interprets this to mean that it is only legitimate if others do not suffer any net harm by a person acquiring these property rights. This is an interesting idea, especially when applied to pharmaceutical drugs and the Aids crisis, which is acknowledged by many to be a public emergency. That patents prevent people in poor countries being able to get access to cheap drugs could be said to be a net harm. For example, in Swaziland four in ten people have HIV and life expectancy is now 37 years when a decade ago it was 61 years. When patents block the production and distribution of cheap drugs that could help prevent this, then it can be said that patents are causing great harm to others.

Another theory of intellectual property is based on the idea of the maximisation of net social welfare. It is thought that a balance needs to be made between stimulating creation and the limiting of general access to the use of creations. It takes the idea that patents are necessary to some extent for innovation but that there needs to be a balance between encouraging innovation and the harm caused. When the harm caused by patents is the deaths of many in some of the world's poorest countries, we have to ask if this is an acceptable balance.

Nozick argues that patents do actually benefit consumers, because although they limit access to a product by others, the new discovery would not have been made without the incentive of a patent. Poorer countries benefit as patents encourage research and they will be able to use the products freely once the patents expire. New drugs depend on research and profits and so patents, which are a way of ensuring a return on investment, are important as a public policy tool to be an incentive for research and discovery. The average cost of developing a new drug is estimated to be around $500

million and so it has been argued that without a patent system that rewards for taking risks, anti-Aids drugs would not exist. The idea that patents are necessary for innovation is questionable. There were many important inventions and discoveries made before patents existed and not all persons who develop new medicines choose to get patents. For example, Alexander Fleming did not get a patent on penicillin and Jonas Salk did not get a patent for his polio vaccine. This shows that significant research and scientific progress can be made without the incentive of patents. Although patents may be a useful policy tool to encourage innovation, this does not add to the argument that there must therefore be a right to get a patent.

There are further problems in trying to portray patents as property rights using the labour theory. Locke thought of property rights as lasting forever. Patents differ from Locke's conception of property rights, as they are limited in time and need to be registered to come into being. They are not rights that arise automatically and are not natural rights in the same way more traditional property rights are.

Even if patents are a property right, the right to own property is not an absolute right. Article 17(2) of the Universal Declaration limits the right to own property. As long as it is proscribed by law, a state can regulate property rights to adjust them to social and economic circumstances. In this way property rights differ from other fundamental rights, as they can be limited in ways other rights cannot and so there is a conceptual problem when comparing property rights to other fundamental human rights. Another conceptual problem in trying to portray patents as human rights is that intellectual property rights can be 'exhausted', which is not a feature shared by fundamental human rights.

Even within patent law, patents are not given the status of being absolute. For example, Article 31 of the TRIPS Agreement allows for compulsory licensing, recognising that there are circumstances when patent protection should be relaxed. It is also interesting to note that Canada recently overrode a patent held for the antibiotic to anthrax, ordering a generic copy to be made. The US threatened to do the same, so the drug company agreed to provide cheap bulk supplies to the government. This shows how even America, one of the strongest advocates for patent protection, does not consider patents absolute rights. Yet it is America who, out of 144 countries, was the only one to oppose an agreement that would have provided cheaper drugs to poorer countries by relaxing global patents on pharmaceuticals. If the US and Canada can use compulsory licensing, or the threat of it, to respond to the problem of anthrax, which

has only killed a few so far, then developing countries should be allowed to relax patent protection in the same way to respond to the Aids crisis which has killed 23 million.

Peter Drahos makes a stark comparison between intellectual property rights and human rights by saying that a person having their work copied is not the same as that person being stripped of essentials such as food. When thinking about what it is that human rights try to protect, intellectual property is not high on the list of what is essential. Intellectual property can be seen as a western notion, and is not yet at a stage where it should be given the protection of a universal norm. Many countries do not have patent systems but it is not said that they are in breach of fundamental human rights. Whether it is to develop to such a universal norm is perhaps dependent on society and the values we wish to promote. Other countries have resisted patents for pharmaceutical drugs until relatively recently. For example, pharmaceutical products only became patentable in West Germany and France in 1967, in Italy in 1979 and as recently as 1992 in Spain.

It is arguable that patents are not property rights at all within the Universal Declaration but are grants of monopoly privileges by the state. A patent is not automatic but needs to be registered and is limited in time. It is not absolute. So patents actually resemble a grant more than they resemble a right. The problem is that they are increasingly promoted as natural rights. They are portrayed as the right of the creator to the product of their labour, which gives them a certain moral force. It becomes posed as a question of whether it is right that others should be able to copy and gain from the success of the inventor. But this masks the reality. As already said, often pharmaceutical drugs are the result of research by many people and institutions. Posing the issue in terms of creator's rights and the need for profits to fund further research, sidelines the issue of how patents for pharmaceutical drugs enable the patent holder to charge high prices for drugs to the detriment of the lives and health of many of the poorest people in the world

The main arguments, then, for recognising the necessity of protecting patents are that they are a natural right deriving from the right to property and that they are necessary to encourage innovation. However, it has been shown that patents, while they can be thought of as property, do not share the same nature as more traditional property rights and cannot be said to have the status of a fundamental human right. The Commission for Intellectual Property Rights said that intellectual property rights should not

take precedence over human rights. This shows that in their view patents and other forms of intellectual property are not rights in the same way that fundamental human rights are and so should be subject to these other rights accordingly. Patents are granted by the state in furtherance of policy objectives and these should respect fundamental human rights, not impede them

Intellectual property rights are not actually rights in the way we consider human rights to be, or within a strict definition of property rights. Yet western countries and multinational corporations are often criticised of prioritising patents over the demands of developing countries for affordable healthcare. In the context of healthcare in poorer countries and the Aids crisis in particular, patents can be seen to conflict with a number of human rights.

12.3 The right to life

The most significant human right that patents for pharmaceutical drugs impede upon is the right to life. This is set down as a fundamental human right in Article 3 of the Universal Declaration. An associated right, and one that is relevant in the context of the Aids crisis, is the right to a standard of living adequate for the health and well-being of the person, contained in Article 25 of the Universal Declaration.

One issue that arises is how far such rights should extend. It could be argued that patents actually support such rights because they encourage research into drugs and without patents these drugs would not be invented in the first place. However, as discussed in the previous section, this link between patents and innovation is not certain. Even if it were, a balance needs to be made so that the reward for innovation does not come at the expense of people's lives and standard of living. Gordon Brown wants multinational pharmaceutical companies to allow poor countries to buy cheap versions of their drugs. It could be argued that as part of the rights to life and health, companies should not be allowed to impede people's access to the healthcare that can save their lives. The Commission for Intellectual Property Rights stated that in 'the absence of patents more people would be able to afford the treatments they need'. While patents allow companies to sell their drugs at unaffordable prices, people will continue to die unnecessarily.

Patents can be a tool of public policy to help promote innovation, but this should not be taken too far. As said in the previous section, patents are grants and should not be

treated as natural rights. While developed countries seek to protect their pharmaceutical industries, developing countries are struggling to meet the needs of their citizens for more affordable medicines. Millions are dying in the developing world although the drugs exist that could help them.

Generic drugs would be more affordable and give more people access to the medicines that could help them. Yet pharmaceutical companies object to the selling of generic drugs because it damages their profits, even though the TRIPS Agreement allows for the use of generic drugs and also for the parallel imports of drugs when there is a public emergency. Millions dying is clearly a public emergency. Yet when the South African government passed a law to allow for the importing of cheaper drugs to protect the health of the public, 39 pharmaceutical companies took the government to court and the USA placed South Africa on a 'Special 301' list of countries subject to trade sanctions.

South Africa resisted the pressure and, supported by several non-governmental organisations, was taken off the 'Special 301' list and reached a settlement with the drugs companies. However, this settlement provides for co-operation between the pharmaceutical companies and the South African government, which means that the government is still forced to consider the drug companies' interests when making policy decisions about public health. The TRIPS Agreement should not interfere with public health, but when states try to use its more lenient provisions they meet with resistance and even bullying. In this way, patents are being protected at the expense of greater access to medicines and at great cost to human life. It seems ridiculous that a grant is favoured over a fundamental human right.

It is not just the right of control that patents enable, but the right to make a profit. That companies were able to cut their prices so much, for example by up to eighty per cent in South Africa after the court case, does suggest that previously the profit margins for pharmaceutical companies were huge. Profits in the pharmaceutical industry had reached a rate of return on investment that was more than twice the US average. Patents enable the drugs companies to control prices. This has meant that drugs can be more expensive in developing countries then developed countries. For example, drugs can cost up to ninety-eight per cent more in South Africa than in Europe. It has been said that the theory of price discrimination is a way of reducing the number of people priced out of the market while the company can make the maximum profit. However, the drugs companies seem to pursue a 'high-price, low-volume' strategy with regards

to marketing their drugs in poorer countries. So price discrimination clearly does not give greater access to medicines in developing countries.

Pharmaceutical companies argue that they have the right to control their business affairs and to price discriminate as they wish. A report in The Guardian said that access to Aids drugs boils down to the difference between life and death for many. When millions are infected with HIV and cannot get the medicine they need because it is unaffordable this would certainly seem to be so. Access to drugs is made impossible when they can cost up to $15,000 a year, a figure twenty-four times the average annual income in Zimbabwe for example, where one in four adults are HIV positive.

While profits may be important for further research, the 'right' to profit is not a human right and should not be pursued to the detriment of the human rights of others. Drugs companies are making huge profits and patents allow them to do this. Meanwhile, millions are dying because the drugs they need are too expensive. Stephen Lewis asked why this is not called murder.

12.4 The right to scientific development

Article 27(1) of the Universal Declaration states that everyone has the right to share in scientific advancement and its benefits. It could be argued that in addition to this, developing states also have a claim to being able to share in the benefits of what is discovered, as often it is resources which are taken from the South for free which are used and transformed into protected property.

The right to benefit from scientific advancement can be seen as supporting the rights to life and health. It is particularly relevant to medicines and the Aids crises. Many cannot benefit from scientific discoveries because they cannot afford the drugs. A patent allows the owner to charge prices at which they can make a profit and to stop others from selling cheap copies while others are dying for lack of being able to afford the drug. This right to benefit can be used to argue that patents should not be granted for pharmaceutical drugs, as this is progress which everyone should be able to benefit from and one person should not be allowed monopoly control over such products that have the ability to save lives.

Article 27(2) protects the author's moral and material interests resulting from scientific production. This could be seen to limit the extent to which Article 27(1) should be

interpreted. However, Article 27 should be read with the other rights in the Universal Declaration. The rights to life and health are particularly relevant when discussing pharmaceutical patents and the Aids crisis. They suggest the need for a balance. There is a tension between the rules protecting creators of information and the rules that ensure the general use of information. The rights of owners should not be pursued to such an extent that they act contrary to other rights in the Universal Declaration and can even be seen to be destructive of those rights. Millions dying of a disease for which a treatment exists is not an acceptable balance. We should use our collective discoveries and inventions to benefit humanity

12.5 The right to development

The right to development is attached to the debate on patents for pharmaceutical drugs and the Aids crisis in two ways. Firstly there is the effect that the Aids epidemic is having on countries which are among the poorest in the world. There is the question of whether richer countries and multinational companies have a duty to help, or at least not to restrict access to drugs which could help stop the Aids epidemic, which is killing and infecting millions unnecessarily. The second issue is to do with the international enforcement of patents and to ask what effect it has when developing countries are forced to protect patents.

Development is not a right under the Universal Declaration. It was not until 1986 that such a right was properly articulated by the UN. Article 1 of the Declaration on the Right to Development put forward the right of development as an inalienable human right. Only America opposed this Declaration. The problem with the right of development is that it is difficult to enforce and the bearer is undefined.

As a UN General Assembly declaration, the Declaration on the Right to Development does have significant weight in customary international law and this could be strengthened further depending on state practice. A global consultation on the right to development in Geneva in 1990 reaffirmed that the right to development is a human right but said that the definition of development is largely subjective. This led them to conclude that development strategies must therefore be decided by the people themselves.

The idea that the right of development should include the right of a people to choose their own model of development, as well as a right to receive a share of resources, is

significant in relation to the discussion on pharmaceutical drug patents. Rich countries are insisting that poorer countries should protect patents. Their argument is that patents can help economic development, for example by encouraging foreign investment and local innovation. However, it is unlikely that there will be much investment or local innovation unless the infrastructure already exists. There are huge costs involved in setting up and running a patent system, which affects resource allocation at a time when some of these states are struggling with large-scale health crises. Development includes the right of a state to choose their own model of development and allocate resources where they are most necessary. The right to development is subjective and it needs to be recognised that there is no one universally applicable model of development. The TRIPs agreement removes the ability of developed countries to balance their particular development needs with their need for the protection of intellectual property rights and limits their ability to make decisions about their own path of development.

Further, it can be questioned as to how suitable a patent system is for developing countries. When countries that are now developed were in the stages of developing, they did not have patent systems. France, Germany, Italy, Japan, Sweden and Switzerland, which have some of the most innovative pharmaceutical companies, did not provide pharmaceutical products with patents until their industries had reached a certain level of development. When the USA was still a relatively young and developing country, it refused to respect international intellectual property rights on the grounds it was freely entitled to copy foreign works to further its social and economic development.

It is cruelly ironic that it is now the USA that is the strongest voice in insisting on the protection of international intellectual property rights. If at the same stage in their development developed countries had had to adhere to the minimum standards set by TRIPs, it is doubtful many of them would have attained the levels of technological development that they have. Developing countries are being asked to adhere to intellectual property standards that would effectively prevent them from being able to take the same path of technological development. It is difficult not to see international patent protection as anything but purely for the benefit of developed countries and a few multinational drugs companies, reinforcing the current wealth and power allocation. The rhetoric of patents and the 'rights talk' surrounding them has its origins in western developed countries and reinforces a certain state of affairs. Patents may

only be part of it, but they are still a way, in which wealth continues to flow from poor to rich countries because of the high prices that can be charged, thus reinforcing the unequal state of affairs that exists and supporting the capitalist markets of the west. As the Commission for Intellectual Property Rights said, the 'globalisation of intellectual property protection will result in very substantial net transfers from developing to developed countries'.

Economic growth is not the only relevant factor. The United Nations has rejected the idea that development simply means economic growth. In 1990 the UN started to use the Human Development Index, which takes into account other factors besides wealth when considering development. Health is a very important one.

Aids workers are comparing the epidemic to the Black Death, which wiped out a third of Europe's population in the fourteenth century, but say that in the long term the current epidemic could be worse. 2.5 million People died of Aids in Africa in 2001. Dr Glenda Gray, Director of an HIV clinic in Soweto, says that in her opinion the biggest threat to South Africa is HIV, describing the situation as 'genocide'. It is not hard to see why when confronted with the figures. It is estimated that in South Africa alone, Aids will have killed 1 million people by the end of 2003 and that by 2010 3 million children will be orphans. In Swaziland the estimate is that one in three children will be orphans by next year.

It has to be asked how a country can cope with losing so many people so quickly and with so many becoming infected. 1600 people contract HIV every day in South Africa and it is predicted that by 2005 6 million of South Africa's population of 40 million will be infected with HIV and that within five to ten years 3 million will have died from Aids. With deaths of this scale, a whole generation is close to being lost. In terms of development, countries are losing the important resource of a healthy workforce. Plus, as more people become infected and the numbers of orphans increases due to Aids related deaths, the problems will become worse for states, as these people will need to be supported. Aids is not the only problem, for example malaria causes many deaths too, but when over 30 million people in Africa have HIV and millions are dying of Aids, the crisis is pressing. It is not a problem that is going to fade away by itself. For example, in South Africa 130,000 children a year is infected by their parents alone.

According to Dr Jonathan Quick, who works for the World Health Organisation, the implications of not increasing access to HIV drugs will be millions of disrupted

families, millions of deaths, and a number of countries whose basic economy and future are disrupted. Patents enable a few people to make access to life-saving medicines impossible for some of the poorest people in the world. The impact of this will be catastrophic for what are some of the poorest countries in the world. Their workforce will diminish and state dependency will increase as people become ill and as the number of orphans rises. This crisis comes as these states are trying hard to develop and it will be even harder with these problems.

If countries are to have chance of fighting the problem of Aids they need to be able to have access to the medicines that help treat patients. It is a public emergency and so they should be allowed to use compulsory licensing as provided for in Article 31 of the TRIPS Agreement. Pharmaceutical companies and developed countries should not seek to protect their profits and economic development over the lives and health of the world's poorest citizens. Patents should not be a block to development.

12.6 Summary

Patents are not human rights and should not be treated as having the status of fundamental rights. Patents are acting as obstacles to basic human rights, such as the rights to life and health, the right to the benefits of scientific advancement and the right to development. Western states and multinational companies are often seeking stronger protection for patents regardless of fundamental human rights. It is the responsibility of the international community to uphold these human rights.

Restricting the use of patents for pharmaceutical drugs will not by itself solve the Aids crisis, but it is an important practical step. It will allow access too much needed drugs, previously denied because of price. In Brazil the government issued compulsory licenses for Aids drugs, which were then produced at a cost of seventy per cent below the market price. There was a fifty per cent decrease in Aids-related deaths between 1998-2002. This shows that more affordable healthcare is important in fighting the battle against Aids. Relaxing patent protection will also be symbolic of the commitment to uphold human rights and to show that developed countries are committed to helping tackle one of the worst epidemics seen in the world.

12.7 Self- Assessment

1. What is the nature of a right to a patent?

2. Explain the right to life and its relation with a right to a patent?
3. Explain the relation between the right to scientific development and right to a patent?
4. How the right to development can be brought in consonance with a right to a patent?
5. Explain the statement "The viability of the Life Saving Drugs vis-à-vis patent and human rights?

12.8 Further Readings

1. TRIPS Agreement.
2. Universal Declaration of Human Rights.
3. Patents Act, 1970.

Unit 13
Patent and Health Rights Issues

Objectives

Although scientific and technological innovation has contributed to significant improvements in health conditions, health crises, relating, in particular, to HIV/AIDS, malaria, tuberculosis, and, most recently, avian influenza, continue to create major problems in many parts of the world. In various national and international fora, solutions are sought in respect of the role of patents in pharmaceutical innovation and fair and affordable access to health care.

The patent system is designed to promote innovation and, at the same time, offer a mechanism ensuring that the fruits of that innovation are accessible to society. In the contexts of public health, the challenge for policy makers is to find an optimal balance between the rights of patent owners, who provide technological innovations to improve health conditions, and the needs of the general public.

Structure

13.1 Introduction

The notion of intellectual property (IP) is contentious. Nonetheless there is justification for granting exclusive rights to some original useful products or processes if the result benefits the common good. This is recognized in Article 1, Section 8 of the U.S. Constitution, which establishes the power of Congress "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." The length of time is somewhat arbitrary, has varied over the past century, and is vastly different for copyright than for patents, the latter offering much stronger protection for a shorter period of time.

Although scientific and technological innovation has contributed to significant improvements in health conditions, health crises, relating, in particular, to HIV/AIDS, malaria, tuberculosis, and, most recently, avian influenza, continue to create major problems in many parts of the world. In various national and international fora, solutions are sought in respect of the role of patents in pharmaceutical innovation and fair and affordable access to health care.

The patent system is designed to promote innovation and, at the same time, offer a mechanism ensuring that the fruits of that innovation are accessible to society. In the contexts of public health, the challenge for policy makers is to find an optimal balance between the rights of patent owners, who provide technological innovations to improve health conditions, and the needs of the general public.

13.2 The Moral Justification of Intellectual Property

Because intellectual property is significantly different from other kinds of property, the ethical defences of intellectual property differ from the defences- such as the Locke an- of other kinds of property, and traditions in different parts of the world treat intellectual property differently. Nonetheless, there is a two-part argument in defence of the ethical legitimacy of limited intellectual property rights that is intuitively attractive, widely held, and, I believe, sound.

The first part is a fairness, or justice, argument that says that, within the economic system of free enterprise, those who spend time and/ or money in developing a product or the expression of an idea deserve a chance to receive recompense if the result they achieve is useful and beneficial to others who are willing to pay for it. It would be unfair or unjust for others to take that result, market it as their own, and profit from it

without having expended comparable time or money in development, before the original developer has a chance to recoup his investment and possibly make a profit. Intellectual property protection gives innovators this chance.

The second part of the argument is based on consequences. It states that unless developers are allowed a period during which to recoup their investment and make a profit, the incentive to produce new products beneficial to society will be greatly reduced. Society benefits from new products, both initially and after they are no longer protected and fall into the public domain. Hence, the greatest benefit to the common good or to society is achieved by offering inventors and developers of new products a period during which they can make their profits without the competition of free riders. Both arguments together lead to the conclusion that protection of intellectual property for a limited period of time is just and produces more good for society than an absence of such protection.

I shall call the two arguments together the Standard Argument (SA). For the sake of argument, let us accept SA as a valid moral justification for intellectual property. It is general in form, and applies to pharmaceutical products as well as to inventions, machines, and other types of intellectual property. There have been many studies by economists to support the second part of the Standard Argument. The pharmaceutical industry and some economist have persuasively argued that more new drugs are developed when pharmaceutical companies make sufficient profits to invest in research and development, and the pharmaceutical industry argues that the large profits for which the industry is known are necessary to underwrite both the high cost of developing a new drug and the large number of initial attempts that never turn into successful, marketable drugs.

The industry then builds on the Standard Argument to develop what I shall call the Status Quo Approach (SQA), which is a legal economic approach, to reply to critics of their policies who adopt not an economic but a moral approach to pharmaceuticals. The Status Quo Approach takes existing intellectual property law, especially patent law, as setting the appropriate parameters within which to view and answer all challenges to the practices of pharmaceutical companies. Taking this approach leads to concentration on using the law to help these companies protect and increase their profits so that they can develop new drugs. Thus they defend their techniques to extend the time before which generic drugs can be introduced, to extend patent protection on an international level through the World Trade Organization (WTO), to

produce me-too drugs or drugs that are only marginally different from existing drugs rather than concentrating on breakthrough drugs, and so on. Morally based attacks that make a link between patents and the availability of drugs for the poor are rejected as misconceived. Nonetheless, there is an attempt to diffuse the latter attacks by giving away some drugs in some circumstance

These giveaway programs are presented as the industries or a particular company's living up to its social responsibility. Social responsibility is the surrogate for moral responsibility, is part of the Status Quo Approach, and is seen by the industry as answering morally based criticism.

The SQA is an approach that pharmaceutical companies are comfortable with, as well as one that is widely accepted. It has the benefits of tradition, of requiring no change in current practices or law, and of having produced beneficial results in the past. Hence, one can argue, it is more likely than untried alternative schemes of intellectual property protection to produce beneficial results in the future. The approach thus entrenches and sanctifies the status quo.

Both the Standard Argument and the Status Quo Approach, however, are coming under increased strain and attack, and in this paper I shall attempt to examine the direction of those strains and the validity of these attacks. Only if we fully appreciate the Standard Argument and the Status Quo Approach, and their shortcomings, can we make sense of the continuing charges made by critics and the responses made by the pharmaceutical industry.

13.3 The Limits of the Standard Argument

Patents, I have argued, can be justified from an ethical point of view. But that justification is limited. Despite the constitutionally stated basis for patents, neither common good (nor utilitarian) considerations form part of what is required for a patent. Nor have ethical considerations been a dominant consideration in changes that have been made in patent law. Hence the details of how patent protection has developed do not follow from the ethical justification. It is not that the way in which patent law has developed is unethical, but that it is only one of many sets of ethically justifiable ways of protecting pharmaceuticals.

Discussions of intellectual property are very complex and involve knowledge of convoluted laws, legal decisions, and economic and business analyses. Typically, at

any negotiation involving intellectual property prior to the drafting of legislation, the parties are government officials, lawyers, and corporate representatives. Thus the best defence of those policies is given not in ethical but in legal and economic terms. This is why the SQA uses these. Critics, however, fail to be convinced by such considerations. It is not clear to them who, if anyone, represent the general public in the general process. It is difficult for any government to represent both the consumer and the industry, and the public's trust in government as representing the public's interest is lessened when the industry present in the negotiations is the pharmaceutical industry, which is known for being one of the most successful lobbying groups and for being among the top spenders of lobbying money.

The complaint about the Standard Argument is not that it is wrong, but that it is taken to prove too much and to respond to all objections. The mantra that is repeated by industry representatives in every context and in reply to every criticism with respect to intellectual property protection, pricing, and access is that unless the pharmaceutical companies are profitable enough to have the funds to do so and can expect future profits from their products, they will not engage in R&D and will not develop new drugs, which, of course, benefit society as a whole. When critics point to the fact that the industry has the highest rate of profit of any industry year after year, this is the primary answer. When critics complain about the high cost of drugs and the fact that the price of drugs increases much faster than the inflation rate, this is their answer.

When the critics claim that the developed nations are forcing the less-developed ones to adopt standards of intellectual protection that go against their traditions and may not be in their best interests, this is their answer. When critics say that the reason for intellectual property protection is not private profit but the common good, this is the answer.

13.4 The Right-To-Health-Care Argument

Just as the Standard Argument is often assumed by the pharmaceutical industry, the defence of the right to health care is often assumed by its critics. The critics do not deny the overall validity of the SA and the SQA, but at its limits the critics challenge the application of the argument and the defences of their practices given by representatives of the pharmaceutical industry. The central claim is that although the Standard Argument justifies the right to intellectual property, the right is only a prima

facie and not an absolute right. In many cases the right holds sway and trumps other considerations. But in the case of pharmaceuticals it comes up against other prima facie rights, namely the right to life, the right to adequate health care, and the right to access essential lifesaving drugs; it comes up against the obligation to aid those in need; and it comes up against competing claims made in the name of the common good. The right to life, the right to adequate health care, the right to access to essential lifesaving drugs, and the obligation to aid those in need, critics note, must be given at least as much consideration as intellectual property rights. Not only do IP rights not necessarily trump those other rights, but they are in fact often trumped by them. The pharma industry tends to argue that intellectual property rights are always sacrosanct, when they are not. Although critics sometimes give too little weight to the actual strength ofIP rights, the rights to health and to health care raise serious issues in certain circumstances about the pharma industry's claims. Hence the discussion does not end with simply asserting the Standard Argument and the SQA.

What then are the arguments in support of the right to health and health care and the right to access, and how can they be weighed against the right to intellectual property? There is considerable confusion in the literature, and although the basic ethical claims are usually fairly clear, how they are justified is not.

We can start by distinguishing two different rights that are often confused

They are related but are not identical. One is the right to health; the other is the right to health care. The UN Declaration of Human Rights, Article 25, states

(1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age, or other lack of livelihood in circumstances beyond his control.

Although there are a number of different rights included in this sentence, for our purposes two are central. One is the right to health; the other is the right to medical or health care. It is generally agreed that the rights stated in the Declaration are primarily rights that members of a state enjoy vis-à-vis their governments. Thus, the primary obligation that is correlative to the right to health falls on the state. The right to health has perhaps received so little attention in developed nations because in its most plausible sense these nations face no problem with respect to it. Most plausibly the right to health is analogous to the right to life. The state cannot give anyone health. Its

obligation, rather, is to ensure that the conditions necessary for maintaining good health are provided and to prevent any party from damaging the health of another. Understood in this way, the state has the obligation to provide those conditions that promote the health of its citizens, such as ensuring clean water and air, providing sewers and sanitation, and taking other basic measures necessary to promote and protect the health of its members. But although states may have that general obligation, their obligation does not exhaust the obligation of others. The rights impose obligations on business, individuals, and others as well. It is a violation of the human right to health, for instance, for manufacturers to dump toxic waste that will infiltrate a community's water supply and cause people to fall ill. The obligation not to cause harm to people's health and thus not to act in this way is a negative obligation. Positively, companies are bound to provide safe and healthy working conditions for their employees. Providing these conditions is an obligation imposed on them by their employees' right to health, whether or not it is also required by law. And positively, the government has the obligation to pass and enforce such laws.

If one reads the right to health care in the same way, then it is an obligation of states or governments to see that medical care is available to their people, whether or not the governments actually provide it. Although states are generally held responsible for protecting the health of their citizens by providing the common goods of clean drinking water and sewers and other general sanitation facilities, they are not usually held responsible for providing health care in the same way. The reason is that the principle of subsidiary comes into play. The principle of subsidiary states that one does not call on a higher level to do a job that can be done at a lower level. With respect to health care, it is usually applied intuitively, even by those who do not use that term. Thus, when children get sick, for instance, it is typical for their parents to care for them, and family members usually are the primary caregivers, rather than the state. When a family is unable to adequately care for someone who needs medical care, they might first go to the circle of friends, or to the larger community. When the community cannot handle the need, they go to the city or the state or federal level. Although in a developed society the structures are in place to handle the needs of people at the appropriate level, they are considerably different in a country that has a socialized medicine program than in a country that does not. If a government is unable to handle the need or needs it faces, it might appeal to the international community. Also assumed by this process is that individuals having not only the right to health and

health care, but they also have the obligation to do what they can to preserve their health and to care for themselves to the extent they are able to do so. Thus the rights to health and to health care impose correlative obligations on many parties. So far the obligations of pharmaceutical companies are no different from the obligations of other companies. But this is only part of the story.

Another argument comes into play here that develops the obligation to help others in serious need to the extent that one can do so. There are two versions of this. One is a weak version which says that one has the obligation to help others in serious need to the extent that one can do so with little or moderate cost to oneself. A stronger version says that one must do so even at great expense to oneself, although one does not have to make oneself worse off than the person or persons one is helping. The obligation to aid others in serious need can be justified by either a rule-utilitarian approach, which argues that more good is achieved overall if this rule is followed than if it is not; or by a deontological approach, which bases it on the respect due others as persons and beings worthy of respect. The obligation is one that is widely acknowledged. Intuitively, if one sees a child drowning and one can save the child's life by extending a hand, one has the obligation to do so. Not to do so would be characterized by most people as inhuman or barbaric. The obligation holds even if one will be late to an appointment, or if one will get one's shoes wet in the process of saving the child. The obligation becomes less clear as the cost to oneself increases, and most would agree that one is not obliged to save the child at the risk of one's drowning oneself.

The application of this principle with respect to an individual vis-a-vis a drowning child is straightforward. It becomes more and more problematic as the case becomes more complex. What if the child is drowning in the water of a crowded beach, with a thousand people on it? Is it the obligation of each of the thousand to save the child? Is the obligation greater for those closer? Is it exculpatory for someone who is dressed to say that the obligation falls on those in bathing suits? Would all be equally blameworthy if no one did anything and the child drowned? Now increase the number of children drowning, say from an overturned boat, to twenty. Each person on the beach can save at most one of the children. Is it the obligation of every person on the beach to save all the children, or to save only one, and, if the latter, which one? When we then move to millions of people in danger of death from the lack of medical care in the world and ask what is the obligation of developed countries, of those living in developed countries, of NGOs, and of pharmaceutical companies with respect to the

needy, the arguments tend to get more and more tenuous. This is not to say that there is no obligation to help based on the right of the people to health or medical care. But the complexity of the situation suggests the need for action by many parties on many levels.

If one accepts the obligation of aid, then it is not difficult to argue that those in the best position to help have the greatest obligation to do so. Now join that with the fact that those in the health professions have special obligations with respect to health and health care. They have these special obligations because of the field they have freely chosen, because they are related to health care in a way others are not, because they have the expertise that others lack, and because they make their living or profit from health-related activities. A doctor, for instance, has a greater obligation to help an accident victim if other aid is not available, than does someone without medical training. A hospital has a greater obligation to help an accident victim brought through its doors than does a bank or a department store, and people naturally would bring such victims to a hospital rather than to some other kind of enterprise.

With this background we can develop the right to access to needed medicines. But the argument works differently with respect to lifesaving medicines, to those which are necessary for health but which treat non-life-threatening illnesses, and to those that are neither and are simply life-enhancing.

The strongest case can be made for the right to access to those drugs that are essential for the preservation of life. If one has the right to life, then one has the right to that which is necessary to sustain one's life—be it food and shelter, or medicines and medical care. Medicines, obviously, are included in medical care. The right of access to available lifesaving medicine has both a negative and a positive aspect. Negatively, all have the obligation not to prevent anyone from having access to what they need to sustain their lives. The positive obligation to ensure that access is available, as in the earlier case, falls on a variety of parties (applying the principle of subsidiary) and is practically limited by the goods and resources available in a given situation. I shall call the set of arguments I have sketched out above the Moral Argument

People typically invoke something like the above general arguments with respect to the drug industry and drug companies. The various claims are that the industry as a whole and the individual companies that make it up have special obligations; that these are related to what they produce, namely pharmaceutical drugs; that they are in a special position to help and that therefore they have the special obligation to do so; and

that those in dire need, because of their right to health care, impose obligations on those able to help, including the pharmaceutical industry.

We can apply this claimed right to access both on the international and on the national level in the United States and see how we can weigh it against the right to intellectual property.

We should note that approaching ethical issues relating to the pharmaceutical industry from the perspective of the Moral Right to Access dramatically changes the issues that rise to the surface as opposed to those that arise when taking the Standard Argument and the Status Quo Approach. To see how, we can start with the pharmaceutical companies' use of the term "social responsibility."

13.5 The Moral Responsibility of Pharmaceutical Companies

With this background, we can now ask: What are the obligations, from an ethical point of view, of the pharmaceutical industry as a whole and of individual pharmaceutical companies? The above discussion forms the background that is generally understood by critics, even though they do not often articulate their arguments very clearly. Can we come up with general obligations that stem from the rights of those in need of medical care? Clearly, pharmaceutical companies are not the only healthcare providers and the entire obligation to fulfil the rights in question does not fall on them. And clearly if they have special obligations, that does not mean that governments, individuals, families, NGOs, and so on do not also have obligations. Since governments have the primary responsibility to provide for the health care of their citizens, they bear the primary obligation. They may either meet this obligation directly or indirectly by ensuring the needs of the public are met in some other way.

Given present structures, the pharmaceutical industry, as part of the health-care system, arguably has two basic ethical obligations. I shall call the first the Production Obligation and the second the Access Obligation. The obligations of the industry with respect to health care are broader and more general than the obligations of any particular pharmaceutical company. The industry's obligations can only be met to the extent that individual companies take the appropriate action. Yet the two levels—industry and company—should be kept distinct, even though many critics conflate the two.

13.6 The Production Obligation

The Production Obligation consists in the obligation to develop and produce beneficial drugs. This is the area of the industry's expertise and it is that which the companies in the industry can do that others cannot. Moreover, in this regard one can argue that the pharmaceutical industry as well as individual companies have the obligation to pursue needed new lifesaving drugs more than to pursue alternatives to drugs that already exist and are effective, namely, so-called me-too drugs. Benefit to the patient, and hence to the public and the common good, should play a greater role in the case of health care than in other industries, just as safety is paramount in the engineering industries, whether it be in airplane or building and bridge safety

This first obligation is not an unjust imposition by society, but simply reflects part of the role ofpharmaceutical companies in society. The obligation is one that is arguably shared by governments also. The United States Government funds billions of dollars' worth of medical research, and it is appropriate that it does so because of its obligation to fulfill the rights of its citizens to health and to health care. In a free enterprise system governments do not engage directly in production, although they can encourage and promote production through their system of intellectual property protection and their tax system, among others. To the extent that the pharmaceutical industry fails to produce needed drugs, it is up to governments to ensure that they are produced.

Many pharma companies and the industry in general, as well as government-sponsored programs, are engaged in the search for cures or remedies for cancer, various kinds of heart disease, new and improved antibiotics to fight infections, and so on. The industry as a whole, therefore, not only is actively engaged in fulfilling this obligation, but individual pharmaceutical companies have an economic interest in pursuing breakthrough and essential new drugs. The market for such drugs, if they treat diseases suffered by large numbers of people in the developed countries, is potentially lucrative.

Nonetheless the market incentive fails with respect to orphan drugs. Diseases which are lifethreatening but in which the market is either small or the potential recipients poor, require a different approach.

In the United States the Orphan Drug Act has proven to be a successful marriage of government and pharmaceutical companies. The government provides tax incentives

and guarantees 7 years of exclusivity (after FDA approval) to encourage drug makers to develop drugs that affect fewer than 200,000 people and are generally unprofitable. The result has been, on the whole, positive, despite abuses.

The market similarly fails with respect to the development of drugs for diseases restricted to those living in tropical countries. Although the governments in such countries have the responsibility for providing for the health of their people, they have insufficient funds to promote research and in addition they lack the facilities and the expertise needed. With minimal budgets for health care, they have difficulty providing the bare essentials of clean water and sanitation and developing an adequate delivery system for health care, regardless of the cost of drugs. Under these conditions the obligation of aid comes to the surface. In this case the appropriate aid is the development of drugs for the diseases in question. The obligation does not clearly fall on any particular pharmaceutical company, and how it is to be apportioned among countries and the pharmaceutical industryworldwide is a topic that urgently needsaddressing. The first step in any solution, however, is to recognize the obligation. Perhaps something comparable to an international orphan drug act can be agreed upon; perhaps governments can subsidize special research in these areas; perhaps companies can agree to fund joint research for drugs that would not be covered by patents and would be produced and distributed at cost. The actual action taken should be the result of negotiations among all the interested and affected parties. The pharmaceutical industry clearly has an important role to play in any such negotiations. But approaching the problem from the point of view of the Moral Argument brings to the fore obligations in this regard that the Standard Argument and the Status Quo Approach do not.

Although I have indicated the financial incentive that drug companies have to pursue important new drugs, critics of the pharmaceutical industry have concentrated on whether the drug industry is actually doing either all it can and should do, or all it claims to be doing with respect to the development of new drugs. The issue arises in part because of the industry's use of the Standard Argument and the Status Quo Approach. The many tacticsused by pharmaceutical companies to produce profits are justified, the SA and SQA claim, because these profits are necessary to fund the research that has led to and will lead to the development of new essential drugs. The industry thus implicitly acknowledges that the production of such drugs is its goal, even if it does not acknowledge that it is also its obligation.

It is in this context that some critics claim that the amount that the industry spends on R&D is less than the amount that it spends on marketing (including advertising, free samples to doctors, etc.), that the amount may even be less than the amount it spends on lobbying government officials; that most of the profits it makes are not in fact ploughed back into research but distributed as dividends to shareholders; and that most of the research that leads to new drugs comes from government-funded research, the results of which are appropriated for private gain. All of this may be appropriate. But it is not self-evidently so, and this is what most concerns the critics. The industry in its blanket claims fails to be convincing.

According to a 2002 study of the National Institute for Health Care Management Research and Educational Foundation for the period 1989-2000, only 35 percent of new drug applications contained new active ingredients (of which only 15 percent were considered to provide "significant improvement over existing drugs"), while 54 percent were incremental modifications of existing drugs (and under Hatch-Waxman get up to 3 years of market exclusivity)and 11 percent were identical to existing drugs. Although these facts by themselves prove nothing with respect to the obligation to provide new drugs, they are used by critics to offset the image that the pharmaceutical industry suggests by its use of the SA to justify its approach to the development of new drugs.

To be convincing the industry must first acknowledge its obligations; but even more important it must be willing to show why the above activities are necessary to produce new drugs. Simply pointing to new drugs as proof is an instance of a logical fallacy. Simply because new drugs have been produced and the industry has been profitable using its advertising, lobbying, and other techniques, does not show that these techniques are necessary to produce new drugs.

If one takes the obligation to produce new lifesaving drugs seriously, then one might consider changes in the status quo with respect to IP. Essential, lifesaving drugs can and arguably should be distinguished from other drugs for a variety of purposes. Me-too drugs and incremental changes, as well as cosmetic changes, do not clearly deserve the same protection or the same encouragement and inducement on the part of government.

13.7 The Access Obligation

The second obligation, the Access Obligation, is the obligation to make the drugs the industry or a company develops available to those who need them. Simply developing them would not serve any purpose otherwise. Fulfilling this obligation may be compatible with the existing structures relating to existing practices concerning intellectual property, pricing, government regulation, charity, and so on. Yet critics claim that both the industry and the market fail to some extent with regard to this obligation, and they claim that if and when current practices impede the fulfilment of this obligation, then the right to access and the concomitant obligation to provide access take precedence over IP and other rights.

The argument as we have developed it so far imposes a stronger obligation on governments to ensure access than it does on the pharmaceutical industry. As we have developed the argument to aid, it comes into play most clearly in times of dire need. This would apply most clearly with respect to essential lifesaving drugs. The obligation to help those in need in less dire circumstances is proportionately weaker. But the obligation of governments is not to ensure access only for lifesaving drugs, but for all drugs needed for health. Governments are obliged to ensure their people have access, whether by actually buying and supplying the drugs or by other means—such as making sure the price of drugs makes them accessible. The right to access puts a strain on any strong claim to intellectual property rights in drugs, if what stands in the way of people receiving lifesaving drugs is maximizing corporate profit.

(a) Let us look at the poor countries first. The question of access to many medicines is a pressing need. Although governments have the responsibility to enable or provide access, it is beyond the ability of many of them to do so. Hence the obligation falls on others able to do so. Included in that number are pharmaceutical companies, especially those that manufacture the needed drugs. The issue was brought to global attention by the AIDS epidemic. The drugs in question are very expensive and only a few are on the current WHO list of essential drugs because of that. The most widely used such drug in poor countries is a combination of three generic drugs produced by the Indian pharmaceutical company Cipla. Nonetheless, it is clear from the Moral Argument that when millions of people are dying and can benefit substantially from available medicines, they have a right to access with respect to them. A consensus is emerging that many parties are ethically responsible for access—the patient, the local government, other governments that can help, NGOs, international organizations, and the drug companies. The problem is clearly not only

the result of practices of pharmaceutical companies. Even if the drugs were given away free, access by many of the needy would still be a problem. And a number of pharmaceutical companies have instituted plans to give away antiretroviral drugs, to sell them at cost, or to license them for production by generic manufacturers in less developed countries under certain conditions. Arguably they are at least to some extent meeting their obligation to be part of the solution. (We have already seen the arguments of critics to the industry's approach that it is being socially responsible by its programs.)Both nations and companies seem to acknowledge in principle the obligation to respond in case of dire need. Thus, for instance, a provision of the TRIPS agreement states that mandatory licensing of necessary medicines is justifiable in times of extreme national emergencies (such as epidemics) as decided by the country in question. Yet despite the Agreement the right to access is not being met and the pharmaceutical industry bears part of the blame. The TRIPS Agreement, despite its recognition of the obligation to aid, has in practice had little effect and has been faulted for a number of reasons. In 2001 Pharma and a group of pharmaceutical companies charged South Africa with violating the WTO's rules on patents by producing the drugs needed by their people and 40 companies filed suit. After much adverse publicity, the charges and the suit were withdrawn. But neither the industry nor the companies involved ever acknowledged the right of the South African government to provide access to the needed lifesaving drugs in accord with the spirit of TRIPS, if not with its letter

The TRIPS Agreement requires that poor countries adopt the type of IP protection found in the developed countries. They must do so whether or not it impedes the government of the country in question from meeting its obligation to provide access to needed drugs for its people. In this way it fails to consider the common good of the people of the country in question. For instance, while strong defences of intellectual property with respect to pharmaceuticals may produce the best results overall for developed countries, they do not seem to do so for poor and developing countries, such as India. If, as drug companies claim, new drugs cost $800,000,000 to develop, then developing countries are probably not able to develop any. They are better served by developing generic drugs or by requiring compulsory licensing of drugs or by some other strategy. Compulsory licensing and parallel importing policies—with measures adopted to prevent the development of a gray market—would arguably benefit poor countries more than present arrangements. The Moral Argument puts these as well as

other suggestions on the table for consideration, while the Standard Argument and the Status Quo Approach—used in negotiating TRIPS— in effect prevent their being raised.

(b) As opposed to poor countries that cannot afford drugs, the United States can afford to pay for drugs. In fact the United Stated both pays more for drugs and contributes more to the profit of the pharmaceutical companies than any other nation. So the aspect of the right to access that has received the greatest attention is the barrier of high prices to access, even though access and price are not the same thing. Even if drugs were free, access requires that the drugs be transported, distributed, and administered to patients. At issue is accessibility, especially of the newer drugs for which no competitive generic drug is available. Although the lack of accessibility for the poor and elderly on restricted incomes gets most publicity, more and more people are complaining that the high cost of drugs is limiting accessibility by putting the cost of insurance out of their reach. As insurance prices rise, employers are less and less willing to pay the escalating costs and are forcing employees to bear a larger and larger portion of the cost. The complaints against the pharmaceutical industry focus especially on two issues that are seen as limiting access. One is the high and ever increasing price of new drugs covered by patents. Not only the poor and elderly, but even middle-class families find that the "co-pay" portion of medicines is increasing at a rate so much faster than inflation that they are having a harder time keeping up. The second is what is seen as illegitimate attempts by drug companies to "extend" their patents and to prevent generic drugs from entering the market, thereby keeping prices high and restricting access for those who can afford only the lower cost of the generics.

The Status Quo Approach simply applies market economics, assuming the force of law in protecting intellectual property rights with respect to patents, and adding that the overall result is not only fair but produces the most good for society. A rights approach to health care yields a different focus. If the right to access to needed drugs is more important than the right to property, then the status quo is up for evaluation and becomes a candidate for change, rather than for passive acceptance.

13.8 Access and the Cost of Drugs

My earlier argument distinguished between those drugs that are necessary for life and those that are important for illnesses that are not life-threatening. In the United States critics of pharmaceutical industry pricing are critical of both, and for the most part insurance plans do not distinguish clearly between the two kinds of drugs. The assumption—and as we have seen a dubious assumption—of most Americans is that they are entitled or have a right to the best drugs available for their condition. The relation between the cost of health insurance and the price of medicines and between the cost of health care and the price of medicines is complicated. But the cost of medicines has increased much faster than the cost of health care generally, and the justification for the increase in not obvious, except if one invokes market economics and produces the not-surprising result that the market has been willing to pay the higher prices.

The right to access argument in the U.S. is joined to a fairness argument. That argument says that fairness involves all parties paying their fair share for medicines, including paying sufficient amounts so that drug companies have a continuing incentive to produce more beneficial drugs. The complaint is not that American consumers are subsidizing drugs for the poor countries, or even that they are subsidizing the pharmaceutical companies' compassionate programs. That would be acceptable, and the better off—such as Americans in general—may well have the obligation to bear this cost. But under the Status Quo Approach, in effect, Americans are subsidizing not only poor countries but also seem to bear a disproportionate load. Japan, Canada, and the countries of Europe all negotiate much lower prices than are available in the United States. Americans are increasingly finding it not only ironic but unfair that U.S. drugs cost more in the United States than in other developed countries. This leads to such anomalies as the U.S. government presently prohibiting the importation of U.S.-made drugs from Canada for personal use while various state governments attempt to find ways of making it legal for senior U.S. citizens to buy U.S.-made drugs from Canada, where the government helps keep the price lower than it is in the United States.

The standard reply to all questions about the high cost of drugs is to appeal to the SA and the SQA and claim that unless there are the profits brought about by high prices, there will be many fewer future drugs. The Status Quo Approach tends to present a questionable dichotomy: either protect drugs and drug pricing to the maximum or face a future with fewer new innovative drugs. The claim is made no matter what the

percent of profit, no matter what the prices, no matter how much the industry spends on lobbying and advertising to consumers. The claims are blanket, the justification is blanket, and the public is asked to take the claims on faith. The consuming public must take it on faith that money spent on the recently developed technique of advertising prescription drugs to the general public, for instance, is necessary to produce the profits that will lead to new drugs. They must take it on faith that money spent on researching minor changes in existing drugs is necessary to produce the profits that will lead to new drugs. They must take it on faith that the various tactics that seek loopholes in legislation— whether with respect to the Orphan Drug Act to garner windfall profits or Hatch-Waxrnan or other legislation to keep competition at bay as long as possible—are necessary to produce the profits that will lead to new drugs.

That faith has been shaken. Because there is very little transparency in drug pricing economics, the claims have worn thin. That the industry needs the highest rate of profit of any industry is not obvious, even for the production of new products. The lack of adequate transparency exacerbates the communication gap and hinders fruitful dialogue. Abuses and attempts at gaming the system further erode trust.

13.9 Access and Patents

If there is a difference between different kinds of drugs, and if people have a greater right to access to the more essential drugs than to the less essential ones, then at least it becomes an open question what the best means of protecting the different kinds is. If one takes seriously the Moral Argument, then the assumption of the SQA that all drugs deserve the same length or strength of protection and that they should be treated the same as all other patents in all other areas, is on the table for discussion. Although the laws governing patents are uniform for all products and processes, the range of processes and products is extensive, the differences among them considerable, and so the argument for a one size-fits-all approach is questionable. Moreover, the pressure on pharmaceutical patents is different from the pressure on patents in general. No one has a right to a better mouse trap, and the market may legitimately determine who gets one; but the right to access to essential medicines places an obligation on all those who can satisfy that right to come up with an equitable means of doing so.

Since access and price are related, attempts to extend the protected life of a drug by introducing slight modifications to get new patents or to delay the entry of generic

competitors— which would lower the price and increase accessibility— are not justified by the Standard Argument and are more appropriately seen as taking advantage of the system.

The task with respect to pharmaceutical products is to balance claims to intellectual property rights against the rights to access to needed medicines, the common good, and the obligation to aid. The economic argument that unless companies can make a profit from their research in discovering, developing, and producing drugs, they will not produce them, is only a partial defence of the existing patent system and one that focuses only on property rights. It is only a partial defence because patent protection is not the only conceivable way of either protecting intellectual property or of guaranteeing profits. It does not show that other alternatives—public financing of research and development, cooperation instead of competition on some drug development, government regulation of prices or guarantees of profits at a certain level for certain drugs, and so on, are not viable alternatives. In particular, the SA and SQA do not show that intellectual property rights, no matter how strong and justifiable, trump the right to basic health care and the right of access to needed medicines or that the right to profits trumps these, the common good, or the obligation to aid.

13.10 Summary

It is essential for developing countries to devise strategies to curtail the current expansionist trends in international patent law. In the midst of growing demands for stronger patent laws, the right to health can be utilized to reclaim some policy space for developing countries to design their national patent laws in a manner that facilitates access to medicines. Domestic courts have a major role to play in this regard: when they are adjudicating disputes involving patents on pharmaceutical products, they can recognize the tension between patent rights and the right to health and resolve this tension by distinguishing between the instrumental nature of patent rights and the fundamental nature of the right to health.

13.11 Self-Assessment Test

1. Explain the Moral Justification of Intellectual Property.
2. Discuss the Moral Responsibility of Pharmaceutical Companies

3. Explain the concept of Production Obligation and how can it be maintained with right to health.
4. Explain the concept of access obligation vis-à-vis cost of drugs.
5. Explain the concept of access obligation vis-à-vis patents.

13.12 Further Readings

1. TRIPS Agreement
2. US Constitution
3. Universal Declaration of Human Rights

Unit 14
Patents and Food Securities Issues

Objectives

Food insecurity is a major problem throughout the South. It is a concern at all levels, from individuals to states. At a basic level, food security is about fulfilling each individual's human right to food. Within the broad question of the human right to food, food security also relates more specifically to issues of agricultural policy, economic development and trade. This study picks up on the specific link between food security and intellectual property rights (IPRs), one – but only one – of the important perspectives from which food security must be analysed.

Structure

14.1 Introduction

IPRs have become increasingly important in the past couple of decades in a number of fields. This includes, for instance, agricultural biotechnology where IPRs provide a basic incentive for the development of the private sector in this area. The extension of IPRs to agriculture is of special significance because agriculture and food security are

closely interlinked. In other words, the introduction of IPRs in agriculture is directly linked to the realisation of basic food needs.

The introduction and strengthening of IPRs in the agricultural sector of developing countries has been and remains contentious. On the whole, food security constitutes the central concern of all relevant actors. The introduction of IPRs in plant varieties is justified by the need to foster food security in the long-term. Similarly, arguments in favour of an open system where private IPRs are not enforced are also based on the premise that this will contribute to food security. At present, IPRs in agriculture have been and are being introduced in developing countries that are members of the World Trade Organization (WTO). This is taking place in a context where food insecurity remains a central concern for a majority of developing countries where a large proportion of the population does not have access to sufficient good quality food. A host of conceptual and practical issues need to be addressed in the context of the paradigmatic shift from a system seeking to foster food security on the basis of the free exchange of knowledge to a system seeking to achieve the same goal on the basis of the private appropriation of knowledge. This is not only due to the fact that IPRs provide different kinds of incentives for inventiveness than a system based on the free sharing of knowledge but also because some of the new plant varieties are the product of genetic engineering. The latter bring in other environmental and socio-economic dimensions to the subject considered.

This study examines the issue of food security from the narrow perspective of intellectual property. The first section provides a general introduction to the issues and challenges in this field. The second section goes on to introduce the relevant international legal framework for food security and intellectual property. The third section examines some of the implications of recent developments in international law for developing countries and looks in more detail at the way in which India has been implementing its international obligations in this field. Finally, the fourth section, building on the analysis provided in the previous sections provides recommendations for the implementation of existing international legal obligations and the further development of the legal regime in this field.

14.2 Food Security

Food security can be understood at different levels, from the household to the international level. While the overall availability of food at a global level is not a major concern at present, food availability in specific regions of the world and access to food by specific individuals remains a major concern in most parts of the South. Further, population growth in countries where undernourishment is already a problem and diminishing arable land availability make food insecurity one of the most important policy challenges of coming years.

Food security is not only dependent on the availability of food but also on effective access and appropriate distribution of existing foodstuffs. Unavailability of foodstuffs is not a major concern at present a worldwide level since the world produces enough food for its present population. Availability is a concern at present in the case of countries suffering from armed conflicts, in situations where sufficient arable land is not available or in the case of persistent drought. Food availability will also be an increasing concern in the future if food production does not keep pace with population growth. At present, however, the problem of under nourishment is often more linked to the problem of lack of access to food and mal-distribution of foodstuffs than the problem of unavailability. In countries like India, overall food availability has been more than sufficient for a number of years but the numbers of undernourished keep rising. This indicates that food security must be analysed at different levels at the same time. The availability of sufficient food within the country does not indicate that each and every household and every individual has access to sufficient food, the latter being the ultimate measure of food security.

Food security at an individual level implies that people must either have a sufficient income to purchase food or the capacity to feed themselves directly by growing their own food. There is therefore a direct link between poverty and food security. More specifically, food security is influenced by individuals' capacity to work, individual and household access to land and their control over the land and other productive assets, including seeds. Further, food security is also influenced by policies concerning the management of the environment in general and agricultural biodiversity specifically. Diversity constitutes from an environmental point of view one of the ways in which resilience of agricultural systems can be ensured while from a socio-economic point of view, agro-biodiversity constitutes to a large extent one of the basic productive assets of poor farmers.

One of the major debates with regard to food security today is the contribution that agro-biotechnology can make to meeting the food needs of the world's population. This happens in a context where it is expected that most of the increase in food production will continue to come from further intensification of crop production where part of this increase will come in the form of higher yields and part in the increase of multiple cropping and reduced fallow periods. It is hoped that transgenic plant varieties can contribute to at least part of this food production increase. In practice, the impacts of transgenic plant varieties on agricultural management are partly similar to the impacts of Green Revolution varieties. The main differences are concerns over environmental safety on the one hand and the impacts of the close link between agro-biotechnology and IPRs. At present, the potential of modern biotechnology for food security in developing countries remains an open question. Firstly, it appears that plant biotechnology research is only likely to benefit poor farmers if it is applied to 'well define social or economic objectives'. To date, commercialised genetically modified crops have generally not focused on the needs of developing country agriculture. In fact, it is uncertain whether the large life-science companies that are responsible for most of the applied agro biotechnology research thanks to the incentives provided by IPRs can ever be expected to focus their research efforts on plant varieties of specific interest to poor farmers and consumers in developing countries. Secondly, the scale of overall benefits derived from the introduction of transgenic plant varieties remains a matter of debate when agricultural and other factors, such as environmental and socioeconomic factors are taken into account. Thirdly, according to projections showing an increase in agricultural trade in coming years, it is possible that further specialisation will occur whereby some developing countries may be led to increase the production of non-food cash crops at the expense of basic food crops. This may have significant implications for local and national food security in a context where it is expected that the development of agro-biotechnology may lead to further market concentration and where access to genetically modified seeds may be hampered by their higher cost.

The policy challenges concerning food security are immense. Guaranteeing access to food for each individual around the world today and in the future requires measures to create wealth in poor communities, measures to enhance poor farmers' control over their land and productive assets, measures to conserve the natural resource base while

increasing either agricultural productivity or arable land availability and measures to ensure effective distribution of existing food supplies.

There have been various attempts at the international level to define food security. At present, the most widely accepted definition is that adopted at the 1996 World Food Summit (WFS). The WFS Plan of Action acknowledges that food security must be achieved from the individual and household levels up to the global level. It defines food security as physical and economic access to sufficient, safe and nutritious food by all people to meet their dietary needs and food preferences for an active and healthy life. The Plan of Action openly acknowledges that meeting food security objectives implies improving access to food which is itself linked to poverty eradication. Undernourishment is linked to inadequate access to means of production such as 'land, water, inputs, improved seeds and plants, appropriate technologies and farm credit' which in turn implies an incapacity to produce or purchase sufficient food. The Plan of Action also notes the significance of environmental threats to food security which can come in the form of drought, land degradation or loss of biodiversity and negatively impact on food production.

The WFS definition of food security, though widely accepted, has been criticised from different standpoints. Some actors tend to use a more restrictive definition which focuses more on the question of global increases in food production than on the issue of household access to food. Other actors have criticised the WFS definition because it does not go far enough insofar as it does not include a rights dimension. Notwithstanding disagreements on the exact definition of food security, the fulfilment of food needs constitutes a generally accepted goal. Thus, at the Doha Ministerial Conference, the WTO emphasised that special and differential treatment was necessary to allow developing countries to take into account their development needs, highlighting among them food security. Similarly, the Plan of Action adopted by the World Summit on Sustainable Development (WSSD) singles out among the goals for poverty eradication the necessity to increase food availability and affordability as well as the need to substantially reduce the number of people suffering from hunger.

In addition to the dimensions highlighted, the question of food security can also be looked at from a rights perspective. The human right to food provides, for instance, that freedom from hunger requires steps to improve methods of production, conservation and distribution of food. Further, states have to proactively engage in

activities to strengthen people's access to and utilization of resources and means to ensure their livelihood and food security.

14.3 Intellectual Property Rights and Food Security

There are a number of links between IPRs and food security. In general, IPRs such as patents or plant breeders' rights seek to give incentives, mainly to private sector actors, to develop seeds that either produce higher yields or have specific characteristics which will improve food security and agro-biodiversity management. IPRs were for a long time underdeveloped in the context of agriculture. Firstly, in many countries and at the international level, agricultural management was premised on the basis of the free exchange of germ plasm and knowledge, a system wherein IPRs did not fit well. Secondly, it was generally recognised that agriculture was substantially different from other fields of technology because farmers were often used to save seeds from previous crops and because the link between the fulfilment of basic food needs and agriculture made it undesirable to foster commercialisation in this field.

IPRs have progressively been introduced in agriculture in two main phases. Firstly, a number of developed countries adopted over time a form of intellectual property protection for plant varieties – plant breeders' rights – which is derived from the patent model. Secondly, in the context of the development of genetic engineering, the progressive introduction of patents over life forms has constituted a major incentive for the overall growth of agro-biotechnology. At present, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) provides a number of specific minimum levels of protection that all WTO member states must respect. This includes, for instance, the patentability of microorganisms and a form of intellectual property protection for plant varieties. Beyond these minimums, there is no uniformity around the world insofar as some countries like the United States have gone further than the TRIPS minimums and accept, for instance, the patentability of plant varieties.

A number of justifications can be offered for the introduction of IPRs with a view to foster food security in developing countries. In general, the legal protection offered by IPRs is one of the most important incentives for private sector involvement in agro-biotechnology. IPRs are thus primordial in ensuring the participation of the private sector in the development of improved plant varieties. Improvements that can be brought about by agro-biotechnology include plant varieties that produce higher yields

by enhancing the capacity of the plant to absorb more photosynthetic energy into grain rather than stem or leaf, varieties that have the capacity to combat pests and varieties modified to grow faster through enhanced efficiency in the use of inputs such as fertilisers, pesticides and water. From a food security point of view, another potentially interesting feature of agro-biotechnology is the possibility to modify varieties to improve their nutritional value, such as in the case of the pro-vitamin A rice. Other arguments include the potential of the introduction of IPRs in developing countries to increase foreign direct investment, increase technology transfers and R&D by foreign companies while at the same time giving domestic actors incentives to be more innovative.

14.4 Policy Considerations for Food Security in Context of Intellectual Property Rights

IPRs have the potential to enhance agricultural production. However, in the context of developing countries, this contribution must be analysed in a broader perspective which takes into account a number of other variables. The introduction of IPRs in agriculture has important links with other forms of property rights directly relevant in agriculture, such as land rights and rights over biological resources. In fact, the question of access to biological and genetic resources for food and agriculture has been at the centre of significant debates at the international level for a number of years. Control by individual farmers, private companies and states over the genetic and biological resources they hold and related knowledge has become increasingly contentious with the progressive introduction of IPRs over certain types of plant varieties for instance. While the sharing of resources and knowledge was emphasised until the 1980s, the new system which promotes individual appropriation has led to the formulation of a new set of rules concerning control over knowledge and resources. At the international level, while private individual appropriation of inventions through IPRs has been condoned, state control over primary resources has at least in principle been reinforced. At the national level, the role of farmers in conserving and enhancing agro-biodiversity has generally been recognised but this is not necessarily translated into specific claims over resources or knowledge.

The introduction of IPRs in agriculture raises specific concerns with regard to farmers' control over their resources and knowledge. In general, IPRs tend to facilitate control

over seeds and related knowledge by agri-businesses at the expense of small and subsistence farmers. This is linked in part to the royalties that farmers must pay to acquire protected seeds together with the associated restrictions on saving, replanting and selling saved seeds. In principle, it appears essential that farmers should retain control over plant varieties so that they may continue to innovate, improve and adapt varieties to suit changing needs and conditions. At present, even when IPRs are introduced in the South, it is unlikely that IPRs holders will be able to control farmers' ability to save and replant seeds as much as in countries like the United States where IPRs protection is often enhanced with contractual obligations. However, the introduction of genetic use restriction technologies would constitute a specific challenge in this context since this would provide a tool for patent holders to ensure that farmers fully respect patent rights. The challenge that the progressive introduction and strengthening of IPRs in agriculture imposes on relevant actors is, for instance, quite severe for the Consultative Group on International Agricultural Research (CGIAR). Faced with the complete overhaul of the international agricultural system which is taking place, the International Agricultural Research Centres (IARCs) have specifically indicated that '[t]here is some concern that even the Right to Food, as defined by various governments, could be compromised by certain interpretations of intellectual property and other agreements'. From a broader perspective, the impacts of IPRs can be compared to the broader impacts of globalisation in food in agriculture of which they are one segment. As noted by the FAO, globalisation can have a number of positive impacts but at the same time may contribute to the disempowerment of certain communities and countries. In other words, the potential of transgenic plant varieties to foster food security is partly linked to the development of mechanisms to foster their transfer and ways to ensure that they are affordable for poor farmers.

The introduction and strengthening of IPRs in agriculture fosters two kinds of concerns linked to R&D. Firstly, there are concerns that 'over-patentability' in the biotechnology industry may have the potential to stifle innovation in the private and public sector rather than promote it. This is linked to the scope of the claims that can be made in the field of agro-biotechnology. The perception is often that broad claims are necessary to provide the industry with sufficient incentives to innovate but that IPRs claims should not extend to the primary material for research because this tends to stifle scientific and technological innovation. This constitutes a difficult debate in the present environment. Generally, scientific innovation benefits from free access to

all primary materials for research. However, current scientific research often requires access to patented technologies beyond the primary biological material. Further, the products of scientific research are increasingly often patented. From a policy-making point of view, it is necessary to determine whether the primary holders of biological material and knowledge should avail their resources and knowledge free to the whole of humankind for the greater common good. It is noteworthy in this context that the introduction of plant breeders' rights, as distinguished from patents, was partly based on the premise that innovations by breeders could only be sustained if the primary and protected material remained freely available for further research. Secondly, another point concerns the extent to which it is reasonable to expect the research agenda to be geared towards the needs of individuals below the poverty line as long as most of the research is carried out with a view to develop commercially valuable products. In fact, it is noteworthy that the first generation of genetically modified crops have generally not been bred for raising yield potential, and that any gains in yields and production have come primarily from reduced losses to pests. This tends to indicate that the introduction of IPRs in agriculture in developing countries should be accompanied by further measures to ensure that research is also geared towards the needs of the poor. This concern leads the FAO to suggest that public sector research will have a strong role to play, in particular with regard to the need to raise productivity of the poor in the agro-ecological and socio-economic environments where they practise agriculture and earn their living.

The introduction of IPRs in agriculture must also be examined in its broader context which includes, for instance, the impacts of IPRs in agriculture on biodiversity management. Biodiversity and agricultural-biodiversity in particular, is of primary importance for the sustainability of agricultural systems in the long term. Agro-biodiversity is of special importance because it directly contributes to feeding people. Agriculture and biodiversity management are inextricably intertwined because biological resources constitute a primary input to agricultural production systems and the majority of existing agricultural products have evolved through selection and collection of plant and animal species. In this context, landraces which are geographically or ecologically distinct crops or animals selected by farmers for their overall economic value are of special importance. IPRs in agriculture have an inherent tendency to displace landraces because protected varieties generally offer higher yields than local counterparts. This process of displacement tends to promote homogenisation

in agricultural fields (or in other words monocultures) which leads to a loss in diversity and generally reduces crops' resilience to pests and diseases. Other elements that must be taken into account include problems related to the development of resistance by pests to bio pesticides. Further, there are some specific concerns with regard to the potential harmful impacts of transgenic plant varieties on specific species. While a number of the impacts of the introduction of transgenic plant varieties can be compared from an environmental point of view to the impacts of the introduction of Green Revolution varieties and may not be specific to the context of this study, they should nevertheless be fully considered.

14.5 Agriculture Related Legal and Institutional Framework

1. Legal instruments sponsored by the FAO

The FAO, in keeping with its role as the central UN organisation dealing with agriculture, has logically played an important role in defining the food security related legal framework. In fact, the two main instruments adopted in the FAO context, the 1983 International Undertaking for Plant Genetic Resources (International Undertaking) and the 2001 International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA Treaty) clearly reflect the evolution of the overall legal system in this area. The importance of the International Undertaking and the PGRFA Treaty derives from their focus on the legal status of agricultural plant genetic resources, the focus on farmers' rights and at least an attempt to provide a coherent system taking into account the different interests at stake, from the imperative of access to food to agro-biodiversity management and the granting of incentives to commercial breeders through IPRs.

The international legal regime for the conservation and use of agricultural plant genetic resources has been marked by significant changes over the past few decades. Traditionally, plant genetic resources for food and agriculture (PGRFA) were freely exchanged on the understanding that PGRFA constituted a common heritage of humankind. As a result, rights over PGRFA could not be appropriated by private entities. These principles were embodied in the 1983 International Undertaking. It affirms the principle that plant genetic resources are a heritage of humankind which should be made available without restriction to anyone. This covers not only traditional cultivars and wild species but also varieties developed by scientists in

laboratories. The International Undertaking was adopted as a nonbinding conference resolution. However, the emphasis on the free availability of PGRFA proved to be unacceptable to some developed countries which already had interests in genetic engineering. Broader acceptance of the International Undertaking was only achieved after the FAO Conference passed interpretative resolutions in 1989 and 1991. These resolutions affirm the need to balance the rights of formal innovators as breeders of commercial varieties and breeders' lines on the one hand, with the rights of informal innovators of farmers' varieties on the other. Resolution 4/89 recognises that plant breeders' rights, as provided for in the UPOV Convention, are not inconsistent with the Undertaking, and simultaneously recognises farmers' rights as defined in Resolution 5/89. Resolution 3/91 further recognises the sovereign rights of nations over their own genetic resources.

Further revision of the International Undertaking was prompted by the growing importance of biological and genetic resources at the international level. In 1992, Agenda 21 called for the strengthening of the FAO Global System on Plant Genetic Resources, and its adjustment in accordance with the outcome of negotiations on the Biodiversity Convention. Negotiations for the revision of the Undertaking in harmony with the Convention began with the First Extraordinary Session of the Commission on Plant Genetic Resources in November 1994 and continued until November 2001.

The new Undertaking is now a binding treaty, the PGRFA Treaty. The Treaty was the object of arduous negotiations which led to a final consensus text which was acceptable to all the states present apart from the United States and Japan which abstained from voting. The overall objectives of the PGRFA Treaty are significantly different from those of the 1983 undertaking. The Treaty, reflecting the new orientation given by the Biodiversity Convention, emphasises the conservation of PGRFA, their sustainable use and benefit sharing. The guiding principles for these three objectives are the promotion of sustainable agriculture and food security.

The PGRFA Treaty focuses on issues not addressed in other international treaties such as farmers' rights but it does not address directly patents or plant breeders' rights covered in other treaties. The PGRFA Treaty has a number of unique characteristics. Firstly, it is the first treaty providing a legal framework which not only recognises the need for conservation and sustainable use of PGRFA but also delineates a regime for access and benefit sharing, and in this process provides direct and indirect links to IPRs instruments. Secondly, it directly links plant genetic resource conservation, IPRs,

sustainable agriculture and food security. Thirdly, the element which remains the distinguishing feature of the PGRFA Treaty in the field of plant variety protection is its focus on farmers' rights. In fact, the term farmers' rights are slightly misleading. The PGRFA Treaty gives recognition to farmers' contribution to conserving and enhancing PGRFA. It further gives broad guidelines to states concerning the scope of the rights to be protected under this heading but overall devolves the responsibility for realizing farmers' rights to member states. This includes the protection of traditional knowledge, farmers' entitlement to a part of benefit sharing arrangements and the right to participate in decision-making regarding the management of plant genetic resources. However, the treaty is silent with regard to farmers' rights over their landraces. In fact, the 'recognition' of farmers' contribution to plant genetic resource conservation and enhancement does not include any property rights. In this context, the only rights that are recognized are the residual rights to save, use, exchange and sell farm-saved seeds.

On important aspect of the PGRFA Treaty is the novel scheme devised to regulate access and benefit sharing of PGRFA covered under the Treaty. The underlying reason for the inclusion of a system of facilitated access is that the sovereign rights of states over their PGRFA are qualified by the recognition that these resources are a common concern of humankind and that all countries depend largely on PGRFA that originated in other countries. As a result, donor countries have full control over their PGRFA but there are strict limitations on their ability to restrict access to other states. Under the Multilateral System, a series of crops listed in Annex I which account for most of – but not all – human nutrition are covered by a provision under which member states agree to provide facilitated access. As per the PGRFA Treaty, access is to be provided only for the purpose of utilization and conservation for research, breeding and training for food and agriculture. As a result of the recognition of PGRFA as a common concern, access has to be accorded expeditiously. Concerning material which is under development by farmers or breeders at the time when access is requested, the Treaty gives the country of origin the right to delay access during the period of development.

One of the most difficult part of the Treaty negotiations related to the treatment of IPRs. The compromise solution is that recipients of PGRFA cannot claim IPRs that limit the facilitated access to the PGRFA, or their genetic parts or components, in the form received from the Multilateral System. Further, PGRFA accessed under the Multilateral System must also be made available to other interested parties by the recipient under the conditions laid out by the Treaty. This provision which stops the

appropriation of isolated components from material accessed under the Multilateral System was strongly opposed by some countries which argued that this would stifle innovation. On the other hand, when the PGRFA in question are already protected by intellectual property or other property rights, access can only take place in conformity with the treaties regulating the particular kind of property rights. As is the case with some other treaties like the Bio safety Protocol, the PGRFA Treaty refuses to establish a hierarchy between itself and other related treaties, such as IPRs treaties. This leaves the door open for divergent interpretation at the time of implementation.

The question of access is closely related to that of benefit sharing. In fact, the benefit sharing regime constitutes another part of the bargaining process which seeks to make PGRFA a common concern of humankind. The rationale for benefit sharing is that countries providing facilitated access to their PGRFA are granted in return the right to receive some forms of benefits. Different types of benefit sharing mechanisms are provided for under the Treaty: These include the exchange of information, access to and transfer of technology, capacity building, and the sharing of the benefits arising from commercialisation. With regard to the sharing of information, the Treaty envisages that member states will, for instance, provide catalogues and inventories, information on technologies, and the results of technical, scientific and socio-economic research. Concerning technology transfer, the Treaty provides only a general obligation to facilitate access to technologies for the conservation, characterization, evaluation and use of PGRFA which is further qualified by the fact that access to such technologies is subject to applicable property rights. In the case of developing countries, specific mention is made of the fact that even technologies protected by IPRs should be transferred under 'fair and most favourable terms', in particular in the case of technologies for use in conservation as well as technologies for the benefit of farmers in developing countries. Finally, the Treaty provides for the sharing of monetary benefits. These include, for instance, the involvement of the private sector in developing countries in research and technology development. Further, the standard Material Transfer Agreement, through which facilitated access will be implemented, will include a requirement that an equitable share of the benefits arising from the commercialisation of products that incorporates material accessed through the Multilateral System will have to be paid to the Trust Account set up under the Treaty. The benefits that arise under the benefit sharing arrangements must be primarily directed to farmers who conserve and sustainably use PGRFA.

Overall, the Treaty which constitutes the outcome of many years of negotiations is noteworthy for linking the conservation of PGRFA, their use, the rights of farmers over resources and knowledge and finally the IPRs system. It provides an interesting, though inconclusive, attempt to link these different elements. The provisions concerning access and benefit sharing typically seek to build a bridge between the different forms of property rights recognised under the PGRFA Treaty and in other relevant treaties such as the TRIPS Agreement. They, however, largely lack in specificity, partly because they reflect the difficult balancing of interests that the negotiators had to achieve between the interests of developed and developing countries, big private seed companies and small farmers and a number of other actors in between.

2. The Consultative Group on International Agricultural Research

Since its inception in 1971, the CGIAR has played an important role in the management of genetic resources used to meet food needs and in defining property rights policies in this regard. The CGIAR brings together a network of IARCs which have important *ex situ* germ plasm collections. The CGIAR aims at alleviating poverty, achieving food security and assuring sustainable use of natural resources. It has traditionally sought to fulfil its mandate through the development of freely accessible *ex situ* collections and the production of freely available improved varieties. However, in keeping with the progressive move towards the establishment of sovereign and private property rights over biological and genetic resources, the CGIAR has gradually modified its stance concerning real and intellectual property rights.

In the past decade, a number of important developments have taken place. Firstly, starting in 1994, the Centres have signed agreements that place their collections held in trust for humankind under the auspices of the FAO and that restrict them from claiming IPRs over designated germplasm or related information. Secondly, the CGIAR and the IARCs progressively developed new guiding principles on intellectual property with a view to harmonise the CGIAR's core principles that designated germplasm is held in trust for the world community with the recognition of various forms of property rights, including sovereign rights, farmers' rights and IPRs. To-date, the Centres does not normally apply intellectual property protection to their designated germplasm and require recipients to observe the same conditions. They also refrain

from asserting IPRs over the products of their research. An exception to this rule is made in case the assertion of IPRs facilitates technology transfer or otherwise protects developing countries' interests. The CGIAR also imposes that any IPRs on the IARCs' output should be assigned to the Centre and not an individual. While the guiding principles on intellectual property generally seek to contain to an extent the monopoly elements of IPRs such as patents, plant breeders' rights are specifically welcomed. Recipients of germplasm can apply for plant breeders' rights as long as this does not prevent others from using the original materials in their own breeding programmes.

Thirdly, the PGRFA Treaty will further change the conditions under which the CGIAR operates. In future, guidance concerning the management of CGIAR collections will come from the Treaty's Governing Body. In fact, the Centres having signed agreements with the FAO are now invited to sign new agreements with the Treaty's Governing Body. These agreements will provide that the collections of the Centres that are part of the Annex I list will be governed by the access provisions of the PGRFA Treaty. This will, however, only cover materials collected after the entry into force of the Treaty and that fall within its scope. The Centres are also put under an obligation to provide preferential treatment to countries that provided material to their gene banks and are not to request any material transfer agreement if a country of origin wants to access its own material. Generally, the Centres will have to recognise the authority of the PGRFA Treaty's Governing Body to provide policy guidance relating to their *ex situ* collections. Overall, the PGRFA Treaty will foster more coordination between the FAO and the CGIAR. This will, in particular, have significant impacts in terms of their outlook on IPRs which will have to be broadly similar, at least with regard to the CGIAR collections falling in the scope of the PGRFA Treaty.

The CGIAR has long benefited from its hybrid institutional status among international institutions which contributed in part to making possible its contribution to the alleviation of food insecurity in developing countries. In recent times, however, the CGIAR has found it increasingly difficult to reconcile its original mission with the changing legal and policy framework in which it operates. Thus, the decision to accept the Syngenta Foundation for Sustainable Agriculture as a new CGIAR member has been criticised as sign that the CGIAR is moving away from its public sector research mission. Further, the CGIAR has also found it difficult to adjust to some of the challenges of biotechnology. The case of the controversy over the introduction of genetically modified maize in Mexico – the primary centre of diversity for maize –

illustrates the challenges that lie ahead for an organisation which is striving to maintain its significant collections of germplasm while endorsing at the same time biotechnology as 'one of the critical tools for providing food security for the poor'.

14.6 Intellectual Property Rights Related Legal and Institutional Framework

Developments in the agricultural field are of central importance because they directly concern food security. However, with the large-scale development of genetic engineering, IPRs standards have become increasingly important in their own right and because they influence the development of the legal and policy framework in agriculture and other fields.

This section does not attempt to provide an exhaustive analysis of the IPRs framework in the field of food security but focuses on some of the most important treaties and institutions from the point of view of developing countries. Further, it only covers under the heading of IPRs, rights that have generally been considered as falling within the subject matter of intellectual property protection. *Sui generis* forms of intellectual property protection which could provide alternatives to the current model are considered in Section 4.

1. The TRIPS Agreement

The TRIPS Agreement is today the most important intellectual property treaty for all WTO member states. The TRIPS Agreement is only indirectly concerned with agriculture and environmental management but the IPRs standards it sets have wide-ranging impacts on agricultural management.

The TRIPS Agreement is a general treaty which covers different types of IPRs, such as patents, copyright and geographical indications. It seeks to introduce minimum standards of IPRs in all member states. In practice, this generally has the effect of extending the application of IPRs standards already in use in most OECD countries to all WTO member states and thus imposes a significant burden of adjustment on developing country member states. The framework provided by the TRIPS Agreement must be understood in the context of the interpretative clauses that are part of the treaty. Article 7 recalls that IPRs protection must both contribute to the promotion of technological innovation and at the same time to the transfer and dissemination of technology in a manner conducive to social and economic welfare, and to a balance of

rights and obligations. Further, Article 8 concedes that in implementing TRIPS obligations at the domestic level, states have the possibility to adopt measures to protect nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development.

Among the types of IPRs protected under the TRIPS Agreement, patent rights stand out in the context of food security. The Agreement uniformly provides that patents must be available for inventions, whether products or processes, in all fields of technology. Some general exceptions are granted and states can, for instance, exclude patentability where this is necessary to protect human, animal or plant life or health, or to avoid serious prejudice to the environment. They can also exclude from patentability plants and animals other than micro-organisms.

Questions relating to patents in agro-biotechnology are dealt with in two ways. Firstly, the TRIPS Agreement imposes the patentability of micro-organisms. Secondly, it also requires all member states to introduce intellectual property protection for plant varieties. The question of plant variety protection is the object of a separate provision, Article 27(3)b framed as an exception to the general rule of Article 27(1). It provides that all member states 'shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof'. This provision will have significant repercussions because most developing countries have to reorient their policies in this field to comply with the TRIPS Agreement. This is due to the fact that most developing countries implemented until 1994 the principles upheld in the International Undertaking and favoured the sharing of resources and knowledge rather than the commercialisation of a sector mainly concerned with the satisfaction of basic food needs.

Article 27(3)b is, however, an interesting provision within the TRIPS context because it does not impose the patentability of plant varieties but gives member states significant liberty to introduce an alternative system. This reflects the continuing debates concerning the appropriateness of imposing patents on plant varieties and constitutes one of relatively few cases in TRIPS where protection is required but not necessarily through patents. In other words, all states must introduce some form of intellectual property protection but are given a certain margin of appreciation to implement this obligation. The significance of this provision is that in the case of plant variety protection, member states which do not wish to introduce patent rights have the choice to provide an alternative protection regime. Article 27(3)b is of further

significance in the context of the broader legal regime for food security, IPRs, environmental management and human rights. It provides member states an opportunity to introduce a form of plant variety protection which does not exclusively focus on TRIPS obligations but also takes into account their other obligations in this field, such as the fundamental right to food, their obligations under the PGRFA Treaty and their environmental management obligations under the Biodiversity Convention.

While issues concerning patentability have taken centre stage and include some of the most sensitive issues in the field of IPRs policy development for the South, geographical indications (GIs) constitute another type of IPRs that is also of interest in the context of food security. GIs were for a long time seen as a supplementary means of intellectual property protection for specific products, with a significant emphasis on wines and spirits. This perception has changed in the aftermath of the adoption of the TRIPS Agreement linked to the realisation by a number of countries that they have indications of geographical origin with commercial potential. Protection for GIs under TRIPS can be obtained for the specific quality of a good, its reputation or other characteristics of the good that is essentially attributable to its geographical origin. At present, TRIPS offers a two-tier system of protection. All GIs are protected under the general regime whereby rights holders are protected against the use in the designation or presentation of a good which misleads the public as to the geographical origin of the good and are protected against unfair competition. A special, more stringent, regime was adopted for wine and spirits. This bars the use geographical names for products produced outside the specific region associated with a name even if the true origin of the product is indicated and even if it clearly indicates that it is only similar to the original or derives from it.

2. The International Convention for the Protection of New Varieties of Plants

The International Convention for the Protection of New Varieties of Plants (UPOV Convention) is the only intellectual property treaty which directly focuses on agriculture. It was adopted in 1961 by a group of western European countries which sought to introduce IPRs in agriculture but were not prepared to accept the introduction of patents in this field. As a result, the UPOV Convention proposes the adoption of plant breeders' rights. The UPOV Convention's main aim is to protect

new varieties of plants in the interests of both agricultural development and commercial plant breeders.

Plant breeders' rights differ from patent rights but they also share a number of basic characteristics with them. Plant breeders' rights provide exclusive commercial rights to rights holders, reward an inventive process, and are granted for a limited period of time after which they pass into the public domain. More specifically, UPOV recognises the exclusive rights of individual plant breeders to produce or reproduce protected varieties, to condition them for the purpose of propagation, to offer them for sale, to commercialise them, including exporting and importing them, and to stock them for production or commercialisation. Protection under UPOV is granted for developed or discovered plant varieties which are new, distinct, and uniform and stable. While novelty is a criterion shared with patent law, UPOV adopts a different approach. Under UPOV, a variety is novel if it has not been sold or otherwise disposed of for purposes of exploitation of the variety. Novelty is thus defined in relation to commercialisation and not by the fact that the variety did not exist previously. UPOV gives a specific time frame for the application of novelty. To be novel, a variety must not have been commercialised in the country where the application is filed for more than a year before the application and in other member countries for more than four years. The criterion of distinctness requires that the protected variety should be clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application. Stability is obtained if the variety remains true to its description after repeated reproduction or propagation. Finally, uniformity implies that the variety remains true to the original in its relevant characteristics when propagated.

One of the main distinguishing features of the UPOV regime is that the recognition of plant breeders' rights is circumscribed by two main exceptions. Firstly, under the 1978 version of the Convention, the so-called 'farmer's privilege' allows farmers to re-use propagating material from the previous year's harvest and to freely exchange seeds of protected varieties with other farmers. Secondly, plant breeders' rights do not extend to acts done privately and for non-commercial purposes or for experimental purposes and do not extend to the use of the protected variety for the purpose of breeding other varieties and the right to commercialise such other varieties. The 1991 version of the Convention, by strengthening plant breeders' rights, has conversely limited existing exceptions. The remaining exceptions include acts done privately and for non-

commercial purposes, experiments, and for the breeding and exploitation of other varieties. Breeders are now granted exclusive rights to harvested materials and the distinction between discovery and development of varieties has been eliminated. Further, the right to save seed is no longer guaranteed as the farmer's privilege has been made optional.

UPOV provides that plant breeders' rights are time-bound IPRs. The period of protection has evolved over time: Under UPOV-1978, the period of protection is of a minimum of 15 years. For vines, forest trees, fruit trees and ornamental trees, the minimum is 18 years. UPOV-1991 extends the minimum period from 15 to 20 years. For trees and vines, the minimum is 25 years.

As noted, plant breeders' rights were first conceived as an alternative to patent rights. As a result, UPOV originally provided that the two kinds of IPRs should be kept separate. Under UPOV-1978, member states can, for instance, only offer protection through one form of IPRs. The grant of a PBR on a given variety implies that no other IPRs can be granted to the same variety. This restriction has been eliminated under UPOV-1991 and double protection is now allowed.

14.7 Environment Related Legal Framework

International environmental legal instruments have increasingly taken a broad perspective of the environment over time. This is in keeping with the shift of international environmental law towards an international law of sustainable development. As a result of the broader perspective of environmental treaties, environmental management is seen in a broader light which includes for instance links with agricultural management, human rights and IPRs. Among the different treaties with food security links, the regime for biodiversity management is noteworthy because it provides the general legal framework for biological resource management.

The Convention on Biological Diversity (Biodiversity Convention) is a framework treaty which seeks to regulate the conservation and use of biological resources. Its three main goals are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits derived from the use of genetic resources. In the context of food security and IPRs, the Biodiversity Convention makes several distinct contributions. Firstly, the specific role and importance of agro-biodiversity has been recognised by the Conference of the Parties

and a special programme on agro-biodiversity was established in 1996. It generally aims to promote the positive effects and mitigating the negative impacts of agricultural practices on biological diversity in agricultural ecosystems and their interface with other ecosystems. Further, it seeks to promote the conservation and sustainable use of genetic resources of actual or potential value for food and agriculture. Over time, the agro-biodiversity programme has taken up specific challenges, deepened its cooperation with the FAO and examined cross-sectoral issues such as the potential impacts of patented genetic use restriction technologies on farmers.

Secondly, the Biodiversity Convention provides one of the few existing statements on the relationship between the management of biological and genetic resources and IPRs. Article 16 clearly indicates that IPRs should not undermine the working of the Convention. The actual relationship of the Biodiversity Convention with the TRIPS Agreement is an issue which has not been solved. This is partly due to the fact that a clear statement on the matter would have significant repercussions for the development of international law in these two fields.

Thirdly, the Biodiversity Convention has also made its own contribution to the development of access and benefit sharing schemes, effort supplemented with the adoption by the Conference of the Parties of the Bonn Guidelines on access and benefit sharing. The Convention attempts to provide a framework which respects donor countries' sovereign rights over their biological and genetic resources while facilitating access by users. Access must therefore be provided on 'mutually agreed terms' and is subject to the 'prior informed consent' of the country of origin. Further, the Biodiversity Convention provides that donor countries of micro-organisms, plants or animals used commercially have the right to obtain a fair share of the benefits derived from use. Benefit sharing as conceived under the Convention and the Bonn Guidelines can take the form of monetary benefits or non-monetary benefits such as the sharing of research and development results, collaboration in scientific research and access to scientific information relevant to conservation and sustainable use of biological diversity. Overall, the contribution of the Biodiversity Convention and the PGRFA Treaty concerning access and benefit sharing are complementary even though the latter's framework goes further insofar as it constitutes an integral part of the treaty while the Bonn Guidelines remain at present purely voluntary.

Fourthly, the Biodiversity Convention also provides in general terms for the conservation of traditional knowledge, a question that is closely linked to the

fulfilment of basic food needs and to the protection of agro-biotechnology through IPRs. The Convention provides under Article 8(j) a general duty for all member states to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities pertaining to the management of biological resources, promote their wider application with prior informed consent and encourage the equitable sharing of the benefits arising from such utilisation. This provision has been supplemented with the setting up of a working group mandated with the task of giving advice on legal and other means of protection of traditional knowledge. While the Convention has addressed the conservation of traditional knowledge and the issue of access and benefit sharing, it has not really tackled questions surrounding the ownership of biodiversity-related traditional knowledge, an area which remains generally unsettled in international law.

While the Biodiversity Convention plays a dominant role in the international environmental law field, a great number of other treaties are also significant in the context of this study. Of particular relevance is the Desertification Convention. This Convention is noteworthy because it directly recognises the links between desertification as an environmental problem and socio-economic problems such as food security. It also specifically indicates that national action programmes to be developed by state parties must include among the measures to mitigate the effects of drought the establishment and strengthening of food security measures, including storage and marketing facilities. Further, the Desertification Convention is more specific than most treaties with regard to the protection of traditional knowledge insofar as it directs states not only to respect it but also to provide 'adequate protection'.

14.8 Human Rights Related Legal Framework

The realisation of food security at the level of each and every individual level can be broadly equated with the realisation of the human right to food. While the realisation of the right to food can be analysed separately from the concerns examined in this study, it provides the underlying guiding framework for analysing the relationship between IPRs and food security. Further, even though human rights and IPRs operate largely independently, some specific links need to be analysed.

The human right to food is recognised, for instance, in the Covenant on Economic Social and Cultural Rights (ESCR Covenant) which provides a right to adequate food and a right to be free from hunger. The right to food, like other socio-economic requires the state to take measures to progressively realise this right through positive steps which include the improvement of production methods and output, the improvement of food distribution networks and at the international level a better distribution of world food supplies in relation to the needs of each country. In practical terms, the right to food is realised when all individuals have physical and economic access at all times to adequate food or means for its procurement. Adequate food under the Covenant does not just imply a minimum package of calories and nutrients but takes into account a much broader set of factors to determine whether particular foods or diets that are accessible can be considered the most appropriate under given circumstances. As expounded by the Committee on Economic Social and Cultural Rights, the realisation of the right to food requires the availability of food in a quantity and quality that is sufficient to satisfy the dietary needs of individuals and that is free from adverse substances. It also implies that the accessibility of food must be sustainable and should not interfere with the enjoyment of other human rights.

The link between IPRs and human rights surfaces at different levels. The ESCR Covenant recognises everyone's right to take part in cultural life and the right 'to enjoy the benefits of scientific progress and its application'. This general entitlement promoting the sharing of knowledge is supplemented by another provision which recognises everyone's right 'to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author'. The interpretation of these two provisions together may be interpreted as indicating that the recognition of the material interests of an individual IPRs holder does not prevail over everyone's right to the enjoyment of scientific and technological development.

14.9 Summary

The challenge of enhancing food security for each individual and each country around the world will require tremendous efforts on the part of all actors involved if malnutrition is ever to be eradicated. Food insecurity in developing countries has been a concern for long and is associated with a number of general and specific policy

challenges. The development of genetically modified plant varieties and the introduction of IPRs in agriculture constitute two related and significant changes in the policy environment for addressing food security.

The actual implications of the introduction of IPRs in the agricultural sector in developing countries are yet to be ascertained given that legal frameworks are in many cases still in the process of being adopted and implemented. However, a number of points can already be made in the context of food security. Potential benefits of agro-biotechnology include the development of plant varieties that help meeting some of the challenges linked to existing food insecurity. Potential concerns include a number of socio-economic impacts as well as some environmental impacts, in particular with regard to the loss of agro-biodiversity and bio safety.

14.10 Self-Assessment

1. Explain the relation between Intellectual Property Rights and Food Security.
2. What are the Policy Considerations for Food Security in Context of IPRs?
3. Explain Agriculture Related Legal and Institutional Framework vis-à-vis food security.
4. Explain Environment Related Legal Framework vis-à-vis food security.
5. Explain Human Rights Related Legal Framework vis-à-vis food security.

14.11 Further Readings

1. TRIPS Agreement.
2. Covenant on Economic Social and Cultural Rights
3. Universal Declaration of Human Rights

Unit 15
Patent and Environmental Issues

Objectives

It is seldom recognized that one of the main purposes of GATT and now World Trade Organization (WTO) is to promote sustainable development through a rule bound international trade environment. However, to what extent various instruments of trade have helped in conservation of environment and in turn towards sustainable development has not been empirically demonstrated. Committee on Trade and Environment (CTE) under WTO has pursued discussions on this subject for almost five years including the interface between TRIPS and environment. In this unit I review in part one the general concerns about IP and environment, review the debate and discussion in the CTE on the subject in part two. The specific interface between CBD and TRIPS is pursued in part three though some of it does get covered in part two as well. I discuss the ethical aspects of this interface in part four. And finally, I conclude with future options that can be pursued to ensure positive interface between intellectual property protection and the environment. I also identify some of the gaps which need to be filled up through further studies in future.

Structure

15.1 Introduction

A system of intellectual property (IP) rights can encourage inventions by scientists and help promote the transformation of research achievements into marketed products. But associated restrictions on access can reduce utilization of inventions by other scientists. How is this trade-off working out in practice?

This question has been of particular concern for the biological sciences, where production and exchange of biological 'research tools' are important for ongoing scientific progress. Recent studies addressing this issue in the United States, Germany, Australia and Japan find that "patent thickets" or an "anticommons" rarely affect the research of academic scientists. It is well known that biological scientists report increasing difficulties associated with access to research tools but only if the tools are embodied in physical property controlled by others and not easily duplicated. Fear of infringing a prior patent on this material, or the high cost of licensing, is rarely a factor.

Here we report scientists' assessments regarding the overall effects of IP protection, as revealed in a survey of academic agricultural biologists. Scientists believe that, contrary to the current consensus, proliferation of IP protection has a strongly negative effect on research in their disciplines. Our respondents' answers on the details of access problems are highly consistent with those reported in the recent literature, but they ultimately relate these problems to the proliferation of IP protection in academia.

Follow-up interviews, which recorded scientists' extended accounts of selected cases, provide further insights on how bench scientists experience the negative effects of IP protection (Supplementary Interviews online). They attribute problems of delayed or blocked access to needed research tools to material transfer agreements (MTAs). Academic administrators mandate use of MTAs to protect the value of the IP rights held by their institutions or to reduce their exposure to lawsuits by third parties. In short, the major impediment to accessing research tools is not patents *per se*, but patenting as an institutional imperative in the post-Bayh-Dole era.

Our respondents do not encounter an anticommons or a patent thicket. Rather, they believe that institutionally mandated MTAs put sand in the wheels of a lively system of intradisciplinary exchanges of research tools. Seeing no countervailing effect on the supply of these tools, they conclude that patenting impedes the progress of research.

15.2 Dimensions of IP and Environment Interface

Is it a paradox that the regions which are best conserved today in terms of biodiversity whether aquatic or terrestrial are generally the regions where markets are weak and level of development low? Why should regions of high biodiversity have high poverty? The conservation was not a function of just economic incentives but also cultural and ethical value systems that guide the decisions of local communities in this regard. The role of state and markets has been quite contradictory in some cases and complimentary in other cases. In some cases, states have helped the conservation with or without involvement or support of local communities whereas in most of the cases the states have supported the market forces in eroding both the biodiversity and other environmental resources along with the associated knowledge systems. They have done this by not according appropriate place to the local conservation ethic in curriculum used in educational institutions at different levels, through public policies which do not value resources and knowledge of communities in these regions, and by not providing economic and social incentives to peoples in these regions to stay and conserve resources. The migration of people from economically depressed regions such as forest areas, hill areas, some of the flood prone regions and drought prone areas has been far higher compared to migration from any other rural area. The issue obviously arises as to whether conservation can take place without paying respect to the moral and ethical values of such communities.

The respect for values of those who conserve biodiversity can not be shown by keeping them poor. If their knowledge is considered public domain and beyond any kind of protection of their IPP, whether at individual or community level, the ways they could be rewarded for their knowledge could be a) patronage of state, b) support by well-meaning NGOs, c) demand by consumers of their diverse products with attendant high transaction cost in pooling diverse range of products arranging their transportation, or d) movement away from the regions to seek non-farm employment and in return they put their knowledge in some knowledge banks or data bases (an archival approach which truly speaking cannot conserve or reward knowledge completely but can help store whatever is possible), e) development of local health care and enterprise systems based on their knowledge, innovations and practices and we hope that the aspirations of the younger people in these communities will remain in check and contented with local incentives, meager as these might be), and f) other mechanisms that local communities may evolve including insurgent movements against the indifferent states because nothing mentioned under points a-g happens and

their life support systems become weaker and weaker eroding resources, knowledge and cultural and social solidarity of these communities.

I am thus conscious that IPP will contribute only in one of the many ways towards conservation of environment. It is true that so far almost all the western companies and institutions, which accessed the knowledge and biodiversity from third world, did not share much benefits with the providers in a fair and equitable manner(for exception, see the case studies submitted to CBD on the subject). And yet to explore the linkage between IPP and environment, we have to see the way debate on the subject has evolved with or without the emergence of supporting mediating, and watchdog mechanisms. IPP itself does not generate incentives. It is the commercialization of Intellectual properties that *may* generate the incentives.

Commercialization of goods and services particularly those which have a favourable impact on environment depends upon the public policies, regulatory environment, consumer choices, willingness and capacity to pay premium for green technologies, products and services(GTPS). The role of state in providing incentives for such GTPS has been rather subdued in most societies. Will markets provide such incentives and whether some consumers who may value GTPS, have an opportunity to chose from among variety of GTPS. How can state, markets and civil society join hands in making emergence and popularization of GTPs possible, is an urgent concern in current worsening environmental health of globe? It is in this context that we should study the role of intellectual property rights, a very important instrument of public policy providing incentives for innovation and technological development by public and private sectors. We should also realize that intellectual property protection laws merely provide rights to an inventor to exclude others from commercial applications of a patented invention for a given period of time.

These do not permit the inventor to actually operationalise or implement the invention. The operationalisation depends upon the regulatory policies of any country about manufacturing marketing and distributing goods and services after following necessary laws and environmental, food safety and health safety regulations. It is possible that an invention, which is not considered safe today, may provide insights for doing something in future which is safe and desirable by the society. So long as an invention does not pose any environmental hazard in the process of research itself (or at the level of consumption or distribution) or raises ethical or moral dilemma, there is little achieved by stifling the process of research. However, whether to allow application of

such research, every country has a right to devise policies and institutional mechanisms that are in the best interest of the environment and society of the country concerned.

The problem basically arises when many developing countries do not have the capability and institutional infrastructure to evaluate whether a given patented technology would or would not have an adverse environmental impact. In such cases, the bio safety protocol would take care of some of the issues regarding the risk associated with living modified organisms (LMO). We have to be careful in identifying the implications of technologies governed by Multilateral Environmental Agreements (MEAs) as distinct from technologies that are not covered by MEAs but have environmental implications either in the positive or negative direction. In the case of positive, environmentally Sound Technologies and Products (ESTPs) the implication of intellectual property protection will be different than in the case of environmentally risky technologies. Likewise, the environmental implication of a technology protected by IP for conservation of biodiversity and associated knowledge will be different when there is a benefit sharing and when there is not. Whether the benefit sharing arrangements be governed by law of contract within the framework of CBD or be required to be reflected in the international property framework or patent applications is an issue to be explored. Within the various intellectual property instruments such as patents, trademarks, copyrights, geographical indications, plant variety protection, etc., the major impact could be of patenting though other instruments can also have implications for environment.

The intellectual property protection basically tries to provide incentives to inventors to disclose their inventions, which are supposed to be novel, non-obvious, requiring human inventive effort and having industrial applications. The patent or plant variety protection is granted for a maximum period of twenty years in case of crop varieties or other products and fifty years in case of horticultural varieties. The trademarks require registration, which can be renewed periodically for as long as required. In some cases, the protection can be obtained as a well-known mark even if registration has not been done. The copyright is granted on published or unpublished work without having to register. The geographical indications are granted when a product acquires its unique characteristics because of the production or processing being done in a specific region involving traditional or other ways.

In case there is no intellectual property protection, an individual has a choice of keeping his/her knowledge secret without providing any opportunity to others to add value to one's ideas, innovations or inventions. One also has a choice of disclosing one's research and development effort to everybody. Such an individual must be public spirited or be a public servant obliged to produce public domain technologies or services as a part of his/her job. State may through various rewards, or other encouragement, motivate such people to produce new innovative technologies having positive environmental impacts. Whether such a thing will actually happen or not, will vary from case to case.

The extremely poor returns to public sector investments in most developing countries indicate that such motivations may not be easy to provide under ordinary circumstances. At the same time, the fact that public funded agricultural research has delivered tremendous gains supported by International Agricultural Research Centres proves that given the right kind of infrastructure and incentives, results are not impossible to achieve. In view of increasing budget deficit and constraints of public finance, most developing countries are not only inviting domestic and international private capital to their shores but also competing with each other to make conditions as liberal and friendly as possible for private investment. This is being done to ensure that public systems are not burdened with jobs that are not productive or responsibility to provide goods or services which may be more efficiently produced in private sector. While attracting such investments from abroad or within their boundaries, different countries are developing variety of institutional mechanisms to ensure that investments take place within the ambit of national policies on environment, food safety, employment, health and other socio economic concerns. In addition, each state is obliged to comply with the requirements of MEAs as well as other international agreements such as WTO and TRIPS notwithstanding the exceptions and flexibility available therein.

The important articles of TRIPS which may have implication for environment have been abstracted by CTE and given in annexure one. It will suffice to conclude here that intellectual property is a means of rewarding creativity and innovation. To what extent it actually rewards innovation and facilitates development and diffusion of ESTPs will depend upon the transaction cost incurred by various stakeholders, i.e., (a) inventors (formal or informal, individual or communities, private or public sector firms, individuals from organised or unorganised sector), (b) patent office's (to access

and survey prior art i.e., previously published information or knowledge made available in public domain by various other researchers, communities or other inventors), (c) state to provide resources to those who are unable to afford filing patents or enforcing them, (d) international regulatory agencies, patent database management institutions (WIPO), MEA Secretariats, and (e) consumers, environmental NGOs and other interest groups concerned about the interest of not only larger civil society but also other living beings such as wildlife, non-human sentient beings, and of course, most importantly, future generation.

The transaction costs are generally of two kinds, *ex ante* and *ex post.* The former includes the cost of searching information, finding suppliers, negotiating agreements and drafting them. The latter, i.e. *ex post* includes the cost of supervision, enforcement, monitoring, side payments, and if the contract does not work renegotiating and redrawing the contract. For many local communities, researchers, developing country professionals, policy makers and environmental watchdog groups, these costs will be enormous. Generally if we spend adequate resources for *ex ante* cost the *ex post* cost can come down drastically (Gupta and Aseem, 1993, Aseem and Gupta, 1994). The implication of this is that discussions on TRIPS should include ways and means of reducing the costs for those whose knowledge or resources may be used in many of the biotechnological or other biodiversity based inventions for which patent may be being sought by various researchers/ corporations/ institutions. The TCs will have to be reduced likewise for other providers or users of technologies also who may not have means to enforce the compliance with the terms of contract. The argument in this context that the patent office has no role in seeking the information about lawful and rightful obtaining of knowledge, resources and materials claimed in an invention by an applicant or making this information known to the affected parties (i.e., countries) is not valid.

15.3 Interfaces between TRIPs and Environment: Discussions in CTE

Despite the fact that the concern for environment has been eloquently articulated in the preamble to the GATT, the strong reservations against WTO's appropriateness to pursue environmental concerns in international trade have been raised by developing countries. On the other hand, the civil society organizations in even the developed

countries feel that GATT is not green enough and that the WTO has failed to uphold their legitimate concerns. The paradox of not accepting the WTO's eligibility to deal with environmental goals and yet pursuing a very serious dialogue under the auspices of Committee of Trade and Environment, in WTO needs to be studied and understood better before identifying future issues to be resolved. We are restricting the study of interface between trade and environment to look at only one trade instrument and that is the scope and application of intellectual property rights (IPRs). The CTE deliberations on this subject are very comprehensive.

CTE notes two implications of this important issue: (i) The strengthened protection of IPRs which might flow from the TRIPS Agreement "*will* help indigenous and local communities benefit from their contributions where the conditions for protection of patents, plant varieties, trade secrets, industrial designs, geographical indications, copyright and performers' rights (e.g. in respect of expressions of traditional culture) are met. And it further notes that (ii) "the question of new forms of protection adapted to the particular circumstances of such peoples/local communities was not raised during the TRIPS negotiations". In addition, CTE recognizes the potential of Article XX OF GATT 1994 AND THE TRIPS AGREEMENT which specifies certain conditions under which a Member is exempted from obligations under other provisions of GATT 1994.

The discussions also took place in FAO regarding rights to genetic resources in the context of International Undertaking. Commission on Plant and Genetic Resources (CPGR, it is now called as CGRFA) in FAO had interest in IPR over plant varieties, related technologies and farmers' germplasm. During the sessions of the Commission, discussions on these matters have been conducted among member countries since 1983, and following UNCED, further discussions were held on access to plant genetic resources for food and agriculture, access to related technologies, and the realization of farmers' rights. The impact of IPRs on the environment, (especially the distinctiveness, uniformity and stability criteria for plant breeders' rights), and a revision of the International Undertaking on Plant Genetic Resources to harmonize it with the Biodiversity Convention (including negotiations on access to plant genetic resources and the realization of farmers' rights) were also discussed.

In WTO symposium with NGOs on Trade, Environment and Sustainable Development (May 20-21, 1997, Geneva) the relationship between TRIPS and environment was examined. Some participants viewed it as a positive relationship in which TRIPS

Agreement was seen. "as an instrument for promoting the development of environmentally sound technologies. Some noted that intellectual property rights (IPRs) provided time-limited exclusivity which fostered creativity in the development of new technologies, including environmentally sound technologies". It was felt that in the absence of IPRs private sector might be hesitant in allocating significant investments towards research and development of new environmentally sound technologies. There were others who strongly disagreed with this view. And raised concerns about difficulty in recognizing traditional or community based knowledge under TRIPS. They also felt that IPRs, "favoured large industrialized-country enterprises; established monopoly rents in areas related to public policy goals, such as adherence to technology-specific environmental regulations; and the inflexibility of the TRIPS Agreement to ensure equitable compensation to traditional knowledge (holders) and local communities." A concern was also expressed about the link of IPRs with genetically modified organisms and ethical problems inherent in patenting of microorganisms and life forms. Suggestions were made to amend the TRIPS to make it more flexible and to include in its provisions for the development and transfer of environmentally sound technologies; allowing State right to grant compulsory license and shortening the duration of patent protection for environmentally sound technologies. The Art.27.2b of TRIPS should include precise reference to biodiversity and environmental goals.

The Committee on Trade and Environment (CTE) at WTO was informed (WTO/CTE/W/18 dated January 30, 1996) of the decision of Second of the Conference of Parties to the Convention on Biological Diversity requiring the paper on synergies and relationship between the objectives of Convention on Biological Diversity and the TRIPS Agreement. In its meeting in May 1996 CTE reviewed the discussion on TRIPS and environment. It was suggested that CTE should address the situation in which Environmentally Sound Technologies (ESTs) required under Multilateral Environmental Agreements (MEAs) were not available on fair and most favourable terms and IP protection stood in the way of their use. Some other countries including Canada and US felt that the solution was not to be found in the TRIPS agreement but in the Conference of the Parties to the MEAs itself. They felt that TRIPS agreement fostered the creation and dissemination of ESTs by providing adequate and effective IP protection. Undermining its provision, in their view, would diminish incentives to develop and disseminate ESTs. There were other delegates

who felt that relationship between biodiversity convention and the TRIPS agreement was important. CTE was requested to contribute to the debate on compatibility between TRIPS and CBD particularly on the issue of rights over biological resources and sharing of benefits from the exploitation. The Canadian delegation questioned the applicability of IP to the traditional knowledge – a view with which US agreed. The US view was that even in the discussions under FAO on revising the International Undertaking of Plant Genetic Resources, the issue of `farmers' rights' was pursued as a means to support on farm conservation and plant breeding efforts and not to create an IP instrument for legal protection. It was further added that traditional and indigenous knowledge could be recognized and rewarded through benefit sharing approaches including voluntary, contractual agreements on mutually agreed terms. US therefore, did not see the need for international *sui generis* system to be established to protect or grant some right of compensation for this type of subject matter.

In a WTO symposium of non-governmental organization on Trade, Environment and Sustainable Development (March 17-18, 1998). The WTO position was that if a problem was environmental, the effort should be to develop an environmental rather than trade policy solutions. The UNCTAD representative felt that trade and environment were complimentary although the constituencies representing these interests were often in conflict. The UN Executive Director addressing WTO first time felt that the questions regarding new property rights, and also about the responsibility must be addressed as soon as possible. The need for transparency in public policy, he added, had to go hand in hand with public accountability. The discussion on TRIPS and environment was inconclusive and the general refrain was that clear relationship between TRIPS and technology transfer was weak even when such technologies had strong environmental implications.

A detailed discussion under item 8 on the relevant provisions of the agreements on TRIPS with the implications for the environment took place in the CTE meeting in July 1998. US representative felt that Indian proposal (WT/CTE/W/82) suggesting a need for reduction in patent protection for environmentally friendly products was not in the right direction. He inquired as to why someone would invest time and money in inventing and developing ESTs. In fact, there was a need he felt to increase the patent protection for such products to spur their development. He did not agree with the India's position that patents restricted competition causing restricted output and higher prices. He felt that countries which had strong patent protection had higher varieties

of goods available and in most cases with decrease in prices. The US representative felt that Indian paper had not studied the factors most directly affecting technology transfer and trade (for example, a country's foreign investment climate, import laws and regulations, marketing approval procedures, market conditions, transportation and distribution infrastructure, etc.) and therefore, these factors, "could not have uniformly contributed" towards the non-availability of ESTs. He also did not agree with India's argument for amending Art.29 of the TRIPS to implement its obligation under CBD. Likewise, he did not see a connection between the prior informed consent (PIC) and the patent process, nor did he see a need for designing a *sui generis* IP system for local contemporary innovations. In his view, having concluded the CBD in June 1992, the modifications in TRIPS should have been suggested until December 1993 when it was finalised.

15.4 CBD and TRIPS: Emerging Issues

The Intellectual Property Policy Directorate of Canada in a study on the interface between IP and biodiversity convention reviewed the global experience and summarised the position of Andean Pact Countries, Costa Rica, Mexico, Cameroon, Gambia, India, Philippines, Indonesia, Australia and New Zealand. Most countries have either enacted or in the process of enacting law (in case of Philippines, the issue is governed by an executive order). In some countries, like Indonesia the access is governed by the Rules and Procedures Governing Permission from the Government of Indonesia for foreign researchers to conduct in Indonesia issued by the Indonesian Institute of Science (the so-called LIPI rules). In this case, the contracts govern the access rather than a national law. In New Zealand the cultural and indigenous properties of indigenous people has become a major issue. There is a case under hearing in New Zealand where Mori people have claimed under the Treaty of Waitangi that New Zealand government violated the Treaty by allowing the patenting of inventions and the granting of plant breeders rights based on flora under their command.

In preparation for the 1999 Ministerial Conference on IPR India communicated in February 1999 to the General Council of WTO several proposals. India feared that TRIPS agreement in its current form might tempt the IPR holders to charge exorbitant and commercially unviable prices for transfer or dissemination of technologies held

through such intellectual property rights. India recalled its proposals made to the Committee on Trade and Environment that "owners of ESTPS should sell such technology and products at fair and most favourable terms and conditions upon demand to any interested party which has an obligation to adopt these under national law of another country or under international law". India also suggested the need for recognising the intrinsic linkage between CBD and TRIPS. It felt that commercial exploitation of innovation based on traditional knowledge should be encouraged only "on the condition that innovators share the benefits through material transfer agreement / transfer of information agreements." Under Art.29 of TRIPS a provision should be made, as mentioned earlier, about mention of the country of origin and nature of biological materials. The applications should be open to full public scrutiny after filing so that interested countries could file their opposition in time. The provision in domestic laws requiring prior informed consent of the countries of origin and the knowledge holder of the biological raw material intended to be used or actually used in a patentable invention, as compatible with TRIPS agreement. India also suggested that protection available under geographical indications for wines and spirits should be available for other goods also.

In a study on the impact of TRIPS and agricultural research Ghayur Alam (1999) feels that strengthening of law in developing countries will restrict the ability of these countries to develop and commercialize biotechnology based agricultural technologies. Author refers to an UNCTAD study (1996) which did not find any correlation between the strength of IPR regime and the level of foreign investment and transfer technology to a country. The author concludes that effect of strong IP system can be mitigated to some extent by encouraging use of IP intelligently by public sector institutions, by strengthening biotechnology capabilities, by modernizing their patent office, by refusing to grant broad patents, insistence on local production instead of considering the import of a patent product as sufficient to meet the condition of working of patent, etc. He feels that overall effect of TRIPS related changes would be negative on agricultural research in developing countries. Nijar (1999) decries the view of developed countries that the creativity represented by the indigenous knowledge could not be protected and rewarded under TRIPS. He also feels that Europe and US have blurred the distinction between invention and discoveries by allowing patents either on purified form of natural product or allowing patents on substance found in nature characterized in such a manner that it made available some of its constituents which

earlier were not available in that form or in that manner. He suggests that moral arguments can be used as provided under TRIPS for refusing patents on life forms. He feels that the *sui generis* option given under TRIPS does not require countries to join UPOV or enact UPOV-like laws. He suggests that while recognising the rights of farmers and healers whether indigenous people or communities recently or inter generationally, their prior consent must be sought for using their varieties, breeders be denied any right in respect of plant varieties, "that are derived from plants which are invested with the knowledge or indigenous people or local communities". The right of the communities must be recognized without the need for recognition of other inventors, seems to be the refrain. Further, farmers should be entitled to save seeds for their own use and plant breeders right should not be allowed in cases where biodiversity may be adversely affected, where variety might not possess normal regenerative and reproductive capacity or where there could be ethical reasons for rejecting the rights. He concludes that it is possible to enact a law for community rights outside TRIPS but compatible with TRIPS or within TRIPS which takes into account the innovations of farmers.

Cecilia Oh (1999) articulates a very widespread fear of developing countries, "that the control of the nature and distribution of new life forms by transnational corporations may affect their food security and development prospects." She advocates the need for developing countries to insist on a broader review of Art.27.3 (B). She feels that negotiations on Art.27.3 (B) should not be unduly delayed and coupled with either the next round of WTO trade negotiations or with other measures. The option one, according to her, is to exclude plants, animals, their parts and the processes which are related to them from patenting. The patent should not be allowed not just on animals but also their genes, gene sequences, cells, etc. Under this option, even microorganisms will be excluded from patenting. Under option two, she suggests that country should be free to exclude the animals, plants, microorganisms, part thereof and any process making use thereof or related thereto. Under this option, the patenting on life is not disallowed but national sovereignty over the patent laws and biological resources is maintained. In this the existing Art.27.3 (B) will almost be maintained. In option three, the current text of Art.27.3 (B) will remain unchanged.

Watal suggested against opening of TRIPS discussions so as to redefine the terms. She observed, "The focus on TRIPS will, for developing countries, shortly shift to dispute settlement in the WTO. Developing countries would be making a serious mistake to

re-open TRIPS to seek definitions of undefined terms as this would restrict their own current flexibility and freedom. To seek the inclusion of clauses that may, in the end, be only hortatory and unoperational may prove costly in terms of concessions given in the WTO".

In a recent report on Australian Indigenous Cultural and Intellectual Property Rights authored by Terri Janke (1998) brings together the collective understanding of various Australian indigenous organizations about the options indigenous peoples have to use and control their cultural and intellectual property. The author suggests several amendments to the Patent Act and the Plant Breeders Rights Act to deny, "any person or corporation the right to obtain a patent for any element of Indigenous Heritage without adequate documentation of the prior free and informed consent of the Indigenous Owners to an arrangement for the sharing of ownership, control, use and benefits." Further, it is required "that rights granted under the Patents Act and the Plant Breeders Rights Act should not interfere with the traditional and customary use of indigenous cultural material." The other amendments suggested for modification of these Acts include (a) allowing indigenous Australians to register their interest or to patent indigenous knowledge notwithstanding its prior publication, (b) allow secrecy of these processes so that people are not forced to disclose details of any remedy or whether the remedy should become public domain when the patent expires, (c) a new clause of proprietary rights for traditional knowledge or new procedures which ensure the information to indigenous people about any patent application or plant breeders right application including indigenous material, (d) requirement of prior informed consent and (e) right of indigenous people to negotiate the type of use they would permit and to share any economic benefits that might accrue. Author also suggests amendments to the copyright act, designs act, trademark act, and cultural heritage legislation so that misappropriation or unauthorized use of indigenous traditions and knowledge system can be prevented and incentives for conservation of local knowledge, culture, natural and other resources, and institutions can be provided.

Novartis Foundation for Sustainable Development (1999) articulated strong support for intellectual property rights regardless of who owned them as these constituted, in its view, “a positive element in the context of innovation in the field of genetic engineering and biotechnology.” While analysing ethical and ecological aspects of intellectual property rights, Leisinger noted that excluding human genes and human gene therapy, there were no unique ethical aspects of IPR in the context of genetic

engineering and biotechnology. He cited several examples in support of the argument that genetic engineering had advanced higher food security either through resistance to fungal and virus diseases in major food crops or through various other crop improvements. Likewise, bio pesticides were cited as an illustration of benevolent outcomes of IP in biotechnology. He does not address the issue of control of this technology and benefit sharing. For instance, some of the bacteria used in developing patented BT technology were obtained from developing countries and yet no attribution (in some cases or compensations) had ever been contemplated. He discusses risks in considerable detail. In the context of bio safety risks, he argues that no major disasters have occurred despite deliberate release of plant pathogens, soil macros and plant and animal symbiotic into new habitats or new areas where potential for harm existed. In his view, there was a consensus among the scientists that fear about release of recombinant organisms was unwarranted. However, he added, that poor developing countries should not become the testing ground for potentially risky technologies. In his view, it was unethical to export risks from technologically highly developed countries into poor countries even if local laws permitted it. He acknowledged many cases where the benefits of research had not reached the people whose knowledge had been used in developing the patented technologies. So far as the decline of genetic diversity was concerned, the main responsibility in his view definitely did not lie with genetic engineering and biotechnology. The conservation of *in situ* biodiversity would require financial or other incentives to small farmers in developing countries. Otherwise, given varieties with higher yield and less pesticide consumption, they might be expected to switch over to high yielding varieties if ecological conditions permitted. He acknowledged that motivation behind patenting and other forms of intellectual property would not be conservation as such. But, he added, "granting intellectual property rights to scale genetic information could become part of successful conservation strategy, as it would assign value to resources that are otherwise considered to be free". Finally, in a strong defence of the industry view, he cited the example of his own company i.e., Novartis which had made available a particular gene of *Bacillus thuringiensis* to International Rice Institute (IRI). Whether this is an exceptional donation or a systematic policy has not been elaborated.

The environmental risks involved in biotechnologies are becoming well known in recent times. Herbicide tolerant soya bean represent about 27 per cent of total area under soya bean while genetically modified maize was assumed to represent about 25

per cent of the total area in 1998 (Williams, 1998). The case for increased chemical pesticide consumption due to diffusion of herbicide resistance varieties is quite strong (Oh and Traavik, 1999). Benbrook (1999) showed that Roundup Ready Soya Beans not only produced lover yield compared to the non GM counterparts but farmers use 2 – 5 time more herbicides per acre in RR soya beans compared to other weed management systems. Although, recently the area under genetically modified crops is reportedly decreasing in US because of the widespread consumer concern about safety and demand for labelling.

The fear about transgenic crops affecting the wild biodiversity is no more a matter of speculation. Scientists at Cornell University have found that larvae of monarch butterflies were killed if the pollen from the BT corn crop fell on the milk weed – the host plant for the larvae of monarch butterflies. It was found that no mortality occurred in larvae which were fed non-transgenic pollen but in the case of larvae fed by the pollen from BT corn, 44 per cent of the larvae were killed after four days. There was a clear indication that environmental implication of biotechnology needed special attention.

15.5 Ethical Issues in interface between IPP and Environment

In a recent paper, Gupta (1994) identified seven dimensions of ethical responsibility relevant to this discussion. These are:

(1) Accountability of researchers and biodiversity prospectors working in public and private sectors in national or international organizations towards providers of biodiversity resources from wild, domesticated, and public access domains;

(2) Accountability of researchers and prospectors toward the host country;

(3) Accountability of professionals toward academic communities and professional bodies guiding the process of exploring or extracting biodiversity;

(4) Accountability of international, UN, or other organizations possessing globally pooled germplasm collections deposited in good faith but accessible to public or private institutions without reciprocal responsibilities;

(5) Accountability of institutions of governance legitimizing various kinds of property right regimes leading to different ethical and moral dilemmas;

(6) Accountability of civil society and consumers of products derived from prospected biodiversity or competing alternatives; and,

(7) Accountability of conservators, users, and consumers toward future generations, and other living, non-human sentient beings.

Two other kinds of accountability also seem relevant to this discussion:

1. Our own accountability toward nature, including plants, animals, and other forms of life and habitats,

2. Our accountability toward our own consciences, as well as toward universal ethical values

Research collaborations between local communities and outside researchers involve a dilemma which has already been brought into sharp focus years ago (i.e. the Camelot project). Important issues related to covert and overt research, inadequate provision of information to the respondents, information being obtained through deceit, violation of local cultural and spiritual beliefs during the acquisition of information or material, etc. Three issues that must be kept in mind while looking the accountability of researchers: the responsibility of national and international researchers toward local communities differs only in degree and not quality; the fact that poor people are not better off being exploited by national researchers or institutions than by international institutions; and the responsibility for conservation is higher and not lower for national researchers, private, and public institutions, than that of their international counterparts.

In conservation biology and ethno biology, standards of accountability towards one's peers have not yet been clearly outlined. Some professionals have developed codes of conduct but their mechanisms for enforcement of those codes are often very weak. For instance, a researcher can present a paper in a conservation biology conference without having been required to share the findings with local communities. Similarly, a national or corporate gene bank in a western country may accept an accession from a scientist without confirming whether the material was obtained legally and in a morally acceptable manner. Patent offices can issue patents to scientists without ensuring that the patentees declare lawful and rightful property rights over the invention.

Standards of good practices have been defined in several professions, but professionals have frequently forgotten that they could or should also be applied when dealing with non-professionals. For instance, it is an accepted professional value in academia that any communication having substantive implications for one’s ideas should be acknowledged. Accordingly, personal communications find place in academic

discourse. However, this accountability is generally observed only towards ones professional colleagues. It is extremely rare that the farmers, indigenous people, artisans, etc., who have working knowledge of certain problems are ever acknowledged in such discourses. We would go so far as to say that the whole discipline of ethno biology has gained legitimacy through extraction of information without acknowledgement. The wealth accumulated from this knowledge is seldom shared with the providers.

When researchers have no control over the use of their data and conclusions, they have often been dismayed by the way in which their work has been interpreted. But similar concern has not been expressed about the way indigenous communities might think about the same process. Hopkins suggests that "in normative terms, when any two individual cultures have differences regarding the morality of a particular action or behaviour, both can be right because morality is relative. This sense of moral relativism suggests that absolute notion of right or wrong is not valid". This implies that the notion of universal morality is invalid. Is it that a universal value system exists only within certain specified limits? We do not think that differences in cultural diversity should be used to argue for total relativism in moral values. To take something such as biodiversity or related knowledge from someone who is not aware of its true worth without due consideration and informed consent can be considered by many as a case of fraud. Can the cultural core of any society condone it as a legitimate and fair activity?

No scheme of incentives for conservation should lead to the erosion of the natural resource base for which the incentives were put in place. In this context, some people have argued that providing material incentives may distort the values of the local communities supposed to be living in harmony and peace with nature. There might be substance in this suggestion, but it should not be stretched too far. Material rewards in the absence of local institution building can indeed lead to environmental and cultural degradation. In many North American Indian Reservations the welfare system, unsupported by investment in local institution building, killed the spirit of local enterprise in many communities. However there are communities like the Zunis who have won major law suits and have obtained large amounts of monetary compensation to undo the damage to their natural resources that had resulted from unauthorized dumping by the State.

Recognizing that the absence of monetary rewards and other opportunities is unlikely to either preserve the resource or the ethics which has helped to conserve the resource so far, we suggest a matrix for combining material and non-material incentives on one side with individual and collectives or communities as targets of reward. Incentives are needed to conserve biodiversity, reward creativity and innovation, generate respect for local institutions and ethical behaviour, and influence the values of future leaders of society

The first category of individual material rewards includes the conventional incentives such as patents, license fees, contract fees, monetary rewards for innovations and conservation efforts, etc. It is up to the innovators to decide what to do with their reward. For instance, we know of cases in which individual innovators have refused any private reward. In such cases, one can try setting up a trust fund for collective use of the reward money, under the leadership of individuals whose contributions made this possible. Such a measure generates non-material individual reward in the form of honour or esteem. The accountability of consumers and other members of civil society are crucial in generating material incentives for conservation. Ultimately it is the consumers who pay or do not pay for upholding the values which we, as conservators of biodiversity, cherish.

The second category, non-material individual incentives, includes honour, recognition, and respect for such individuals who have contributed extraordinarily to the goals of conservation, value addition, or both. SRISTI has honoured about seventy such individuals from different parts of the country, in India. We have also organized biodiversity contests among school children and honoured the most knowledgeable children. Small material prizes accompanied by honour certificate contribute in building respect for local knowledge. Conservation through competition has been a very successful experiment, and has been pursued by SRISTI in different parts of India and the world

The third category, material and collective incentives, offers enormous scope for experimentation. Several kinds of trust funds, guarantee, risk or ventured capital funds can be set up to promote conservation, value addition, commercialization, etc. These funds should provide enough flexibility for communities to pursue culture-specific norms of conservation as well as offer reward and/or compensation to outstanding local contributors. Some of these funds will operate at the regional level, while others may be implemented at the community level.

Finally, the fourth category, non-material collective benefits, includes policy reform, institution building, and incorporation of local ecological knowledge in the educational curriculum at different levels, development of markets for organic and other local products at national and global level, and more. Although no one incentive may be sufficient to generate the right kind of respect for traditional knowledge and contemporary conservatory innovations, we believe that a combination of these incentives can provide positive, sustainable outcomes.

The ethical issues with regard to patenting life forms such micro-organisms are not the same as patenting animals or plants. The life forms which have feelings are distinguished in many cultures from the one which are not. Substantive issue here is that laws which provide protection to a corporate or formal sector inventor and innovator cannot claim its inability to safeguard the interests of local communities and individual experts. It is not important whether most local people want to patent their knowledge or innovations or not. The point is that their cultural and intellectual resources deserve similar respect as is applicable to formal sector.

15.6 Summary

IPP can create incentives for right holders of traditional varieties of crop or horticultural plants to create demand for these products so that they have incentives for conservation. The trading channels such as fair trade intermediaries or even major super chains may invest in promoting ethnic or less known foods and crafts when protected through relevant IPP so that rent on promotional investment can be extracted. In organic agriculture, the blending of agro-biodiversity with organic certification has generated incentives for local communities and individual farmers in several countries. Most of the compulsively organic farmers (that is organic because of less developed markets, uneven terrain, rain fed regions, and poor economic conditions), also conserve and grow land races and local breeds of animals. In some places thee exist high demand for eggs of local scavenger poultry breeds which commands premium over battery managed poultry. Thus market mediated incentives can be complimented with non-market ones and IPPs (plant variety protection, geographical indications, etc.,) can be used to increase incentives for conservators as also the investors in the market chains.

Geographical indications for the forest and biodiversity based crafts and other natural products can generate demand for these gods and thus enhance incentives for conservation if appropriate institutions are also simultaneously built to generate long term stakes, together with security of tenures for local communities over the basic resources. After the recent 73rd amendment of Indian constitution, tribal communities in designated areas have been made owners of all non-timber forest produce and thus new avenues emerge for developing their market access combined with the ethic of sustainable extraction of resources.

Trademarks, folk lore protection, and other kind of protection for local cultural artefacts, music styles and art forms may increase economic incentives for local communities and thus improve the probability of people staying in the biodiversity and the knowledge rich regions. If the emigration continues at the present alarming rate from these regions, the possibility of co-evolutionary processes for conservation continuing is remote. Thus any incentive that helps local communities to stay in the region without remaining poor, will help in conservation to. Obviously, we cannot conserve biodiversity by keeping people poor as many conservationists seem to suggest (for they fear that improvement in economic opportunities will not help local communities conserve resources). Indirect incentives must also receive adequate attention. GEF suggests that providing such incentives may be a national obligation and thus avoids financing such incremental costs. It may be right `technically' but then the result will be that biodiversity will not be conserved.

Database development may help link innovators, investment and entrepreneur

Downes and Laird, 1999 however, caution," making databases public creates risks that their contents will be used in ways that the knowledge providers do not approve, without sharing of benefits, and without acknowledgement. Contract obligations agreed to by users can be difficult to enforce. Thus, many traditional knowledge holders may not be willing to make their databases of knowledge available until changes are made to the legal system that make it easier for them to manage how their knowledge is used", a view with which I agree. However, unless synoptic information is kept in such web based data bases, the Golden Triangle linking innovation, investment and enterprise may not get linked. That is the reason SRISTI has proposed INSTAR (International Network for Sustainable Technology Applications and Registration) since 1992.

WIPO could administer an international registry of small green innovations so as to achieve the goals of point 4 above. This could supplement the national innovation system, with shorter duration, quick registration (within three months), lower inventive threshold, lesser number of claims (5-7), and easy access to any one from any part of the world through Internet as well conventional means. Honey Bee database can provide the initial spur for the purpose.

Collective management of intellectual property rights should also be explored. Given the high transaction costs of standard intellectual property rights, if association of healers, herbalists, or other artisans could file, maintain, license and recover the dues, it will parallel a very god example provided by performers' associations or collecting associations.

Concession in cost of applications (lesser fees, or no fees in case of small green inventors), other forms of assistance, longer duration for local landraces (99 years), just as to aid pharmacy industry, many patent office's like in Australia are allowing extension in the patent term due to time lost in getting FDA approvals. Similarly, local communities and informal breeders and innovators may be given some concessions for not having filed for protection so far.

15.7 Self-Assessment Test

1. Explain the dimensions of IP and Environment Interface.
2. Explain the interface between TRIPs and Environment.
3. What are the emerging issues in CBD and TRIPS?
4. What are the ethical Issues in interface between IPP and Environment?

15.8 Further Readings

1. TRIPS Agreement
2. Patent Cooperation Treaty
3 Paris Convention