UTTRAKHAND OPEN UNIVERSITY

LL.M.-103

SCHOOL OF SOCIAL SCIENCE

बौद्धिक सम्पदा विधि

(INTELLECTUAL PROPERTY LAW)

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UTTRAKHAND OPEN UNIVERSITY HALDWANI

INTELLECTUAL PROPERTY LAW
बौद्धिक सम्पदा विधि

LL.M.-103

LL.M. Part-1

Subject: Intellectual property Law

Block I- Introduction
Unit-1- TOPIC: IPR AND INTERNATIONAL PERSPECTIVES

STRUCTURE

1.1 INTRODUCTION

Intellectual Property, as a creation of the human intellect, is found almost everywhere – in creative works like books, films, records, music, art and software, and in everyday objects like cars, computers, drugs and new varieties of plants. The distinctive signs and features, like trademarks and designs, which help us choose the products we buy, can be protected by the IP system. Even the place of origin of a product can have rights attached to it, as is the case with Champagne and Gorgonzola. Much of what we see and use on the Internet, be it a web page or a domain name, also includes or represents some form of IP.

In today's world, the IPR system plays a vital role in the economic growth strategies of countries in all stages of development worldwide. The IPR system helps to spur innovation and create a relationship of trust, both of which are crucial for creating and delivering better goods and services to users and consumers. By fostering fair play in the marketplace, the IPR system benefits users, consumers and society at large by supporting the creation of innovative, new and improved products and knowledge that improves the quality of life of peoples worldwide.

In this unit we will discuss about the concept, definition, nature, types of IPR and IPR laws in India. We will also discuss about the international perspectives of IPR such as WTO and TRIPS. Further, we will also discuss the issues of public health pertaining to IPR.

1.2 OBJECTIVES

After reading this unit you will be able to:

- ✓ Understand the concept of IPR.
- ✓ Explain and define the meaning of IPR.
- ✓ Describe the nature of IPR.
- ✓ Write the different types of IPR.
- ✓ Write the different protections of IPR laws under the WTO and TRIPS obligations.
- ✓ Discuss the International perspectives of IPR.
- ✓ Discuss the TRIPS obligations pertaining to public health and IPR.

1.3 INTELLECTUAL PROPERTY RIGHTS (IPR) LAWS IN INDIA

1.3.1What is an IPR?

The term intellectual property includes, in the broadest sense, all rights resulting from intellectual activity in the industrial, scientifically, literary, or artistic fields. The conventions establishing the WIPO defines 'Intellectual Property' in a broad sense. But the term Intellectual Property was defined first time in Paris Convention. Intellectual Property is derived from the term Industrial Property which includes trademarks, design marks, service marks, commercial names and designations, including indications of source and appellations of origin, and the protection against unfair competition. The main objectives of Paris Convention provides that "the protection of industrial property like patents, utility models, industrial designs, trademarks, service marks and the repression of unfair competition". But in the WIPO defines it broadly and intellectual property shall include the right relating to:

- ✓ Literary, artistic and scientific works;
- ✓ Performance of performing artists;
- ✓ Inventions in all fields of human endeavor;
- ✓ Scientific discoveries;
- ✓ Industrial designs;
- ✓ Trademarks, service marks and etc;
- ✓ Protection against unfair competition.

This definition although inclusive in nature, is very comprehensive. As we know that the intellectual property is intangible. It is a new form of property which got greater recognition only in the 18th century. The Intellectual Property is a property in mental labour as distinguished from physical labour. Therefore the Intellectual Property is to be understood as a result of mental labour in contradistinction with purely physical labour. It is mostly intangible in nature.

Intellectual property rights have gained at most importance in the modern world. The concept of intellectual property rights as developed in India cannot be divorced from the developments in the international arena as well as in the nation-to-nation relations. Intellectual Property Rights are legal rights, which result from intellectual activity in industrial, scientific, literary & artistic fields. These rights safeguard creators and other producers of intellectual goods & services by granting them certain time-limited rights to control their use. Protected IP rights like other property can be a matter of trade, which can be owned, sold or bought. These are intangible and non-exhausted consumption.

1.3.2 Nature of Intellectual Property Rights

Some see IP rights principally as economic or commercial rights, and others as akin to political or human rights. The TRIPS agreement treats them in the former sense, while recognizing the need to strike a balance between the rights of inventors and creators to protection, and the rights of users of technology (Article 7 of TRIPS). The Universal Declaration of Human Rights has a broader definition recognizing "the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author", balanced by "the right…to share in scientific advancement and its benefits." The crucial issue is to reconcile the public interest in accessing new knowledge and the products of new knowledge, with the public interest in stimulating invention and creation which produces the new knowledge and products on which material and cultural progress may depend.

The difficulty is that the IP system seeks to achieve this reconciliation by conferring a private right, and private material benefits. Thus the right to the protection of "moral and material interests" of "authors" is inextricably bound up with the right to the private material benefits which result from such protection. And the private benefit to the creator or inventor is derived at the expense of the consumer. Particularly where the consumer is poor, this may conflict with basic human rights, for example, the right to life. And the IP system, as manifested in TRIPS, does not allow – except in rather narrow ways - discrimination between goods essential to life or education, and other goods such as films or fast food.

We therefore consider that an IP right is best viewed as one of the means by which nations and societies can help to promote the fulfillment of human economic and social rights. In particular, there are no circumstances in which the most fundamental human rights should be subordinated to the requirements of IP protection. IP rights are granted by states for limited times (at least in the case of patents and copyrights) whereas human rights are inalienable and universal.

For the most part IP rights are nowadays generally treated as economic and commercial rights, as is the case in TRIPS, and are more often held by companies rather than individual inventors. But describing them as "rights" should not be allowed to conceal the very real dilemmas raised by their application in developing countries, where the extra costs they impose may be at the expense of the essential prerequisites of life for poor people.

Regardless of the term used for them, we prefer to regard IPRs as instruments of public policy which confer economic privileges on individuals or institutions solely for the purposes of contributing to the greater public good. The privilege is therefore a means to an end, not an end in itself. Thus in terms of assessing the value of IP protection, it may

be compared to taxation. Hardly anybody claims that the more taxation there is the better. However, there is a tendency among some to treat more IP protection as self-evidently a good thing. More taxation might be desirable if it delivers public services that society values more than the direct and indirect cost of taxation. But less can also be beneficial, for instance if excessive taxation is harming economic growth. Moreover, economists and politicians spend much time considering whether the structure of the tax system is optimal. Are heavy social security taxes harming employment? Are particular tax breaks serving their intended purpose, or merely subsidizing their recipients to do what they are already doing? Is the effect of the tax system on the distribution of income desirable from a social point of view?

We think there are very analogous questions for intellectual property. How much of it is a good thing? How should it be structured? How does the optimal structure vary with sectors and levels of development? Moreover, even if we get the level and structure of protection right, to balance the incentive to invention and creation against the costs to society, we also have to worry about the distribution of gains.

IPR are largely territorial rights except copyright, which is global in nature in the sense that it is immediately available in all the members of the Berne Convention. These rights are awarded by the State and are monopoly rights implying that no one can use these rights without the consent of the right holder. It is important to know that these rights have to be renewed from time to time for keeping them in force except in case of copyright and trade secrets. IPR have fixed term except trademark and geographical indications, which can have indefinite life provided these are renewed after a stipulated time specified in the law by paying official fees.

Trade secrets also have an infinite life but they don't have to be renewed. IPR can be assigned, gifted, sold and licensed like any other property. Unlike other moveable and immoveable properties, these rights can be simultaneously held in many countries at the same time. IPR can be held only by legal entities i.e., who have the right to sell and purchase property. In other words an institution, which is not autonomous may not in a position to own an intellectual property. These rights especially, patents, copyrights, industrial designs, IC layout design and trade secrets are associated with something new or original and therefore, what is known in public domain cannot be protected through the rights mentioned above. Improvements and modifications made over known things can be protected. It would however, be possible to utilize geographical indications for protecting some agriculture and traditional products.

1.3.3 Types of IPRs

Intellectual property rights as a collective term includes the following independent IP rights which can be collectively used for protecting different aspects of an inventive work for multiple protection:-

- ✓ Patents
- ✓ Copyrights
- ✓ Trademarks
- ✓ Registered (industrial) design
- ✓ Protection of IC layout design,
- ✓ Geographical indications, and
- ✓ Protection of undisclosed information

1.3.3.1 Patents

A patent is an exclusive right granted by a country to the owner of an invention to make, use, manufacture and market the invention, provided the invention satisfies certain conditions stipulated in the law. Exclusive right implies that no one else can make, use, manufacture or market the invention without the consent of the patent holder. This right is available for a limited period of time. In spite of the ownership of the rights, the use or exploitation of the rights by the owner of the patent may not be possible due to other laws of the country which has awarded the patent. These laws may relate to health, safety, food, security etc. Further, existing patents in similar area may also come in the way. A patent in the law is a property right and hence, can be gifted, inherited, assigned, sold or licensed. As the right is conferred by the State, it can be revoked by the State under very special circumstances even if the patent has been sold or licensed or manufactured or marketed in the meantime. The patent right is territorial in nature and inventors/their assignees will have to file separate patent applications in countries of their interest, along with necessary fees, for obtaining patents in those countries. A new chemical process or a drug molecule or an electronic circuit or a new surgical instrument or a vaccine is a patentable subject matter provided all the stipulations of the law are satisfied.

The Indian Patent Act

The first Indian patent laws were first promulgated in 1856. These were modified from time to time. New patent laws were made after the independence in the form of the Indian Patent Act 1970. The Act has now been radically amended to become fully compliant with the provisions of TRIPS. The most recent amendment was made in 2005 which were

preceded by the amendments in 2000 and 2003. While the process of bringing out amendments was going on, India became a member of the Paris Convention, Patent Cooperation Treaty and Budapest Treaty. The salient and important features of the amended Act are explained here.

Definition of invention

A clear definition has now been provided for an invention, which makes it at par with definitions followed by most countries. Invention means a new product or process involving an inventive step and capable of industrial application. New invention means 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 patent application with complete specification i.e., the subject matter has not fallen in public domain or it does not form part of the state of the art.

Inventive step means a feature of an invention that involves technical advance as compared to existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art. Capable of industrial application means that the invention is capable of being made or used in an industry.

Novelty

An invention will be considered novel if it does not form a part of the global state of the art. Information appearing in magazines, technical journals, books, newspapers etc. constitutes the state of the art. Oral description of the invention in a seminar/conference can also spoil novelty.

Novelty is assessed in a global context. An invention will cease to be novel if it has been disclosed in the public through any type of publications anywhere in the world before filing a patent application in respect of the invention. Therefore it is advisable to file a patent application before publishing a paper if there is a slight chance that the invention may be patentable. Prior use of the invention in the country of interest before the filing date can also destroy the novelty.

Novelty is determined through extensive literature and patent searches. It should be realized that patent search is essential and critical for ascertaining novelty as most of the information reported in patent documents does not get published anywhere else. For an invention to be novel, it need not be a major breakthrough. No invention is small or big. Modifications to the existing state of the art, process or product or both, can also be candidates for patents provided these were not earlier known. In a chemical process, for example, use of new reactants, use of a catalyst, new process conditions can lead to a patentable invention.

Inventiveness (Non-obviousness)

A patent application involves an inventive step if the proposed invention is not obvious to a person skilled in the art i.e., skilled in the subject matter of the patent application. The prior art should not point towards the invention implying that the practitioner of the subject matter could not have thought about the invention prior to filing of the patent application. Inventiveness cannot be decided on the material contained in unpublished patents. The complexity or the simplicity of an inventive step does not have any bearing on the grant of a patent. In other words a very simple invention can qualify for a patent. If there is an inventive step between the proposed patent and the prior art at that point of time, then an invention has taken place. A mere 'scintilla' of invention is sufficient to found a valid patent. It may be often difficult to establish the inventiveness, especially in the area of up coming knowledge areas. The reason is that it would depend a great deal on the interpretative skills of the inventor and these skills will really be a function of knowledge in the subject area.

Usefulness

An invention must possess utility for the grant of patent. No valid patent can be granted for an invention devoid of utility. The patent specification should spell out various uses and manner of practicing them, even if considered obvious. If you are claiming a process, you need not describe the use of the compound produced thereby. Nevertheless it would be safer to do so. But if you claim a compound without spelling out its utility, you may be denied a patent.

Term of the patent

Term of the patent will be 20 years from the date of filing for all types of inventions.

Application

In respect of patent applications filed, following aspects will have to be kept in mind:-

- ✓ Claim or claims can now relate to single invention or group of inventions linked so as to form a single inventive concept
- ✓ Patent application will be published 18 months after the date of filing
- ✓ Applicant has to request for examination 12 months within publication or 48 months from date of application, whichever is later

No person resident in India shall, except under the authority of a written permit sought in the manner prescribed and granted by or on behalf of the Controller, make or cause to be made any application outside India for the grant of a patent for an invention unless (a) an application for a patent for the same invention has been made in India, not less than six weeks before the application outside India; and (b) either no direction has

been given under the secrecy clause of the Act or all such directions have been revoked.

Provisional Specification

A provisional specification is usually filed to establish priority of the invention in case the disclosed invention is only at a conceptual stage and a delay is expected in submitting full and specific description of the invention. Although, a patent application accompanied with provisional specification does not confer any legal patent rights to the applicants, it is, however, a very important document to establish the earliest ownership of an invention. The provisional specification is a permanent and independent scientific cum legal document and no amendment is allowed in this.

No patent is granted on the basis of a provisional specification. It has to be a followed by a complete specification for obtaining a patent for the said invention. Complete specification must be submitted within 12 months of filing the provisional specification. This period can be extended by 3 months. It is not necessary to file an application with provisional specification before the complete specification. An application with complete specification can be filed right at the first instance.

Complete Specification

It may be noted that a patent document is a techno-legal document and it has to be finalized in consultation with an attorney. Submission of complete specification is necessary to obtain a patent. Contents of a complete specification would include the following

1. Title of the invention.
2. Field to which the invention belongs.
3. Background of the invention including prior art giving drawbacks of the known inventions & practices.
4. Complete description of the invention along with experimental results.
5. Drawings etc. essential for understanding the invention.
6. Claims, which are statements, related to the invention on which legal proprietorship is being sought. Therefore the claims have to be drafted very carefully.

Compulsory license

Any time after three years from date of sealing of a patent, application for compulsory license can be made provided

1. reasonable requirements of public have not been met
2. patented invention is not available to public at a reasonably affordable price
3. patented invention is not worked in India among other things, reasonable requirements of public are not satisfied if working of patented invention in India on a commercial scale **is being prevented or hindered**

by importation of patented invention. Applicant's capability including risk taking, ability of the applicant to work the invention in public interest, nature of invention, time elapsed since sealing, measures taken by patentee to work the patent in India will be taken into account. In case of national emergency or other circumstances of extreme urgency or public non commercial use or an establishment of a ground of anti competitive practices adopted by the patentee, the above conditions will not apply.

A patentee must disclose the invention in a patent document for anyone to practice it after the expiry of the patent or practice it with the consent of the patent holder during the life of the patent.

Patenting of microbiological inventions

The Indian Patent Act has now a specific provision in regard to patenting of microorganisms and microbiological processes. It is now possible to get a patent for a microbiological process and also products emanating from such processes.

As it is difficult to describe a microorganism on paper, a system of depositing strain of microorganisms in some recognized depositories was evolved way back in 1949 in USA. An international treaty called "Budapest Treaty" was signed in Budapest in 1973 and later on amended in 1980. India became a member of this Treaty, with effect from December 17, 2001.

This is an international convention governing the recognition of deposits in officially approved culture collections for the purpose of patent applications in any country that is a party to this treaty. Because of the difficulties and virtual impossibility of reproducing a microorganism from a description of it in a patent specification, it is essential to deposit a strain in a culture collection centre for testing and examination by others. An inventor is required to deposit the strain of a microorganism in a recognized depository, which assigns a registration number to the deposited microorganism. This registration number needs to be quoted in the patent application dealing with the microorganism.

Obviously a strain of microorganism is required to be deposited before filing a patent application. It may be observed that this mechanism obviates the need of describing a microorganism in the patent application. Further, samples of strains can be obtained from the depository for further working on the patent. There are many international depositories in different countries such as ATCC, DSM etc. which are recognized under the Budapest Treaty. The Institute of Microbial Technology (IMTEC), Chandigarh is the first Indian depository set up under the Budapest Treaty.

Exclusive Marketing Right

TRIPS requires that member countries of the WTO not having provision in their laws for granting product patents in respect of drugs and

agrochemical, must introduce Exclusive Marketing Rights (EMR) for such products, if the following criteria are satisfied:

1. A patent application covering the new drug or agrochemical should have been filed in any of the WTO member countries after 1 January 1995;
2. A patent on the product should have been obtained in any of the member countries (which provides for product patents in drugs and agrochemical) after 1 January 1995;
3. Marketing approvals for the product should have been obtained in any of the member countries;
4. A patent application covering the product should have been filed after 1 January 1995 in the country where the EMR is sought;
5. The applicant should apply seeking an EMR by making use of the prescribed form and paying requisite fee.

EMR is only a right for exclusive marketing of the product and is quite different from a patent right. It is valid up to a maximum period 5 years or until the time the product patent laws come into effect. The necessary amendment to: the Patents Act, 1970 came into force on 26 March 1999. The provision is applicable with retrospective effect from 1 January 1995. As per the 2005 amendments in the Patents Act, the provision of EMR is no longer required. However, these rights were awarded in India from time to time and there have been some litigations as well where the courts came up with quick decisions.

Timing for filing a patent application

Filing of an application for a patent should be completed at the earliest possible date and should not be delayed. An application filed with provisional specification, disclosing the essence of the nature of the invention helps to register the priority by the applicant. Delay in filing an application may entail some risks like (i) other inventors might forestall the first inventor by applying for a patent for the said invention, and (ii) there may be either an inadvertent publication of the invention by the inventor himself/herself or by others independently of him/her. Publication of an invention in any form by the inventor before filing of a patent application would disqualify the invention to be patentable. Hence, inventors should not disclose their inventions before filing the patent application. The invention should be considered for publication after a patent application has been filed. Thus, it can be seen that there is no contradiction between publishing an inventive work and filing of patent application in respect of the invention.

Protecting new plant variety

New plant varieties can now be protected in India under the New Plant Variety and Farmers Rights Protection Act in 2001. New plant varieties

cannot be protected through patents. However, the Act has not become operational as subsidiary legislation is yet to be put in place.

India has enacted the which, in addition to meeting the technical features of UPOV, provides rights to farmers to use the seeds from their own crops for planting the next crop. Further, there are provisions for benefit sharing with farmers, penalty for marketing spurious propagation material and protecting extant varieties. There is a provision for protecting extant variety and farmers' varieties as well. The total period for protection is 10 years from the date of registration.

There are 5 main criteria to arrive at a decision whether a plant variety is really new or not. These are distinctiveness, uniformity, stability, novelty and denomination. The variety shall be deemed to be distinct if it is clearly distinct from any other variety whose existence is a matter of common knowledge at the time of filing of the application. The variety shall be deemed to be uniform if, subject to the variation that may be accepted from the particular features of its propagation, it is sufficiently uniform in its relevant characteristics. The variety shall be deemed to be stable if its relevant characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation at the end of each such cycle. The variety shall be deemed to be new if, at the date of filing of the application for breeders right, propagating or harvesting material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder for the purpose of exploitation of the variety.

1.3.3.2 Copyrights

Copyright is a right, which is available for creating an original literary or dramatic or musical or artistic work. Cinematographic films including sound track and video films and recordings on discs, tapes, perforated roll or other devices are covered by copyrights. Computer programs and software are covered under literary works and are protected in India under copyrights. The Copyright Act, 1957 as amended in 1983, 1984, 1992, 1994 and 1999 governs the copyright protection in India. The total term of protection for literary work is the author's life plus sixty years. For cinematographic films, records, photographs, posthumous publications, anonymous publication, works of government and international agencies the term is 60 years from the beginning of the calendar year following the year in which the work was published. For broadcasting, the term is 25 years from the beginning of the calendar year following the year in which the broadcast was made.

Copyright gives protection for the expression of an idea and not for the idea itself. For example, many authors write textbooks on physics covering various aspects like mechanics, heat, optics etc. Even though these topics

are covered in several books by different authors, each author will have a copyright on the book written by him / her, provided the book is not a copy of some other book published earlier. India is a member of the Berne Convention, an international treaty on copyright. Under this Convention, registration of copyright is not an essential requirement for protecting the right. It would, therefore, mean that the copyright on a work created in India would be automatically and simultaneously protected through copyright in all the member countries of the Berne Convention. The moment an original work is created, the creator starts enjoying the copyright. However, an undisputable record of the date on which a work was created must be kept. When a work is published with the authority of the copyright owner, a notice of copyright may be placed on publicly distributed copies. The use of copyright notice is optional for the protection of literary and artistic works. It is, however, a good idea to incorporate a copyright notice. As violation of copyright is a cognizable offence, the matter can be reported to a police station. It is advised that registration of copyright in India would help in establishing the ownership of the work. The registration can be done at the Office of the Registrar of Copyrights in New Delhi. It is also to be noted that the work is open for public inspection once the copyright is registered.

Computer program in the Copyright Act has been defined as a set of instructions expressed in words, codes, schemes or any other form, including a machine-readable medium, capable of causing a computer to perform a particular task or achieve a particular result. It is obvious that algorithms, source codes and object codes are covered in this definition. It is advisable to file a small extract of the computer program at the time of registration rather than the full program. It is important to know that the part of the program that is not being filed would remain a trade secret of the owner but would have to be kept well guarded by the owner. It may be noted that computer programs will become important in the area of medicines when one talks about codification of DNA and gene sequencing. Generally, all copyrightable expressions embodied in a computer program, including screen displays, are protectable. However, unlike a computer program, which is a literary work, screen display is considered an artistic work and therefore cannot be registered through the same application as that covering the computer program. A separate application giving graphical representation of all copyrightable elements of the screen display is essential. In the digital era, copyright is assuming a new importance as many works transacted through networks such as databases, multi media work, music, information etc. are presently the subject matter of copyright.

Coverage provided by copyright

(i) Literary, dramatic and musical work. Computer programs/software are covered within the definition of literary work.
(ii) Artistic work
(iii) Cinematographic films, which include sound track and video films.
(iv) Recording on any disc, tape, perforated roll or other device.

Infringement of copyright

Copyright gives the creator of the work the right to reproduce the work, make copies, translate, adapt, sell or give on hire and communicate the work to public. Any of these activities done without the consent of the author or his assignee is considered infringement of the copyright. There is a provision of 'fair use' in the law, which allows copyrighted work to be used for teaching and research and development. In other words making one photocopy of a book for teaching students may not be considered an infringement, but making many photocopies for commercial purposes would be considered an infringement. There is one associated right with copyright, which is known as the 'moral right', which cannot be transferred and is not limited by the term. This right is enjoyed by the creator for avoiding obscene representation of his /her works. Following acts are considered infringement of copyrights:-

(a) In the case of **literary, dramatic or musical work**, not being a computer program---
(i) to reproduce the work in any material form including the storing of it in any medium by electronic means;
(ii) to issue copies of the work to the public not being copies already in circulation;
(iii) to perform the work in public, or communicate it to the public;
(iv) to make any cinematography film or sound recording in respect of the work;
(v) to make any translation of the work; to make any adaptation of the work;
(vi) to do, in relation to a translation or an adaptation of the work, any of the acts specified in relation to the work in Sub-clauses (i) to (vi);
(b) in the case of **computer program -**
(i) to do any acts specified in clauses (a);
(ii) to sell or give on hire, or offer for sale or hire any copy of t he computer program, regardless of whether such copy has been sold or given on hire on earlier occasions;
(c) in the case of an **artistic work** –
(i) to reproduce the work in any material form including depiction in three dimensions of a two dimensional work or in two dimensions of a three dimensional work;
(ii) to communicate the work to the public;

(iii) to issue copies of the work to the public not being copies already in circulation;
(iv) to include the work in any cinematography film .
(v) to make any adaptation of the work;
(vi) to do, in relation to a translation or an adaptation of the work, any of the acts specified in relation to the work in sub-clauses (i) to (vi);
(d) in the case of a **cinematography film** -
(i) to make a copy of the film including a photograph of. any image forming part thereof;
(ii) to sell or give on hire or offer for sale or hire, any copy of the film, regardless of whether such copy has been sold or given on hire on earlier occasions;
(iii) to communicate the film to the public;
(e) in the case of **sound recording** -
(i) to make any other sound recording embodying it;
(ii) to sell or give on hire or offer for sale or hire, any copy of the ,sound recording, regardless of whether such copy has been sold or given on hire on earlier occasions;
(iii) to communicate the sound recording to the public;
Explanation –
For the purpose of this section, a copy which has been sold once shall be deemed to be a copy already in circulation.
Transfer of copyright
The owner of the copyright in an existing work or prospective owner of the copyright in a future work may assign to any person the copyright, either wholly or partially in the following manner.
i. for the entire world or for a specific country or territory; or
ii. for the full term of copyright or part thereof ; or
iii. relating to all the rights comprising the copyright or only part of such rights.

1.3.3.3 Industrial Design

We see so many varieties and brands of the same product (e.g. car, television, personal computer, a piece of furniture etc.) in the market, which look quite different from each other. If the products have similar functional features or have comparable price tags, the eye appeal or visual design of a product determines the choice. Even if the similarities are not close, a person may decide to go for a more expensive item because that item has a better look or colour scheme.
What is being said is that the external design or colour scheme or ornamentation of a product plays a key role in determining the market acceptability of the product over other similar products. If you have a good

design that gives you an advantage, then you must have a system to protect its features otherwise there would be wide scale imitation.

Design as per the Indian Act means the features of shape, configuration, pattern, ornament or composition of lines or colours applied to any article - whether in two dimensional or three dimensional or in both forms - by any industrial process or means, whether manual, mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye; but it does not include any mode or principle of construction or anything which is in substance a mere mechanical device. In this context an article means any article of manufacture and any substance, artificial, or partly artificial and partly natural; and includes any part of an article capable of being made and sold separately. Stamps, labels, tokens, cards, etc cannot be considered an article for the purpose of registration of design because once the alleged design i.e., ornamentation is removed only a piece of paper, metal or like material remains and the article referred to ceases to exist. An article must have its existence independent of the designs applied to it. So, the design as applied to an article should be integral with the article itself.

The essential requirements for the registration of design

1. The design should be new or original, not previously published or used in any country before the date of application for registration. The novelty may reside in the application of a known shape or pattern to a new subject matter. However, if the design for which the application is made does not involve any real mental activity for conception, then registration may not be considered.
2. The design should relate to features of shape, configuration, pattern or ornamentation applied or applicable to an article. Thus, designs of industrial plans, layouts and installations are not registrable under the Act.
3. The design should be applied or applicable to any article by any industrial process. Normally, designs of artistic nature such as painting, sculptures and the like which are not produced in bulk by any industrial process are excluded from registration under the Act.
4. The features of the designs in the finished article should appeal to and are judged solely by the eye. This implies that the design must appear and should be visible on the finished article, for which it is meant. Thus, any design in the inside arrangement of a box, money purse or almirah may not be considered for showing such articles in the open state, as those articles are generally put in the market in the closed state.
5. Any mode or principle of construction or operation or any thing, which is in substance a mere mechanical device, would not be a registrable design. For instance, a key having its novelty only in the shape of its corrugation or bend at the portion intended to engage with levers inside the lock it is associated with, cannot be registered as a design under the

Act. However, when any design suggests any mode or principle of construction or mechanical or other action of a mechanism, a suitable disclaimer in respect thereof is required to be inserted on its representation, provided there are other registrable features in the design.
6. The design should not include any trademark or property mark or artistic works.
7. It should be significantly distinguishable from known designs or combination of known designs.
8. It should not comprise or contain scandalous or obscene matter.

Duration of the registration of a design

The total term of a registered design is 15 years. Initially the right is granted for a period of 10 years, which can be extended, by another 5 years by making an application and by paying a fee of Rs. 2000/- to the Controller before the expiry of initial 10 years period. The proprietor of design may make the application for such extension even as soon as the design is registered.

Strategy for protection

First to file rule is applicable for registrability of design. If two or more applications relating to an identical or a similar design are filed on different dates, the first application will be considered for registration of design. Therefore the application should be filed as soon as you are ready with the design. After publication in the official gazette on payment of the prescribed fee of Rs. 500/- all registered designs are open for public inspection. Therefore, it is advisable to inspect the register of designs to determine whether the design is new or not. There is yet another important provision for ensuring that the design is different from anything published any where in the world. This is quite a strict condition. There would be many designs, which are not protected, and these would not be part of any database maintained by design offices. An applicant has to take the responsibility of ensuring that he has done an extensive search and satisfied himself of the novelty of his design. However, in practice as the cost involved in filing and obtaining a design registration is not high, a design application is made if the stakes involved are not high and you have not copied any design. The application for registration of design can be filed by the applicant himself or through a professional person (i.e. patent agent, legal practitioner etc.). An agent residing in India has to be employed by the applicants not resident of
India.

1.3.3.4 Trademarks

A trademark is a distinctive sign, which identifies certain goods or services as those produced or provided by a specific person or enterprise.

Trademarks may be one or combination of words, letters, and numerals. They may also consist of drawings, symbols, three dimensional signs such as shape and packaging of goods, or colours used as distinguishing feature. Collective marks are owned by an association whose members use them to identify themselves with a level of quality. Certification marks are given for compliance with defined standards. (Example ISO 9000.). A trademark provides to the owner of the mark by ensuring the exclusive right to use it to identify goods or services, or to authorize others to use it in return for some consideration (payment).

Well-known trademark in relation to any goods or services, means a mark which has become so to the substantial segment of the public which uses such goods or receives such services that the use of such mark in relation to other goods or services would be likely to be taken as indicating a connection in the course of trade or rendering of services between those goods or services and a person using the mark in relation to the first-mentioned goods or services. Enactment of the Indian Trademarks Act 1999 is a big step forward from the Trade and Merchandise Marks Act 1958 and the Trademark Act 1940. The newly enacted Act has some features not present in the 1958 Act and these are:-

1. Registration of service marks, collective marks and certification trademarks.
2. Increasing the period of registration and renewal from 7 years to 10 years.
3. Allowing filing of single application for registration in more than one class.
4. Enhanced punishment for offences related to trademarks.
5. Exhaustive definitions for terms frequently used.
6. Simplified procedure for registration of registered users and enlarged scope of permitted use.
7. Constitution of an Appellate Board for speedy disposal of appeals and rectification applications which at present lie before High Court.

Well-known trademarks and associated trademarks

A well-known trademark in relation to any goods or services, means a mark which has become known to the substantial segment of the public that uses such goods or receives such services. Associated Trademarks are, in commercial terms, marks that resemble each other and are owned by the same owner, but are applied to the same type of goods or services. For example, a company dealing in readymade garments may use associated marks for shirts, trousers etc. means trademarks deemed to be, or required to be, registered as associated trademarks under this Act.

Service marks

The Indian Act of 1958 did not have any reference to service marks. Service means service of any description that is made available to potential users and includes the provision of services in connection with the business of industrial or commercial matters such as banking, communication, education, financing, insurance, chit funds, real estate, transport, storage, material treatment, processing, supply of electrical or other energy, boarding, lodging, entertainment, amusement, construction, repair, conveying of news or information and advertising. Marks used to represent such services are known as service marks.

Certification Trademarks and Collective Marks

A certification trade mark means a guarantee mark which indicates that the goods to which it is applied are of a certain quality or are manufactured in a particular way or come from a certain region or use some specific material or maintain a certain level of accuracy. The goods must originate from a certain region rather from a particular trader. Certification marks are also applicable to services and the same parameters will have to be satisfied. Further these marks are registrable just like any other trademark. Agmark used in India for various food items is a kind of certification mark although it is not registered as a certification mark; the concept of certification mark was not in vogue at the time of introduction of Agmark.

A collective mark means a trademark distinguishing from those of others, the goods or services of members of an association of persons (not being a partnership within the meaning of the Indian Partnership Act, 1932), which is the proprietor of the mark.

Term of a registered trademark

The initial registration of a trademark shall be for a period of ten years but may be renewed from time to time for an unlimited period by payment of the renewal fees.

1.3.3.5 Protection of Geographical Indications

Indications which identify a good as originating in the territory of a member or a region or a locality in that territory, where a given quality reputation or other characteristics of the good is attributable to its geographical origin. The concept of identifying GI and protecting them is a new concept in India, perhaps in most developing countries, and has come to knowledge in these countries after they signed the TRIPS Agreement. It may be noted that properly protected GI will give protection in domestic and international market. Stipulations of TRIPS would be applicable to all the member countries. According to TRIPS, GI which is not or cease to be protected in its country of origin or which has fallen into disuse in that country cannot be protected.

Homonymous GI for wines will get independent protection. Each state shall determine conditions under which homonymous indications will be differentiated from each other. Principles of national treatment and fair competition are applicable. TRIPS provide for seizure of goods bearing false indications of GI. TRIPS provide for refusal or invalidation of registration of a trademark containing a GI with respect to goods not originating in the territory indicated. The Geographical Indication of Goods (Registration and Protection) Act came into being in 2000. (The Act is not implemented at the time of writing the article as the rules have not been notified.)

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

Applicants for GI's registration

Any association of persons or producers or any organization or authority established by or under any law for the time being in force representing the interest of the producers of the concerned goods, who are desirous of registering geographical indication in relation to such goods shall apply in writing to the Registrar in such' form and in such manner and accompanied by such fees as may be prescribed for the registration of the geographical indication.

Non-registrable geographical indications

Geographical indications having following cannot be registered:

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

Punishment for falsifying GI

A sentence of imprisonment for a term between six months to three years and a fine between fifty thousand rupees and two lakh rupees is provided in the Act. The court may reduce the punishment under special circumstances.

Term of GI protection

The registration of a GI shall be for a period of ten years but may be renewed from time to time for an unlimited period by payment of the renewal fees.

1,3,3,6 Protection of Integrated Circuit Layout Design (IC)

It provides protection for semiconductor IC layout designs. India has now in place Semiconductor Integrated Circuits Layout Design Act, 2000 to give protection to IC layout design. Layout design includes a layout of transistors and other circuitry elements and includes lead wires connecting such elements and expressed in any manner in a semiconductor IC.

Semiconductor IC is a product having transistors and other circuitry elements, which are inseparably formed on a semiconductor material or an insulating material or inside the semiconductor material and designed to perform an electronic circuitry function. The term of the registration is 10 years from the date of filing.

An IC layout design cannot be registered if it is

- ✓ Not original
- ✓ Commercially exploited anywhere in India or in a convention country;
- ✓ Inherently not distinctive
- ✓ Inherently not capable of being distinguishable from any other registered layout design.

Note: Design not exploited commercially for more than 2 years from date of registration of application shall be treated as commercially exploited for the purpose of this Act, reproducing, importing, selling; distributing the IC layout design for commercial purposes only constitutes infringement. A person when creates another layout design on the basis of scientific evaluation of a registered layout design shall not be causing any infringement.

1.3.3.7 Protection of undisclosed information

The protected subject matter is information lawfully within the control of a natural person or legal person that is secret that has commercial value because it is secret and that has been subject to reasonable steps by the person lawfully in control of the information, to keep it secret. Secret is defined as “secret in the sense that it is not, as a body or in the precise configuration and assembly of its components known among or readily accessible to persons within the circles that normally deal with the kind of

information in question." Undisclosed information, generally known as trade secret / confidential information, includes formula, pattern, compilation, programme, device, method, technique or process. Protection of undisclosed information is least known to players of IPR and also least talked about, although it is perhaps the most important form of protection for industries, R&D institutions and other agencies dealing with IPRs.

Protection of undisclosed information / trade secret is not really new to humanity; at every stage of development people have evolved methods to keep important information secret, commonly by restricting the knowledge to their family members. Laws relating to all forms of IPR are at different stages of implementation in India, but there is no separate and exclusive law for protecting undisclosed information / trade secret or confidential information. The Contract Act of 1872 would however cover many aspects of trade secrets.

It is difficult to define the term in its entirety but, for an easy understanding, it may be said that a piece of undisclosed information or a trade secret can be as simple an item as a company's customer list or as complex as a formula for a product or a process. Broadly speaking, the term would encompass information, including a formula, pattern, compilation, program, device, method, technique or process that provides the owner with an advantage over his business competitors who do not know or use it and is of significance or importance to the business of the company holding the information. Expanding it further, it may include new product plans, product costing, best material to use, sources of materials, financial standing of the business, accounting information, employee records, credit rating of customers, production information, manufacturing methods and processes, business methods, blueprints, test data, research reports, professional pollsters, technical drawings and organizational structure, specifications, process manuals, written instructions for operating the process and analytical means to check and control the product and processes, details of workshop practice, technical training and personal visitation and inspection. On the software side it would include source code; the data file structure, the structure sequence and organization of computer program. It may also include information relating to a patented invention not included in the patent specification, inventions capable of being patented but not patented, inventions incapable of being patented in a particular country because of the subject matter being excluded in the patent law of that country, inventions incapable of being patented by reason of lack of inventiveness, industrial designs capable of being registered but not registered, industrial designs having functional characteristics and skills, experience and craftsmanship of technicians. The information can be intangible and invisible as well and can take

myriad forms, and therefore, any attempt to define it in an exhaustive manner would be practically meaningless.

A trade secret is a valuable piece of information with the essential requirement that the information be treated as such, i.e. as a secret. The value of a trade secret resides in the fact that competitors or other interested parties do not have access to it. Therefore, a trade secret must be kept secret so that no one could, with out the consent of the owner, acquire it. Trade secrecy is basically a do-it-yourself form of protection. You do not register with the government to secure your trade secrets. The only way to acquire it with out the consent of the owner would be through devious or unlawful means. The owner has the exclusive right to use / exploit a trade secret as long as it remains a secret. As a result, theoretically speaking, the term of a trade secret could be indeterminate or infinite. It is said that the trade secret of Coca-Cola still has not entered the public domain despite the fact that the common ingredients of Coca-Cola are known. A chemical composition falling in this category need to be protected through a trade secret rather than patent which is a publicly known document. It is usually said that the term of the trade secret relating to a machine tool is only as long as the company keeps it internal secret. The moment the product is in the market, many people will know how to copy the product and the moment the product is copied the trade secret associated with the copied aspects will no longer remain valid and secret, hence the protection will be lost and the term of the protection will be over. By and large this would be true for design features but trade secret can be maintained about say, composition of materials used and the process conditions adopted for manufacturing.

Other related legislations

India enacted the Biodiversity Act 2002 to ensure maintenance, sustenance and development of its biodiversity. The Act has specific provisions about ownership of intellectual property rights associated with exploitation of biodiversity. Industries have to have the prior informed consent of the National Biodiversity Authority before exploring the biodiversity in India. In the event of R&D based on exploitation of biodiversity and associated local knowledge, there is a provision for sharing of benefits of such work with the local community. No direct flow of funds is expected to the community. In stead the Union Government will reach the benefits through State Governments to the community.

The other Act having its influence over other Acts related to IPR is the Information technology Act, 2000 which looks at the security aspect of material being transacted on internet.

1.4. INTERNATIONAL PERSPECTIVES

1.4.1The World Trade Organization and the TRIPS Agreement

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) emerged from the Uruguay Round of trade negotiations completed in 1994. The Final Act of these negotiations created the World Trade Organization (WTO) and set out rules – the WTO Agreements including TRIPS – with which members of the WTO have to comply. A dispute settlement system was also streamlined to resolve trade disputes between WTO Members. The WTO has 144 Members, accounting for over 90% of world trade. Over 30 further countries are negotiating membership.

TRIPS requires all WTO Members to provide minimum standards of protection for a wide range of IPRs including copyright, patents, trademarks, industrial designs, geographical indications, semiconductor topographies and undisclosed information. In doing so, TRIPS incorporates provisions from many existing IP international agreements such as the Paris and Berne Conventions administered by the World Intellectual Property Organization (WIPO). TRIPS however also introduces a number of new obligations, particularly in relation to geographical indications, patents, trade secrets, and measures governing how IP rights should be enforced.

A special body, the Council for TRIPS (commonly known as the TRIPS Council), on which each WTO Member is represented, was established to administer the operation of the TRIPS. The TRIPS Council is responsible for reviewing various aspects of TRIPS as mandated in the agreement itself and also as requested by the biennial WTO Ministerial Conference. Among the issues raised by TRIPS that have provoked the most discussion are:

- ✓ whether the objective set out in Article 7 that IPRs should contribute to the transfer of technology is achievable, particularly in respect of developing country members of the WTO.
- ✓ the perceived tensions between Article 8 which allows countries to adopt measures necessary to protect public health, and to prevent abuses of IP rights, provided they are TRIPS consistent, and other requirements in the agreement. These include the requirements to provide patent protection for pharmaceutical products, limitations on the conditions for issuing of compulsory licences (Article 31) and on the scope of provisions providing exceptions to patent rights (Article 30).
- ✓ the requirement to protect test data against “unfair commercial use” in Article 39.
- ✓ the justification for providing additional protection for geographical indications for wines and spirits, (Article 23) and whether this

additional protection should also be extended to cover other or all geographical indications.

- ✓ the extent to which patents should be allowed on inventions relating to living forms, for example microorganisms (Article 27.3(b)), and the requirement to provide IP protection for plants. In that context, the compatibility of TRIPS with agreements such as the Convention on Biological Diversity (CBD) has been raised.
- ✓ the cost of meeting the requirements of TRIPS for many developing and least developed WTO Members in relation to the administration of IP rights and their effective enforcement.

TRIPS took effect on 1 January 1995. WTO Members considered as developed countries were given one year to comply whilst developing countries and transition economies were given until 1 January 2000 although for developing countries required to extend product patent protection to new areas such as pharmaceuticals, a further five years was provided before such protection had to be introduced. Least Developed Countries (LDCs) are expected to enact TRIPS by 2006 although the Doha Ministerial Declaration on the TRIPS Agreement and Public Health allowed them a further 10 years in respect of pharmaceutical products. Where there are disputes over the interpretation of TRIPS and its implementation by national laws, members may bring cases to the WTO's Disputes Settlement Body (DSB) to resolve. To date there have been 24 cases involving TRIPS, where the disputes procedures have been invoked. Of these 23 were brought by developed country members, and one by Brazil. Sixteen were disputes between developed countries, seven were cases brought by developed against developing countries, and one by Brazil against the US. Of the 24, ten have been settled by mutual agreement, seven were decided by panels set up under the procedure, and seven are still pending.

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), negotiated during the Uruguay Round, introduced intellectual property rules for the first time into the multilateral trading system. The Agreement, while recognizing that intellectual property rights (IPRs) are private rights, establishes minimum standards of protection that each government has to give to the intellectual property right in each of the WTO Member countries. The Member countries are; however, free to provide higher standards of intellectual property rights protection.

The Agreement is based on and supplements, with additional obligations, the Paris, Berne, Rome and Washington conventions in their respective fields. Thus, the Agreement does not constitute a fully independent convention, but rather an integrative instrument which provides "Convention–plus" protection for IPRs.

The TRIPS Agreement is, by its coverage, the most comprehensive international instrument on IPRs, dealing with all types of IPRs, with the sole exception of breeders' rights. IPRs covered under the TRIPS agreement are:

(a) Copyrights and related rights;
(b) Trade marks;
(c) Geographical Indications;
(d) Industrial Designs;
(e) Patents;
(f) Layout designs of integrated circuits; and
(g) Protection of undisclosed information (trade secrets).

The TRIPS agreement is based on the basic principles of the other WTO Agreements, like non-discrimination clauses - National Treatment and Most Favoured Nation Treatment, and are intended to promote "technological innovation" and "transfer and dissemination" of technology. It also recognizes the special needs of the least-developed country Members in respect of providing maximum flexibility in the domestic implementation of laws and regulations.

Part V of the TRIPS Agreement provides an institutionalized, multilateral means for the prevention of disputes relating to IPRs and settlement thereof. It is aimed at preventing unilateral actions.

1.4.2 TRIPS and Public Health

Recognizing the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, Doha Ministerial Conference made a Declaration on the TRIPS Agreement and Public Health giving directions to the TRIPS Council to find a solution to this problem, particularly for those WTO Members, especially Least Developed Countries (LDCs), who do not have manufacturing capacities in the pharmaceutical sector. Ministers also underscored the countries' ability to use the flexibilities that are built into the TRIPS Agreement, in particular compulsory licensing and parallel importing, and they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016. On one remaining question, they assigned further work to the TRIPS Council — to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can import patented drugs made under compulsory licensing. This is sometimes called the "Paragraph 6" issue, because it comes under that paragraph in a separate Doha declaration on TRIPS and health.

The issue arises because Article 31(f) of the TRIPS Agreement states that products made under compulsory licensing must be "predominantly for the

supply of the domestic market". This applies directly to countries that can manufacture drugs — it limits the amount they can export when the drug is made under compulsory licence. And it has an indirect impact on countries unable to make medicines — they might want to import generics made in countries under compulsory licence, but find that Article 31(f) poses an obstacle to other countries supplying them. The TRIPS Council was instructed to find a solution and report to the General Council on this by the end of 2002. However it was not until 30 August 2003 that consensus could be reached.

After deliberations, the Members arrived at a decision which was adopted by the General Council of the WTO in its meeting held on 30 August, 2003. The Decision is contained in WTO document WT/L/540. It provides waivers from the obligations of Article 31(f) and Article 31(h) of the TRIPS Agreement, i.e. a compulsory licence may be issued not only for predominantly domestic use, but it can also be issued to the extent necessary for the purposes of production of a pharmaceutical product and its export to such countries that have insufficient manufacturing capacity, subject to certain conditions. Para 11 of the document (WT/L/540) stipulates that this Decision, including the resultant waivers granted, would remain operative for a Member till the date on which an amendment to the TRIPS Agreement, replacing its provisions takes effect for that Member. It was also enjoined upon the Council for TRIPS to work on the preparation of such an amendment in the TRIPS Agreement based on the Decision.

After deliberations in the Council for TRIPS, a decision was taken in the General Council about the amendment to the TRIPS Agreement, which is contained in WTO document number WT/L/641 dated 8 December, 2005. This document was later adopted at the Hong Kong Ministerial Conference of the WTO.

The Patents (Amendment) Act, 2005 has already made provisions for taking advantage of the waiver arising out of the General Council Decision of 30 August, 2003.

1.5 SUMMARY

In this unit we have discussed about the concept, definition, nature, types of IPR and IPR laws in India. We have also discussed about the international perspectives of IPR such as WTO and TRIPS. Further, we have also discussed the issues of public health pertaining to IPR.

1.6 GLOSSARY

Non-obviousness- A patentability requirement according to which an invention should be non-obvious in order to be patented
Novelty- A patentability requirement according to which an invention is not patentable if it was already known before the date of filing
Patent- A territorial right to prevent others from commercially exploiting an invention, granted to an inventor or his successor in rights in exchange for the public disclosure of the invention. A patent is regarded as a specific type of intellectual property right, and is granted for a limited period of time, the term of the patent.
Patent infringement- Commercially exploiting an invention claimed in a patent without permission of the patentee
Priority right- The priority right is a right to claim priority from an earlier application. Claiming priority gives the later filed application a priority date of the filing date of the earlier application.
Term of patent- The maximum period during which it can be maintained in force
Copy gene - Genetic material that contains the genetic code for a desirable trait which has been copied from the DNA of the donor to transfer to the host organism. (Currently, it is not technically possible to take a gene from a donor organism and insert it directly into the host organism).
DNA - Deoxyribonucleic acid, the fundamental genetic material of all cells that acts as the carrier of genetic information.
Gene - The biological unit of inheritance, which transmits hereditary information of a physical, behavioral, or biochemical trait.
Genetic modification - Technique for copying and transferring individual genes to another living organism to alter its genetic make up, thereby incorporating or deleting specific characteristics into or from the organism.
Toxin - A poison, usually originating in a plant or microorganism.

1.7 SUGGESTED READINGS/REFERENCE MATERIAL

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Suggested Readings

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2. Iver P. Cooper : Biotechnology and Law (1998), Clerk Boardman

Callaghan, New York

3. David Bainbridge : Software Copyright Law (1999)
4. Sookman : Computer Law (1998)
5. Carlos M. Correa(ed.) : Intellectual Property and International Trade (1998)
6. Sweet and Maxwell : Patent Co-operation Treaty Hand Book (1998)
7. Christopher Wadlow : The Law of Passing-Off (1998)
8. W.R. Cornish : Intellectual Property Law (1999)
9. Special attention should be given to literature of the U.N. System, WIPO and the UNESCO.

1.8 Terminal and Model Questions

Q1. What do you understand by the concept of IPR?

Q2. Explain and define the meaning of IPR.

Q3. Describe the nature of IPR.

Q4. Discuss various types of IPR.

Q5. Discuss the International perspectives of IPR.

Q6. Write the different protections of IPR laws under the WTO and TRIPS obligations.

Q7. Discuss the TRIPS obligations pertaining to public health and IPR.

LL.M. Part-1

Subject: Intellectual property Law

Block-II- INTRODUCTION

Unit-2- TRADE MARKS AND CONSUMER PROTECTION (Study of UNCTAD report on the subject)

STRUCTURE

2.1 INTRODUCTION

In the previous unit you have learned about the concept, definition, nature, types of intellectual property rights (IPR) and IPR laws in India. The concept of Intellectual Property is defined in general is that the proprietor or owner may use his property as he wishes and that nobody else can lawfully use his property without his authorization. Of course there are certain recognized limits for the exercise of that right. You have also learned about the international perspectives of IPR such as WTO and TRIPS. Further, you have also learned the issues of public health pertaining to IPR.

In today's world, the abundant supply of goods and services on the markets has made life very challenging for any business, big or small. In its on-going quest to remain ahead of competitors in this environment, every business strives to create new and improved products (goods and services) that will deliver greater value to users and customers than the products offered by competitors. To differentiate their products - a prerequisite for success in today's markets - businesses rely on innovations that reduce production costs and/or improve product quality. In a crowded marketplace, businesses have to make an on-going effort to communicate the specific value offered by their product through effective marketing that relies on well thought-out branding strategies.

All businesses, especially those which are already successful, nowadays have to rely on the effective use of one or more types of intellectual property (IP) to gain and maintain a substantial competitive edge in the marketplace. Business leaders and managers, therefore, require a much better understanding of the tools of the IP system to protect and exploit the IP assets they own, or wish to use, for their business models and competitive strategies in domestic and international markets.

The law of unfair competition serves five purposes. First, the law seeks to protect the economic, intellectual, and creative investments made by businesses in distinguishing themselves and their products. Second, the law seeks to preserve the good will that businesses have established with consumers. Third, the law seeks to deter businesses from appropriating the good will of their competitors. Fourth, the law seeks to promote clarity and stability by encouraging consumers to rely on a merchant's good will and reputation when evaluating the quality of rival products. Fifth, the law seeks to increase competition by providing businesses with incentives to offer better goods and services than others in the same field.

Although the law of unfair competition helps protect consumers from injuries caused by deceptive trade practices, the remedies provided to redress such injuries are available only to business entities and proprietors. Consumers who are injured by deceptive trade practices must

avail themselves of the remedies provided by state and federal Consumer Protection laws. In general, businesses and proprietors injured by unfair competition have two remedies: injunctive relief (a court order restraining a competitor from engaging in a particular fraudulent or deceptive practice) and money damages (compensation for any losses suffered by an injured business).
In this unit we will discuss about the concept, definition, nature, types of trademark and trademark laws in India. We will also discuss about the meaning of consumer Protection, problems faced by consumers, need for consumer protection, and legal protection to consumers in India and at international level. Further, we will also discuss the reports and resolutions of UNCTAD (United Nations Conference on Trade and Development) and AIPPI's Trademarks and consumer protection Resolution.

2.2 OBJECTIVES

After reading this unit you will be able to:

- ✓ Understand the concept of trademark and consumer Protection.
- ✓ Explain and define the meaning of trademark and consumer Protection..
- ✓ Describe the nature of trademark.
- ✓ Write the different types of trademark.
- ✓ Write the different protections of trademark and consumer Protection laws under the WTO and TRIPS obligations.
- ✓ Discuss the problems faced by consumers, need for consumer protection, and legal protection to consumers in India and at international level.
- ✓ Discuss about the reports and resolutions of UNCTAD (United Nations Conference on Trade and Development) and AIPPI's Trademarks and consumer protection Resolution.

2.3. EVOLUTION OF TRADE MARK LAWS

Intellectual Property Rights allows people to assert ownership rights on the outcomes of their creativity and innovative activity in the same way

that they can own physical property. Intellectual Property arises out of human labour hence it is bound by a number of changes. The four main types of Intellectual Property are Patents, Trademarks, Designs and Copyrights. In this unit we will deal with Trademarks, which is an important aspect of Intellectual Property.

2.3.1 What is a Trade Mark?

A trademark is any sign that individualizes the goods of a given enterprise and distinguishes them from goods of its competitors. Marketing of a particular good or service by the producer is much better off as by trademark because recognition becomes easier and quality is assured. The owner of the mark can prevent the use of similar or identical signs by competitors if such marks can lead to confusion. By this way similar low quality substitutes will be prevented from replacing good quality ones.

A trademark is a word or symbol or combination thereof used by manufacturer or vendor in connection with a product or service. The distinctiveness is maintained as well as sales are much smoother as people are able to identify with that particular commodity or service.

The Trade Mark Act, 1999 defines well Known Trade mark ¨as a mark in relation to any goods and services which has become so to the substantial segment which uses such goods or receives such services that the use of such mark in relation to other goods or services would be likely to be taken as indicating a connection in course of trade or rendering of services between those goods or services and a person using the mark in relation to the first mentioned goods or services.

Trademark is one of the areas of intellectual property and its purpose is to protect the mark of the product or that of a service. Hence a trademark is defined as a mark capable of being represented graphically and which is capable of distinguishing the goods and services of one person from those of others and may include shape of goods, their packaging and combination of colours ,they include a device ,brand, heading ,label ticket ,name ,signature, word ,letter ,numeral ,shape of goods, packaging or combination of colours or any combination thereof. Registration of trademark is not mandatory but in the present day scenario there is increasing infringement and a lot of cases are challenged so it is advisable to register Trademarks. There is also a need for trademarks to be globally protected. This is said because most have regional or local name brands and most constantly push these weak names while struggling to get global clearance.

A trademark can thus be called a device that gives distinctiveness and a mode of identification to a particular product or service. An increasing number of countries also allow for the registration of less traditional forms of trademarks such as single colours, three dimensional signs (shapes of product packaging), audible signs (sounds) or olfactory signs (smell).

It is said that a trademark is a valuable business asset and a marketing tool which could help in financing of the business in a way. A brand is always a trademark but a trademark is not always a brand. This is quoted because there is often confusion between trademarks and brands, a brand is simply a name, logo or symbol whereas a trademark is a distinctive sign or indicator of some kind in a business organization, because of these trademarks has a wider connotation than brands. A trademark may also function to symbolize or guarantee the quality of goods which bear the trademark. People are often induced to buy a particular product due to its distinctive trademark that denotes quality .Trademark symbolizes the value or goodwill associated with the goods and which can be assessed by the extent to its perception in the public mind with regards to its quality and specific source.

Trademarks are generally placed in any manner on the goods, their containers, and displays or on tags or labels attached to the goods or service. The immense economic value a successful trademark has is the primary reason for their protection under the law. Trade mark owners by powerful advertising campaigns in collaboration with licensees create a brand loyalty and establish product differentiation. This results in establishing an enviable goodwill and market power so as to nip competition in the bud and place a barrier to the entry of new firms in that particular field of activity. Trademarks are of many kinds they may be logos, moving image marks, pictorial marks, slogans etc.

2.3.2 Types of Trade Marks

There are basically four types of trademarks they are

- ✓ Service Mark
- ✓ Collective Mark
- ✓ Certification Mark
- ✓ Trade Dress

All these types of Trademarks are equally important and promote activity as well as maintain the distinctiveness of the product.

SERVICE MARKS

A service Mark is any word, name, symbol, device, or any combination used or intended to be used in commerce to identify and distinguish the services of one provider by others and to indicate the source of services. It is basically useful in distinguishing one service provider from the other. Service Marks do not cover physical goods but only the provision of services. Service marks are used to identify a service, as Trademarks are used for protection of goods Service Marks are used in a number of day to day services some examples of them are:-

- ✓ Management and investment services
- ✓ Housing development services
- ✓ Advertising Promotional services
- ✓ Sponsorship
- ✓ Speed reading instruction
- ✓ Hotel and motel services
- ✓ Entertainment services rendered by individual, group or theatre.

A service mark is generally adopted so that it can play a crucial role in marketing, promoting and sales of a product or service, it also plays the role of referring to a particular quality or standard for which the service mark is used.

Service mark is denoted by the letters SM. Mark¨ may sometimes be used to refer to both a trademark and a service mark, because the terms are nearly but not completely interchangeable. Like trademark when choosing a name for a service mark a full research has to be conducted to make sure no other firm is using the same name.

COLLECTIVE MARK

A collective Mark is one used by members of a cooperative association, union or other collective group or other group or organization to identify source the of goods or services. A collective mark means a mark which is utilized for goods and services with same characteristics which are to be traded by one or more person acting jointly or legal entity for differentiation with other goods or services of same kind.

There are two types of Collective Marks or legal entity for differentiation with other goods or services of same kind. They are:-

1. Collective Membership Mark

These marks are not used to indicate source of goods or services but they indicate that the seller is part of a defined group.

2. Collective Trademarks and collective Service marks

These are used to indicate the source. Such collective marks are used by a group to indicate that the goods or services offered by each individual member of the group are products or services of the collective.

A collective mark is for use by the individual members of an organization but is registered as a whole. That is a collective mark may be used by the collective association that owns the mark. So the collective is the owner of the mark, a conceptual problem may arise when an association is unincorporated because an unincorporated association does not have legal personality and so cannot normally own property itself.

CERTIFICATION MARK

A certificate is evidence or probative matter providing assurance that some act has or has not been done or some event occurred or some legal formality has been complied with.

A certification Mark is a mark which indicates that certain qualities of goods or services in connection with which the mark are used is certified. A certification mark is thus defined in the Trademarks Act 1994, Section 50 as a mark indicating that the goods or services in connection with which it is used are certified by the proprietor of the mark in respect of origin, material, and mode of manufacture of goods or performance of services, quality, accuracy, or other characteristics.

Registration of Certification Mark is done according to the Trademarks Act 1994. An important requirement for registration of certification mark is that entity which applies for registration is competent to certify¨ the products concerned. Thus owner of certification mark must be representative of products to which certification mark applies. An authorized user of a certification Mark is expressly likened to a license of a trademark in specified circumstances, namely unauthorized application of the mark to certain material, prohibition of importation of infringing goods and order as to disposal of infringing goods. A registered mark maybe assigned according to registrar.

TRADE DRESS

Trade dress refers to combination of elements that make up the look, feel, or environment of a product or business; the term can refer to individual elements of a product or business image as well as to the image the combination of those elements creates as a whole. Trade Dress is non functional physical detail. Trade Dress may include a few important features like: - Packaging Size Shape Colour Colour Combination Texture

Graphics Design Placement of words and decorations on a product Particular Sale Technique.

Trade Dress can be mere coloring, surface ornamentation or a general appearance, a design patentable invention has to be a shape or appearance of a specific article which is more than a surface appearance, which relates to the overall appearance of the article and which is different enough to be considered unobvious.

2.3.3 Evolution of Trade Mark Laws

From ancient times human beings have been under the process of creating and innovating things, during pre-historic period man had made stone, jewellery, hunting materials, vessels etc, when spirituality started to sprout up he made figurines of gods and goddesses. Originally, marks were placed on objects to identify ownership and to deter would be thieves. By this way the ancient people tried to control low quality goods, and as the maker of the product was identified automatically the infringers were punished.

The more a trademark came to be known the more it inspired confidence in the goods and services to potential clients. When a mark was placed it meant that any other third party other than the manufacturer did not have any right over it, in a large way it helped deter people with vested interest. In the middle ages two basic kinds of marks could be found:-

- ✓ Merchants Mark
- ✓ Production Mark

The Merchants Mark indicated ownership whereas the Production mark indicated the Origin. Production marks were used by guilds to guarantee quality and to control entry to particular trade. People also started engraving their names in ships this was the first widely recognized method of using trademarks, where in case of ship wreckage, identification would be possible. The other people who started using trademarks were people doing business or in guilds started asserting it as a mark on their goods. This made the manufacturer responsible for the quality of the goods that are being produced and to retain their customers.

Nowadays it is up to a seller to use or not use a mark. Modern marks do not aim at identifying ownership as was the case with the proprietary marks of the Middle Ages. Modern marks are an asset for the producer whereas in earlier times the trade marks were a liability. Many of the laws like the aforesaid law of bread and beer assizes fought to bring about a

mode of standardization as well as protect the consumers so that they do not get cheated with adulterated goods. A specific mode of measurement was fixed.

2.3.4 Trade Mark Laws in India

While some form of proprietary protection for marks in India dates back several millennia, India's statutory Trademarks Law dates back to 1860. Prior to 1940 there was no official trademark Law in India. Numerous problems arouse on infringement, law of passing off etc and these were solved by application of section 54 of the specific relief act 1877 and the registration was obviously adjucated by obtaining a declaration as to the ownership of a trademark under Indian Registration Act 1908.

To overcome the aforesaid difficulties the Indian Trademarks Act was passed in 1940, this corresponded with the English Trademarks Act. After this there was an increasing need for more protection of Trademarks as there was a major growth in Trade and Commerce. The replacement to this act was the Trademark and Merchandise Act 1958.This Act was to provide for registration and better protection of Trademarks and for prevention of the use of fraudulent marks on merchandise. This Law also enables the registration of trademarks so that the proprietor of the trademark gets legal right to the exclusive use of the trademark. The objective of this act was easy registration and better protection of trademarks and to prevent fraud.

The reappellation of the Trademarks and Merchandise Act gave rise to the Trademark Act 1999; this was done by the Government of India so that the Indian Trademark Law is in compliance with the TRIPS obligation on the recommendation of the World Trade Organization. The object of the 1999 Act is to confer the protection to the user of the trademark on his goods and prescribe conditions on acquisition, and legal remedies for enforcement of trademark rights. It will for the first time protect service marks and give provision of registration for collective marks, it will also differentiate between well known trademarks and trademarks in general, and also special treatment and rights are envisaged for well known trademarks. The act of 1999 also gives police the right to arrest in case of infringement. There are some points of changes that are present between the 1958 act and 1999 act, it can be said that the 1999 act is a modification of the 1958 act, it has provided exhaustive definitions of terms frequently used, enhanced punishment for offenders, increased the period of registration, registration of non- traditional trademarks. The rules of this act are called as Trademark Rules 2002. Both the Act and its set of

rules came to effect on September 15th 2003. The trademark act 1999 and its trademark rules 2002 presently govern Indian Trademark Laws in India. Laws of trademarks are based on distinctiveness and deceptive similarity. If distinct signs are freely used the brand equity created by one person will be freely used by another. The value of distinctive sign depends on sales volume and public association of sign with quality.

2.3.5 Why Protect Trade Marks?

In the modern world there is a desire by most manufacturers to sell their products and offer their services by means of a mark or a brand. Before the industrial revolution, traders displayed marks of various kinds to distinguish their products. The hallmarks of Goldsmiths and the marks of Sheffield's Cutlers have their own marks to distinguish their goods.

Most legal systems therefore developed registration to protect the imitation of marks and names. Trademarks have a variety of functions. Cornish summarize the functions into three broad categories: -

1. Origin Function – marks deserve protection so that they may operate as indicators of the trade source from which goods or services come or are in some other way connected.

2. Quality or Guarantee Function – marks deserve protection because they symbolize quality associated by consumers and certain goods or services and guarantee that the goods or services measure up to expectation.

3. Investment or Advertising Function – marks are ciphers around which investment in the promotion of a product is built and that investment is a value, which deserves protection as such, even when there is no abuse arising from misrepresentation either about origin or quality.

Bainbridge observes that Trademark serves two main purposes. First to protect business reputation and goodwill and secondly to protect consumers from deception, that is to prevent the public purchasing inferior goods or services in the mistaken belief that they originate from another trader. In regard to Consumer Protection the law becomes an effective weapon against counterfeit and inferior goods, which is considerably strengthened by the criminal sanctions imposed in regard to the fraudulent applications of Trademarks. Another way of justifying the system of Trademark is that it gives effect to the concept of Unfair Competition. The overriding purpose of Trademark Law is to ensure that Trademarks serve to distinguish the goods or services of one undertaking from those of

another and consumer protection however desirable it may be is only a little more than a by-product of Trademark Law. This was emphasized by Lord Nicholls in Scandcor Developments A B v Scandcor Marketing A B when he stated, “inherent in this definition is the notion that distinctiveness as to business source (the goods of one undertaking) is the essential function of a Trademark”.

The basis of a Trademark is to show a connection between the undertakings and their goods or services and to distinguish them from other undertakings. This concept has far reaching implications particularly in regard to Character Merchandising and in relation to memorabilia in Elvis Presley (1997) RPC 543. In this case Laddie J “when a man buys poster or a cup bearing an image of a star he is buying a likeness, not a product from a particular source. Similarly the purchaser of any one of the myriad of cheap souvenirs of the Royal Wedding bearing pictures of Prince Charles and Diana Princesses of Wales wants mementoes with likenesses, is likely to be indifferent to the sources.

The basic assumption in a competitive economy is that the consumer benefits by being able to choose among a wide variety in the quality and price of the goods and services. However when there is a range of products offered a consumer could only choose rationally if he knows the relevant differences between the goods. For this purpose it would be necessary to acquire all the appropriate information which would be weary and time consuming and costly as far as the consumer is concerned. Furthermore the consumer may not be able to check or test the qualities before he purchases and may have to purchase the goods on trust. The seller may emphasize the various qualities of the price, which differentiate from one product of those of the competitors but a seller could always exaggerate such qualities. As the consumer cannot always trust the information, which he receives he may buy things of lower quality. However the law of trademarks gives the State some control over the quality in the market and the efficiency and genuineness of the goods in the market.

As we have seen earlier historically traders applied marks to indicate the origin of marks. Such marks were proprietary or possessory marks. For instance farmers branded their sheep to identify their life stock. In medieval time marks were used in the guild structure to ensure that goods were of a satisfactory quality. With the demise of the guild and advent of the industrial revolution it was realized that marks indicated a particular manufacturer, which in turn guarantee goods of a certain standard. In the twentieth century marks changed from being indicates of origin to become valuable assets in their own right. The mark itself attracted customers not

as a result of any assumption of origin or quality but as a result of "advertising" quality. A trademark therefore changes its function from a "signal" to a "symbol". As a signal a Trademark triggered an automatic response to identify the producer of the goods whilst as a symbol trademarks evoke a broader set of association and identifies the product or gives a product the identity.

Three important reasons are given as a justification for the protection of Trademarks. They are –

- ✓ Creativity
- ✓ Information
- ✓ Ethical justification

Creativity

It is argued that one of the justifications for the protection of intellectual property rights is the protection of labour, which is involved in the creation of such rights. This is also one of the bases of the concept of unfair competition. However in regard to trademarks it may be difficult to contend that there is creation as in the case of patents or copyright. However this argument may be somewhat weak in that a trademark is nurtured not only by the trader but by the customer and the public as well. It is also argued as stated by Justice Breyer in the US Supreme Court in the case of Qualitex v Jacobson Products that trademark law helps to assure a producer that it (and not an imitating competitor) will reap the financial reputation and related awards associated with a desirable product.

Information

It is argued that trademarks are a shorthand way of communicating information that purchasers need in order to make informed decisions. Information provided by trademarks is particularly important in relation to goods that a consumer cannot inspect. Trademarks also encourage the manufacturer to maintain consistent quality standards. In a leading article Brown maintains that "advertising depends on the remote manipulation of symbols, most importantly of symbols directed at a mass audience through mass media or imprinted on mass protected goods. Brown drew a distinction between persuasive and informational advertising and maintained that the only justification for advertising was informational and persuasive functions of marks is of dubious social utility.

Ethical justification

It is argued that by adopting another's trademark a person is taking advantage of the goodwill generated by the original trademark owner and therefore on the principle that a person should not reap what he has not sown trademarks should be protected. It is on this basis that objections were made in respect of comparative advertising and the principle of dilution of trademarks justified.

Trademarks and Anti-competition

Sometimes it has been said that trademarks confer monopolies. In New York Times it was observed, "Traders could not obtain a monopoly in the use of such words". In Re Coca Cola Trademark the court observed, "This raises a spectre of total and perpetual monopoly in containers and articles. In defending trademark rights Pattishal in his leading article "Trademarks and the monopoly phobia" argues that "in the rush to destroy monopolies and promote free competition the means and basis for competition are destroyed too. Trademarks do not exist to provide incentives to create new words but instead are creatures of commerce arising through necessity and protected as such. Trademarks are analogous to the persons name and signature and forgery of one's signature or defaming one's character is actionable and as such trademarks also should be protected. This view has also been expressed by the Chicago Law Review article "The Anti-competitive aspects of trade name protection and policy against consumer deception".

However a hostile view has been expressed by authors who are sometimes referred to as the Harvard School, which stems mainly from the work of E.H. Chamberlin 'The Theory of Monopolistic Competition' Cambridge Mass 1962 8th Edition. He argues the protection of trademarks from infringement and of business generally from the imitation of their products is the production of a monopoly, to permit such infringements would be to purify by competition by eliminating monopoly elements. The attack based on monopoly appears to aspire to the classical model of perfect competition and its perceived benefits even though it is entirely divorced from reality.

Finally, we can say that Intellectual Property reflects the idea that its subject matter is the product of the mind or the intellect. As it is the product of a creative and artistic mind it is bound to changes. It can be sold, bought, bequeathed and owned. As all this can be done there are bound to be issues related that have to be dealt. Trademarks and Patents are very important aspects of Intellectual Property. Trademark Protection has become important in present day competitive world because, every producer of a good or service will want his mark to be unique, eye

catching as well as it should be easily distinguishable from others. Creating a mark like this is quite difficult and after all this when infringing of the mark takes place it will case utmost difficulty to the manufacturer. Intellectual Property is not an alien concept in fact it is a concept which is seen in everyday life whether a movie, book, plant variety, food item, cosmetics, electrical gadgets, software¡¦s etc. It has become a concept of prevalence in everyday life. People have also started celebrating World Intellectual Property Day on 26th April every year.

Intellectual Property Protection is very important and there should be a movement towards Global Intellectual Property Order, if there is no IPR protection, it can be argued that inventive activity will cease. The rationale for Intellectual Property protection is that it can stimulate creativity and innovation and encourage the exploitation of inventions for the good of the society. Public policy here aims at maintaining an intellectual Property system which encourages innovation through proactive protection initiatives, while at the same time ensuring that this is not at the cost of societal interests. In this context, the challenge for World Intellectual Property Organization would be to incorporate public policy issues in programs carried out with developing countries, such as raising awareness of flexibilities in existing international intellectual property treaties¨. Many treaties and conventions have taken place in the field of Intellectual Property particularly Patents and Trade Marks. If India's international affiliations are to be talked about India is an active member of the International body WIPO (World Intellectual Property Organization).It is also part of two treaties namely Paris Convention 1883 where Industrial Property is protected and Berne Convention 1886 where Literary and Artistic Works are protected. India adheres to TRIPS and has modified its Trademark laws to conform according to it. The purpose of all this is to protect individuality of the manufacture, prevent infringement and improper usage of signs.

2.4 CONSUMER PROTECTION

2.4.1 Meaning of Consumer Protection

You are familiar with the fact that consumers have certain basic rights like the right to safety, right to be informed, right to choose, and the right to be heard. But do we always remember these rights while buying goods? Perhaps not! But even if we are aware of these rights, sellers very often

take advantage of our position and supply goods which are defective or harmful or unsafe and cause injury.

Suppose you have gone to buy edible oil in a store. The shopkeeper tells you that it is available in a closed tin or container. You want to be sure that the oil is not adulterated, that is, it is not mixed with some inferior or harmful oil. The shopkeeper will show you the name of the producer on the label and say that it is a well-known company which does not supply impure oil. But after using the oil you fall ill. Can you go to the shopkeeper and return the oil? No, he will not take back the partly used oil in the open tin. He will perhaps tell you that your illness must be due to something else. So, at best you can stop buying edible oil of the same label. But what is the assurance that you will not face the same problem with the oil of another producer?

Again, take for example the defect that consumers may find in a fan regulator, or electric heater, or a TV. During the warranty period, the dealer may repair it free of charge, but the defect may be there even afterwards. What will you do? Suppose the defect in the electric heater causes injury. Is there any remedy? You may take it to the seller, who may put the blame on you, saying that you did not take necessary precaution while using it.

These are some instances of consumer helplessness even if he is a wise buyer. So, to safeguard the interest of consumers it is felt that some measures are necessary to help the common-man.

Thus, consumer protection refers to the steps necessary to be taken or measures required to be accepted to protect consumers from business malpractices. It may be regarded as a movement like consumerism. This is necessary primarily because businessman aim at maximizing profits and this is often done at the expense of consumers. Let us consider the nature of business practices which prevail in our country causing monetary loss and injuries to health and life of people.

2.4.2 Problems Faced by Consumers

Consumers may be deceived in various ways by unscrupulous businessmen including traders, dealers, producers and manufacturers as well as service providers. Some of the following unfair practices must have come to your notice sometime or the other:

1. Adulteration, that is, adding something inferior to the product being sold. This is a practice we come across in the case of cereals, spices, tea leaves, edible oil, petrol, etc. For example, mustard oil may be adulterated with rape seed oil or argemone oil, black pepper is known to be adulterated with dry papaya seeds, petrol is mixed with kerosene oil,

vanaspati may be mixed with ghee/butter. Sometimes, the inferior material used with the product may be injurious to health.

2. Sale of spurious products, that is, selling something of no value instead of the real product. This is often found in the case of medicines and drugs or health care products. Cases have been reported where ampoules for injections contained only water or glucose water in bottles contained only distilled water.

3. Use of false weights and measures is another malpractice which some traders adopt while selling the goods. Goods which are sold by weight (kg.) like vegetables, cereals, sugar, etc., those sold by measures (meter) like textile fabrics, suit pieces, are sometimes found to be less than the actual weight or length. False weights (Kg, 500 grams, 250 grams etc) or measuring tapes or sticks having false markings are used for the purpose and buyers are cheated. Sometimes packaged goods and sealed containers (tins) contain less quantity, than what is stated on the label or packet. This cannot be easily verified. Sweets are often weighed along with the card board box which may weigh up to 50-100 grams. You pay for it at the same rate as the sweets.

4. Sale of duplicates, that is, goods that indicates a mark which shown it is of superior quality than what it actually is. For example, goods which are locally made are sold at a higher price as imported items expected to be of superior quality. Certain products like washing soap, detergent powders, tube lights, jams, edible oil, even medicines, carry well known brand names although these are made by others.

5. Hoarding and black-marketing is another problem that consumer often face. When any essential commodity is not made available in the open market and stocks are intentionally held back by dealers it is known as hoarding. Its purpose is to create an artificial scarcity, to push up the prices. Black marketing is the practice of selling hoarded goods, secretly at

a higher price. These practices are sometimes adopted when there is short supply of any product. You may have read in the newspapers sometime back about scarcity of onions in the open market in some states and high prices being charged by traders who had stocks.

6. Tie-in-Sales: Buyers of durable consumer goods are sometimes required to buy some other goods as a pre-condition to sale or may be required to pay after-sales service charges for one year in advance. You may have heard about tying up of new gas connections with the sale of gas stoves (burners). Also TV sets are sometimes sold on the condition that the buyers will make advance payment of a year's service charge.

7. Offering gifts having no additional value, or coupons to collect a gift on the next purchase of some product are practices aimed at alluring consumers to buy a product. Often gifts are offered after the price of the

product on sale has been increased. Dealers also announce contests or lottery among buyers of a product without the intention of awarding any prize.

8. Misleading advertisement is yet another practice by which consumers are deceived. Such advertisements falsely represent a product or service to be of superior quality, grade or standard, or falsely asserts the need for or usefulness of a product or service. A pharmaceutical company advertised that use of its paracetamol tablet did not have any side effects like aspirin, but it suppressed the experts' report that the use of paracetamol had adverse effect on the liver. A company announced in its advertisement that it was manufacturing 150 cc. scooters in technical collaboration with a foreign company, although no such collaboration had been entered into. In another case, a company used the trademark of a well-known company 'Philips' in its advertisement for TV sets. On enquiry it was found that the company did not have the necessary permission from Philips for the use of its trade mark on TV sets. It was a case of misrepresentation of facts although that company was authorized to use the trademark 'Philips' on its audio products (radio sets) only.

9. Sale of sub-standard goods i.e., sale of goods which do not conform to prescribed quality standard particularly for safety. Such products include pressure cookers, stoves, electric gadgets (heaters, toasters, etc.) and cooking gas cylinders.

2.4.3 Need for Consumer Protection

The necessity of adopting measures to protect the interest of consumers arises mainly due to their helpless position and the unfair business practices. No doubt consumers have the basic right to be protected from the loss or injury caused on account of defective goods and deficiency of services. However, consumers are unable to make use of their rights due to lack of awareness and ignorance. For example, as consumers we have the right to choose the goods of right quality from a variety of similar goods available in the market. But often we fail to make the right choice because of misleading advertisements by which we are carried away and buy sub-standard goods.

Under certain circumstances, we are helpless in the sense of our inability to verify the quality of products. The clever shopkeeper can deceive us by his persuasive words. If the date of expiry on a strip of medicinal tablets is not legible, we may be in a hurry and depend on what the seller tells us. If the medicine does not have the desired effect, we may go to the doctor again and request him to prescribe some other medicine, we forget that

the medicine we bought might not have had the effect as we were supplied the medicine after its date of expiry. Often we are guided by some of our beliefs without any basis. For instance, many of us believe that 'higher price indicates better quality' and so do not mind paying higher price for a product if the salesman recommends it to be of good quality. Again, it is a common belief that imported goods are inevitably of a superior quality. So if there is a printed label or a mark that shows a product is made in a foreign country, we may buy it at a higher price without verifying its place of manufacture.

Processed food sold in packets, like potato chips, are not good for health. but young boys and girls buy these because they are tasty. Certain brands of soft drink are popular with young people as the brand ambassadors shown on the TV are popular film artists or cricketers and what they say carries lot of weight with their fans. Excessive use of soft drinks is also not good for health. If seems we have forgotten fresh lime water with sugar or salt as a good drink.

Producers of goods often put standard certification marks like ISI on the package which are genuinely certified. Similarly, if packaged good are sold short of weight we pay for, it is very difficulty to verify always the weights before buying. Sometimes the weighing machines are defective.

Above all, consumers are not fully aware of remedies open to them if goods are defective or there is deficiency of service. So, you can very well realize why steps must be taken to protect consumers from business practices which are unfair and may cause loss and injury to health and other dangerous effects.

2.4.4 Legal protection to Consumers in India

A number of laws have been passed by the Government of India over the years to protect the interest of consumers. Brief outlines of the purpose of these laws are given below.

(I)Agricultural Products (Grading and Marketing) Act, 1937

This Act provides for grading and certifying quality standard of agricultural commodities which are allowed to be stamped with AGMARK seal of the Agricultural marketing department of the Government.

(ii) Industries (Development and Regulation) Act, 1951

This Act provides for control over production and distribution of manufactured goods. According to this Act, the central government may order investigation of any industry, if it is of the opinion that there has been substantial fall in the volume of production, or a marked decline in the quality of a product, or any unreasonable rise in price. After due investigation, the government may issue directions to set things right. If

the directions are not acted upon, the government may take over the concerned undertakings.

(I) Prevention of Food Adulteration Act, 1954

This Act provides for severe punishment for adulteration of food articles. In the case of sale of adulterated food which is injurious to health and likely to cause death, life imprisonment with a minimum fine of Rs 3000 may be payable. Food inspectors are appointed and they have powers to lift samples and send them for analysis. Penalties are also provided under the act for offences committed by persons with regard to manufacture, import, storage, sale and distribution of adulterated food articles.

(iv) Essential Commodities Act, 1955

Under this Act, the Government has power to declare any commodity as essential in the public interest. Thereby the government can control the production, supply and distribution of the trading of such commodities. It also provides for action against anti-social activities of profiteers, hoarders and black-marketers.

(v) The Standards of Weights and Measures Act, 1956

This Act provides for the use of standard weights and standard measures of length throughout the country. 'Metre' has been specified as the primary unit for measuring length, and 'kilogram' as the primary unit for measuring weight. Before this act came into force, different system of weights and measures were used in different parts of the country like 'pound', 'Chhatak' and 'Seer' as weights, yard, inch and foot for length, etc. These differences provided opportunities for traders to exploit the consumers.

(vi) Monopolies and Restrictive Trade Practices Act, 1969

Under the provisions of this Act, as amended in 1983 and 1984, consumers and consumer groups can exercise their right of redressal by filing complaints relating to restrictive and unfair trade practices. The government has constituted the MRTP commission which is empowered to deal with consumer complaints after due investigation and enquiry. The Commission has power to award compensation for any loss or injury suffered by consumers.

(vii) Prevention of Black-marketing and Maintenance of Essential Supplies Act, 1980

The primary objective of this act is to provide for detention of persons with a view to prevention of black-marketing and maintenance of supplies of commodities essential to the community. The maximum detention for persons acting in any manner against the intention of the act can be imprisonment up to 6 months.

(viii) Bureau of Indian Standards Act, 1986

The Bureau of Indian Standards has been set up under this Act, replacing the Indian Standards Institution (ISI), to protect and promote consumer interest. It has two major activities : formulation of quality standards for

goods and their certification through the BIS certification marks scheme by which manufacturers are permitted to use the standardization mark (ISI) on their products after due verification of conformity with prescribed quality standards of safety and performance. The Bureau has set up a consumer affairs department to create quality consciousness among ordinary consumers. There is also a public grievances cell to which consumers can make complaint

The MRTP Act in going to be repealed when the Competition Act, 2002, comes into force. The Competition Commission to be set up under the new Act will also replace the MRTP Commission about the quality of products carrying ISI mark.

(ix) Consumer Protection Act, 1986

This Act provides for consumer protection more comprehensively than any other law. Consumers can seek legal remedy for a wide range of unfair practices not only with respect to goods but also for deficiency in services like banking, insurance , financing, transport, telephone, supply of electricity or other energy, housing, boarding & lodging, entertainment, amusement, etc. This Act also includes provision for the establishment of consumer protection councils at the centre and the state. For the settlement of consumer disputes, the act has provided for a semi-judicial system. It consists of District Form, State Commission and National Commission for redressal of consumer disputes. These may be regarded as consumer courts.

2.5 TRADEMARK LAWS AND CONSUMER PROTECTION

2.5.1 UNCTAD (United Nations Conference on Trade and Development)

UNCTAD, a United Nations entity, is the most authoritative and reliable source of information about global Foreign Direct Investment (FDI) by country and by activity and its statistics and diagrams are quoted equally by right wing corporate hacks and left wing activists.

Functions of UNCTAD

Established in 1964 as a permanent intergovernmental body, UNCTAD is the principal organ of the United Nations General Assembly dealing with trade, investment and development issues.

UNCTAD explains that it undertakes the following tasks:

1. Globalization and Development Strategies

- ✓ Examines trends in the global economy and evaluates their impact upon the development process
- ✓ Undertakes macroeconomic policy analysis in the context of interdependence among countries and sectors of the economy
- ✓ Analyzes specific development challenges and successful experiences, and draws lessons for developing countries and countries in transition to a market economy
- ✓ Studies questions related to financial flows and indebtedness, and helps developing countries manage their debt
- ✓ Develops databases and provides statistical information related to trade and development

2. International Trade in Goods and Services, and Commodities

- ✓ Analyzing trade info, etc.

3. Investment, Technology and Enterprise Development

- ✓ Examines global trends in foreign direct investment (FDI) flows; the interrelationships between FDI, trade, technology and development; and the development implications of a possible multilateral framework on investment
- ✓ Advising countries with information about FDI and its effects

4. Services Infrastructure for Development, and Trade Efficiency

- ✓ Helps developing countries and countries in transition improve the efficiency of their trade-supporting services through technical cooperation programmes
- ✓ Supports the formulation of national policies and regulations promoting services infrastructure for development, trade facilitation and trade efficiency

2.5.2 What is AIPPI?

The International Association for the Protection of Intellectual Property or AIPPI, an acronym for Association Internationale pour la Protection de la Propriété Intellectuelle in French (formerly International Association for the Protection of Industrial Property), is a non-profit international organization (NGO) whose members are intellectual property (IP) professionals, academics, owners of intellectual property and others interested in the

subject. AIPPI was established in 1897 and is based in Zurich, Switzerland. It played an active role in the work which led to the successive revisions of the Paris Convention for the Protection of Industrial Property of 1883. It continues to play a major role in harmonizing IP laws around the world.

AIPPI operates by conducting studies of existing national laws and proposing measures to achieve harmonization of these laws on an international basis after consultation and input from its members Groups around the world. It is currently involved in a number of topics to be discussed at its Forum in Buenos Aires in October 2009 and continues to work jointly, with other NGOs and WIPO on issues relating to privileged communications between clients and their intellectual property advisors.

2.5.3 Trademarks and consumer protection Resolution

I. The AIPPI welcomes the fact that WIPO has examined the problem of consumer
protection within the framework of industrial property law and considers that the
Memorandum in its revised form of 1982 (WIPO document COPR/III/1) constitutes a careful and overall balanced study, which forms a valuable basis for further discussions.
II. The AIPPI makes the following observations with regard to the general problems dealt with in the WIPO memorandum:
1. AIPPI agrees with the WIPO memorandum that
- industrial property law has in many respects a close connection with consumer protection,
- industrial property law and in particular trademark law, is of great economic importance not only for the manufacturer and the merchant but also for consumers,- because of the trade mark's function to distinguish goods or services of one enterprise from those of another, it enables consumers to recognize goods or services with which they were content and to avoid others; and that thereby the trade mark presents an important means which permits to achieve market transparency (i. e. the ability to distinguish more clearly the different goods or services),
- even without recognition of a direct quality function, the trade mark generally enables consumers to expect a certain level of consistency as regards the quality of the goods or services,
and is pleased to note that the WIPO memorandum is largely of the same opinion as the AIPPI in its resolution to Question 68 (Economic Significance, Functions and Purpose of the Trademark) adopted 1978 in Munich.

2. The AIPPI emphasizes that
- the trademark, because of its nature and its economic and legal functions, in the
property of the enterprise which apposes and uses the trade mark and consumers can therefore not claim any direct right to the trade mark,
- because of the economic and social relevance of the trade mark to the consuming
public, the interest of consumers should however be adequately taken into account in trade mark law,
- in many respects this interest has already been taken into account in existing trade mark law; but enquiry should be made whether trade mark law, within its given boundaries, should go further in considering the legitimate interests of consumers,
- in principle, trade mark proprietors and consumers have parallel interests, especially in relation to deceptive and confusingly similar trade marks,
- therefore the conclusions of the WIPO-Memorandum can be accepted that "in principle consumer interests are best served by an effective protection and regulation of industrial property rights",
- any erosion of the exclusive rights of the trade mark proprietor can also have negative consequences for consumers.
3. The AIPPI emphasizes further that
- trade marks should not be misused to the detriment of consumers,
- in this connection, insofar as consumer interests are concerned, a distinction has to be made between the trademark itself and the way it is used in a particular case.
Prevention of a misleading use of a trademark should primarily be left to the general provisions against misleading practices and to the law against unfair competition.
Provided that the general provisions against misleading practises and/or the provisions against unfair competition sufficiently prevent the misleading use of a trademark, there seems to be no need for additional reputations in trademark law.
III. The position of the AIPPI as regards the particular problems examined in the WIPO memorandum and dealt with in the Summary Report of the Reporter General is as follows:

1. Deceptive trade marks

Although the interest of consumers can only be affected directly by the use of a trade mark, which is misleading, it should be recognized as a legitimate interest of consumers that they be able to raise objections to the registration of a inherently deceptive trade mark or to request its cancellation. It can be left to the different countries to grant consumers or

their organizations locus standi to defend their interests in opposition or cancellation proceedings.

As to the misleading use of a trade mark which is not inherently deceptive, sanctions directed against the trade mark itself, especially cancellation of the trade mark, are in general not appropriate. The interests of competitors and of the public can be sufficiently protected by injunctive relief and/or if necessary by an action for damages based on general provisions and/or on provisions of the law against unfair competition.

2. Trade marks without distinctive character

If a trademark is contested because of its alleged lack of distinctiveness or of its descriptive character or its degeneration into a generic name, it is above all in the interests of the trade mark proprietor and of competing manufacturers to be able to use freely the names that are primarily affected. It is not evident that consumers need to have locus standi in such proceedings.

3. Confusingly similar trade marks

In view of the relevance of trademarks for the consuming public, in principle consumers also have an interest in the prohibition of the use of a confusingly similar trademark. That interest is, however, taken into account by an ex-officio-examination by the Trademark Office, or by allowing the owner of a prior right to oppose the registration and/or the use of a conflicting more recent trademark in opposition, cancellation or infringement proceedings. Experience up to the present has shown that there is little interest of consumers in preventing the registration and/or use of confusingly similar trademarks; therefore it does not seem necessary to grant locus standi to consumers, especially in infringement proceedings. Consumer participation would not only complicate and delay these proceedings but would also unduly restrain the freedom to determine the rights by those directly concerned, namely the owner of the trade marks in question and his adversary.

4. Assignment and licensing of trademarks

It is generally recognized that there is an economic need for the assignment and especially the licensing of trademarks. Such transactions should therefore not be subject to unduly restraining and inflexible conditions. But considering the trust that consumers generally have in trade marks, adequate and sufficient precautions are necessary in order to prevent the deception of consumers. As a result of the assignment or licensing what particular measures within the framework of trade mark law or the general provisions against misleading practices are most appropriate to achieve this goal should be the subject of further study.

5. Obligation to identify goods or services with a trade mark

The majority of the national groups is of the opinion that there should be no obligation to label goods or to associate services with a trade mark. At

least in a market economy, each enterprise should be free, to decide if and how it wishes to use a trade mark. So far as consumers interests require information relating to the marking of goods or services, this requirement can be served by labelling regulations outside trade mark law. These regulations should not, however, lead to an undue restriction of the freedom to use or not to use a trade mark.

6. Different trade marks for identical products

It is agreed that there may be a legitimate economic reason for one and the same enterprise to use different trade marks for identical products in the same marketing areas. Further there is no reason to believe that the use as such of different trade marks for identical products negatively affects the interests of consumers. Consequently, trade mark law sanctions, for instance the cancellation of one or all of the respective marks, must be opposed. If misuse in particular cases should occur, it should rather be dealt with under the existing general or special provisions against misleading indications as to the price or the quality of goods or by providing appropriate information to the consumer.

7. Foreign trade marks

It is agreed that no general distinction should be drawn between national and foreign trade marks. If in certain cases the manner of use of a foreign trade mark for domestic goods or of a national trade mark for foreign goods is likely to lead to deception as to the geographic origin of the goods and if national trade mark law provides insufficient sanctions against this result, resort can be made to the general provisions against misleading practices and/or the provisions against unfair competition.

8. Exhaustion of trade mark rights

The exhaustion of trade mark rights has again been brought up by the WIPO Memorandum under the aspect of consumer protection. As in earlier discussions of AIPPI, no unanimous opinion has been reached. The majority of the national groups tend towards the principle of international exhaustion and point out that the admission of parallel imports may be in the interest of consumers because they can increase competition and thus lead to lower prices. On the other hand even in these letter reports it is noted that the unrestricted admission of parallel imports can lead, not only to a disturbance of the system of distribution but can also have negative effects for consumers, for instance, if the parallel imported goods do not meet the special quality expectations of the consuming public in the import country, or because after-sales service and guarantees are not assured.

9. Special jurisdiction provisions for consumers

If consumers are to have locus standi in trade mark proceedings such should be conferred within the framework of existing procedures without establishment of any special administrative or judicial tribunals.
IV. The AIPPI decides to continue the study as to the following problems:
1. Which actions and sanctions are in general appropriate to counter a possible deception of consumers in relation to the assignment or licensing of trade marks?
2. To what extend is there a conflict between the right of an enterprise to decide whether and how to use a trade mark which is basic to trade mark law and the provisions in the field of marketing and labelling of goods or services, and if so how can such be reconciled?
3. Which actions and sanctions are in general appropriate to counter a possible deception of consumers in relation to the transfer or licensing of trademarks?
4. To what extent is there a conflict between the right of an enterprise to decide whether and how to use a trademark which is basic to trademark law and the provisions in the field of marketing and labelling of goods or services, and if so, how can such is reconciled?

A. Transfer of trademarks and granting of licences

I. The AIPPI recalls that the transfer and granting of trademark licences corresponds to economic need on the part of the trademark owner and that this is generally accepted in the various legal systems and that these transfers and granting of licences must not be subject to exceedingly restrictive or rigid terms.

II. The AIPPI points out that if following such a transaction the transferee or licensee uses the trademark in a misleading way, it is not the trademark itself which is the cause of deception but rather the conditions of its use. Therefore, as AIPPI has already stated in its resolution adopted in Paris, sanctions directed against the trademark itself, especially cancellation of the trademark, are in case of misleading use of a trademark in general not appropriate. The interests of the consuming public can be sufficiently protected by actions prohibiting the misleading use which are based on general provisions of law and/or on special provisions for the protection of consumers or against unfair competition.
III. The AIPPI is of the opinion:
a) that, in case of misleading use of a trademark by a transferee or by a licensee or a related enterprise, neither the nullity of the trademark transfer or the trademark license nor forfeiture of the trademark nor in general its cancellation from the register would constitute an appropriate sanction of trademark law against such misleading use;
b) that it should not be required by law that the product of the licensee must necessarily have the same characteristics, including quality, as those

of the licensor but that as far as licenses are concerned, it is generally in the interest of the trademark owner and the consuming public that the trademark owner imposes quality standards on the licensee and provides for an adequate control.

IV. Furthermore, the AIPPI considers that the following measures are not appropriate:

a) Validity of the granting of the licence being made subject to its entry in the Trade Mark Register.

b) Examination of licence agreements by the Trade Mark Office as to the question of their misleading the consuming public.

c) An obligation, in every case, for the licensee to include, on the products, a notice stating that the trademark is used under licence.

B. Relationship between "informative labelling" of products and trademark law

Informative labelling or the marking of products must not be confused with the identification of a product or its packaging with distinctive signs (trademarks, trade names).

I. The AIPPI has observed that in the field of food products, pharmaceuticals, cosmetics and common-use goods, for instance, more and more, legal provisions are being set up to make mandatory informative labelling on the characteristics of the product or its area of use which are included on the labels, tagging or packaging of the product (informative labelling).

II. The AIPPI recognizes that the use of informative labelling - in so far as it is limited to information which is necessary for the consumer and is easy to comprehend - can make the market more transparent and can thus be a valuable aid for the consumer when the time comes to choose. Moreover, in many sectors, trademark proprietors already voluntarily provide such information.

III. However, the AIPPI hereby states that such a regulation must not obstruct the fundamental principle of trademark law which is that the adoption of a trademark is optional. As it currently stands trademark legislation only confers a right to use a mark; it does not entail any overall obligation whatsoever to affix a trademark on the goods. In free-market economy countries at any rate, the decision whether or not to mark goods and the way this is done should be left to the initiative of each enterprise (Annual 1984/1, p. 164).

IV. The AIPPI particularly points out that if the national legislature makes informative labelling obligatory for the benefit of consumers, such regulation should preferably not:

a) be instituted within the framework of trademark law, as this law only concerns the right to apply the trademark;

b) in any case include an overall obligation to distinguish goods or services by the affixing of a particular mark or include rules which impose the choice of a particular mark;
c) encourage the degeneration of existing trademarks into generic terms by way of mandatory provisions as to the use of "designations which are usual in the trade";
d) diminish the role of the trademark in such a way that it lessens its capacity of distinguishing the goods or services of one enterprise from those of another;
e) change the economic value of the trademark in such a way that proprietary rights are substantially affected. This could in some jurisdictions have an impact on the proprietors constitutional rights.
V. The AIPPI considers therefore, that the question of informative labelling of goods must be reviewed by the national legislature in every case in two ways:
- Does the labelling, having regard to the nature of the goods considered, provide information which is required by the consumer?
- Do the rules of labelling unjustifiably threaten the freedom of companies to choose and use a trademark?
Finally, the AIPPI stresses that a policy depreciating trademarks has adverse consequences for the consumer for whom trademarks are indispensable to make an easy and clear choice in the market place.

2.6 SUMMARY

In this unit we have discussed about the concept, definition, nature, types of trademark and trademark laws in India. We have also discussed about the meaning of consumer Protection, problems faced by consumers, need for consumer protection, and legal protection to consumers in India and at international level. Further, we have also discussed the reports and resolutions of UNCTAD (United Nations Conference on Trade and Development) and AIPPI's Trademarks and consumer protection Resolution.

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Suggested Readings

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2.8 SELF ASSESSMENT QUESTIONS

Q1. What do you understand by the concept of trademark and consumer Protection?

Q2. Explain and define the meaning of trademark and consumer Protection?

Q3. Describe the nature of trademark and write different types of trademark.

Q4. Write the different protections of trademark and consumer Protection laws under the WTO and TRIPS obligations.

Q5. Discuss the problems faced by consumers, need for consumer protection, and legal protection to consumers in India and at international level.

Q6. Discuss the reports and resolutions of UNCTAD and AIPPI's Trademarks and consumer protection Resolution.

LL.M. Part-1

Subject: Intellectual property Law

Block I- Introduction

Unit-3- The Legal Regime of Unfair Trade Practices and of Intellectual Industrial Property

STRUCTURE

3.1 INTRODUCTION

In the previous unit you have learned about the concept, definition, nature, types of trademark and trademark laws in India. You have also learned about the meaning of consumer Protection, problems faced by consumers, need for consumer protection, and legal protection to consumers in India and at international level. Further, you have also learned about the reports and resolutions of UNCTAD (United Nations Conference on Trade and Development) and AIPPI's Trademarks and consumer protection Resolution.

According to U.S. industry and government officials, intellectual property rights (IPRs) infringement has reached critical levels in the United States as well as abroad. The speed and ease with which the duplication of products protected by IPR can occur has created an urgent need for industries and governments alike to address the protection of IPR in order to keep markets open to trade in the affected goods. Copyrighted products such as software, movies, music and video recordings, and other media products have been particularly affected by inadequate IPR protection. New tools, such as writable compact discs (CDs) and, of course, the Internet have made duplication not only effortless and low-cost, but anonymous as well.

In this unit we will discuss about the merits of IPR protection and its importance to the economy. It then provides background on various technical, legal, and trade policy methods that have been employed to control the infringement of IPR domestically and internationally. We will also discuss about the meaning of unfair trade practices, protection against unfair competition and the role of World Trade Organization (WTO). Further, we will also discuss the meaning of intellectual industrial property, infringement of intellectual industrial property and future challenges facing global industry with regard to IPR protection, particularly the challenges presented by the Internet and digital piracy.

3.2 OBJECTIVES

After reading this unit you will be able to:

- ✓ Understand the concept of IPR infringement.
- ✓ Explain and define the meaning of intellectual industrial property.
- ✓ Describe the meaning and nature of unfair trade practices.
- ✓ Discuss the Role of WTO in the protection against unfair trade practices.

- ✓ Discuss the future challenges facing global industry with regard to IPR protection, particularly the challenges presented by the Internet and digital piracy.

3.3 IPR INFRINGEMENT

According to U.S. industry representatives, intellectual property rights (IPRs) infringement has reached critical levels in the United States as well as abroad. The speed and ease with which the duplication of products protected by IPR can occur has created an urgent need for industries and governments alike to address the protection of IPR. At the same time, an increasingly digital world has spawned vigorous debate about how to maintain the appropriate incentives afforded to creators of copyright content, given the ease of digital copying, while continuing to provide for certain non-infringing uses of works for socially beneficial purposes. In turn, this debate has highlighted international differences in views among industrialized nations and developing countries.

The protection of IPR has long been a fractious issue. While the United States established copyright, patent, and trademark protections early on in U.S. history, these issues were first addressed internationally in the 1880s with the Paris and Berne Conventions. Despite subsequent attempts to adequately address intellectual property issues globally, IPR protection remains a challenge. Industries deeply dependent on the development of intellectual property, including software, entertainment media, and pharmaceuticals, are those most affected by the lack of adequate protection of this property abroad. Because of an inadequate level of protection, many potential markets are unavailable to U.S. manufacturers due to the proliferation of commercial piracy.

Thus, IPR protection has become a pressing issue with respect to international trade. The international community agreed on common IPR rules and enforcement programs during the last global round of trade negotiations establishing the World Trade Organization (WTO), and established new copyright norms in the World Intellectual Property Organization (WIPO) “Internet” treaties, which bring copyright into the digital age. However, problems remain in the implementation of these norms. For instance, the United States and other industrialized countries continue to urge many developing countries to live up to their new obligations by implementing the necessary legislation and enforcement mechanisms with respect to protecting intellectual property.

Industries are affected in a number of different IPR areas, including patents, copyrights, trademarks, semiconductor layouts (i.e., mask works), geographic indications, industrial designs, and trade secrets. However, many of the most significant international trade disputes involving

copyright issues have been in the software, consumer electronics, and entertainment media industries.

3.3.1 IPR Protection: Balancing the Rights of Innovators and Society

The costs of developing new products in intellectual property-related industries, particularly in copyright industries such as software, entertainment, and publishing, and patent-based industries such as pharmaceuticals and chemicals, can be very high. Developing a new software operating system, movie, book, or drug can cost millions or even billions of dollars. The Pharmaceutical Research and
Manufacturers of America states that its members spent over $30 billion in discovering and developing new drugs in 2001. This investment is very risky since the product under development is not assured success in the market place. Only a small percentage of new drugs, software programs, books, or music recordings become financially successful for their producers.
The greatest expense by far in bringing most intellectual property-dependent goods to market is in development rather than manufacture or duplication. While the costs and risks involved in product development are high, the costs of product imitation or intellectual property theft are generally low. Once a successful book is published, it may be replicated with little effort. A successful new software program may easily be copied or transmitted via the Internet. A drug developed and approved by the government for marketing after extensive research and development and clinical testing by the developer can often be duplicated with relatively inexpensive chemical ingredients and processes.
Because individuals or companies developing new products would not do so unless they felt they had a good chance of receiving an adequate return on their investment, governments often provide a minimum level of market exclusivity to inventors or developers of products, particularly those that benefit consumers and society. For example, pharmaceutical and other inventions may receive patent protection from governments to provide their developers with minimum periods in which they may exclude others from practicing their patented inventions. Authors of books, computers software, movies, music, and other related works, meanwhile, upon creation of their work, secure copyright protection in their “expression” of ideas, though not in the ideas themselves. Conferring intellectual property rights such as copyrights and patents encourages individuals and companies to continue to develop creative works of art and entertainment, and technologically advanced products such as pharmaceuticals, that are perceived to greatly benefit a society. In the United States, the purposes of U.S. intellectual property policies have

been to “promote public welfare; private property rights have been the means to that end.”

Nevertheless, there have always been diverse opinions on the amount of exclusivity that should be provided to a protected product or process. One result of market exclusivity is that it permits the intellectual property rights holder to demand higher prices than he otherwise could if he faced competition in providing the protected product. Some argue that stiff intellectual property protection obviates the expressed purpose of benefiting the economy or society since it puts the price of protected products out of the reach of poorer persons. In response, the rights holders indicate that products would never be developed if the developer could not be assured of a certain minimum level of market exclusivity to provide some assurance it could recover its costs and make a sufficient profit to make the risks of development worthwhile.

Copyright laws have often attempted to strike a balance between the rights of the consumer and society and the rights of the innovator to benefit from his creation. For example, although the period of exclusivity for U.S. copyright law has been lengthened to a period approaching two lifetimes of the author, limits have been placed on its scope in such a way as to benefit society as a whole even during the time the work in question is protected. Further, protection provided to software and other works is limited in scope to cover only the expression, and not the idea itself. Thus, a copyright may be obtained for a story in its written form but not for the idea of its plot, or for a software operating system such as Microsoft Windows but not for the general concepts or ideas underlying the operating system. Also, the “fair use” doctrine has emerged in U.S. copyright law to allow shared uses of small portions of publications (for example, in the face-to-face classroom setting), and even copying of small sections of copyrighted works for purposes such as reporting, criticism, commentary or quotation, and other scholarly and journalistic uses.

Many developing countries have in recent years come to recognize the importance of IPR protection to the development of their economies. However, especially in the patent area, a number of developing countries continue to assert that IPR protection harms their economies. For example, the existence of patent protections and the associated higher prices could affect the availability of advanced agricultural inputs and medicines in developing countries. Leaders of some developing countries have also argued that their societies can never advance educationally or technologically if they do not have lower cost access to products stringently protected by developed countries. That being said, U.S. industry representative’s point to recent studies conducted by industry groups as well as new studies commissioned by international organizations such as the World Intellectual Property Organization

(WIPO), these studies demonstrate or aim to demonstrate that increased IPR protection in developing countries would lead to greater numbers of jobs, increases in the amount of tax revenue collected by a government, increased opportunities for foreign direct investment (FDI), and increased economic welfare in general.

3.3.2 Importance of IPR Industries to the Economy and the Costs of Infringement.

IPR industries are among the fastest growing in the world and are particularly important to the strength of the economy. They are characterized by above average growth in employment and higher than average wages and salaries. A study completed in 2002 showed that the share of U.S. gross domestic product (GDP) accounted for by U.S. copyright-based industries, including all types of computer software, printed materials, movies, home videos, CDs, audiocassettes, and other media products, rose during 1977-2001 at an annual rate of growth of 7 percent, compared to 3 percent for the remainder of the U.S. economy. In 2001, those industries accounted for $531.1 billion in value-added, or almost 5 percent of GDP. Meanwhile, domestic employment in copyright-based industries more than doubled from 1977 to 2001 to 4.7 million workers, representing an average annual rate of employment growth of 5 percent, or almost three times the rate of the U.S. economy as a whole.
Quantifying the economic losses to copyright industries as a result of Internet piracy is extremely challenging. Accordingly, none of the estimates of trade losses due to IPR infringement cited above take into account piracy on the Internet. However, to demonstrate its growing importance, some officials have stated that illegal, inexpensive, and free music swapping services such as those of Napster were largely responsible for a 7-percent drop in worldwide music revenues. Movie companies, represented by the Motion Picture Association MPA, reportedly, “are determined not to let that happen to them.”

3.4 UNFAIR TRADE PRACTICE

3.4.1 Definition

Any trade practice that provides or is thought to provide an inequitable advantage to one party. For example, a country may keep its currency

artificially weak so as to make its exports cheaper than the situation warrants.

“Any fraudulent, deceptive, or dishonest trade practice that is prohibited by statute, regulation, or the Common Law is unfair trade practice”.

Any wrongful, fraudulent and/or business methods to gain an unfair advantage over competitors, including:

a) Untrue or misleading advertising or promotion which misrepresent the nature, characteristics, qualities or geographic origin (such as where wine comes from),

b) misleading customers by imitative trademark, name, or package, including trademark infringement,

c) falsely disparaging another's product.

Under federal statute and many state laws, unfair competition is the basis for a legal action (suit) for damages and/or an injunction to halt the deceptive practices against an unfair competitor if the practices tend to harm one's business.

The law of unfair competition includes several related doctrines. Nevertheless, some courts have attempted to simplify the law by defining unfair competition as any trade practice whose harm outweighs its benefits. The U.S. legal system is a cornerstone of the free enterprise system. But the freedom to compete does not imply the right to engage in predatory, monopolistic, fraudulent, deceptive, misleading, or unfair competition. On balance, competition becomes unfair when its effects on trade, consumers, and society as a whole are more detrimental than beneficial.

3.4.2 Protection against Unfair Competition

The Paris Convention for the Protection of Industrial Property, Article 10, requires its member countries to provide protection of industrial property against unfair competition. This article is directed against acts of competition that are contrary to honest practices in industry or commerce. The Paris Convention lists the following as acts of unfair competition in relation to industrial property:

- ✓ all acts of such a nature as to create confusion with the establishment,
- ✓ the goods or the industrial or commercial activities of a competitor;
- ✓ false allegations in the course of trade of such a nature as to discredit the establishment,
- ✓ the goods or the industrial or commercial activities of a competitor;

- ✓ Indications or allegations, the use of which in the course of trade is liable to mislead the public as to the characteristics of certain goods.

Protection against unfair competition supplements the protection of inventions, industrial designs, trademarks and geographical indications. It is particularly important for the protection of knowledge, technology or information which is not protected by a patent but which may be required in order to make the best use of a patented invention.

3.4.3 Early International Efforts to Address IPR Issues

Although interest in IPR infringement problems has especially come to the fore in the United States in recent years, there has been an awareness of the importance of IPR since the founding of the country, when specific provision was made for the protection of intellectual property in the U.S. Constitution. Many European countries have had similar concerns for a longer period of time. The increase in the flow of ideas and inventions between the United States and European countries with the emergence of industrialization in the late 1700s and 1800s, increasingly spurred cooperation with respect to IPR protection.

In the latter part of the 19th century, several conventions were entered into which address intellectual property protection internationally, including the Paris Convention, which dealt with patent and trademark protection; the Berne Convention, a copyright treaty; and the Madrid Treaty covering the importation of goods bearing false origin indications. Treaties covering other intellectual property areas were established afterwards, and the Paris and Berne agreements were revised and updated in 1967 and 1971, respectively. The Paris and Berne conventions provided both national treatment and most favored nation status for foreign countries, enabling inventors and other innovators an opportunity to apply for patents and copyrights in member countries on the same basis as citizens in the country of interest. In 1967, a diplomatic conference among 51 largely industrialized countries established WIPO to administer the treaties.

WIPO joined the United Nations system in 1974. Its mission is to promote the protection of intellectual property throughout the world. Among its responsibilities are to help member countries create multilateral norms, assist developing countries in writing and administering national laws and establishing patent and copyright offices, and serve the member states through administration of the treaties. WIPO also provides a service to patent applicants from member countries under the Patent Cooperation Treaty (PCT), an international clearinghouse in which applicants may submit one patent application that may take effect in some or all (almost 100) PCT member countries.

In general, intellectual property intensive companies from industrialized countries have been very satisfied with the PCT and training functions of the WIPO. However, they have often been critical of the level of protection offered by the treaties it administers. Some experts attribute this to the fact that the international intellectual property regime established by the major conventions and WIPO was developed with “loose rules, weak dispute settlement mechanisms, and no ability to enforce the provisions of international treaties.” For instance, despite the obligations placed on member countries by the Paris and Berne conventions, the lack of provisions requiring minimum standards of enforcement protection hindered the ability of the WIPO system to enforce strong intellectual property protection, particularly in the industrializing countries.

3.4.4 The Role of WIPO

The World Intellectual Property Organization (WIPO) is an international organization dedicated to ensuring that the rights of creators and owners of intellectual property are protected worldwide and that inventors and authors are thus recognized and rewarded for their ingenuity.

As a specialized agency of the United Nations, WIPO exists as a forum for its Member States to create and harmonize rules and practices to protect intellectual property rights. Most industrialized nations have protection systems that are centuries old. Many new and developing countries, however, are now building up their patent, trademark and copyright laws and systems. With the rapid globalization of trade during the last decade, WIPO plays a key role in helping these new systems evolve through treaty negotiation, legal and technical assistance, and training in various forms, including in the area of enforcement of intellectual property rights.

WIPO also provides international registration systems for patents, trademarks, appellations of origin and industrial designs. These greatly simplify the process for simultaneously seeking intellectual property protection in a large number of countries. Instead of having to file national applications in many languages, these systems enable applicants to file a single application, in one language, and to pay a single application fee. The WIPO-administered systems of international protection include four different mechanisms of protection for specific industrial property rights:

- ✓ The Patent Cooperation Treaty (PCT) for filing patent applications in multiple countries.
- ✓ The Madrid System for the International Registration of Marks for trade and service marks.

- ✓ The Hague System for the International Deposit for Industrial Designs.
- ✓ The Lisbon System for the International Registration of Appellations of Origin.

Anyone applying for a patent or registering a trademark or design, whether at the national or international level, needs to determine whether their creation is new or is owned or claimed by someone else. To make this determination, huge amounts of information must be searched. Four WIPO treaties have created classification systems, which organize information on different branches of industrial property into indexed, manageable structures for easy retrieval:

- ✓ Strasbourg Agreement Concerning the International Patent Classification.
- ✓ Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks.
- ✓ Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks.
- ✓ Locarno Agreement Establishing an International Classification for Industrial Designs.

Major international conventions, treaties, and other agreements on intellectual property Agreement

Instruments of protection	What they protect	Relevant international agreements
Patents and utility models	Inventions	Paris Convention for the Protection of Indus Property (1883) Patent Cooperation Treaty (1970) Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977) Strasbourg Agreement Concerning the International Patent Classification (1971) Patent Law Treaty (2000)
Industrial design	Independently created industrial designs that are new or original	Hague Agreement Concerning the International Registration of Industrial Designs (1934) Locarno Agreement Establishing an International Classification for Industrial Designs (1968)

Trademarks, Certification Marks and Collective Marks	Distinguishing signs and symbols	Madrid Agreement Concerning the International Registration of Marks (1891) Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (1989) Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks (1957) Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks (1973) Madrid Agreement for the Repression of False or Deceptive Indications of Source on Goods (1891) Trademark Law Treaty (1994)
Geographical indications and appellations of origin	Geographical name of a country, region or locality	Lisbon Agreement for the Protection of Appellations of Origin and their International Registration (1958)
Integrated circuits	Lay-out designs	Washington Treaty on Intellectual Property in Respect of Integrated Circuits (1989)
Protection against unfair competition	Honest practices	Paris Convention for the Protection of Industrial Property (1883)

WIPO also provides an Arbitration and Mediation Center, which offers services for the resolution of international commercial disputes between private parties involving intellectual property. The subject matter of these proceedings includes both contractual disputes (such as patent and software licenses, trademark coexistence agreements, and research and development agreements) and non-contractual disputes (such as patent infringement).

The Center is also now recognized as the leading dispute resolution service provider for disputes arising out of the abusive registration and use of Internet domain names.

3.5 INTELLECTUAL INDUSTRIAL PROPERTY

Industrial property legislation is part of the wider body of law known as intellectual property. The term intellectual property refers broadly to the creations of the human mind. Intellectual property rights protect the interests of creators by giving them property rights over their creations.

The Convention Establishing the World Intellectual Property Organization (1967) does not seek to define intellectual property, but gives the following list of the subject matter protected by intellectual property rights: literary, artistic and scientific works; performances of performing artists, phonograms, and broadcasts; inventions in all fields of human endeavor; scientific discoveries; industrial designs; trademarks, service marks, and commercial names and designations; protection against unfair competition; and "all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields."

Intellectual property relates to items of information or knowledge, which can be incorporated in tangible objects at the same time in an unlimited number of copies at different locations anywhere in the world. The property is not in those copies but in the information or knowledge reflected in them. Intellectual property rights are also characterized by certain limitations, such as limited duration in the case of copyright and patents.

The importance of protecting intellectual property was first recognized in the Paris Convention for the Protection of Industrial Property in 1883 and the Berne Convention for the Protection of Literary and Artistic Works in 1886. Both treaties are administered by the World Intellectual Property Organization (WIPO).

Countries generally have laws to protect intellectual property for two main reasons. One is to give statutory expression to the moral and economic rights of creators in their creations and to the rights of the public in accessing those creations. The second is to promote creativity and the dissemination and application of its results, and to encourage fair trade, which would contribute to economic and social development.

3.5.1 The Two Branches of Intellectual Property; Copyright and Industrial Property.

Intellectual property is usually divided into two branches, namely industrial property and copyright.

Copyright

Copyright relates to artistic creations, such as poems, novels, music, paintings, and cinematographic works. In most European languages other

than English, copyright is known as author's rights. The expression copyright refers to the main act which, in respect of literary and artistic creations, may be made only by the author or with his authorization. That act is the making of copies of the literary or artistic work, such as a book, a painting, a sculpture, a photograph, or a motion picture. The second expression, author's rights refers to the person who is the creator of the artistic work, its author, thus underlining the fact, recognized in most laws, that the author has certain specific rights in his creation, such as the right to prevent a distorted reproduction, which only he can exercise, whereas other rights, such as the right to make copies, can be exercised by other persons, for example, a publisher who has obtained a license to this effect from the author.

Industrial Property

Industrial Property is the term given to protective rights conferring an exclusive monopoly on exploitation and is obtained upon completion of filing and registration formalities. Falling into this category are patents for inventions intended to protect innovations of a technical nature, designs and models aimed at protecting inventions of an aesthetic nature, plant variety rights for protecting creations in the agricultural domain (e.g. new types of roses, new maize hybrids, etc.), and also trade-mark law, which reserves for the owner of the trade mark the designation under which goods and services are marketed. If copyright, otherwise known as literary and artistic property rights, which are obtained, at least in most European countries, without filing formalities and arise simply from creative activity, is added to industrial property, the result being whole forms Intellectual Property.

The broad application of the term "industrial" is clearly set out in the Paris Convention for the Protection of Industrial Property (Article 1 (3)): "Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour."

Industrial property takes a range of forms, these include patents to protect inventions; and industrial designs, which are aesthetic creations determining the appearance of industrial products. Industrial property also covers trademarks, service marks, layout-designs of integrated circuits, commercial names and designations, as well as geographical indications, and protection against unfair competition. In some of these, the aspect of intellectual creation, although existent, is less clearly defined. What counts here is that the object of industrial property typically consists of signs transmitting information, in particular to consumers, as regards products and services offered on the market. Protection is directed against

unauthorized use of such signs likely to mislead consumers, and against misleading practices in general.

3.5.2 General Principles

The freedom to pursue a livelihood, operate a business, and otherwise compete in the marketplace is essential to any free enterprise system. Competition creates incentives for businesses to earn customer loyalty by offering quality goods at reasonable prices. At the same time, competition can also inflict harm. The freedom to compete gives businesses the right to lure customers away from each other. When one business entices enough customers away from competitors, those rival businesses may be forced to shut down or move.

The law of unfair competition will not penalize a business merely for being successful in the marketplace. Nor will the law impose liability simply because a business is aggressively marketing its product. The law assumes, however, that for every dollar earned by one business, a dollar will be lost by a competitor. Accordingly, the law prohibits a business from unfairly profiting at a competitor's expense. What constitutes unfair competition varies according to the Cause of Action asserted in each case. These include actions for the infringement of Patents, Trademarks, and copyrights; actions for the wrongful appropriation of Trade Dress, trade names, trade secrets, and service marks; and actions for the publication of defamatory, false, and misleading representations.

3.5.3 Interference with Business Relations

No business can compete effectively without establishing good relationships with its employees and customers. In some instances parties execute a formal written contract to memorialize the terms of their relationship. In other instances business relations are based on an oral agreement. Most often, however, business relations are conducted informally with no contract or agreement at all. Grocery shoppers, for example, typically have no contractual relationship with the supermarkets they patronize.

Business relations are often formalized by written contracts. Merchant and patron, employer and employee, labor and management, wholesaler and retailer, and manufacturer and distributor all frequently reduce their relationships to contractual terms. These contractual relationships create an expectation of mutual performance—that each party will perform its part under the contract's terms. Protection of these relationships from outside interference facilitates performance and helps stabilize

commercial undertakings. Interference with contractual relations upsets expectations, destabilizes commercial affairs, and increases the costs of doing business by involving competitors in petty squabbles or litigation.

Virtually any contract, whether written or oral, qualifies for protection from unreasonable interference. Noncompetition contracts are a recurrent source of litigation in this area of law. These contracts commonly arise in professional employment settings where an employer requires a skilled employee to sign an agreement promising not to go to work for a competitor in the same geographic market. Such agreements are generally enforceable unless they operate to deprive an employee of the right to meaningfully pursue a livelihood. An employee who chooses to violate a noncompetition contract is guilty of breach of contract, and the business that lured the employee away may be held liable for interfering with an existing contractual relationship in violation of the law of unfair competition.

Informal trade relations that have not been reduced to contractual terms are also protected from outside interference. The law of unfair competition prohibits businesses from intentionally inflicting injury upon a competitor's informal business relations through improper means or for an improper purpose. Improper means include the use of violence, Undue Influence, and coercion to threaten competitors or intimidate customers. For example, it is illegal for a business to blockade the entryway to a competitor's shop or impede the delivery of supplies with a show of force. The mere refusal to deal with a competitor, however, is not considered an improper means of competition, even if the refusal is motivated by spite.

Any malicious or monopolistic practice aimed at injuring a competitor may constitute an improper purpose of competition. Monopolistic behavior includes any agreement between two or more people that has as its purpose the exclusion or reduction of competition in a given market. Predatory pricing is the use of below-market prices to inflict pecuniary injury on competitors. A tying agreement is an agreement in which a vendor agrees to sell a particular good on the condition that the vendee buys an additional or "tied" product. Exclusive dealing agreements require vendees to satisfy all of their needs for a particular good exclusively through a designated vendor. Although none of these practices is considered inherently illegal, any of them may be deemed improper if it manifests a tendency to appreciably restrain competition, substantially increase prices, or significantly reduce output.

3.5.4 Trade Name, Trademark, Service Mark, and Trade Dress Infringement

Before a business can establish commercial relations with its customers, it must create an identity for itself, as well as for its goods and services. Economic competition is based on the premise that consumers can distinguish between products offered in the marketplace. Competition is made difficult when rival products become indistinguishable or interchangeable. Part of a business's identity is the good will it has established with consumers, while part of a product's identity is the reputation it has earned for quality and value. As a result, businesses spend tremendous amounts of resources to identify their goods, distinguish their services, and cultivate good will.

The four principal devices businesses use to distinguish themselves are trade names, trademarks, service marks, and trade dress. Trade names are used to identify corporations, partnerships, sole proprietorships, and other business entities. A Trade Name may be the actual name of a business that is registered with the government, or it may be an assumed name under which a business operates and holds itself out to the public. For example, a husband and wife might register their business under the name "Sam and Betty's Bar and Grill," while doing business as "The Corner Tavern." Both names are considered trade names under the law of unfair competition.

Trademarks consist of words, symbols, emblems, and other devices that are affixed to goods for the purpose of signifying their authenticity to the public. The circular emblem attached to the rear end of vehicles manufactured by Bavarian Motor Works (BMW) is a familiar example of a trademark designed to signify meticulous craftsmanship. Whereas trademarks are attached to goods through tags and labels, service marks are generally displayed through advertising. As their name suggests, service marks identify services rather than goods. Orkin pest control is a well-known example of a Service Mark.

Trade dress refers to a product's physical appearance, including its size, shape, texture, and design. Trade dress can also include the manner in which a product is packaged, wrapped, presented, or promoted. In certain circumstances particular color combinations may serve as a company's trade dress. For example, the trade dress of Chevron Chemical Company includes the red and yellow color scheme found on many of its agricultural products (Chevron Chemical Co. v. Voluntary Purchasing Groups, Inc., 659 F.2d 695 [5th Cir. 1981]).

To receive protection from infringement, trade names, trademarks, service marks, and trade dress must be distinctive. Generic language that is used to describe a business or its goods and services rarely qualifies for protection. For example, the law would not allow a certified public accountant to acquire the exclusive rights to market his business under the name "Accounting Services." Such a name does nothing to distinguish

the services offered by one accountant from those offered by others in the same field. A court would be more inclined to confer protection upon a unique or unusual name like "Accurate Accounting and Actuarial Acumen."

When competitors share deceptively similar trade names, trademarks, service marks, or trade dress, a cause of action for infringement may exist. The law of unfair competition forbids competitors from confusing consumers through the use of identifying trade devices that are indistinguishable or difficult to distinguish. Actual confusion need not be demonstrated to establish a claim for infringement, so long as there is likelihood that consumers will be confused by similar identifying trade devices. Greater latitude is given to businesses that share similar identifying trade devices in unrelated fields or in different geographic markets. For example, a court would be more likely to allow two businesses to share the name "Hot Handguns," where one business sells firearms downtown, and the other business runs a country western theater in the suburbs.

Claims for infringement can be strengthened through registration. The first business to register a trademark or a service mark with the federal government is normally protected against any subsequent appropriation by a competitor. Although trade names may not be registered with the federal government, most states require businesses to register their trade names, usually with the Secretary of State, and provide protection for the first trade name registered. Trade dress typically receives legal protection by being distinctive and recognizable without any formal registration requirements at the state or federal level.

3.5.5 Theft of Trade Secrets and Infringement of Copyrights and Patents

The intangible assets of a business include not only its trade name and other identifying devices but also its inventions, creative works, and artistic efforts. Broadly defined as trade secrets, this body of commercial information may consist of any formula, pattern, process, program, tool, technique, mechanism or compound that provides a business with the opportunity to gain advantage over competitors. Although a Trade Secret is not patented or copyrighted, it is entrusted only to a select group of people. The law of unfair competition awards individuals and businesses a property right in any valuable trade information they discover and attempt to keep secret through reasonable steps.

The owner of a trade secret is entitled to its exclusive use and enjoyment. A trade secret is valuable not only because it enables a company to gain advantage over a competitor but also because it may be sold or licensed

like any other property right. In contrast, commercial information that is revealed to the public, or at least to a competitor, retains limited commercial value. Consequently, courts vigilantly protect trade secrets from disclosure, appropriation, and theft. Businesses or opportunistic members of the general public may be held liable for any economic injuries that result from their theft of a trade secret. Employees may be held liable for disclosing their employer's trade secrets, even if the disclosure occurs after the employment relationship has ended.

Valuable business information that is disclosed to the public may still be protected from infringement by Copyright and patent law. Copyright law gives individuals and businesses the exclusive rights to any original works they create, including movies, books, musical scores, sound recordings, dramatic creations, and pantomimes. Patent law gives individuals and businesses the right to exclude all others from making, using, and selling specific types of inventions, such as mechanical devices, manufacturing processes, chemical formulas, and electrical equipment. Law grants these exclusive rights in exchange for full public disclosure of an original work or invention. The inventor or author receives complete legal protection for her intellectual efforts, while the public obtains valuable information that can be used to make life easier, healthier, or more pleasant.

Like the law of trade secrets, patent and copyright law offers protection to individuals and businesses that have invested considerable resources in creating something useful or valuable and wish to exploit that investment commercially. Unlike trade secrets, which may be protected indefinitely, patents and copyrights are protected only for a finite period of time. Applications for copyrights are governed by the Copyrights Act, and patent applications are governed by the Patent Act.

3.5.6 False Advertising, Trade Defamation, and Misappropriation of a Name or Likeness.

A business that successfully protects its creative works from theft or infringement may still be harmed by False Advertising. Advertising need not be entirely false to be actionable under the law of unfair competition, so long as it is sufficiently inaccurate to mislead or deceive consumers in a manner that inflicts injury on a competitor. In general, businesses are prohibited from placing ads that either unfairly disparage the goods or services of a competitor or unfairly inflate the value of their own goods and services. False advertising deprives consumers of the opportunity to make intelligent comparisons between rival products. It also drives up costs for consumers who must spend additional resources in examining and sampling products.

Laws regulate deceptive advertising. The Trademark Act regulates false advertising, which prohibits three specific types of representations:
(1) False representations that goods or services have certain characteristics, ingredients, uses, benefits, or quantities;
(2) False representations that goods or services are new or original; and
(3) False representations that goods or services are of a particular grade, standard, or quality. Advertisements that are only partially accurate may give rise to liability if they are likely to confuse prospective consumers. Ambiguous representations may require clarification to prevent the imposition of liability. For example, a business that accuses a competitor of being "untrustworthy" may be required to clarify that description with additional information if consumer confusion is likely to result.
Trade Defamation is a close relative of false advertising. The law of false advertising regulates inaccurate representations that tend to mislead or deceive the public. The law of trade defamation regulates communications that tend to lower the reputation of a business in the eyes of the community. Trade defamation is divided into two categories: Libel and Slander.
Trade libel generally refers to written communications that tend to bring a business into disrepute, whereas trade slander refers to defamatory oral communications. Before a business may be held liable under either category of trade defamation, the First Amendment requires proof that a defamatory statement was published with "actual malice," which the Supreme Court defines as any representation that is made with knowledge of its falsity or in reckless disregard of its truth (New York Times v. Sullivan, 376 U.S. 254, 84 S. Ct. 710, 11 L. Ed. 2d 686 [1964]). The actual malice standard places some burden on businesses to verify, prior to publication, the veracity of any attacks they level against competitors in print or electronic media.
It is also considered tortious for a business to use the name or likeness of a famous individual for commercial advantage. All individuals are vested with an exclusive property right in their identity. No person, business, or other entity may appropriate an individual's name or likeness without permission. Despite the existence of this common-law tort, businesses occasionally associate their products with popular celebrities without first obtaining consent. A business that falsely suggests that a celebrity has sponsored or endorsed one of its products will be held liable for money damages equal to the economic gain derived from the wrongful appropriation of the celebrity's likeness.

3.5.7 Challenges of Digital Piracy

Digital piracy takes two primary forms. The **first** is the replication and distribution of illegal copies of tangible media, most frequently of the optical disc variety (CDs and DVDs). Also included in this category is the unauthorized usage of the content on discs across multiple users. This problem occurs around the world (including in the United States) with varying degrees of severity. The **second** is the transmission of copyright-protected data over the Internet, as information can just as easily be sent across the world as it can be sent across the room. In both cases, digital piracy is an international problem. The digital world facilitates the making of perfect copies quickly and efficiently, at negligible cost. Companies naturally have taken advantage of these characteristics in order to distribute their content easily (at low cost) and in a format that consumers value. Yet at the same time, the very qualities that make the digital format so attractive are also available to the consumer. Thus, almost anyone can become a distributor if he has the incentive to do so.

To reduce overseas infringement of intellectual property, the policy of the United States has been to export the high standards contained in its own domestic laws and enforcement practices through various trade agreements, trade actions, and offers of technical assistance to other countries to slow the problem to an acceptable rate. In other words, in countries where illegal replication and sales of such products take place, it has been an important part of U.S. trade policy to make sure that strong intellectual property laws and enforcement mechanisms are in place, civil and criminal penalties are applied, and illegal production facilities are closed down. This basic model, which has worked well in the past for audio and videocassettes, can also be employed to address illegal replication of newer tangible digital media forms such as optical discs, including CDs and DVDs. However, traditional copyright laws alone have been found insufficient to curtail pirate production of CDs and DVDs and other “optical media.” Therefore, special optical media regulations, including robust licensing of plants producing such media, tracking mechanisms for the import and export of the raw materials and machinery, and requiring codes to identify the loci of production, have been necessary in countries experiencing severe optical media piracy.

The success of traditional approaches for tangible media products is due to the fact that the physical availability of pirated media can be controlled within national borders with strong IPR laws and enforcement mechanisms for optical disc piracy. Thus, the conventional “export of the model,” where copyright infringement is first successfully controlled in one pirate country, then the controls are spread to the country where the pirate phenomenon has migrated, is appropriate. Nevertheless, the much greater ease, speed, and lower relative costs of replication enabled by

digital technology will significantly increase the efforts required to control such piracy.

Internet piracy represents an equal if not greater challenge to firms and policymakers because there are no national borders in Internet piracy. Even though it is possible for a country to control piracy within its own borders if it has the incentive or external pressure on it to do so, it cannot easily control Internet piracy without the cooperation of all countries. For instance, an Internet user may look for copyrighted material online, such as an illegal digital copy of a feature film. Because Internet users can access websites from any country, in order to prevent unauthorized access to copyrighted material, every site providing protected content around the world must be blocked. To accomplish this feat, every economy must not only agree to the same online copyright laws (the goal of the WIPO "Internet Treaties"), but also cooperate fully in enforcing these laws. If even one country dissents, access is available (at least in theory) throughout the world.

The United States has placed pressure on both domestic and international Internet sites to shut down if in violation of U.S. copyright law. For example, in February 2002, Taiwan authorities, with encouragement from the MPA, shut down an Internet site based in Taiwan providing unauthorized video on- demand that violated U.S. copyright law. But indicative of the troubles encountered by the iniquitousness of the Internet, the site reappeared in June with a slightly altered name and based in another country. This site was also shut down, and later was sued by the MPA in the hopes it would not reappear yet again. Websites providing illegally copied software, music, and entertainment software are also targeted frequently by the Business Software Alliance and the Software and Information Industry Association (SIIA)'s Internet Anti-Piracy division, the Recording Industry Association of America, and the Interactive Digital Software Association. However, the "cease-and-desist" letters sent to web hosts abroad, for example, for business software piracy, only receive 40- to 50-percent compliance, as opposed to the 90- to 99-percent compliance received in the United States.

Many U.S. industry representatives believe that there must be more consensus on digital IPR issues among interested parties in the United States before effective technical, legislative, and trade policy antipiracy strategies can be pursued overseas. Once a domestic consensus can be attained, the debate can be carried to an international level. This has successfully been done through organizations such as the WTO and WIPO, as well as in many bilateral, multilateral, and other fora around the world. But as evidenced by any number of historical international efforts, it takes time to translate domestic IPR priorities into foreign ones because so many countries and interests are involved. As well, efforts must be

comprehensive—all countries must participate--for them to be completely effective. There are many players in the digital media industries, each with different objectives and business models.

In his book Knowledge Diplomacy, Michael P. Ryan categorizes the various stakeholders in the intellectual property industries as follows: Interests and policy preferences in the United States and internationally have arranged themselves into four groups: producers of copyrighted entertainment, information, and software content; users of copyrighted content, including individuals, libraries, governments, and universities; on-line and communication service providers, the deliverers of content; and makers of hardware, including computers and peripheral equipment, video and audio equipment and other consumer electronics, and broadcast equipment.

Each of these parties has different incentives and goals. For instance, producers of content want to ensure their ownership rights, users want easy and inexpensive access to such content, Internet and other communication service providers want to ensure delivery of such content free of liability for piracy, and hardware makers want to ensure a market for equipment on which entertainment, information, and software can be used. A closer look suggests that the value chain, or the series of entities required to bring goods or services from its conception to the ultimate user, is extraordinarily complex in each of the digital intellectual property industries. Many parties from the artists and programmers to the firms, whose equipment is used to access the content, have a vested stake in the success of the industry. But not all parts of the chain feel the effects of digital piracy equally.

There is little question that entertainment industries have a great stake in having their content protected stringently in both U.S. and overseas markets. The MPA estimates annual losses from overseas video and optical disc piracy (not including Internet piracy) at $3 billion. Meanwhile, the number of prerecorded

CDs shipped in 2001 decreased by 6 percent from 2000 levels, and is expected to fall by another 6 to 10 percent in 2002; however, the number of blank CDs sold (frequently used to “burn” music downloaded from the Internet) has risen dramatically in each of the past 4 years. Showcasing a similar trend, sales of recordable DVD discs, a common format used for both legal and illegal duplication of digital versatile discs, increased by 268 percent between 2000 and 2001, and sales of writable disc drives increased by 225 percent over the same period. While these facts should not be interpreted to say that the producers of recordable DVDs and blank CDs are benefitting at the expense of the U.S. motion picture and recording industries, they do suggest that perhaps certain groups have a greater incentive to stop digital piracy than others.

Further, there have been suggestions that some software and hardware firms may have less incentive in protecting copyright law and online piracy than entertainment companies and other content producers. However, because of their interdependence, it is obvious that all parties involved in digital technology have to work together to establish common positions if they are to maximize domestic and overseas sales.

Similar to entertainment firms, software manufacturers themselves are the producers of content, using creative developers to produce "copyrightable expressions" that are in danger of theft and illegal reproduction. Further, because of their own interest in establishing consensus, the Computer Systems Policy Project (CSPP), an advocacy organization representing several high technology hardware companies, including Dell, IBM, and Hewlett-Packard, drafted a letter in February 2002 to the CEOs of several media conglomerates, pledging the commitment of its members to finding a solution to the problem of distributing digital content that is optimal for all parties.

This is not to say that all attempts to come to a consensus among intellectual property-intensive industries on domestic and overseas digital piracy issues will be easy, as previous attempts to do so have proven difficult. For instance, in 1998, over 200 companies tied to the digital music industry, from record labels and artist associations to consumer electronics firms and computer manufacturers, came together in an effort to develop a technology standard that would help control the distribution of digital music "both online and in new emerging digital distribution systems." The effort was named the Secure Digital Music Initiative (SDMI). However, despite the enthusiasm behind it, the struggle to unite the goals of so many different parties continuously delayed SDMI's progress, while the market it was trying to control evolved too quickly.

Another attempt to bring market participants together to achieve a common approach to digital piracy occurred several years before, when the motion picture industry debated how and whether DVDs should be technically protected. In 1996, entertainment industry associations, including the Motion Picture Association of America (MPAA) and the Recording Industry Association of America (RIAA), combined with information technology and consumer electronics companies to form the Copy Protection Technical Working Group (CPTWG). The goal was to develop a universal encryption standard to protect DVDs from "casual piracy." The working group, after long negotiations and repeated review of several iterations of technology to ensure the capture of all interests, ultimately rolled out the Content Scrambling System (CSS) in 1997. By some standards, this was considered a success. All interested commercial parties (at least those that participated in the working group) came to agreement and were able to develop a fairly successful and universally

accepted product. But industry analysts point out that CPTWG was not a complete success. Its output, CSS, does not prevent the illegal duplication of DVDs; rather it restricts the type of device on which a disc can be played. Furthermore, CSS has since been hacked and the circumvention algorithm (aptly named DeCSS) has been widely distributed on the Internet. SDMI and CPTWG are only two of many such working groups determined to control digital piracy through market consensus. Others include the Digital Media Device Association's Interoperability Working Group (DMDA-lWG), whose mission is the "quick establishment and acceptance of an interoperability and content protection standard for portable and networked audio devices," and the Broadcast Protection Discussion Group (BPDG), a subcommittee of the CPTWG developed "to evaluate proposed solutions" for the protection of digital TV broadcasts against unauthorized redistribution.

Recently proposed legislation supported by the motion picture and recording industries mandating certain technical measures has had difficulty gaining the support of other intellectual property industries. The Consumer Broadband and Digital Television Promotion Act (CBDTPA), introduced in Congress in March 2002, calls for mandatory inclusion of security technology in most consumer electronics and PC devices. The proposed law has met with mixed reaction from other digital and copyright dependent industries. Industry associations supporting the bill indicate that the bill represents a "wake-up call to the information technology and consumer electronics industries" to put forth an earnest effort to solving digital piracy. But opposition from other technology industries has argued that the bill imposes inefficient, non-market solutions while hindering innovation. Even the opposition to the bill is split on fundamental issues; some believe that technical protection measures should not be used at all, while others, including the Information Technology Industry Council, simply believe that a market-based solution, rather than one achieved through government intervention as envisioned by the CBDTPA, is best for the economy. No action was taken on CBDTPA before Congress adjourned at the end of 2002.

The development of common positions of industry players dependent on intellectual property rights in the digital era will continue to be a challenge. However, simply recognizing the vast potential that can be realized on an international level if parties work together to come to a general consensus on digital piracy should continue to motivate U.S. computer hardware, software, consumer electronics, entertainment, and other intellectual property industries to reach general consensus. Such consensus should enable U.S. industry and government leaders to develop unified positions for addressing the specific challenges of digital piracy both at home and in overseas markets.

3.6 SUMMARY

In this unit we have discussed about the merits of IPR protection and its importance to the global economy. It then provides background on various technical, legal, and trade policy methods that have been employed to control the infringement of IPR domestically and internationally. We have also discussed about the meaning of unfair trade practices, protection against unfair competition and the role of World Trade Organization (WTO). Further, we have also discussed the meaning of intellectual industrial property, infringement of intellectual industrial property and future challenges facing global industry with regard to IPR protection, particularly the challenges presented by the Internet and digital piracy.

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3.8 SELF ASSESSMENT QUESTIONS

Q1. What do you understand by IPR infringement?

Q2. Explain and define the meaning of intellectual industrial property.

Q3. Describe the meaning and nature of unfair trade practices.

Q4. Discuss the Role of WTO in the protection against unfair trade practices.

Q5. Discuss the future challenges facing global industry with regard to IPR protection, particularly the challenges presented by the Internet and digital piracy.

LL.M. Part-1

Subject: Intellectual property Law

Block II- Biotechnology Patents

Unit-4-NATURE AND TYPES OF BIOTECHNOLOGY PATENTS

STRUCTURE

4.1 INTRODUCTION

In the previous unit you have read about the intellectual property rights. The concept of Intellectual Property is defined in general is that the proprietor or owner may use his property as he wishes and that nobody else can lawfully use his property without his authorization. Of course there are certain recognized limits for the exercise of that right.

The term intellectual property includes, in the broadest sense, all rights resulting from intellectual activity in the industrial, scientifically, literary, or artistic fields. The conventions establishing the WIPO defines 'Intellectual Property' in a broad sense .But the term Intellectual Property is define first time in Paris Convention. Intellectual Property is derived from the term Industrial Property which includes trademarks, design marks, service marks, commercial names and designations, including indications of source and appellations of origin, and the protection against unfair competition. The main objectives of Paris Convention provides that "the protection of industrial property like patents, utility models, industrial designs, trademarks, service marks and the repression of unfair competition". But in the WIPO defines it broadly and intellectual property shall include the right relating to:

- ✓ Literary, artistic and scientific works;
- ✓ Performance of performing artists;
- ✓ Inventions in all fields of human endeavor;
- ✓ Scientific discoveries;
- ✓ Industrial designs;
- ✓ Trademarks, service marks and etc;
- ✓ Protection against unfair competition.

This definition although inclusive in nature, is very comprehensive. As we know that the intellectual property is intangible. It is a new form of property which got greater recognition only in the 18^{th} century. The Intellectual Property is a property in mental labour as distinguished from physical labour. Therefore the Intellectual Property is to be understood as a result

of mental labour in contradistinction with purely physical labour. It is mostly intangible in nature.

Intellectual property rights have gained at most importance in the modern world. The concept of intellectual property rights as developed in India cannot be divorced from the developments in the international arena as well as in the nation-to-nation relations. New areas of development, especially plant patenting and patenting of new forms of life (biotechnology) should receive special attention in this unit.

4.2 OBJECTIVES

After reading this unit you will be able to:

- ✓ Understand the concept of Patenting in India.
- ✓ Explain and define the meaning of biotechnology and biotechnology patents.
- ✓ Describe the nature of biotechnology patents.
- ✓ Write the different types of biotechnology patents.
- ✓ Discuss the Role of Patent in the area of Biotechnology.
- ✓ Why morality is an issue in patent in biotechnology?

4.3 DEFINITION AND NATURE OF BIOTECHNOLOGY PATENTS

4.3.1 What is a patent?

A patent can be defined as a grant of exclusive rights to an inventor over his invention for a limited period of time. The exclusive rights conferred include the right to make, use, exercise, sell or distribute the invention in India. The term of a patent is twenty years, after the expiry of which, the invention would fall into the public domain.

A patent is an exclusive right granted by a country to the owner of an invention to make, use, manufacture and market the invention, provided the invention satisfies certain conditions stipulated in the law. Exclusive right implies that no one else can make, use, manufacture or market the

invention without the consent of the patent holder. This right is available for a limited period of time. In spite of the ownership of the rights, the use or exploitation of the rights by the owner of the patent may not be possible due to other laws of the country which has awarded the patent. These laws may relate to health, safety, food, security etc. Further, existing patents in similar area may also come in the way.

A patent in the law is a **property right** and hence, can be gifted, inherited, assigned, sold or licensed. As the right is conferred by the State, it can be revoked by the State under very special circumstances even if the patent has been sold or licensed or manufactured or marketed in the meantime. The patent right is **territorial in nature** and inventors/their assignees will have to file separate patent applications in countries of their interest, along with necessary fees, for obtaining patents in those countries. A new chemical process or a drug molecule or an electronic circuit or a new surgical instrument or a vaccine is a patentable subject matter provided all the stipulations of the law are satisfied.

4.3.2 What are the requirements for a patent?

Patents are granted only after the satisfaction of certain requirements, which include the patentable subject-matter, utility, novelty, obviousness and specification. To be patentable, an invention should fall within the scope of patentable subject matter as defined by the patent statute. The invention must be a product or a process in order to be eligible for patent protection. With regard to medicine or drug and certain classes of chemicals no patent was granted for the product itself even if new, only the process of manufacturing the substance was patentable. After the Patents Amendment Ordinance, 2004, which commenced on January 1st, 2005, the provision relating to food, drugs and other chemicals have been omitted. Both product and process patents are now available for Food and Drugs. An invention, which is a product or process, is not eligible for a patent grant, if it falls within the scope of non patentable inventions mentioned under section 3 of the Patent Act.

Industrially applicable

A patent can be obtained only if an invention is industrially applicable. An invention is said to be industrially applicable, if it can be made and used in an industry.

Novelty

The invention claimed must be novel indicating that it should be new at the time of conception. Novelty of invention must be considered in the light of prior art. Prior art means the technology that is relevant to the invention and was publicly available at the time the invention was made. It includes prior specifications, patents, printed and published literature and other materials related to the invention. An invention is not novel if it can be anticipated in the light of prior art.

Obviousness/Inventive step

An invention should also not be obvious to a person having ordinary skill in the art to which it relates. If the invention is obvious and does not have any inventive step, it is not patentable. Existence of a prior publication of the invention in any Indian specification or in any document in India or elsewhere or public use of the invention would make an invention obvious. In order to be ineligible for a patent, an invention should be obvious at the time of conception of the invention and not at the time of contention of obviousness.

Specification

Specification is an essential part of a patent. It should consist of the subject-matter, description and at times including the drawing of the invention indicating its scope. The specification has to enable a person with ordinary skill in the art to practice and use the invention. It should also describe the best mode of performing the invention. A patent will be granted only if it satisfies all the aforementioned requirements.

4.3.3 Patent Law in India

The Patent System in India is governed by the Patents Act, 1970 (No. 39 of 1970) as amended by the Patents (Amendment) Act, 2005 and the Patents Rules, 2003, as amended by the Patents (Amendment) Rules 2006 effective from 05-05-2006.

ADMINISTRATION

The Patent Office, under the Department of Industrial Policy & Promotion, Ministry of Commerce & Industry, performs the statutory duties in connection with the grant of patents for new inventions and registration of industrial designs. Patent Offices are located at Kolkata, Mumbai, Chennai and Delhi to deal with the applications for patents originating within their respective territorial jurisdictions. Patent Information System (PIS) located at Nagpur maintains a comprehensive collection of patent specifications and patent related literature, on a worldwide basis and provides technological information contained in patent or patent related literature through search services and patent document supply services.

INTERNATIONAL TREATIES

India is a member-state of Word Intellectual Property Organization (WIPO), an International Organization, responsible for the promotion of the protection of intellectual property throughout the world. India is a member of the following International Organizations and Treaties in respect of Patents:

- ✓ World Trade Organization (WTO) with effect from 01-01 -1995.
- ✓ Convention establishing World Intellectual Property Organization, (WIPO).
- ✓ Paris Convention for the protection of Industrial Property with effect from Dec.7, 1998.
- ✓ Patent Co-operation Treaty (PCT) with effect from Dec.7, 1998.
- ✓ Budapest Treaty with effect from 17th December, 2001.

TYPES OF PATENT APPLICATIONS

- ✓ Ordinary Application
- ✓ Application for Patent of Addition (granted for Improvement or Modification of the already patented invention, for an unexpired term of the main patent).
- ✓ Divisional Application (in case of plurality of inventions disclosed in the main application).
- ✓ Convention application, claiming priority date on the basis of filing in Convention Countries.
- ✓ National Phase Application under PCT.

WHO MAY APPLY?

The inventor may make an application, either alone or jointly with another, or his/their assignee or legal representative of any deceased inventor or his assignee.

GENERAL PRECAUTIONS FOR APPLICANT

The first to file system is employed, in which, among persons having filed the same invention, first one is granted a patent, therefore, a patent application should be filed promptly after conceiving the invention. It is common experience that through ignorance of patent law, inventors act unknowingly and jeopardize the chance of obtaining patents for their inventions. The most common of these indiscretions is to publish their inventions in newspapers or scientific and technical journals, before applying for patents. Publication of an invention, even by the inventor himself, would (except under certain rare circumstances) constitute a bar for the subsequent patenting of it. Similarly, the use of the invention in Public, or the commercial use of the invention, prior to the date of filing patent application would be a fatal objection to the grant of a patent for such invention, thereafter. There is, however, no objection to the secret working of the invention by way of reasonable trial or experiment, or to the disclosure of the invention to others, confidentially.

Another mistake, which is frequently made by the inventors, is to wait until their inventions are fully developed for commercial working, before applying for patents. It is, therefore, advisable to apply for a patent as soon as the inventor's idea of the nature of the invention has taken a definite shape.

It is permissible to file an application for a patent accompanied by a "Provisional Specification" describing the invention. The application may, therefore, be made even before the full details of working of the invention are developed. The filing of an application for a patent disclosing the invention would secure priority date of the invention, and thereby, enable the inventor to work out the practical details of the invention and to file complete specification within 12 months from the date of filing of provisional specification.

WHAT IS PATENTABLE INVENTION?

"A new product or process, involving an inventive step and capable of being made or used in an industry", it means the invention to be patentable should be technical in nature and should meet the following criteria -

- ✓ Novelty: The matter disclosed in the specification is not published in India or elsewhere before the date of filing of the patent application in India.
- ✓ Inventive Step: The invention is not obvious to a person skilled in the art in the light of the prior publication/knowledge/ document.
- ✓ Industrially applicable: Invention should possess utility, so that it can be made or used in an industry.

WHAT IS NOT PATENTABLE?

The following are Non-Patentable inventions within the meaning of the Act:

- ✓ an invention which is frivolous or which claims anything obviously contrary to well established natural laws;
- ✓ an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;
- ✓ the mere discovery of a scientific principle or the formulation of an abstract theory (or discovery of any living thing or non-living substances occurring in nature);
- ✓ 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 or the mere discovery of any new property or mere new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant ;

  Explanation- For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, and mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

- ✓ a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;
- ✓ the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;
- ✓ a method of agriculture or horticulture;
- ✓ 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 of disease or to increase their economic value or that of their products.
- ✓ 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;
- ✓ a mathematical or business method or a computer programme per se or algorithms;
- ✓ a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;
- ✓ a mere scheme or rule or method of performing mental act or method of playing game;
- ✓ a presentation of information;
- ✓ topography of integrated circuits;
- ✓ an invention which in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components.
- ✓ Inventions relating to atomic energy and the inventions prejudicial to the interest of security of India.

WHAT DOES A PATENT GRANT?

A patent grants exclusive rights to the patent owner. It grants the right to make, use, sell, offer for sale, and import the invention into India. Only the patent owner has the right to exercise any or all of the aforementioned rights over the invention.

WHAT IS APATENT INFRIGEMENT?

Infringement of a patent is the violation of the exclusive rights of the patent holder. If any person exercises the exclusive rights of the patent holder without the patent owner's authorization then that person is liable for patent infringement.

WHAT ARE THE DEFENSES FOR PATENT INFRINGEMENT?

Use of a patent for research or experiment, government use, inequitable conduct, patent misuse and laches are some valid defenses for patent infringement.

4.3.4 Definition of Biotechnology

Biotechnology (sometimes shortened to "**biotech**") is a field of applied biology that involves the use of living organisms and bioprocesses in engineering, technology, medicine and other fields requiring bio-products. Biotechnology also utilizes these products for manufacturing purpose. Modern use of similar terms includes genetic engineering as well as cell- and tissue culture technologies. The concept encompasses a wide range of procedures (and history) for modifying living organisms according to human purposes — going back to domestication of animals, cultivation of plants, and "improvements" to these through breeding programs that employ artificial selection and hybridization. By comparison to biotechnology, bioengineering is generally thought of as a related field with its emphasis more on higher systems approaches (not necessarily

altering or using biological materials directly) for interfacing with and utilizing living things. The United Nations Convention on Biological Diversity defines biotechnology as:

"Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use"

In other terms: "Application of scientific and technical advances in life science to develop commercial products" is biotechnology. Biotechnology draws on the pure biological sciences (genetics, microbiology, animal cell culture, molecular biology, biochemistry, embryology, cell biology) and in many instances is also dependent on knowledge and methods from outside the sphere of biology (chemical engineering, bioprocess engineering, information technology, bio-robotics). Conversely, modern biological sciences (including even concepts such as molecular ecology) are intimately entwined and dependent on the methods developed through biotechnology and what is commonly thought of as the life sciences industry.

4.3.5 Definition and Nature of Biotechnology Patents

IPR are largely territorial rights except copyright, which is global in nature in the sense that it is immediately available in all the members of the Berne Convention. These rights are awarded by the State and are monopoly rights implying that no one can use these rights without the consent of the right holder. It is important to know that these rights have to be renewed from time to time for keeping them in force except in case of copyright and trade secrets. IPR have fixed term except trademark and geographical indications, which can have indefinite life provided these are renewed after a stipulated time specified in the law by paying official fees.

Trade secrets also have an infinite life but they don’t have to be renewed. IPR can be assigned, gifted, sold and licensed like any other property. Unlike other moveable and immoveable properties, these rights can be simultaneously held in many countries at the same time. IPR can be held only by legal entities i.e., who have the right to sell and purchase property. In other words an institution, which is not autonomous may not in a position to own an intellectual property. These rights especially, patents,

copyrights, industrial designs, IC layout design and trade secrets are associated with something new or original and therefore, what is known in public domain cannot be protected through the rights mentioned above. Improvements and modifications made over known things can be protected. It would however, be possible to utilize geographical indications for protecting some agriculture and traditional products.

Now you know that Biotechnology can be defined as the creation of valuable products and processes for therapeutic, agricultural or industrial purposes by making use of living organisms". **Biotechnological products can be subject to various intellectual property regimes – trade secrets, patents and copyrights. Of these, patents are the most common, and are typically held as assets by biotechnology companies.** They entitle the holder to produce, make use of and trade with the biotechnology product over a limited period of time, and are in the **nature of a proprietary right**. The foremost justification behind granting patent protection to biotechnological products is that such protection potentially encourages the high risk and heavy investment involved in biotechnology research and development. This, it is argued, will assist in combating endemic diseases and hunger, enhancing cultivation and furthering other benefits of genetic engineering. The trade-off that the inventor makes is disclosure of the product or process which is sought to be patented. The advantage of disclosure lies in the fact that it benefits both the patentee and society. The patentee is encouraged to disclose the invention in exchange for the patent protection that allows him scope for commercial exploitation. In addition, society benefits from the disclosure of an invention, since it adds to the general store of knowledge in society, and may stimulate further research in the technological art.

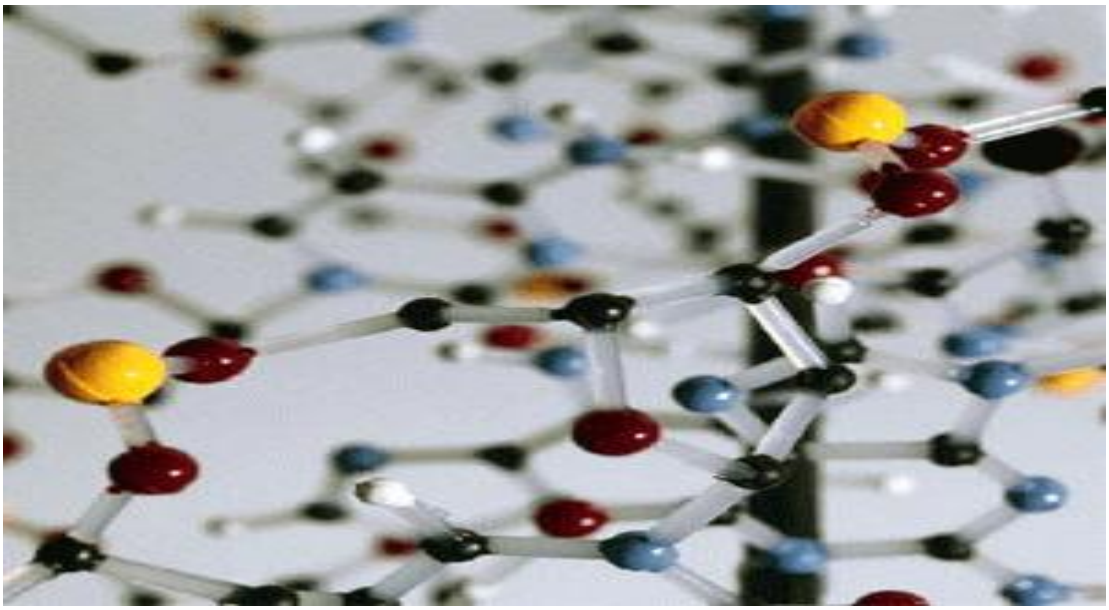
4.4 TYPES OF BIOTECHNOLOGY PATENTS

The patent protection is obtainable for most of the bio-technological innovations. The protection thus provided serves as an incentive for the further development and technical innovations. Accepting the traditional approach the new premise of patent law state that natural life is the creation of god but the non natural life is the creation of human being. So the new idea of patent law is that creation of god or the creation of the nature could not be patented, where as creations of man which involves

the applications of human intelligence to natural things could be patentable.

4.4.1 Patenting of Micro-organism

Art 27 of the TRIPS Agreement forms the basis for the provisions on the patentability of micro-organism. Nevertheless, micro-organisms also have to satisfy the novelty, utility and non-obviousness criteria to be patentable. However, TRIPS agreement does not provide a precise definition of the term micro-organism. The term is generally understood to include viruses, bacteria, yeast and other forms of fungi Protozoa and unicellular algae and non differentiated animal or plant cells. Even though micro-organisms can be patented as per TRIPS agreement; one is often faced with a dilemma whether at all micro-organism constitute a patentable subject matter since they are real life forms.



The law which opened the gates for inventions in the field of biotechnology, particularly in micro organism, was a land marked judgement of the US Supreme Court in 19809 in diamond v. chakaravarty. The dispute was with regard to a modified micro organism developed by the Anada Chakravarty which has the ability of breaking down the crude oil. This property introduced into the naturally occurring bacterium to produce a genetically modified organism. The commissioner of patent in the US field held that the subject matter of the invention was a living organism and was hence not patentable. The US Supreme Court judge,

however, decided in favour of the patentee and stated that everything under sun is patentable. The landmark judgement paved the way for the grant of a number of such biotechnology related patents.

In India the position of patentability of the micro-organism is parallel to that of the UK and Europe. The Calcutta high court gave a path breaking judgement in the case of Dimminico A.G v. Controller of patents and designs which has been hailed in the Indian counter to Diamond V.Chakravarty of the U.S.A. The case related to the patentability of a process for preparation of bursitis vaccine useful for the protecting poultry against the infectious bursities. The ground for rejection of the patent by the controller was that the examiner found that the claim did not fall within sec.2 (1) (j) of Indian patent Act, 1970 and therefore is not an invention. The court held that merely because the end product of process contains a living organism does not preclude the process from being an invention and consequently patentable. Further, the court found that the patent claimed was useful as it protected poultry against contagious disease and the end product resulted in a new article.

4.4.2 Patenting of Animals and Plants

The TRIPS agreement provides that the member states may excludeplants and animals from patentability. This option has been adopted by a number of countries such as the United Kingdom, Europe and India. The issue of the patentability of animals arises mainly because the patentability of animals is considered to be moral issue rather than a legal one. In India the plant varieties may be protected under the protection of Plant Varieties and Farmers Rights act. This act will come into force soon for the protection of plant variety as it is a requirement under the TRIPS agreement. Inventions which concern plants and animals may be patentable if the technical feasibility of the invention is not confined t o a particular plant or animal variety. The on co-mouse case showed that the exclusion is confined to varieties of animal alone. The EPO applied examinee of animals which subdivides a species into subspecies and varieties. Varieties constitute the lowest sub-division .although the invention was to be applied to mice, any non-human mammal was claimed .As this did not confine the claims to a variety, the patent was granted.

Another aspect which is important to consider under biotechnology is patentability of genes and DNA sequences. Genetic inventions encompasses medical. Agricultural environmental and industrial

application patenting of genes would be essential since it would provide an incentive for the manufacture of new and important therapeutic drugs and its application in different areas of biotechnology. The trend of granting patent on non-natural loving being took an interesting turn which claims patent on human genetic material. In john Moors case, patent was granted to cell lines of human beings useful in producing cancer fighting protein, followed by patent on human genetic materials like D NA and RNA in amezen Ins vs. Chuga Pharmaceuticals. After this case, European patent office also started granting patents on human genetic material. So it through many case laws that DNA, RNA and human cells could be patented. At the same time it was also made clear that human beings though genetically engineering or none naturally produced could not be patented.

4.4.3 Patenting of Biotechnological Processes

Non natural or genetically modified living beings are the results of non natural and genetically modified biological processes. Addition of human intelligent to the natural processes renders it non natural. Since patents are available to the products as well as processes, so the task ahead for the inventor of the biological processes was to convince the patent office that biotechnological processes are non natural and there is a role of human agency which differentiate a human process and natural process. In Hybertech Inc Vs Monoclonal Antibodies Inc, a patent was claimed for process of utilising protein to fight against the diseases. The inventors convinced the court that the method is non natural process. Since it utilise proteins produced inside the body on human prescription and obtained patent.

The current trend in the patent however states that the non natural life, living beings and non natural living processes are patentable. Biotechnological processes and micro biological processes are non natural processes which involve addition of human intelligence to the natural process in producing none natural and genetically modified living beings. The inventions of biotechnology ranges from non natural micro organisms like bacteria plasmid, non natural plant, non natural animal and non natural human genetic material which are undoubtedly patentable. Besides, biotechnological process could also be patented in the upsurge of the new period in patent law.

4.5 ROLE OF PATENT IN THE AREA OF BIOTECHNOLOGY

The system of patent is subjected to continuous changes in its philosophy and in its purview. The invention of new technologies is always a subject for the system of patent with the emergence of the two pioneer technologies of the modern world namely information technology and biotechnology. The fact that philosophy of patent law is dynamic and prone to continuous changes has had its impact on patenting the invention of new technologies. The modern world is very much influenced by these technologies. For the improvement of research and development many inventions with great ability and function have been claimed for patent. In today's world biotechnology has become a whole new industry and patent protection for this is of immense commercial importance. Patents are exclusive rights granted to inventions that satisfy the criteria of patentability in the form of novelty, non obviousness and potential for industrial application.

Biotechnology is a new term evolved in the 20 the century. It is the scientific manipulation of living organism for human benefit and its best known form is genetic engineering, industrial agriculture, plant breeding, animal breeding are the backgrounds of biotechnology. In simple biotechnology brings together technology with the science of the living cells. This paper is focused on the role of patents in the area of Biotechnology, an important tool to protect Biotechnological inventions. TRIPS that came into force in 1995, provides the minimum standard of patent protection that requires mandatory compliance by all the member countries. Art.27 (3) (b) of TRIPS states that members may also exclude from patentability: plants and animals other than micro-organisms, and essentially biological process for the production of plants and animals other than micro-organisms, and essentially biological process for the production of plants and animals other than non-biological and micro-biological process. However, members shall provide for the protection of plant varieties either by patent or by an effective sui-generis system or by any combination thereof.

4.6 WHY MORALITY IS AN ISSUE IN PATENTING BIOTECNOLOGY?

The debut concerning the legal, social and moral problems concerned with modern biotechnology give rise to a very different attitude not only among

the internal participants of the patent system namely only scientists lawyers but also the general public.

Another moral argument against the biotechnology is that animal testing for genetic engineering purposes is wrong because pain and suffering is inflicted upon animals for ends that appear frivolous in contrast. On the purely moral basis science should be research driven.

The most complex issues arise when considering genetic modification of human beings viewed from the public perspective the threat posed by contemporary biotechnology is the possibility that will alter human nature in an irrevocable manner, some questions arising are:

Do we as a human own our genetic material or does it belong to society as a whole? The common heritage argument i.e., material passed in abundance by vast numbers of people cannot be the subject of a private monopoly.

Is intervention into the human genome an attack on human dignity?

Proponents of genetic engineering argue that intervention into human genome is necessary, ultimately leading to an increase human biodiversity, while opponents, on the other hand claim such a step is making the sacred into the profane. Only the society can ultimately decide the degree of importance to be attached to the benefits, the hazards and their impact.

However moral arguments enter the patent area directly through the gateway of the Art. 53 of European Parent Convention, 1973 Art 53, inter alia, that patent shall not be granted for inventions the publication and exploitation of which would be contrary to public order and morality. Through this gate way have come arguments, which previously, were not considered real issues in patent law. Biotechnology has changed all that, patent law is now one of the central areas in which moral issues are raised. Cloning raise several ethical issues and problems in the society. On the representation of several organisations, press, judiciary of the American Government banned the experiments on human cloning. This can be understood in another aspect. In 1970 when test tube baby took birth, the same kind of criticism were flooded. Soon such criticisms are calmed down. Like this, in tomorrow, human cloning may be helpful to human beings for the enhancement of the health and prosperity.

Arguments against biotechnology per se suggest that it is the creation of such inventions which is problematic. The core objection is that

biotechnology and more specifically genetic engineering, is wrong in itself, even if the net benefits outweigh the harm caused. Genetic engineering is considered to be intrinsically wrong for the following reasons:

- ✓ It is an attempt at playing God.
- ✓ Genes represent the common heritage of mankind and should be passed from generation to generation without technical intervention by man.
- ✓ Genes occur naturally in organisms and should not suffer interference

Any science, including genetic engineering, will morally amount to a mixed blessing, having both advantages and disadvantages. The Biotechnology Patent law is primarily an instrument of economic policy. It provides incentive to invest and innovate. Also the development of society depends on the development of science and technology. The development in the entire sphere depends on the encouragement and support provided through rewards for the efforts and labour in the production of new inventions. As far as regulating the biotechnological invention is concerned denying patentability on the basis of the morality is misguided as such a solution does not match the nature of the problem. On the other hand for the improvement of the law, science and economics a strong patent system is a core aspect of commercial development. Economic and moral policies are not of equal validity. If a technology is excluded from patentability, there is no incentive to invest in research. In such a situation the public may be deprived of knowledge, and any advantage of the technology might have to offer. Patent law is component in regulating the creation of biotechnology.

4.7 SUMMARY

In this unit we have discussed about the concept, definition, nature and types of biotechnology patent. We also learned about law of patenting in India. Further, we have learnt the role of patent in the area of biotechnology. And finally we discussed why morality is an issue in patent in biotechnology.

4.8 GLOSSARY

Non-obviousness- A patentability requirement according to which an invention should be non-obvious in order to be patented

Novelty- A patentability requirement according to which an invention is not patentable if it was already known before the date of filing

Patent- A territorial right to prevent others from commercially exploiting an invention, granted to an inventor or his successor in rights in exchange for the public disclosure of the invention. A patent is regarded as a specific type of intellectual property right, and is granted for a limited period of time, the term of the patent.

Patent infringement- Commercially exploiting an invention claimed in a patent without permission of the patentee

Priority right- The priority right is a right to claim priority from an earlier application. Claiming priority gives the later filed application a priority date of the filing date of the earlier application.

Term of patent- The maximum period during which it can be maintained in force

Copy gene - Genetic material that contains the genetic code for a desirable trait which has been copied from the DNA of the donor to transfer to the host organism. (Currently, it is not technically possible to take a gene from a donor organism and insert it directly into the host organism).

DNA - Deoxyribonucleic acid, the fundamental genetic material of all cells that acts as the carrier of genetic information.

Gene - The biological unit of inheritance, which transmits hereditary information of a physical, behavioral, or biochemical trait.

Genetic modification - Technique for copying and transferring individual genes to another living organism to alter its genetic make up, thereby incorporating or deleting specific characteristics into or from the organism.

Toxin - A poison, usually originating in a plant or microorganism.

4.9 SUGGESTED READINGS/REFERENCE MATERIAL

REFERENCES

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R.K. Siede & F.A. Smith, “Intellectual Property Protection and Biotechnology”, 67 – JUN N.Y.

D.I. Bainbridge, “Intellectual Property”, (2002), p. 373.

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Iver P. Cooper, Biotechnology and Law (1998), Clerk Boardman Callaghan, New York.

See The New York Times, March 24, 2005, Section C , Page 6 , Column 5

P. Narayanan, Intellectual Property Law (2nd edition) at page 14, Eastern Law House.

Section 2(1)(j) of The Patent Act, 1970. This definition has been retained by the amended law.

P. Narayanan, supra at page 14.

Asthana, B. N., Patents in the WTO Regime, Chartered Secretary, December 2002, page 1657

Section 5 of Th e Patent Act, 1970 states, inter alia, "In the cases of inventions - (a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or (b) relating to substances prepared or produced by chemical processes .... no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

Shrikumar Suryanarayan, President for Research & Development at Biocon Ltd., Bangalore, India. See Wall Street Journal, dated April 11th, 2005 at A20.

A Confusing Patent Law for India, Economic and Political Weekly, April 16, 2005

V. Sridhar, A Tempered Patents Regime, Frontline, Volume 22 - Issue 08, Mar. 12 - 25, 2005

There are also provisions allowing companies that make generics to copy drugs in the future. However, there are relatively tough criteria for such copying, and activists predict that prices for newly invented drugs will be much higher, because drug-makers will have the same 20-year patent monopolies as they have in the Western countries. See http://www.doctorswithoutborders.org/.

As Indian economy opens up to foreign competition, its leading companies are increasing their spending on research and development to stay competitive. Indian companies applied for nearly 800 patents at the World Intellectual Property Organization last year - more than twice the number of patents it applied for four years ago. See Wall Street Journal dated April 11th, 2005, page A20

The "mailbox" system designed by Indian Government two years ago in which drug makers could deposit patents they hoped to file when the law was amended had 1,500 proposals from Indian companies and 7,000 from foreign ones, suggesting the new law would benefit foreign companies more.

See Wall Street Journal, dated April 11th, 2005 at A20.

Couple of years ago, U.K.- based GlaxoSmithKline demanded 40 percent of the sales proceeds of an AIDS drug it licensed to a South African company. However, under pressure from South African regulators and activists, it later licensed it to three rival companies for only 5 percent.

Francis Bacon, quoted in Mainly on Patents at page 1, edited by Felix Liebesny, Butterworths

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2. Terenee P. Stewart (ed.), The GATT Uruguay Round: A Negotiating History (1986-1994) the End Game (Part - 1)(1999), Kluwer

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4. Patent Co-operation Treaty Hand Book (1998), Sweet and Maxwell

5. Iver P. Cooper, Biotechnology and Law (1998), Clerk Boardman Callaghan, New York.

4.10 SELF ASSESSMENT QUESTIONS

Q1. What do you understand by a patent? What are the requirements of a valid patent?

Q1. Define biotechnology and biotechnology patents. What is the nature of biotechnology patents?

Q2. Discuss various types of biotechnology patents. Why morality is an issue in the biotechnology patents.

Q3. Who may apply for a patent? Discuss the precautions for applying a biotech-patent.

Q4. Explain the concept of biotechnology patents in India. Discuss factors that influence the process of patenting.

Q5. Discuss the role of patent in the area of biotechnology.

Q6.What is a patent infringement? What are the defenses of patent infringement?

LL.M. Part-1

Subject: Intellectual property Law

Block- II- Biotechnology Patents

Unit-5- PLANT PATENTING; SUI-GENERIS PROTECTION FOR PLANT VARIETIS

STRUCTURE

5.1 INTRODUCTION

In the previous unit you have read about the concept, definition, nature and types of biotechnology patent. You have also read that The TRIPS agreement provides that the member states may exclude plants and animals from patentability. But there are some benefits of plant patenting.

In India the plant varieties may be protected under the protection of Plant Varieties and Farmers Rights act. This act is a requirement under the TRIPS agreement. Inventions which concern plants and animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

In this unit we will discuss about the definition concept and benefits of plant patenting. We will also discuss the sui generis protection of plant varieties in India.

5.2 OBJECTIVES

After reading this unit you will be able to:

- ✓ Understand the concept of Plant Patenting.
- ✓ Explain the meaning and benefits of sui generis system of biotechnology patents.
- ✓ Describe the sui generis protection of plant verities of biotechnology patents.
- ✓ Write the different Requirements for a plant patent.
- ✓ Understand What Makes Sui Generis System Effective?
- ✓ Discuss the Requirements for plant protection under TRIPs.
- ✓ Describe Indian Sui Generis Legislation for Protection of Plant Varieties and Farmers Rights.

5.3 WHAT IS PLANT PATENTING?

5.3.1 Definition

A plant patent is granted by the Government to an inventor (or the inventor's heirs or assigns) who has invented or discovered and asexually reproduced a distinct and new variety of plant, other than a tuber propagated plant or a plant found in an uncultivated state. The grant, which lasts for 20 years from the date of filing the application, protects the inventor's right to exclude others from asexually reproducing, selling, or using the plant so reproduced. This protection is limited to a plant in its ordinary meaning:

A living plant organism which expresses a set of characteristics determined by its single, genetic makeup or genotype, which can be duplicated through asexual reproduction, but which can not otherwise be "made" or "manufactured." Sports, mutants, hybrids, and transformed plants are comprehended; sports or mutants may be spontaneous or induced. Hybrids may be natural, from a planned breeding program, or somatic in source. While natural plant mutants might have naturally occurred, they must have been discovered in a cultivated area. Algae and macro fungi are regarded as plants, but bacteria are not.

5.3.2 Provisions and Limitations

Patents to plants which are stable and reproduced by asexual reproduction, and not a potato or other edible tuber reproduced plant, are provided for by Title 35 United States Code, Section 161 which states:

> Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefore, subject to the conditions and requirements of title. The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.

As noted in the last paragraph of the statute, the plant patent must also satisfy the general requirements of patentability. The subject matter of the

application would be a plant which developed or discovered by applicant, and which has been found stable by asexual reproduction. To be patentable, it would also be required:

- ✓ That the plant was invented or discovered and, if discovered, that the discovery was made in a cultivated area.
- ✓ That the plant is not a plant which is excluded by statute, where the part of the plant used for asexual reproduction is not a tuber food part, as with potato or Jerusalem artichoke.
- ✓ That the person or persons filing the application are those who actually invented the claimed plant; i.e., discovered or developed and identified or isolated the plant, and asexually reproduced the plant.
- ✓ That the plant has not been sold or released in the United States of America more than one year prior to the date of the application.
- ✓ That the plant has not been enabled to the public, i.e., by description in a printed publication in this country more than one year before the application for patent with an offer to sale; or by release or sale of the plant more than one year prior to application for patent.
- ✓ That the plant be shown to differ from known, related plants by at least one distinguishing characteristic, which is more than a difference caused by growing conditions or fertility levels, etc.
- ✓ The invention would not have been obvious to one skilled in the art at the time of invention by applicant.

Where doubt exists as to the patentability of a specific plant, a qualified legal authority should be consulted prior to applying to assure that the plant satisfies statutory requirements and is not exempted from plant patent protection.

5.3.3 Inventorship

Because there are two steps which constitute invention in plant applications, there may be more than one inventor. An inventor is any person who contributed to either step of invention. For example, if one

person discovers a new and distinct plant and asexually reproduces the plant, such person would be a sole inventor. If one person discovered or selected a new and distinct plant, and a second person asexually reproduced the plant and ascertained that the clone(s) of the plant were identical to the original plant in every distinguishing characteristic, the second person would properly be considered a co-inventor. If either step is performed by a staff, every member of the staff who performed or contributed to the performance of either step could properly be considered a co-inventor. Thus, a plant patent may have a plurality of inventors. However, an inventor can direct that the step of asexual reproduction be performed by a custom propagation service or tissue culture enterprise and those performing the service would not be considered co-inventors.

5.3.4 Asexual Reproduction

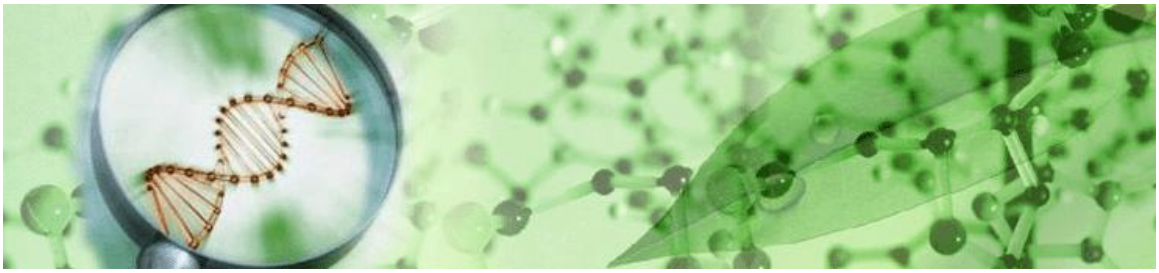
Asexual reproduction is the propagation of a plant to multiply the plant without the use of genetic seeds to assure an exact genetic copy of the plant being reproduced. Any known method of asexual reproduction which renders a true genetic copy of the plant may be employed. Acceptable modes of asexual reproduction would include but may not be limited to:

Rooting Cuttings Grafting and Budding

Apomictic Seeds	Bulbs
Division	Slips
Layering	Rhizomes
Runners	Corms
Tissue Culture	Nucellar Embryos

The purpose of asexual reproduction is to establish the stability of the plant. This second step of the invention must be performed with sufficient time prior to application for patent rights to allow the thorough evaluation of clones of the claimed plant for stability thus assuring that such specimens retain the identical distinguishing characteristics of the original plant.

5.3.5 Rights Conveyed by a Plant Patent



Grant of a patent for a plant precludes others from asexually reproducing or selling or using the patented plant. A plant patent is regarded as limited to one plant, or genome. A sport or mutant of a patented plant would not be considered to be of the same genotype, would not be covered by the plant patent to the parent plant, and would, itself, be separately patentable, subject to meeting the requirements of patentability. A plant patent expires 20 years from the filing date of the patent application. As with utility applications, when the plant patent expires, the subject matter of the patent becomes public domain. A plant patent is a patent issued for newly invented strains of asexually reproducing plants. Tuber propagated plants or wild uncultivated plants may not be patented. Not all countries allow plant patents. The USPTO (United States Patent and Trademark Office) provides for the granting of a patent to anyone who has invented or discovered and asexually reproduced any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber-propagated plant or a plant found in an uncultivated state.

Asexually propagated plants are those that are reproduced by means other than from seeds, such as by the rooting of cuttings, by layering, budding, grafting, inarching, etc. With reference to tuber-propagated plants, for which a plant patent cannot be obtained, the term “tuber” is used in its narrow horticultural sense as meaning a short, thickened portion of an underground branch. Such plants covered by the term “tuber-propagated” are the Irish potato and the Jerusalem artichoke.

A plant patent is granted to an inventor who has invented or discovered and asexually reproduced a distinct and new variety of plant, other than a tuber propagated plant or a plant found in an uncultivated state.

5.3.6 Benefits of a Plant Patenting

A plant patent lasts for 20 years from the date of filing the patent application and gives the inventor the right to exclude others from asexually reproducing, selling, or using the plant so reproduced. This protection is limited to a plant under the following conditions: A living plant organism which expresses a set of characteristics determined by its single, genetic makeup or genotype, which can be duplicated through asexual reproduction, but which can not otherwise be "made" or "manufactured." Sports, mutants, hybrids, and transformed plants are comprehended; sports or mutants may be spontaneous or induced. Hybrids may be natural, from a planned breeding program, or somatic in source. While natural plant mutants might have naturally occurred, they must have been discovered in a cultivated area. Algae and macro fungi are regarded as plants, but bacteria are not.

A living plant organism which expresses a set of characteristics determined by its single, genetic makeup or genotype, which can be duplicated through asexual reproduction, but which can not otherwise be "made" or "manufactured."

The Plant Variety Protection Office (PVPO) administers the Plant Variety Protection Act (PVPA), by issuing Certificates of Protection in a timely manner. The Act provides legal intellectual property rights protection to developers of new varieties of plants which are sexually reproduced (by seed) or tuber-propagated.

5.3.7 USPTO Plant Patents - What Defines Being the Inventor

Because there are two steps which constitute invention in plant applications, there may be more than one inventor. An inventor is any person who contributed to either step of invention. For example, if one person discovers a new and distinct plant and asexually reproduces the plant, such person would be a sole inventor.

If one person discovered or selected a new and distinct plant, and a second person asexually reproduced the plant and ascertained that the clone(s) of the plant were identical to the original plant in every distinguishing characteristic, the second person would properly be considered a co-inventor. If either step is performed by a staff, every member of the staff who performed or contributed to the performance of either step could properly be considered a co-inventor.

However, an inventor can direct that the step of asexual reproduction be performed by a custom propagation service or tissue culture enterprise and those performing the service would not be considered co-inventors. The USPTO grants a plant patent to whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state. The plant must be found stable by asexual reproduction by definition that means, “Creating a plant using techniques such as grafting, budding, or using cuttings, layering, or division without using seeds. Plant offspring will be substantially identical to the parent”.

5.3.8 Requirements for a plant patent

Other requirements for a plant patent include the following:

- ✓ That the plant was invented or discovered and, if discovered, that the discovery was made in a cultivated area.

- ✓ That the plant is not a plant which is excluded by statute, where the part of the plant used for asexual reproduction is not a tuber food part, as with potato or Jerusalem artichoke.
- ✓ That the person or persons filing the application are those who actually invented the claimed plant; i.e., discovered or developed and identified or isolated the plant, and asexually reproduced the plant.
- ✓ That the plant has not been sold or released in the United States of America more than one year prior to the date of the application.
- ✓ That the plant has not been enabled to the public, i.e., by description in a printed publication in this country more than one year before the application for patent with an offer to sale; or by release or sale of the plant more than one year prior to application for patent.
- ✓ That the plant be shown to differ from known, related plants by at least one distinguishing characteristic, which is more than a difference caused by growing conditions or fertility levels, etc.

The invention would not have been obvious to one skilled in the art at the time of invention by applicant. Where doubt exists as to the patentability of a specific plant, a qualified legal authority should be consulted prior to applying to assure that the plant satisfies statutory requirements and is not exempted from plant patent protection.

5.4 WHAT IS SUI-GENERIS PROTECTION FOR PLANT VARITIES?

5.4.1 Definition

Sui generis is a Latin word. It means “unique” or “special”, leaving the sui generis system open to interpretation. Sui generis offers a unique type of intellectual property right (IPR), which is different from the classical IPR, as is the case with the patent. All sui generis models that could be tailored to the specific needs and circumstances of the Members are legally recognized systems. The plant varieties constitute the principal means of production and growth in agricultural productivity. It is also recognized that the specific needs and circumstances of agriculture in each country vary

and in this respect the differences between the developing and the developed countries are very wide in several aspects. Therefore, it is obvious that a sui generis system of protection appropriate for a developing country may require certain modifications in another developing country and these systems may not be even relevant to a developed country. These differences in ground realities and perceptions have made major contribution to the raging controversy on sui generis system.

5.4.2 What Makes Sui Generis System Effective?

According to the TRIPs, the sui generis system should be “effective”. However, it neither specifies which essential elements shall provide the effectiveness nor mentions about any existing plant protection system as the model. The essential elements identified to contribute effectiveness to sui generis IPR system by the International Plant

Genetic Resources Institute include: (i) definition of protectable subject matter,(ii) creation of a setup for such protection, (iii) definition of scope of protection and its duration, (iv) ensuring balance of privilege for the right holder, (v) inclusion of benefit sharing mechanism with holders of genetic variability which was used for breeding the new plant variety, and (vi) scope for public responsibility like creation of community gene fund to promote conservation of agro-biodiversity and provision of a public defender.

There is a general consensus among developing countries that satisfaction of these basic elements, according to the specific need and agricultural circumstances of the member, may make the sui generis IPR system effective for protection of plant varieties as specified in the TRIPs. An important element of sui generis law is that contrary to the exclusive IPR awarded to the individuals or corporations, it offers a special type of IPR protection and benefit sharing system to communities which have either collectively created and incrementally improved an innovation or provided prior art underlying a new innovation, either process or product.

This community could be indigenous rural or tribal communities or farmers communities. In the case of community ownership no right of custodianship can be established or claimed by anyone in the community. This community rights assumes special significance in countries like India where agriculture has been practiced for thousands of years and the farmers have been singularly responsible for conserving and enriching the bio-resources which constitutes the mainstay for national agriculture and food security.

5.5 Requirements for plant protection under TRIPs

Members of the World Trade Organization (WTO) are bound by their membership to adhere to the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs). The Agreement sets out the minimum standards of intellectual property protection the member countries are required to provide.

One of the most controversial provisions of the Agreement surrounds protection of plant varieties. Article 27(3)(b) of the Agreement allows countries to exclude plants and essentially biological processes for their production from their patent system of protection. The same Article however, states that countries must "provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof". Under the Agreement, a country can implement more than one form of plant protection.

The meaning of "sui generis" is one of the contentious issues surrounding the agreement. It is generally believed that the term enables member countries to design their own system of protection for plant varieties if they have elected not to use their patent system for plant protection.

5.5.1 International Union for the Protection of New Varieties of Plants (UPOV)

The International Union for the Protections of New Varieties of Plants (UPOV) is an intergovernmental organization and not a 'treaty' as such. Countries are not obliged to join UPOV as a result of their affiliation with

any other organization or the ratification of any specific treaty. Membership is purely voluntary.

Each member of the organization becomes bound to the UPOV Convention. The Convention requires member countries to provide an intellectual property right specifically for plant varieties. This form of IP protection is often referred to as Plant Breeder's Rights (PBR). As a result of the PBR, the plant breeder is granted a legal monopoly over the commercialization of her plant varieties. Protection allows the breeder to try to recover the costs associated with the development of the variety. By conferring protection on plant varieties, UPOV also aims to provide an incentive to individuals or companies to invest in plant breeding, thereby providing a positive stimulus in the plant breeding industry. The rights granted are for a specific time only (depending on the plant variety), and upon expiration of the time period, the protected variety passes into the public domain.

The UPOV Convention has been revised three times, however not all member countries are bound by the latest convention (1991). Approximately 26 countries remain bound by the 1978 Convention, while Spain and Belgium are bound by the original Convention (1961). The main differences in the two latest agreements can be seen in the table below:

UPOV Convention	**1978**	**1991**
Requirements	Distinct, Uniform and Stable	Distinct, Uniform, Stable, New
Protects	Commercial use of reproductive material of the variety	All plant varieties and products including plants that are derived
Duration of Protection	15 years from application date for most species. 18 years for trees and vines	20 years from application date for most species. 25 years for trees and vines
Breeder's Exemption	Yes. Acts for breeding and development of other varieties are not	Optional. The decision to include an exemption is dependent on each member’s

	prohibited.	national legislation.

The requirements for protection under UPOV require distinctness. The variety must be distinguishable from any other variety which is publicly known at the time of filing the application. The variety must have predictable characteristics and be able to be reliably reproduced. The additional requirement under the 1991 Convention states that the variety must be 'new'. The word 'new' is held to mean that the variety has not been sold or otherwise disposed of by the breeder for commercial purposes prior to filing for protection. However, similarly to a utility patent, natural source material is not protectable. The UPOV Convention does allow a 12 month 'grace period' for sales of the new variety before protection is no longer available (Article 6(1b)).

The latest Convention protects all plant varieties including those that are 'essentially derived' i.e. plants which require the protected variety for their production. The protection offered to the plant variety is an exclusionary right. Protection confers the right to **exclude** others from:

- ✓ producing or reproducing,
- ✓ propagating,
- ✓ offering for sale,
- ✓ selling or other marketing,
- ✓ exporting,
- ✓ importing or
- ✓ stocking for any of the above purposes the protected variety.

However, the protected plant can be used for non-commercial acts (provided they are done privately) and for experimental purposes without infringement. Considering that many UPOV members are also bound to the TRIPs agreement (due to their WTO membership), UPOV provides a framework by which countries can implement a protection system that generally fulfills the TRIPs requirement of providing 'an effective sui generis system' (see Section 2A).

5.6 Plant protection mechanisms provided by sample countries

5.6.1 Plant Variety Protection Certificates (United States)

The United States is bound by the TRIPs Agreement and is also a UPOV member. Because the United States offers patents for plant varieties, technically it does not need to also provide a sui generis system.

In the U.S. the UPOV Convention is implemented by the Plant Variety Protection Act (1970). Changes to the Act made by Amendments in 1994 extended statutory protection to F1 hybrids and tuber propagated plants and generally brought the United States into compliance with the 1991 UPOV Convention. The Plant Variety Protection Act is administered by the U.S. Department of Agriculture, which issues Plant Variety Protection Certificates (PVPC) for qualifying plant varieties.

The Plant Variety Protection Act protects sexually reproduced plants, including first generation (F1) hybrids and tuber propagated plants (e.g. potato varieties). The requirements and term of this protection offered are exactly the same as those outlined in the UPOV Convention.

The Plant Variety Protection Act requires that a deposit of seeds of the new variety be made at an authorized depositary, and in the case of F1 hybrids, seeds of the parents must also be deposited.

The U.S. has in its national legislation only a limited farmer's exemption. In the case of farmers, protected seed may be "saved" for replanting on their own individual holdings provided that it is not sold to any third parties who use it for reproductive purposes. Simultaneous protection by both a utility patent and a PVPC is allowed.

5.6.2 Plant Breeder's Rights (Australia)

Similarly to the U.S., Australia is both a WTO and UPOV member and has implemented the UPOV protection system as a mechanism for complying with TRIPs. Australia is signed onto the 1991 Convention. As a result, plant varieties are protected in Australia by a Plant Breeder's Right (PBR) under the Plant Breeder's Rights Act (1994).

The requirements, term and rights conferred by the UPOV Convention are implemented under the Plant Breeder's Rights Act.

In Australia, a PBR is obtained from and administered by the Plant Breeder's Rights Office, in contrast to patents which are granted by IP Australia. Recently the Plant Breeder's Rights Office was brought within IP Australia.

A choice is usually made between the two protection systems depending on the level of protection sought and the ability to satisfy the necessary requirements. PBRs are generally obtained much faster than a patent due to the lack of examination and are also much cheaper to obtain. They are therefore desirable where protection is required in a short period of time and there is no need to acquire rights over the use of the variety for non-commercial purposes. Where comprehensive exclusive rights are desired, protection under the patent system would be more suitable.

5.6.3 Community Plant Variety Rights (European Union)

Plant variety protection in the European Union is a result of the European Convention (Regulation 2100/94/EC), which is based on the 1991 UPOV Convention. It was introduced in order to harmonize and streamline the method of plant variety protection available throughout Europe.

The Community protection of plant varieties (CPVR) enables applicants, on the basis of one application, to be granted a single intellectual property right which is operative throughout all countries that are members of the European Union. A CPVR can only be transferred or ceased within the EU Community on a uniform basis. That is, a CPVR can only be valid (or cancelled) across all EU countries, not selected individual countries.

The CPVR exists alongside individual European countries' national plant protection legislation as an alternative form of protection. As a result, it is not possible to hold protection for the same plant variety under both the Community and a national system at the same time. Where a CPVR is granted in r elation to a variety for which a national right has already been granted, the national right is suspended for the duration of the CPVR.

The CPVR confers protection to all 'new' botanical genera and species, including their hybrids, provided that the varieties meet exactly the same requirements as outlined under the UPOV Convention. A CPVR is issued by the Community Plant Variety Office in Angers, France.

EXAMPLE

George wishes to obtain a CPVR for his new plant variety in Germany. He is unsure as to whether his CPVR will provide protection in Italy and Switzerland. The CPVR obtained by George will confer protection to George in **ALL** European Union countries. There is no need to register individually in each country. George will automatically be granted protection in Italy, however not in Switzerland as Switzerland is not a member of the EU.

5.6.4 Sui generis system (India)

Many developing countries have an agricultural economy that is geared towards the domestic as opposed to the export market. Such an economy is dependent upon farmer-produced seed of varieties that are both maintained and further adapted to their local growing conditions by small-scale farmers. Developing countries with such an economy want to acknowledge the rights of farmers arising from their contribution to crop conservation and development and the sharing of their knowledge on adaptive traits. They also want to encourage farmer-to-farmer exchange of new crop/plant varieties that are adapted to the local growing conditions. As a result, some developing countries have chosen a sui generis system of plant protection that is not compliant with UPOV in that it allows farmers to improve and adapt the seed in order to make it more successful in the local conditions.

Under the Indian Protection of Plant Varieties and Farmers' Rights Act 2001, plants are divided into four main classes: new varieties, extant varieties, essentially derived varieties and farmers' varieties. The regime for plant protection is similar to that set out by UPOV and the requirements for protection are novelty, distinctness, uniformity and stability. Under Article 39(iv) the farmer is entitled to save use, sow, re-sow, exchange, and share or sell his farm produce including seed of a protected variety. However he is unable to sell seed that has is branded with the Breeders name. In this way the breeder has control of the commercial marketplace without threatening the famers' ability to practise his livelihood.

The Indian Act also contains provisions for "benefit sharing" whereby the local communities are acknowledged as contributors of land races and farmer varieties in the breeding of "new" plant varieties.

It is these extra provisions granting rights to both breeders and farmers which make the Indian system a sui generis method of protection. China and Thailand are other examples of countries that do not implement a UPOV style protection system.

5.7 Indian Sui Generis Legislation for Protection of Plant Varieties and Farmers Rights:

When India initiated this legislative process in 1993, the first draft of this Bill appeared to have more similarity with UPOV 1978 Act. This draft encountered severe opposition and protest from farmers, non-governmental organizations led by the Gene Campaign, the civil society and Parliamentarians. A dialogue on this legislation organized at the M.S.Swaminathan Research Foundation, Chennai led to the development of another draft model incorporating equitable PBR, farmers' rights, recognition of farmer as the cultivator, conserver and breeder with entitlement to protect farmers' varieties, new concepts such as benefit sharing, creation of national gene fund for promoting conservation of agro-biodiversity by farmers. Further several interactions with farmers,

NGOs and other interested parties, the draft bill was modified to suit more to the national agricultural scenario with checks and breaks to minimize the monopolistic role of multinational corporate while encouraging their

partnership in plant breeding. The draft Bill was subsequently referred to a Joint Select Committee of Parliamentarians headed by Shri. Sahib Singh Varma. This Committee did a commendable job in shaping the Bill to its final shape taking inputs from all State Governments, academics, scientists, farmers' associations, NGOs, private sector seed companies and all other shades of interested the civil society . The Bill was enacted in August 2001 with the support of main opposition party. What was notable during this total legislative process was the deep concern conveyed by all including many erudite Parliamentarians to effectively safeguard the interests and rights of farmers from the possible adverse consequences of varietal protection on their livelihood and national food security.

The enacted Protection of Plant Varieties and Farmers' Rights Act, 2001 is notable and distinct from the UPOV Acts in several respects, while it meets all important elements to make it an effective sui generis system of IPR. Some of the features are unique with no parallel in the protection of plant varieties. For this reason there is also possibility that a few of the ideological features may encounter certain practical difficulties during their implementation. These problems, how ever, are not insurmountable with motivated implementation agency and willingness for timely review. Some of the major features which are distinct from the UPOV 1978 Act are enumerated here:

1. Establishment of Plant Variety and Farmers' Rights Protection (PPVFR) Authority to administer up on the Act and a Plant Variety Protection Appellate Tribunal for settlement of disputes arising there from.

2. Farmer is defined as a person who cultivates crops, conserves traditional varieties, wild species and breeder who adds value to them through selection and identification of useful properties.

3. Protection is open to farmers' variety, extant variety and new variety, with distinctness, uniformity and stability (DUS) as essential requirements for farmers' and extant varieties and novelty, as the additional essential attribute for new variety.

4. Entitlement for protection is allowed to breeders/successors/ assignees, farmer, group of farmers or their assignee and publicly funded agricultural research institutions.

5. Application for variety protection to include, apart from the denomination, character profile highlighting the claimed distinctness of the candidate variety, passport data of parental lines, declarations on their geographical origin and lawful acquisition, and an affidavit affirming absence of genetic use restriction technology (like terminator gene).

6. Farmer applicants are exempted from providing much of the above details and payment of all fees.

7. Applications in the case of identical varieties to receive priority on the basis of date of submission of complete application.

8. Genera and species of crops which are to be opened for protection to be periodically notified by the Govt. of India.

9. All applications are published to invite objection, if any, for granting protection to the candidate variety and processed further on resolution of such oppositions, where ever applicable. EDVs are exempted from this process.

10. All varieties other than EDVs are subjected to DUS test for at least two seasons. EDV could be subjected to DNA or protein profile analysis.

11. Application on EDV to be accompanied by a declaration stating prior informed consent from the owner of the initial variety.

12. Decision on approval or denial of protection, in most normal cases, is to be taken during 2-3 year time from date of application.

13. The PBR to have exclusive right on the breeder or his agent to produce, sell, market, distribute, import or export of the variety.

14. Researchers' right to be absolute for using a protected variety for conducting experiment or research including its use as an initial variety for creating other varieties with restrictions on the repeated use of a protected variety in crosses.

15. Requirement to annually pay specifically decided maintenance fee for maintenance of protection with risk of forfeiting protection on grounds of failure in timely payment.

16. Entitlement to assign or license out the PBR at the free will of the PBR holder.

17. The duration of protection to be 18 years for vines and trees and 15 years for other plants with the initial registration period to be 9 years for vines and trees and 6 years for other plants, which is renewable to the limits of protection period.

18. Varieties admitted for protection are to be notified with relevant details to invite claim, if any, on benefit sharing for admitted or suspected use of an initial material owned by other individual, institution or farmer community, for developing the protected variety

19. Claim for benefit sharing could also be preferred on grounds of valid doubt that a protected variety .was bred with unauthorized use of a traditional variety conserved by tribal or rural community

20. Benefit sharing where ever eligible is determined and awarded, the quantum of which is decided in commensuration with the commercial value of the protected variety.

21. All benefit shares awarded are to be deposited by the concerned PBR holder in the National Gene Fund (NGF).

22. NGF may also accept donations from national and international institutions/organizations and the fund is to be largely used to promote conservation of agro-biodiversity with recognition and reward farmers doing exemplary conservation assisting to encourage conservation at Panchayat levels.

23. The Act provides exhaustive and wide ranging rights to farmers in accordance with the FAO International Undertaking on Farmers' Rights and relevant CBD Articles on conservation and sharing biodiversity and benefit sharing. All these rights are codified in one chapter in the Act under title Farmers' Rights. These rights include:

(a) Right to save, use, sow, re-sow, exchange, share or sell his farm produce including seed of any protected variety with an exemption to prevent the right to sell seeds of branded varieties.

(b) Entitlement for recognition and reward for those engaged in conservation of economically useful plants, their land races and wild relatives.

(c) Right to seek protection of varieties identified by farmer or their community.

(d) Right for claiming and receiving due compensation from concerned PBR holder, including public institutions and private corporate, in case the seed of their protected variety fails to achieve the expected performance under recommended conditions of cultivation

(e) Right for benefit sharing if any farmer variety or traditional variety conserved by the tribal or rural community is used by a breeder to develop a new protected variety.

(f) Total immunity from legal proceedings for the first innocent infringement of the PBR, on such admission before the Tribunal.

(g) Exemption from paying all usual fees before a Tribunal or Court, in all legal proceedings against the farmer.

24. Investment of responsibility with the PPVFR Authority to ensure supply of propagating material of all registered variety is adequately met against the demand.

25. Empowerment to PPVFR Authority to grant compulsory license on a protected variety on satisfaction that the PBR holder continuously failed to adequately meet the demand on the propagating material of the protected variety or that the price realized on such material is unreasonably high.

26. The Plant Variety Protection Appellate Tribunal to expeditiously decide, with in a time frame, on all disputes arising from the Act.

5.8 SUMMARY

In this unit we have discussed about the concept of Plant Patenting and the meaning and benefits of sui generis system of biotechnology patents. We have also learned about the sui generis protection of plant verities of biotechnology patents. Further we learned about the different requirements for a plant patent under TRIPs. We also discussed that what Makes Sui Generis System so effective and described the Indian Sui Generis Legislation for Protection of Plant Varieties and Farmers Rights.

5.9 GLOSSARY

Sui generis- is a Latin word, it means “unique” or “special”

Asexual Reproduction-Asexual reproduction is the propagation of a plant to multiply the plant without the use of genetic seeds to assure an exact genetic copy of the plant being reproduced; or creating a plant using techniques such as grafting, budding, or using cuttings, layering, or division without using seeds Plant offspring will be substantially identical to the parent

Tuber-propagated plants- the term “tuber” is used in its narrow horticultural sense as meaning a short, thickened portion of an underground branch. Such plants covered by the term “tuber-propagated” are the Irish potato and the Jerusalem artichoke

5.10 SUGGESTED READINGS/REFERENCE MATERIAL

References

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Biswajit Dhar, Sui Generis Systems for Plant Variety Protection A Discussion Paper

Vandana Shiva, The Indian Seed Act And Patent Act: Sowing The Seeds Of Dictatorship

Suggested Readings

33. Terenee P. Stewart(ed.) : The GATT Uruguary Round : A Negotiating History
34. Iver P. Cooper : Biotechnology and Law (1998), Clerk Boardman

Callaghan, New York

35. David Bainbridge : Software Copyright Law (1999)
36. Sookman : Computer Law (1998)
37. Carlos M. Correa(ed.) : Intellectual Property and International Trade (1998)
38. Sweet and Maxwell : Patent Co-operation Treaty Hand Book (1998)
39. Christopher Wadlow : The Law of Passing-Off (1998)
40. W.R. Cornish : Intellectual Property Law (1999)
41. Special attention should be given to literature of the U.N. System, WIPO and the UNESCO.

5.11 SELF ASSESSMENT QUESTIONS

1. What is a plant patent? What does it mean to invent a plant?
2. What do you understand by the concept of Plant Patenting?.
3. Explain the meaning and benefits of sui generis system of biotechnology patents.
4. Describe the sui generis protection of plant verities of biotechnology patents.
5. Write down the different Requirements for a plant patent.
6. What Makes Sui Generis System Effective?
7. Discuss the Requirements for plant protection under TRIPs.
8. Describe Indian Sui Generis Legislation for Protection of Plant Varieties and Farmers Rights.

LL.M. Part-1
Subject: Intellectual property Law

Block- II- Biotechnology Patents

Unit-6- MULTINATIONAL OWNERSHIP; REGULATION OF ENVIRONMENT AND HEALTH HAZARDS IN BIOTECHNOLOGY PATENTS;
INDIAN POLICY AND POSITION

STRUCTURE

6.1. INTRODUCTION

In the previous unit you have read about the concept of Plant Patenting and the meaning and benefits of sui generis system of biotechnology patents. You have also learned about the sui generis protection of plant verities of biotechnology patents. Further you learned about the different requirements for a plant patent under TRIPs and learned about the Indian Sui Generis Legislation for Protection of Plant Varieties and Farmers Rights.

Life sciences and biotechnology are widely regarded as one of the most promising frontier technologies for the coming decades. After information technology, biotechnology is increasingly recognized as the next wave in the knowledge-based economy. A recent estimate of the European Commission suggests that by the end of the decade the global biotechnology market could amount to over 2,000 billion Euros. Despite the capital intensity of the industry, the growth rate of the biotechnology industry during the 1990s, and to a lesser extent, the beginning of the 21st century has been impressive. Biotechnology has been at the core of a number of important developments in the pharmaceutical, agrochemical, energy and environmental sectors. In particular, progress in the field of molecular biology, biotechnology and molecular medicine has highlighted the potential of biotechnology for the pharmaceutical industry.

In this unit we will look at some of the reasons why patents are so crucial for biotechnology companies in the pharmaceutical sector. By looking at the biotechnology business model, we will seek to identify some of the reasons why this sector relies so heavily on patents and the role of intellectual property rights, and patents in particular, play in investment decisions in this sector. In this unit we will discuss about the regulation of environment and health hazards in biotechnology patents. Further we will also discuss the India position and policies regarding the same.

6.2. OBJECTIVES

After reading this unit you will be able to:

- ✓ Understand the concept of multinational ownership in biotechnology patents.
- ✓ Understand the relationship between public health and patents.
- ✓ Describe the regulation of environment and health hazards in biotechnology patents.
- ✓ Describe biotechnology laws in India
- ✓ Discuss steps Taken By Indian Government and Procedural Aspects in Agricultural Biotechnology in India

6.3 MULTINATIONAL OWNERSHIP IN BIOTECHNOLOGY PATENTS

The strong growth of the biotechnology industry in recent years has been mirrored by a higher than average growth rate for patent applications and patent grants that relate to biotechnology inventions. The growth in the number of patents in the field of biotechnology is largely due to the importance that life sciences and biotechnology companies attach to intellectual property, particularly patents. Why are patents so important for companies in these sectors? It is difficult to understand this without taking a look at how the industry operates.

6.3.1 Multinational Patenting in the Biotechnology Sector

"Protection of intellectual property is at the core of the business for biotechnology firms."

Biotechnology is probably one of the most research-intensive industries. Compared with other major industries that also rely on research and development (R&D), such as the chemical industry, for which the ratio of Research and Development expenditure to total revenues is approximately 5%, or the pharmaceutical industry, for which the equivalent figure is generally no more than 13%, biotechnology companies generally invest a significantly higher proportion of their revenues in R&D (often between 40% and 50%). As in any research-based industry, the protection of research results becomes a major issue.

A second important point to bear in mind about the biotechnology industry is that there are generally very high costs for the development of new

products and processes, but relatively low costs of imitation. The costs of performing biotechnology research are to be considered in the context of the high risks involved in any research project. It is hard to predict at the outset whether years of research will lead to breakthrough innovations with a great market potential or may simply leave a company empty-handed with results that are unlikely to bring revenues. Given the high costs involved in R&D, the relative ease of imitation is an issue that is of great concern. According to the founders of Nordic Biotech, "the present reality in drug development (…) is that almost any technology or compound can rapidly be reverse engineered." Adequate IP protection becomes a means to ensure that biotechnology companies can appropriate their R&D results and reduce the likelihood of imitation by competitors.

A third issue to note is that, contrary to many other sectors, in which there is a clear distinction between the basic research performed in universities and public sector R&D institutions on the one hand, and the applied research and development undertaken by private enterprises on the other, in biotechnology, basic and applied research are often profoundly inter-linked. Research undertaken in academic research institutions is often the basis for the establishment of biotechnology spin-offs. Similarly, biotechnology companies are often involved in (and are actively patenting) what some consider to be basic research.

A fourth element is that the biotechnology industry, in most countries, consists mainly of recently-established SMEs, an important number of which have yet to take a product to market. In many cases, biotechnology SMEs are established on the basis of one or more patents developed within, or in partnership with, public research organizations or universities.

Finally, a point that derives from some of the above is that for some biotech companies intellectual property rights are actually the final product. It is not uncommon, in fact, to find biotechnology companies that develop innovative inventions, patent them and then license them to larger companies that have the resources to take the product to market. Such companies may actually never sell a product in the traditional sense of the word but base their revenues on their ability to develop, protect and license innovations.

6.3.2 What to Own or Patent?

"In no other fields is the relationship between patent protection and the incentives to innovate so strong."

One of the key issues for any biotech firm that is seeking to patent its inventions is what type of biotechnology inventions can be patented. The answer to this question is extremely complex as well as specific to each jurisdiction. As is the case with any new technological field, biotechnology has brought new challenges for the patent system. In many countries (or regions), recent guidelines, directives or legislation have sought to clarify what can or cannot be patented in the life sciences.

As in any other field, inventions in the field of biotechnology need to fulfill the three basic requirements of patentability of novelty, inventive step or non-obviousness, and industrial application or utility. The question has been how to interpret these requirements in the field of biotechnology. Is it sufficient to isolate or purify biological material from an organism to satisfy the inventive step requirement? Different countries have taken different approaches. Similar debates have arisen with the other requirements. For example, in view of the number of patent applications claiming partial DNA sequences or protein sequences with unclear utility or industrial application, some patent offices have stressed the importance that patent applications should clearly state a “specific, credible, and substantial utility” for the invention. In addition, the debate on what can be patented in the field of biotechnology has also focused on ensuring that claims in patent applications are not broader than is justified by the invention disclosed in the patent so that no patent owner is accorded undue exclusivity. These issues need to be borne in mind by biotech companies not only while drafting patent applications but also while devising their R&D strategy, particularly if patents over the R&D results will be crucial for the company’s profitability.

For companies in the biotech sector it is also important to understand that there are strong differences amongst countries concerning what is considered an invention and what type of inventions are considered patentable subject matter. In the United States of America, in the context of the landmark case Diamond v. Chakrabarty, the Supreme Court ruled that patentable subject matter included “anything under the sun made by man.” In many other countries, certain inventions are expressly excluded as unpatentable subject matter, such as, for example, therapeutic or diagnostic methods or processes for cloning human beings. It is important to consult the applicable law as well as any jurisprudence on the subject matter that may facilitate the interpretation of such exclusions or exceptions.

As for the sufficiency of disclosure requirement, which is present in most national patent laws, patents that relate to micro-organisms may require

the deposit of the micro-organism at a recognized depositary institution. Further details on this may be obtained from the national patent office. Concerning what is actually patented by biotech companies, a recent OECD report identified at least three common categories of patents in the specific field of genetic inventions, namely, (1) DNA coding for industrially useful expression products (2) Genes as diagnostic tools, and (3) Genes which control biological pathways.

Conclusion

The business model of biotech firms often relies heavily on intellectual property rights, in particular patents, as they are often the most crucial asset they own in a sector that is extremely research-intensive and with low imitation costs. Investors in biotech companies are generally well aware of the centrality of patents and the survival of such companies may very well depend on their ability to convince investors that they have a solid IP strategy and that risks are reduced to a minimum.

6.4 REGULATION OF ENVIRONMENT AND HEALTH HAZARDS IN BIOTECHNOLOGY

6.4.1 Public Health and Patent

Introduction of Patent Law in India took place in 1856 whereby certain exclusive privileges to the inventors of new inventions were granted for a period of 14 years. Presently, the patent provisions in India are governed by the Patents Act, 1970. The Indian Patents Act is fully compatible with the TRIPS Agreement, following amendments to it; the last amendment being in 2005 by the Patents (Amendment) Act, 2005. Product patents in the field of pharmaceuticals and agro-chemicals have been introduced by deleting Section 5 of the Patents Act. A provision has also been introduced in the Patents Act to enable the grant of compulsory licenses for the export of medicines to countries with limited or no manufacturing capacities to meet emergent public health situations. The law effectively balances and calibrates intellectual property protection with public health concerns and national security. This provision is in line with the Decision of the WTO of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

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.

In general, the development of new drugs requires heavy investment and long-term research, coupled with expensive clinical trials and regulatory approval procedures. The exclusive right conferred by a patent is one of the incentives for developers of new drugs to make the necessary

investments into that research. Clearing issues, such as ownership and licensing policies for innovation derived from public research, would contribute to the promotion of a more effective deployment of public funds and public R&D programs. At the same time, the patent system also contributes to society by making available patent information, which is freely available to other researchers to further improve existing technologies. With a view to facilitating commercialization and ensuring access to patented technologies, the patent system is primarily based on conferring an exclusive right, in conjunction with a voluntary licensing mechanism. However, taking into account the public interest and policy objectives beyond the patent system, there are a number of flexible mechanisms built in the patent system, such as the possibility of issuing compulsory licenses, research exceptions and parallel imports.

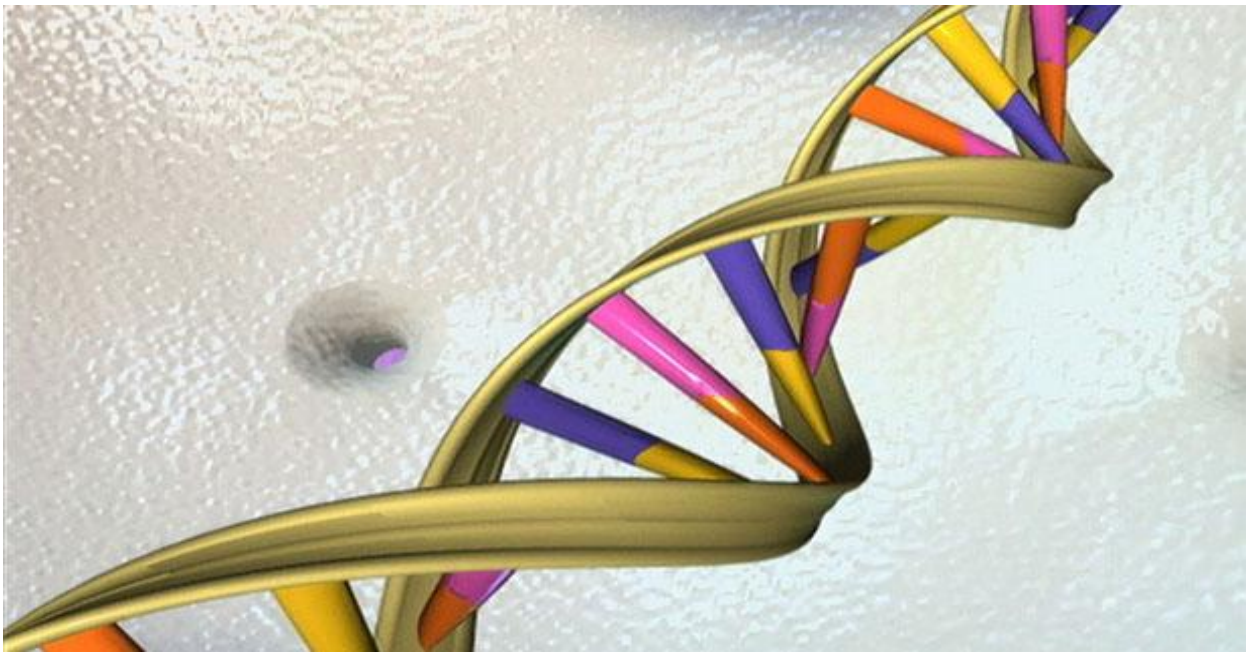
On the other hand, some consider that the current patent system does not adequately address public health crises. It is argued that the commercial incentives provided by the patent system are not sufficient to ensure the development of new products in certain areas, for example, in respect of neglected diseases, and those patent rights, which are enforced on the basis of commercial and market-based considerations, prevent access to, or increase prices of, essential medicines. Some criticize that the safeguard mechanisms built in the patent system, such as compulsory licenses or research exceptions, are not sufficiently broad to cover existing needs. Further, the number and, at times, the broad scope of patents granted in the field of early fundamental research have raised concerns about patent thickets and royalty stacking. In particular, reach-through claims in respect of research tools are considered a potential obstacle to further research and development.

6.5 INDIAN POLICY AND POSITION

6.5.1 Biotechnology Laws in India

Biotechnology involves the modification of the basic genetic material in living things namely DNA , which imparts new properties and capabilities in organisms including plants, animals and micro organisms which can be

harnessed for a number of useful applications. Vast changes to facilitate growth in this sector are taking place in the country.



Approximately, 60% of the industry is devoted to human health applications, 10% to agricultural biotechnology and 30% to industrial applications, bioinformatics and genomics. The Recombinant DNA (rDNA) technology is being successfully used in various sectors such as agriculture, health care, process industry and environment management. The current focus is on genomics, proteomics, transgenics, stem cell research and product development.

6.5.2 Opportunities in India

- ✓ Foreign companies may partner with India at the drug discovery stage of research, and use the Indian companies for contract research and manufacturing. This is because an increasing number of large pharmaceutical companies are finding it difficult to conduct the entire drug discovery process-in-house. India on the other hand provides a cheaper infrastructure. This has given rise to contract research organizations specializing in drug discovery services. Contract research services are largely focused on molecular biology, bioinformatics, genomics & stem

cell research. Clinical research and trials are expected to grow exponentially over the next 5 years.

- ✓ There are tremendous opportunities in India for data-mining, gene annotation, and the development of software interfaces. These require:
- ✓ enormous computing power for which India has established its supremacy.
- ✓ Foreign companies may form joint ventures with Indian companies, or enter into technology transfer agreements or strategic research partnerships with key research institutions.
- ✓ The Indian market provides opportunities to produce and sell vaccines and therapeutics that respond to the needs of the millions of poor in India.
- ✓ In the agricultural biotechnology sector, with the approval for commercial release of first genetically modified product (Bt Cotton), India is expected to approve other crops, including mustard, soya beans, corn and potatoes, in the near future.

Strengths

- ✓ Trained manpower and knowledge base
- ✓ Good network of research laboratories
- ✓ Rich Biodiversity: India's human gene pools offer an exciting opportunity for genomics.
- ✓ Well developed base industries (e.g.: pharmaceuticals, seeds)
- ✓ Access to intellectual resources of Non-residents Indians in this area
- ✓ Extensive clinical trials and research and access to vast & diverse disease population

Weaknesses

- ✓ Lack of venture capital
- ✓ Relatively low R&D expenditure by industry

6.5.3 Steps Taken By Indian Government

- ✓ The Indian government has entered into a number of biotechnology co-operation agreements with various countries in an effort to foster additional growth in this sector.
- ✓ Several State Governments such as Karnataka, Tamil Nadu, Andhra Pradesh, Maharashtra have taken out their specific policies to boost the biotechnology sector in their respective

areas. Some of the key steps taken by the State Governments include: announcing separate Biotechnology Policy for their States, setting up of Task Forces with experts to guide them on policy issues, setting up of exclusive Biotechnology Parks with agriculture and health biotechnology as keyareas. The city of Bangalore, located in the State of Karnataka and known as the IT capital of India, is emerging as the hub of Biotechnology industry in India.

6.5.4 Regulatory Framework in India

Department of Biotechnology [DBT] constituted under the Ministry of Science and Technology is the nodal agency for policy, promotion of R&D, international cooperation and manufacturing activities. Together with DBT, Genetic Engineering and Approval Committee [GEAC] constituted under Ministry of Environment and Forests [MoEF] is the leading regulatory body in the area of Biotechnology in India. Several committees have also been constituted under the said ministries to regulate the activities involving handling, manufacture, storage, testing, and release of genetic modified materials in India. These committees have statutory authority. Most of the committee members are from the scientific community and staff of DBT and MoEF. DBT appoints the members to the committees. The GEAC is supposed to be assisted by the State Biotechnology Coordination Committees (SBCC) and District Level Committees (DLC).

The most important committees are:

- ✓ The Institutional Biosafety Committees (IBSC), responsible for the local implementation of guidelines,
- ✓ Review Committee on Genetic Manipulations (RCGM) responsible for issuing permits;
- ✓ GEAC responsible for monitoring the large scale and commercial use of transgenic materials.

The Biotechnology industry in India is governed by the following enactments depending upon their relevance/applicability on case to case basis:

1. Environment Protection Act, 1986
2. EXIM Policy
3. Foreign Exchange Management Act, 1999
4. Laws pertaining to Intellectual Property Rights

5. Rules for the Manufacture, Use/Import/Export and Storage of Hazardous Micro Organisms/Genetically Engineered Organisms or Cells, 1989 notified by Ministry of Environment & Forests on December 5, 1989 under Environment and Protection Act, 1986.
6. Revised Recombinant DNA Safety Guidelines
7. Guidelines for Research in Transgenic Plants & Guidelines for Toxity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998
8. National Seed Policy, 2002
9. Seeds Act, 1966
10. The Plants, Fruits and Seeds [Regulation of import in India] Order 1989 issued under the Destructive Insects and Pests Act, 1914.
11. Guidelines for Generating Preclinical and Clinical Data for rDNA Therapeutics, 1999
12. Drugs & Cosmetic Act 1940 along with Drugs and Cosmetic Rules
13. Drug Policy, 2002
14. Biological Diversity Act

6.5.5 Foreign Direct Investment in Agricultural Biotechnology

Under the Foreign Direct Investment [FDI] Scheme of the Government of India, a person resident outside India [including foreign companies, Non-Resident Indians (NRIs) and Overseas Corporate Bodies (OCBs)] can invest in the Indian company not engaged in agriculture including plantation by way of subscription of up to 100% of its shares, without obtaining any prior approval provided that the person resident outside India does not have a previous financial or technical collaboration in India.

Under the automatic route of the RBI, an Indian company may issue shares to the person resident outside India provided:

- ✓ that the Indian company does not require an industrial licence under the provisions of the Industrial [Development & Regulation] Act, 1951 or under the locational policy notified by the Government of India under the Industrial Policy; and
- ✓ the shares of the Indian company are not being issued with a view to acquiring existing shares of any Indian company.

If the person resident outside India has a previous financial or technical collaboration or a trademark agreement in India in the same or allied field in which the Indian company is engaged, then the approval of the Ministry of Finance, is required to be obtained prior to making any investment. Also, if the shares are being issued with a view to acquiring the existing

shares of the Indian company, prior approval of the Ministry of Finance and thereafter, of RBI is required. Ministry of Finance approval takes about 4-6 weeks and RBI approval takes about 2 weeks.

6.5.6 Procedural Aspects in Agricultural Biotechnology

The initiation and execution of any research project, production activity and field trials are preceded by necessary procedures of notification and approval of competent authority including IBSC, GEAC depending on the nature of the project and activities.

"Recombinant DNA Safety Guidelines, 1990" were released by Department of Biotechnology which cover areas of research involving genetically engineered organism and these guidelines were further revised in 1994. The revised guidelines are in respect of safety measures for the research activities, large scale use and also the environmental impact during field applications of genetically altered material.

Further, "Research in Transgenic Plants & Guidelines for Toxity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts, 1998" [Guidelines] specifically covers rDNA research on plants including the development of transgenic plants and their growth in soil for molecular and field evaluation. The guidelines also deal with import and shipment of genetic modified plants for research use.

Under the said guidelines, the following clearances are required:

Institutional Biosafety Committee (IBSC):

IBSC is the nodal point of interaction within a commercial organization/applicant company involved in rDNA research for the implementation of rDNA guidelines. Therefore, in the first instance, applicant company intending to carry out research activities involving genetic manipulation of microorganisms should constitute IBSC comprising of the Head of the applicant company, scientists involved in DNA work, a medical expert and a nominee of the DBT.

All recombinant research carried out by the applicant company shall designate a Principal Investigator [PI].

- ✓ In case of Category I routine recombinant experiments mentioned in the guidelines, the PI is required to intimate to the IBSC in the prescribed proforma.

- ✓ In case of Category II experiments, the PI shall seek permission of IBSC before starting the experiment. IBSC shall intimate its decision to the RCGM before execution of the experiments and RCGM shall put the information on record.
- ✓ Category III experiments, where the risk involved in the experiments are considered to be of higher magnitude having the potential of polluting/endangering the environment, the biosphere, the eco system, the animals and the human beings could be conducted only after obtaining clearance from RCGM and upon being notified by the DBT.

All experiments conducted in green house and open field conditions not belonging to the Category II, would fall under Category III.

Therefore, IBSC shall review and give clearance to the project proposals falling under the restricted category that meets the requirements under the guidelines. Where the clearance from the RCGM is required, IBSC shall forward its report to the RCGM after screening along with its recommendation.

Review Committee on Genetic Manipulation (RCGM)

The RCGM under the DBT comprises of representatives of a) DBT; b) Indian Council for Medical Research; c) Indian Council for Agricultural Research; d) Council for Scientific and Industrial Research; and e) other experts in their individual capacity.

Before conducting the research in rDNA work involving risk categorized as category III and above under these guidelines, the PI/Applicant is required to obtain the permission of RCGM following approval from the IBSC. After reviewing the application, the RCGM may recommend the application to Monitoring cum Evaluation Committee [MEC] of the DBT for agronomic benefits and evaluation. After detailed deliberations, the MEC recommends the modified application back to RCGM. For making its evaluations and recommendations, MEC may visit trial sites, analyze data, inspect facilities and conduct environmental risk assessments.

An applicant shall also seek the permission of the RCGM for conducting green house trials and small-scale field trials to generate data to assess the safety of GM/transgenic crops that are intended to be released into open fields. The safety studies include environmental safety studies (pollen flow, emergence of volunteers, persistence etc.), food safety studies (toxity, allergenicity, pathogen drug resistance, alteration of

nutritional value etc.], and the assessment of agronomic advantage over non-transgenic crops. Large-scale field trials would also require the approval of the GEAC.

Genetic Engineering Approval Committee (GEAC):

In case of large scale field trials, deregulation and commercialization, in addition to the DBT approval process mentioned above, permission of GEAC constituted under the MoEF is also required.

Precisely, approval of the GEAC is required from the environmental angle on:

- ✓ Import, export, transport, manufacture, process, selling of any microorganisms or genetically engineered substances or cells including food stuffs and additives that contain products derived by gene therapy.
- ✓ Discharge of genetically engineered/classified organisms/cells from Laboratory, hospitals and related areas into environment.
- ✓ Large scale use of genetically engineered organisms/classified microorganisms in industrial production and applications. Production can only be commenced after obtaining such approval.
- ✓ Deliberate release of genetically engineered organisms.

All approvals of GEAC shall be for a specified period not exceeding 4 years at the first instance renewable for 2 years at a time.

Import and Shipment of Transgenic Material

All imports of seeds and planting material etc. will be allowed freely subject to EXIM Policy guidelines and the requirements of the Plants, Fruits and Seeds (Regulation of Import into India) Order, 1989 and shall require a permit granted by the Plant Protection Advisor to the Government of India.

In addition, permits authorizing the import or receipt of regulated materials for research and specifying the conditions under which the agent or vector is shipped, handled and used are issued by RCGM. The RCGM issues the import certificate after looking into the documents related to the safety of

the material and the national need. Based on such import permit issued by DBT on the recommendations of RCGM, the importer has to apply to the National Bureau of Plant Genetic Resources [NBPGR] for phytosanitary clearance after which the transgenic crops/seeds can be imported. Large scale imports also require the approval of GEAC.

The import consignment is required to be accompanied by an appropriate photo-sanitary certificate issued by the authority of the country of export regarding their transgenic character or otherwise. The consignment on arrival at entry point would be inspected by Plant Protection Advisor, who after inspection, fumigation, disinfection or disinfestations, will accord quarantine clearance for the entry of the crops into India.

Commercialization of GM/Transgenic Crops in India

Transgenic crops/varieties are tested to determine their agronomic value for at least two seasons under the All India Coordinated Project Trials of ICAR, in coordination with the tests for environment and bio-safety clearance as per EPA before any variety is commercially released in the market. Based on such trials and recommendation, GEAC shall inform its decision to the concerned administrative ministry/ authorize body and also inform the applicant to follow the relevant acts.

After the transgenic plant variety is commercially released, its seed is required to be registered and marketed in India as per the provisions of the Seeds Act. After commercial release of a transgenic plant variety, its performance in the field will be monitored for at least 3-5 years by the Ministry of Agriculture and State Departments of Agriculture.

6.6 INTELLECTUAL PROPERTY RIGHTS PROTECTION AND BIOTECHNOLOGY IN INDIA

Being a signatory to the Trade Related Intellectual Property Rights [TRIPs] Agreement of WTO, India has amended its legislations pertaining to intellectual property through various legislations including Patents (Amendment) Act, 1999, formulation of Protection of Plant Varieties and Farmers Rights Act, 2001 [PVP Act].

The current system in India allows patent protection on methods and processes of substances intended for use or capable of being used as food, medicine or drug and not on the end result/product itself. Companies are therefore able to study the end product and produce it using an unpatented processing method. However, in keeping with the TRIPS provision, it is now possible to file application for patent in India on product claims relating to drug/medicinal product and obtaining of priority date for such invention with effect from January 1, 1995 as amended by Patents (Amendment) Act, 1999. These applications are categorized as Mail Box applications and shall not be processed until the end of 2004 due to transition period of 10 years. However, Exclusive Marketing Rights (EMR) can be obtained based on such applications.

TRIPs Agreement allow countries to formulate their own sui generis regime for plants as an alternative to patent protection. To fulfill its commitment, India has passed PVP Act on plant variety protection that incorporates intellectual property rights. This law recognizes farmers' rights and adapts some relevant provisions of UPOV 1978 and 1991 versions, based on the realities and requirements of India as an agriculture-based economy that equally recognizes the contribution of farming communities and private investments in the development of new plant varieties. The PVP Act provides for protection of registered varieties of plants for-- 15 years for annual crops and 18 years for trees and vines and includes the exclusive right to produce, sell, market, distribute, import or export the variety or its propagating material and to licence other persons to do the same.

Present position is that UPOV has allowed India to join the 1978 provisions of the treaty and India has also decided to be a member of the same.

The Biological Diversity Act is India's effort to interpret the Convention of Biodiversity. The Act aims to establish a National Biological Authority (NBA) with powers to protect biological resources in all ecozones within the country, provide approval to foreign agents to access biological resources or inventions derived from them and their exports. It further stipulates that before seeking any form of intellectual property rights on an invention based on India's biological resources, prior permission of the authority constituted under the Act must be obtained. Such authority will have the power to impose conditions to ensure a share of profits accruing from the intellectual property rights of the biological resources. Biological resources have been defined to include plants, animals and micro-

organisms, or parts thereof, their genetic material and by-products, for actual or potential use, but do not include human genetic material.

Tax Incentives

A company engaged in the business of biotechnology and incurring any expenditure on scientific research (not being in the nature of cost of any land or building) on in-house research and development facility as approved by the prescribed authority is allowed deduction of 150% of the expenditure so incurred.

For the purpose of above deduction, 'expenditure on scientific research', in relation to drugs and pharmaceuticals shall include expenditure incurred on clinical drug trial, obtaining approval from any regulatory authority under any Central, State or Provisional Act and filing an application for a patent under the Patents Act, 1970.

- ✓ Tax holiday has been extended to Indian companies carrying on scientific research & development which obtain approval from the prescribed authority upto 31 March 2004. The amount of deduction for such companies is 100% of the profits & gains of such business for a period of 10 consecutive assessment years, beginning from the initial assessment year, if such company fulfills such conditions as may be prescribed.
- ✓ Some Indian States offer concessional or nominal sales tax rates for "high end" new biotechnology products, as may be notified by the respective State Government, manufactured by units located within biotechnology parks established within those States.
- ✓ All units including those dealing with biotechnology products are eligible to avail of Export Oriented Units (EOU) Scheme or Export Processing Zones (EPZ) Scheme. Such units are eligible to import free of duty all types of goods including captive power plants, raw materials and components, prototypes, office equipment and consumables for office use, material handling equipment, except those contained in the negative list. The entire production of EOU/EPZ units shall have to be exported except for permitted levels of rejects and domestic sales. The unit should be a net foreign exchange earner. It shall have minimum net foreign exchange earning as a percentage of exports (NFEP) as specified in the policy and minimum export performance

(EP) of US $ 0.50 Million or 3 times the CIF value of imported capital goods, whichever is higher for five years. Such units are also eligible to get deduction of specified percentage of profits from its total income (90% for the assessment year 2003-04) for calculation of corporate tax till the assessment year 2009-10 and is also eligible to get reimbursement/exemption from other indirect taxes.

Concluding Remarks

The biotechnology industry in India is an emerging industry with significant promise for growth. There is a solid base of expertise in the country and strong government support for the industry at both national and State levels, which provides appropriate opportunities for investment in the biotechnology sector.

6.7 SUMMARY

In this unit we have discussed about the concept of multinational ownership in biotechnology patents. We have also learned about the relationship between public health and patents. Further we learned about the regulation of environment and health hazards in biotechnology patents. We also discussed biotechnology laws in India and steps Taken by Indian Government and procedural aspects in agricultural biotechnology.

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OECD, Genetic Inventions, IPRs and Licensing Practices, 2002.

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Suggested Readings

42. Terenee P. Stewart(ed.) : The GATT Uruguary Round : A Negotiating History
43. Iver P. Cooper : Biotechnology and Law (1998), Clerk Boardman
Callaghan, New York
44. David Bainbridge : Software Copyright Law (1999)
45. Sookman : Computer Law (1998)
46. Carlos M. Correa(ed.) : Intellectual Property and International Trade (1998)

47. Sweet and Maxwell : Patent Co-operation Treaty Hand Book (1998)
48. Christopher Wadlow : The Law of Passing-Off (1998)
49. W.R. Cornish : Intellectual Property Law (1999)
50. Special attention should be given to literature of the U.N. System, WIPO and the UNESCO.

6.9 SELF ASSESSMENT QUESTIONS

1. What is multinational ownership? Why are patents so important for companies in these sectors?
2. Discuss the role of Multinational Patenting in the Biotechnology Sector. Why the protection of intellectual property is at the core of the business for biotechnology firms?
3. What do you understand by the Foreign Direct Investment in Agricultural Biotechnology?
4. Explain the meaning and benefits of sui generis system of biotechnology patents.
5. Do you agree that current patent system does not adequately address public health crises? Discuss.
6. Discuss biotechnology laws in India.
7. What are the procedural aspects in Agricultural Biotechnology? What steps have been taken by Indian Government for the regulatory framework in India?

LL.M. Part-1

Subject: Intellectual property Law

Block- III- Special Problems of Proof of Infringement

Unit-7- STATUS OF INTELLECTUAL PROPERTY IN TRANSIT – TRIPS OBLIGATION – INDIAN POSITION; THE EVIDENTIARY PROBLEMS IN ACTION OF PASSING OFF

STRUCTURE

7.1. INTRODUCTION

In the previous unit you have read about the concept of multinational ownership in biotechnology patents. You have also learned about the relationship between public health and patents. Further, you learned about the regulation of environment and health hazards in biotechnology patents. You also learned about the biotechnology laws in India and steps Taken by Indian Government and procedural aspects in agricultural biotechnology.

In recent times, the relation between international trade and intellectual property ("IP") enforcement has become a controversial topic in international law. On one hand, most IP exporting countries point to increasing trade in counterfeits and fake goods as the primary factor which

destroys markets for the originals and deceives consumers into buying fake and sometimes even dangerous products. The lack of adequate IP enforcement at home, and especially in markets abroad, is identified as a key obstacle to international trade in IP protected goods. New and ambitious international rules on civil, criminal, border and internet IP enforcement are therefore viewed as the main remedy to restore fair global competition and facilitate trade in legitimate goods and services worldwide.

In this unit we will discuss about the infringement of Intellectual Property Rights (IPRs), particularly patents. We will also discuss the status of Intellectual Property in transit, TRIPS obligation and Indian position regarding the same. Further we will discuss about the evidentiary problems in action of passing off.

7.2. OBJECTIVES

After reading this unit you will be able to:

- ✓ Understand the concept of IPR infringement particularly Patent infringement.
- ✓ Discuss the territorial nature of patent rights.
- ✓ Explain the different elements of patent infringement.
- ✓ Describe the relationship between TRIPS agreement and Free trade.
- ✓ Write about ‘in transit goods’ and provisions of TRIPS and Indian provisions.
- ✓ Understand why passing off is necessary?
- ✓ Describe evidentiary problems in action of passing off.

7.3. PATENT INFRINGEMENT

Patent infringement is the commission of a prohibited act with respect to a patented invention without permission from the patent holder. Permission

may typically be granted in the form of a license. The definition of patent infringement may vary by jurisdiction, but it typically includes using or selling the patented invention. In many countries, a use is required to be commercial (or to have a commercial purpose) to constitute patent infringement.

The scope of the patented invention or the extent of protection is defined in the claims of the granted patent. In other words, the terms of the claims inform the public of what is not allowed without the permission of the patent holder.

Patents are territorial, and infringement is only possible in a country where a patent is in force. For example, if a patent is filed in the United States, then anyone in the United States is prohibited from making, using, selling or importing the patented item, while people in other countries may be free to make the patented item in their country. The scope of protection may vary from country to country, because the patent is examined by the patent office in each country or region and may have some difference of patentability, so that a granted patent is difficult to enforce worldwide.

7.3.1 Elements of patent infringement

Typically, a party that manufactures, imports, uses, sells, or offers for sale patented technology, during the term of the patent and within the country that issued the patent, is considered to infringe the patent.

The test varies from country to country, but in general it requires that the infringing party's product (or method, service, and so on) falls within one or more of the claims of the patent. The process employed involves "reading" a claim onto the technology of interest. If all of the claim's elements are found in the technology, the claim is said to "read on" the technology; if a single element from the claim is missing from the technology, the claim does not literally read on the technology and the technology does not infringe the patent with respect to that claim.

In response to allegations of infringement, an accused infringing party will generally assert one or more of the following:

- ✓ it was not practicing the patented invention;
- ✓ it was not performing any infringing act in the territory covered by the patent;
- ✓ the patent has expired;
- ✓ the patent (or the particular claim(s) alleged to be infringed) is invalid, because the invention in question does not meet patentability or includes a formal defect, rendering the patent invalid or unenforceable;
- ✓ it has obtained a license under the patent;
- ✓ the patent holder is infringing patent rights belonging to the accused infringing party, and the party may resolve the dispute in settlement or cross-licensing.

7.3.2 The territorial nature of patent rights

It is commonplace to state that patents are territorial and their protection depends on the national regulation of each country. Given that each State grants its own patents, it comes as no surprise that conferred rights might be only enforceable in the issuing State. Therefore, patent validity and applicability is only to be judged according to the lex loci. Both national intellectual property rights legislations and public international law recognize this rule. The United States (US) Patent Act, for instance, states that a person may be liable for patent infringement if he/she “makes, uses, offers to sell or sells any patented invention, within the United States”.

The Paris Convention for the Protection of Industrial Property article 4bis.1 enshrines the principle of independence, by which “patents applied for in the various countries (…) shall be independent of patents obtained for the same invention in other countries”. Consequently, this independence recognizes the liberty of each State to implement its own national patent regime. The TRIPS, acknowledging such liberty and independence, sets minimum standards and allows WTO Members to adopt higher levels of protection, something which, in fact, implies that intellectual property law may not have, on principle, extra-territorial effects, and that each State is responsible for the level of protection it grants.

Regarding patents, which are the most explicitly territorial among the categories of intellectual property, this basic rule knows some limited exceptions. Both the Paris Convention and the TRIPS recognize extra-territorial effects of patent rights in relation to the importation of products made by a patented process, importation that patent holders may impede pursuant to Paris Convention article 5 and TRIPS article 28.1.b). On the other hand, some extra-territorial activities with effects on national jurisdictions have been addressed by several national legislations. In this regard, and in response to a case where separated components of a patented invention were exported and later on assembled and sold abroad, the US Congress introduced a provision in the Patent Act prohibiting the exportation of components of patented products so as to "induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States".

In the same vein, the US has also forbidden the exportation of components that are meant for use only in a patented device. A different case is the one concerning parallel imports, where no extraterritorial effects of foreign intellectual property rights are recognized, but effects to certain facts occurred abroad: the commercialization of a product and the resulting exhaustion of rights.

None of the exceptions to the territoriality principle, and none of the current legal responses to problems posed by network inventions that also circumvent the territoriality principle, are applicable to the seizures case. Generics in transit were neither the product of a patented process nor were they intended to be entered into the European market. Having ruled out the applicability of TRIPS 28.1.b) to generics, the generic medicines production did not require any exportation from countries where bioequivalent medicines are patented to take place. By its own means, and in accordance with relevant national and international regulations, India produced and other countries bought perfectly legal non-patented medicines. However, with its seizures and the referral to the law of the country where they have been conducted to asses the legitimacy of

goods, the EC may be challenging the implementation of Indian laws. Setting aside sovereignty considerations and the territoriality principle, the difficulties in EC assessing validity of foreign patents are insurmountable.

In 1972, a US District Court noted that:

"courts in the foreign territories whose patents are involved here… (might) disagree with this court's determinations on the validity of the patents. Those courts would at any rate be faced with the hard choice of accepting the inexpert determination of a foreign court or creating an unseemly conflict with the judgment of the court of another country"

It could be argued that, despite not entering into the European internal market, medicines were certainly in European territory, albeit in the customs zone. Together with the legal arguments derived from the national scope of patent rights and the consequent independence of title holder's exclusive rights, it is doubtful that an economic entitlement as a patent without economic effects in a specific jurisdiction can nevertheless be challenged in said jurisdiction.

Although bizarre, this proposal is not unrelated to other cases. Professor Chisum recalls a seminal case that may be worth taking into account in this context. In Brown v. Duchesne, the US Supreme Court constricted the literal territorial scope of a US patent. A French vessel in US territory used a gaff on board covered by a patent, an unauthorized use in the US territory, which the Supreme Court did not, however, consider an infringement. Letters sent by European patent holders to generic companies affirm that in-transit goods infringe patents granted in EC Member States. These allegations are not only against the territoriality principle and basic assumptions regarding the rights a patent confers but also against what the EFPIA, the voice of the European patents-based industry, has commented on. According to the EFPIA, "Where the product is not counterfeit and it is ascertained that no intellectual property rights apply at either country of origin or destination, the customs authorities should allow the product to be released, irrespective of the intellectual property status of the product in the EU". Leaving aside EFPIA and its

Members lack of coordination, an inherent contradiction exists between the territoriality principle and Regulation 1383/2003. Only this contradiction explains positions that claim that if products are not “counterfeit” according to the EC law and are not patent infringing in source and destination countries, they will be released for free circulation.

So, from that standpoint, on the one hand EC Law becomes relevant to assessing the “counterfeit” nature of goods, and on the other hand patent status in third countries also becomes relevant. These ex post contradictory arguments can not let one forget that all that has been achieved is the disruption of generics trade invoking European patent rights of goods not intended for the EC market. Something that EC Regulation 1383/2003 allows, due to its understanding that the law of the transit country is the relevant one when assessing the legality of in-transit goods.

7.4 STATUS OF INTELLECTUAL PROPERTY IN TRANSIT – TRIPS OBLIGATION – INDIAN POSITION

In recent times, the relation between international trade and intellectual property (“IP”) enforcement has become a controversial topic in international law. On one hand, most IP exporting countries point to increasing trade in counterfeits and fake goods as the primary factor which destroys markets for the originals and deceives consumers into buying fake and sometimes even dangerous products.

The lack of adequate IP enforcement at home, and especially in markets abroad, is identified as a key obstacle to international trade in IP protected goods. New and ambitious international rules on civil, criminal, border, and internet IP enforcement are therefore viewed as the main remedy to restore fair global competition and facilitate trade in legitimate goods and services worldwide.

Most developing countries, on the other hand, take a different view: as their goods and services are becoming increasingly competitive with those of developed country producers, new and more stringent international IP enforcement rules seek to introduce a new set of non-tariff barriers to

trade that will preponderantly hinder developing country exporters. Even if agreements such as the Anti-Counterfeiting Trade Agreement ("ACTA") do not directly bind developing countries that are not parties to the treaty, implementing the new IP enforcement rules in the ACTA negotiating countries affects the majority of all goods traded internationally. IP enforcement at the border has the potential to create barriers to trade in goods not even destined to the markets of future ACTA countries. For example, when applied to goods in transit, the IP protection and enforcement standards in the transit country can cause detention and seizures—even if there is no IP infringement in the country of production or destination. Some developing countries consider such enforcement measures as protectionist and their trade restrictive effects as contrary to the main principle of trade liberalization in the World Trade Organization ("WTO").

7.4.1 ACTA Provisions on border measures

The controversy regarding the scope of border measures under ACTA concerns the treatment of goods in transit, or in-transit goods as they are now defined in Art. 5(f)(i)(n) of ACTA Anti- Counterfeiting Trade Agreement ("ACTA") This version defines "in-transit" goods as those under "customs transit," defined as the "procedure under which goods are transported under customs control from one customs office to another," or "transshipment," defined as the "procedure under which goods are transferred from the importing means of transport to the exporting means of transport within the area of one customs office which is the office of both importation and exportation." While ACTA Article 16 now contains a fairly clear rule, art. 16 ("A Party may adopt or maintain procedures with respect to suspect in-transit goods or in other situations where the goods are under customs union control.").

7.4.2 Scope of ACTA border measures

The ACTA provisions on border measures extend the existing minimum standards under TRIPS, which obliges WTO members to provide border measures only against “importation of counterfeit trademark or pirated copyright goods.” Based on the final December 2010 ACTA Section 3 contains the following main provision on the scope of border measures:

ARTICLE 13: SCOPE OF THE BORDER MEASURES

In providing, as appropriate, and consistent with its domestic system of intellectual property rights protection and without prejudice to the requirements of the TRIPS Agreement, for effective border enforcement of intellectual property rights, a Party should do so in a manner that does not discriminate unjustifiably between intellectual property rights and that avoids the creation of barriers to legitimate trade.

Further, Article 16 is decisive for determining the scope of obligations for border measures in ACTA:

ARTICLE 16: BORDER MEASURES

1. Each Party shall adopt or maintain procedures for import and export shipments under which:

(a) its customs authorities may act upon their own initiative, to suspend the release of suspect goods; and

(b) where appropriate, a right holder may request its competent authorities to suspend the release of suspect goods.

2. A Party may adopt and maintain procedures with respect to suspect intransit goods or in other situations where the goods are under Customs control under which:

(a) its customs authorities may act upon their own initiative, to suspend the release of, or to detain, suspect goods; and

(b) where appropriate, a right holder may request the competent authorities to suspend the release of, or to detain, suspect goods.

Together, these provisions determine the types of IP infringements and the trade activities for which future ACTA parties must provide border measures in their national laws. To determine whether ACTA mandates or allows seizures of generic drugs in transit, several aspects pertaining to the scope of border measures under ACTA are particularly relevant. The first subsection answers the question of how ACTA border measures apply to goods suspected of patent infringement. The second subsection examines how ACTA addresses goods in transit. The third subsection then looks at other forms of alleged infringements that might affect international trade in generic medicines. The final subsection scrutinizes the chapeau of ACTA Article 13 to determine which options exist so as to allow countries to exclude from the scope of border measures those forms of IP infringements which may pose a significant threat to generics in transit.

7.4.3 Patent Infringements

The ACTA provision on the scope of border measures has been one of the most contentious among the negotiating parties. This provision concerns primarily the types of IP-infringing goods to be covered, but also addresses what form of trade activities fall under ACTA border measures. Some earlier drafts would have obliged contracting parties to impose border measures against goods “in transit” and in relation to any goods “suspected of infringing intellectual property rights.” The latter phrase was defined in the April ACTA draft as “goods infringing any of the intellectual property rights covered by TRIP,” in principle including patents. As some of the earlier leaked ACTA drafts indicate, the E.U. favored this approach. It pushed for ACTA’s provisions to be broadly defined so as to ensure that infringements of geographical indications (“GIs”) fall under its provisions.

For most commentators, however, the crucial issue was the threat that border measures aimed at alleged patent infringement pose to the free transit of medicines. ACTA negotiators, including the E.U., responded by declaring publicly that “patents will not be covered in the Section on Border Measures.” But even on the basis of the subsequently leaked

ACTA texts, there was no clear expression that goods in transit allegedly infringing patent rights were to be excluded from the general scope of border measures under the ACTA draft.

In the December 2010 ACTA text reproduced above, the matter has finally been addressed: it clarifies that "[t]he Parties agree that patents and protection of undisclosed information do not fall within the scope of this Section." This derogates from the general ACTA definition of the term "intellectual property" as comprising "all categories of intellectual property that are the subject of Sections 1through 7 of Part II of the TRIPS Agreement" and hence from the general obligation under ACTA Article 6(1) to foresee enforcement procedures against "any act of infringement of intellectual property rights covered by this Agreement." It excludes patents and the protection of undisclosed information from the ACTA border measure obligations without the need to resort to the ambiguous provision in Article 13 and its conditions for limiting the scope of border measures to certain types of IP infringements. As a result, no future ACTA party will be obliged to introduce or maintain a system of border measures that applies to suspected patent infringing goods.

From the perspective of international trade and access to medicines, this is certainly an improvement from earlier drafts. As the subsequent analysis will show, however, it is by no means sufficient safeguard to ensure that transit seizures of generic medicines do not occur.

While ACTA does not mandate border measures for suspected patent infringement, a further question is whether ACTA allows its future contracting parties to introduce or maintain such a system.

This concerns not only the E.U., where the BMR covers both patents and transits, but given the dynamics of international IP law and policy, one must expect the trend of a continuous increase in protection and enforcement standards to continue. It is probably not too farfetched that in the near to medium future, some countries might consider ACTA standards as insufficient and strive for "ACTA-plus" standards in their own laws and/or in international agreements. The question then is whether, and to what extent, ACTA would allow its future contracting parties to have

additional, stronger IP enforcement laws such as border enforcement against allegedly patent infringing goods. Here, the general rule in Article 2(1) of the December 2010 ACTA text allows "more extensive protection and enforcement of intellectual property rights than is required by this Agreement, provided that such protection and enforcement does not contravene the provisions of this Agreement."

Future ACTA parties therefore can extend border measures to cover goods suspected of patent infringement, unless this can be argued to "contravene" ACTA provisions. Would such extended coverage amount to contravening the negotiating parties' agreement expressed in Footnote 6 to the Border Measures Section that "patents do not fall within the scope of this Section"? This appears not to be the case: by agreeing to exclude inter alia patent rights from the section on border measures, the negotiating parties primarily wanted to ensure that ACTA does not contain an obligation to foresee border measures against goods suspected of patent infringements. In response to fears that ACTA might require seizures of generics in transit, negotiating parties announced that "patents will not be covered in the Section on Border Measures." Excluding patent infringements from the scope of Section 3 thus means that section's obligations do not apply to national border measures that extend to goods suspected of patent infringements. For example, the obligation under Article 13 that future ACTA parties should not unjustifiably discriminate between IP rights in defining the scope of their national border enforcement systems does not apply to patents. Hence, an extension to cover patent infringements is not contravening Footnote 6 to the Border Measures Section.

However, this conclusion does not rule out the possibility that extending border measures to patent infringements contravenes other ACTA provisions, particularly in light of some of the free trade and public health safeguards which ACTA negotiators borrowed from TRIPS to alleviate public health concerns. In this context, ACTA Article 6 is relevant: it is a verbatim copy of TRIPS Article 41(1) and serves as an important

safeguard against the creation of trade barriers and against abusive reliance on IP enforcement measures in TRIPS.

While Footnote 6 prevents the application of ACTA Section 3 obligations to patent rights, national border enforcement measures which address patent infringement are not immune from the general obligations ACTA imposes with respect to IP enforcement. For example, the text of Article 6(1) refers to all IP enforcement procedures available in national law and demands that "these procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse." Since this horizontal safeguard applies across the board and so affects all ACTA obligations, its operation in the context of transit seizures has been discussed separately.

7.4.4 In-Transit Goods

The controversy regarding the scope of border measure under ACTA concerns the treatment of goods in transit, or in-transit goods as they are now defined shows that anything beyond the treatment of allegedly infringing imports was equally subject to disagreement. Interestingly, certain combinations of a narrow scope (covering only "suspected counterfeit trademark goods" and "suspected pirated copyright goods") and mere optional provisions on transits and exports would arguably have resulted in a treaty without a direct threat to generics in transit.

In Article 16 of the December 2010 ACTA, the negotiating parties agreed that procedures must be available for customs authorities, and right holders where appropriate, to suspend the release of "import and export shipments." On the other hand, the second paragraph of this provision states that "[a] Party may adopt or maintain procedures for suspect in-transit goods or in other situations where the goods are under Customs control." Based on the permissive language of these provisions, ACTA does not obligate contracting parties to introduce or maintain border

measures against any form of goods in transit. This again appears to be a significant improvement from most of the options that were earlier on the table—especially from the perspective of international trade in generic medicines. Given that patents are completely excluded from ACTA's border measure section, and measures against transits are merely optional rather than mandatory, one has to ask whether ACTA still threatens in-transit generics. Before this question is addressed in further detail below, the ACTA definitions pertaining to transits must be assessed.

Article 5 in the December 2010 ACTA contains three definitions that are relevant here. First, the definition of the term "in transit goods" in Article 5(i) distinguishes between two modes of transit: goods under "customs transit" and those under "transshipment." According to Article 5(f), "customs transit" is "the customs procedure under which goods are transported under customs control from one customs office to another." "Transshipment" is in turn defined in Article 5(n) as "the customs procedure under which goods are transferred under customs control from the importing means of transport to the exporting means of transport within the area of one customs office which is the office of both importation and exportation." The leaked ACTA draft of January 2010 reveals that these terms and their definitions are based on the International Convention on the Simplification and Harmonization of Customs Procedures ("Kyoto Convention"). Until the final draft, it was questionable whether analyzing these terms could provide any valuable insights on the general scope of the notion of "transit" in ACTA, as it was not clear that all negotiating parties favor such technical customs definitions. However, the decision to move the definitions into a "General Definitions" section implies consensus amongst the negotiating parties on their relevance to the whole agreement.

The implementation of technical customs law terms in ACTA should be helpful to those authorities responsible for implementing border measures, as they should be familiar with these terms. If one applies the Kyoto Convention's definitions to the case of transiting generics, it appears that the second alternative definition of "transshipment" in ACTA Article 5(n) is relevant: generic medicines produced in one country and in transit through another on the way to a third country of final destination are, after arrival in the transit country, "transferred under customs control from the importing

means of transport to the exporting means of transport within the area of one customs office." The technical customs definitions thus cover the typical scenarios that have led to the seizure of generics in transit. Nevertheless, since it is not mandatory to extend border measures to transits under the final December 2010, does ACTA really continue to pose a significant threat for trade in generics?

The typical juridical answer is particularly apt in this case: it depends. Distinct from TRIPS, ACTA explicitly allows parties to provide "procedures for suspect goods in transit or in other situations where the goods are under customs control." Further, as mentioned above, Article 2(1) of the December 2010 ACTA text generally allows parties to implement more extensive protection, "provided that such enforcement does not contravene the provisions of this Agreement." In relation to extending border measures to cover patent infringing goods, section 1 concludes that such "ACTA-plus" enforcement procedures may contravene the agreement's provisions, particularly the safeguards against trade barriers and abuse set out in the "General Obligations" Section. The same conclusion applies to extending border measures to goods in transit, unless the explicit allowance in ACTA Article 16(2) warrants a different result.

One might argue that this explicit permission implies that making use of this right (i.e. extending border measures to cover transits) cannot be considered "contravening" ACTA. In principle, this is a logically sound argument.

However, while providing enforcement procedures against goods in transit cannot be viewed as contravening ACTA norms, certain methods of doing so certainly may nevertheless contravene ACTA. The general obligation in ACTA Article 6(1) that all enforcement procedures "shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse" also applies to cases where ACTA explicitly allows certain measures. If a future ACTA party decides to make use of this allowance, it must still ensure that it is doing so in a way that does not create trade barriers or allow abuse. Hence, the option to provide border measures against goods in transit is subject to the general obligation to do so in a manner that does not create barriers to legitimate trade. An attempt to give a more concrete meaning to the ambiguous

terms used in the general obligation provision can be found in Part III(C)(1). 110. This may be especially relevant wherever procedures against transits are combined with extending the IP-infringing goods covered, such as patent infringing goods. The transit seizures subject to the WTO dispute brought by India and Brazil indicate the trade distorting potential of such extended IP enforcement regimes. See, e.g., India Consultation Request, supra note 2, at 2.

7.4.5 The relationship between the TRIPS Agreement and free trade

Although the TRIPS Agreement affirms that one of its objectives is to reduce distortions and impediments to international trade, intellectual property rights are by their very nature trade restrictive. In fact, the incorporation of intellectual property into the multilateral trade system during the Uruguay Round has livened up an old debate, concerning the relationship between free trade and intellectual property.

Numerous scholars have highlighted the existing contradiction between WTO trade liberalization objectives and the protectionism introduced by TRIPS into the intensive technological products market. Certainly, a positive link between free trade and intellectual protection would have surprised XIX century free trade promoters.

The then heated debate between intellectual property defenders and opponents had, as major players, on the one hand protectionism promoters aligned with intellectual property rights defenders, and, on the other hand, patent system opponents that simultaneously were free trade promoters.

Circumstances have changed and a more encompassing argument has been elaborated, according to which free trade is not only a matter of increasing trade but trade in legitimate products. Nevertheless, this shared understanding has not avoided a certain consensus on the fact that the TRIPS Agreement was introduced into the multilateral trade system as a concession to developed countries, and not as an instrument to promote free trade.

The tension between free trade and intellectual property protection persists and, to a certain extent, the TRIPS Agreement acknowledges such tension and tries to mitigate conflicting outcomes by framing specific articles on broad free trade promoting principles. This is why TRIPS alludes to the need to avoid intellectual property protection becoming an unnecessary barrier to trade, references being found in the Preamble and several articles. These references can be classified into two groups, depending on their influence over the whole agreement or their rather limited influence on a single topic or part of the Agreement.

The main general references to avoid intellectual property becoming a trade barrier are found in the Preamble and in article 8. The TRIPS Preamble starts by declaring the WTO Members' desire "to reduce distortions and impediments to international trade", and continues pointing out the need "to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade". Additionally, TRIPS article 8, containing the principles to apply to the whole treaty's implementation, also recognizes the need to avoid both intellectual property rights abuses and practices that imply trade restrictions. More precisely, article 8.2 affirms that appropriate measures "may be needed to prevent the abuse of intellectual property rights by right-holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

Article 40 further specifies this power and states that "some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade" and recalls the power granted to states "to prevent or control such practices".

As regards enforcement measures, TRIPS Part III Section 1 contains a single article, which encapsulates several general obligations regarding enforcement. Given its location and comprehensive nature, article 41 guides the implementation and interpretation of the rest of the enforcement part and sections, including Section 4, on border measures. This is important because the second sentence of article 41 "takes account of the public interest in the availability of IPR-protected products" when affirming that enforcement procedures "shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse". It recognizes therefore, the

protection against abuses by right-holders and the protection of legitimate trade as standards to be applied to the entire Part III and, consequently, on border measures legislation and implementation. It is argued that the mandatory language of TRIPS article 41, added to the TRIPS article 1.1 condition imposed upon new standards to "not contravene the provisions of this Agreement", impose a ceiling both to implementation of TRIPS Part III and to new standards related with enforcement.

The article 41 reference to "legitimate trade" may well oblige one to think about the legitimacy of generic medicines international trade. If no disagreement existed on said trade legality, Brazilian Ambassador Roberto Azevedo would probably have been right when claiming at the Council for TRIPS that seizures responded to an "excessive and inappropriate interpretation of intellectual property law".

The WTO Panel report in Canada-Pharmaceutical Products gave a definition of 'legitimate' in a matter also related to medicines and intellectual property rights. According to the Panel, 'legitimate' "must be defined in the way that it is often used in legal discourse –as a normative claim calling for protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms". In this regard, and in addition to the fact that seized medicines were legitimate in exporting and importing countries, the validity of generics international trade is not contested at all. What is more, major international public health organizations, and also WTO Members, have individually, collectively, internally and internationally recognized the need to promote such trade in order to guarantee access to medicines. This public policy goal, together with the human right status granted to access to medicines, should end any debate regarding the "legitimacy" of generics trade. On the basis of all the aforementioned, it is certainly possible for a WTO DSB panel to be asked as to whether EC Regulation 1383/2003 restricts legitimate trade and, thus, TRIPS Preamble and articles 1.1, 8, 41, 51 and 52 become relevant. The fact that the trade of legitimate generic products has been disrupted proves not only that Regulation 1383/2003 is potentially trade restrictive and can be abused, but that this is also the case in practise. Moreover, pharmaceutical companies' allegations when

challenging transit goods expose further problems related to their understanding of rights granted by their patents.

Although EFPIA official statements would indicate the opposite, the facts and above quoted letters show that R&D based companies understand that national patent rights permit disrupting international trade despite challenged goods not having effects in their jurisdictions and being legal in foreign jurisdictions. The EC Regulation is instrumental in fostering that view, which makes it necessary for the EC to clarify whether it also shares that understanding and what measures could be adopted to avoid EC Regulation 1383/2003 being used to stop legitimate trade.

7.4.6 Indian Position

The Indian Customs Act, 1962, is the primary legislation for the enforcement of the border measures in India. Chapter IV, Section11 (2 (n)23 makes it possible to issue notifications to protect certain forms of intellectual property rights with regard to the border measures. It is pertinent to note that the section concerns only relating to patents, trademarks and copyrights and does not extend to other forms of intellectual property rights.

Section 106 of the customs act vests with the custom authorities the power to stop and search conveyances in case of them having a reason to believe that any smuggling operations are being carried on. Further, the power to seize the goods, if liable to confiscation has been entrusted to the custom authorities, with an added requirement of issuing a notice within a period of six months from the date of seizure. It is pertinent to note that the goods imported or attempted to be imported contrary to any legal provision can be confiscated without the requirement of any legal notice (Section111 (d)). The Act also provides for the imposition of penalty up to Rs 1000, or even to the extent of five times the value of the goods in case of improper importation of goods (Section112).

Further, there are provisions providing for imprisonment of the importer up to a period of three years in case of improper importation(Section135 (1)(b)(ii)). The goods once confiscated vest with the government (Section126), and the Commissioner of Customs has the authority to take measures for the imposition of penalty (Section122) after observing the requirements of natural justice (Section126).

7.5 THE EVIDENTIARY PROBLEMS IN ACTION OF PASSING OFF

Passing off is a common law tort which can be used to enforce patent rights. Passing off essentially occurs where the reputation of party A is misappropriated by party B, such that party B misrepresents this reputation and damages the goodwill of party A. The law of passing off prevents one person from misrepresenting his or her goods or services as being the goods and services of the plaintiff, and also prevents one person from holding out his or her goods or services as having some association or connection with the plaintiff when this is not true.

The passing off action depends upon the principle that nobody has a right to represent his goods as the goods of somebody. In other words a man is not to sell his goods or services under the pretence that they are those of another person.

Passing off is not defined in the Act. It is referred to in section 27(2), 134(1) (c) and 135.Section 27(2) states that the rights of action against any person for passing off goods as the goods of another person or the remedies in respect thereof. Section 134(1) (c) refers to injunction of courts to try suits for passing off arising out of the use of any trade mark. Section 135 specifies the remedies available in respect of passing off arising from the use of a trademark.

7.5.1 Why passing off is necessary?

The Trademark is providing protection to registered goods and services, but the passing off action is providing a protection to unregistered goods and services. The most important point is that the remedy is same in both the cases but the Trademark is available to only the registered goods and

services and passing off is available to unregistered goods and services. To more knowledge of this context we can summaries the case of Durga Dutt vs. Navaratna Pharmaceutical; in this case the Supreme Court set out the distinction between infringement and passing off. The action for infringement is a statutory remedy conferred on the registered owner of a registered Trade mark and has an exclusive right to the use of the trade mark in relation to those goods. And the passing off is available to the unregistered goods and services.

The second most important point is that the use by the defendant of the trade mark of the plaintiff is not essential in an action for passing off, but in the case of an action for infringement this will not applicable.

The third important distinction between these two is that if the essential features of the trade mark of the plaintiff have been adopted by the defendant, the fact that the get up, packing and other writing or marks on the goods or on the packets in which he offers his goods for sale marked differences or indicate clearly a trade origin different from that of the registered owner of the mark would be immaterial; but in case of passing off the defendant may escape liability if he can show that the added matter is sufficiently to distinguish his goods from those of the plaintiff.

In the cases of infringement the burden always lies to the plaintiff. In S.M. Dyechem Ltd. v. Cadbury (India) Ltd an infringement action is failed where plaintiff could not prove registration or that its registration extended to the goods or to all the goods in question or because the registration was invalid and yet the plaintiff showed that by imitating the mark otherwise, the defendant had done what was calculated to pass off his goods as those of plaintiff.

7.5.2 Evidence in a passing off action

It is essential for success in a passing off action based on the use of a mark or get up that the plaintiff should show that the disputed mark or get up has become by user distinctive of the plaintiff's goods so that the use in relation to any goods of the kind dealt in by the plaintiff of that mark or get up will be understood by the trade and the public as indicating the plaintiff's goods. The passing off action is arise when there is

misrepresentation, when it is harm the existence plaintiff's goodwill, when it is made by a trader in the course of trade, which is injure the business of another trader and which cause actual damage to the business or goodwill of the trader by the whom action is brought. But these requirements were reduced to in Reckitt & Colman Products Ltd. V. Borden Inc. now there are only three essential requirements for the passing off action:

- ✓ **The Claimant's Goodwill**: Although damage is the gist of an action for passing off, but the plaintiff must show that there is a reasonable reason of his being injured by the defendant's action, even if the conduct of the defendant might be calculated to deceive the public. A private individual cannot institute a suit for passing off even if the defendant practices deception upon the public, unless it is proved that the defendant's action is likely to cause damage to the individual.
- ✓ **Misrepresentation**: Misrepresentation in the simplest form of passing off. If A says falsely these goods I am selling are B's goods. It is a clear case of passing off. In simple way we can say that misrepresentation should lead. Or be likely to lead confusion on the part of consumers. In case of Khemraj v. Garg**,** in this case the defendants had copied the get up, layout, design and colour scheme, etc. and the name "manavpanchang,mani ram panchang" and "shri vallabh Mani Ram panchang" of the plaintiff's panchang.The court held that it is similar to the plaintiff's product and Interim injunction was granted. In the case of Rupa & Co. Ltd v. Dawn Mills Co. Ltd. In this case the defendant manufacture an underwear which named dawn as similar to the plaintiff's manufactured underwear don, which is creating confusion in the minds of people because the layout, get up and colour combination is same to the plaintiff's product.
- ✓ **Damage**: Damages are available in a passing off action. And remedy is available in both cases whether the infringement suit or passing off action in both the cases remedy is given.

7.5.3 How the passing off action arises?

To answer this question of how the passing off action is established we will just discuss two cases. First case is relating to passing off action in domain name. In Akash Arora vs. Yahoo Inc the court held that the "yahooindia" is creating a confusion in the mind of the people. And the

defendant “yahooindia” is same as the plaintiff’s yahoo. The second is Reckitt & Colman of India Ltd. vs. M.P. Ramachandran & Another in this case Honourable Calcutta High Court (Barin Ghosh, J.) laid down five principles for granting an injunction in case of comparative advertising:

- ✓ A tradesman is entitled to declare his goods to be best in the world even though the declaration is untrue;
- ✓ He can also say that his goods are better than his competitors, even though such statement is untrue;
- ✓ For the purpose of saying that his goods are the best in the world or his goods are better than his competitors he can even compare the advantages of his goods over the goods of others;
- ✓ He however, cannot, while saying that his goods are better than his competitors, say that his competitor’s goods are bad. If he says so, he really slanders the goods of his competitors and their goods, which is not permissible.
- ✓ If there is no defamation to the goods or to the manufacturer of such goods no action lies, but if there is such defamation an action lies and if an action lies for recovery of damages for defamation, then the court is also competent to grant an order of injunction restraining repetition of such defamation.

The Hon’ble court also observed in this case that “One can boast about technological superiority of his product and while doing so can also compare the advantages of his product with those which are available in the market. He can also say that the technology of the products available in the market has become old or obsolete. He can further add that the new technology available to him is far more superior to the known technology, but he cannot say that the known technology is bad and harmful or that the product made with the known technology is bad and harmful. What he can claim is only that his product and his technology is superior. While comparing the technology and the products manufactured on the basis thereof, he can say that by reason of the new superior technology available to him, his product is much superior to others. He cannot, however while so comparing say that the available technology and the products made in accordance therewith are bad and harmful.”

Finally, we can safely conclude that the passing off action is applied in unregistered goods and services and in infringement of suit and passing off in both the cases the remedy will be the same. Further, the passing off arises in three cases first when it is injured the claimants good will, secondly in misrepresentation and thirdly in damages, where the position is same like in infringement suit.

7.6 SUMMARY

In this unit we have discussed about the territorial nature of patent rights**,** the infringement of Intellectual Property Rights (IPRs), particularly patent infringements, different elements of patent infringement and the relationship between TRIPS agreement and Free trade. We have also discussed the status of 'Intellectual Property in transit', TRIPS obligations and Indian position regarding the same. Further, we have discussed about the evidentiary problems in action of passing off.

7.7 SUGGESTED READINGS/REFERENCE MATERIAL

BOOKS

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Dr. Wadhera B.L., "Law Relating To Intellectual Property", Published by Universal Law Publishing Co., Edition: IV 2007.

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Mukherjee Sunando, Passing off in Internet Domain Names, Journal of Intellectual Property Rights volume IX, March 2009,

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(1990) 1 AII ER 873.

AIR 1975 DEL 130.

1999 PTC 334(GUJ).

AIR 1965 SC 980.

2000 PTC 297.

1999 PTC 201(DEL).Rediff Communications Ltd vs. cyberbooth AIR 2000 Bom 27.

1999 PTC (19) 741

References

See TRIPS Agreement art. 51. The border measures obligations under TRIPS cover easily detectable forms of copyright and trademark infringements, which custom authorities should be able to identify without the need for technical expertise. Id. art. 51, n.14.

See ACTA Text—Dec. 3, 2010, supra note 60, art. 13. Footnote 4 to Article 13 states: "Where a Party has dismantled substantially all controls over movement of goods across its border with another Party with which it forms part of a customs union, it shall not be required to apply the provisions of this Section at that border." provides: "It is understood that there shall be no obligation to apply the procedures set forth in this section to goods put on the market in another country by or with the consent of the right holder." Finally, says: "The Parties agree that patents and protection of undisclosed information do not fall within the scope of this Section."

See ACTA Draft—Apr. 21, 2010, supra note 57, art. 2.X:1-2.

Its application to patents was, however, unclear. Article 2.X:2 continued

by allowing to exclude certain types of IP infringements if the rights concerned

were inter alia "[protected by [non-product- or sector-specific] [registration] sui

generis systems]." The heavily bracketed text indicated that goods infringing

certain (registration) sui generis rights may be excluded from the scope of ACTA's

border measures. The relevant question then was whether this optional exception

would cover goods infringing patents. While patent rights under TRIPS Article

27(1) must be granted without discrimination to the field of technology and hence

arguably are non-product and non-sector specific, they would normally not be

considered a sui generis system of protection. The term refers to an IP protection

mechanism "of its own kind." It is commonly used for rights in investment bearing

databases outside copyright (for example, see Council Directive 96/9, arts. 7-11,

1996 O.J. (L 77) 20, 21 (EC)) or to systems of plant variety protection outside

patent law. See TRIPS Agreement art. 27.3(b). More recently, certain mechanisms

to protect traditional knowledge and/or related genetic resources have been

referred to as sui generis. See Traditional Knowledge, WORLD INTELL. PROP. ORG.,

http://www.wipo.int/tk/en/tk/ (last visited Mar. 1, 2011). It therefore seems

unlikely that the negotiating parties had patent rights in mind when they allowed

excluding rights protected by certain sui generis systems.

See Anti-Counterfeiting Trade Agreement: Informal Predecisional/

Deliberative Draft art. 2.X:2, Mar. 18, 2010 [hereinafter ACTA Draft—Mar. 18,

2010], available at https://sites.google.com/site/iipenforcement/ acta (follow “Full

Leaked Text Dated Mar. 18, 2010”). The approach chosen also strongly resembles

Article 1 of the BMR. See ACTA Draft—July 1, 2010, supra note 58, art. 2.X:1.

See EU, U.S. to Discuss Differences Over ACTA Scope in Bilateral

Meeting, 28 INSIDE U.S. TRADE, no. 30, July 30, 2010, http://insidetrade.com/

Inside-US-Trade/Inside-U.S.-Trade-07/30/2010/eu-us-to-discuss-differences-overacta-

scope-in-bilateral-meeting/menu-id-710.html (discussing the E.U.’s desire to

broaden the scope of ACTA to protect any infringement of GIs in the same manner

as infringements of trademarks and copyrights). This report notes that the “scope

of the agreement is expected to be a main issue of discussion since both [the

United States and the E.U.] have reached a deadlock on whether products with

geographic indications (“GIs”) should be included in the agreement.” Id. See

generally Jimmy Koo, Comparing ACTA Texts April 2010 v. July 2010, AM. U.

WASH. C. L. PROGRAM ON INFO. JUST. & INTELL. PROP. (Aug. 12, 2010),

http://www.wcl.american.edu/pijip/ go/koo08122010 (discussing the issues

surrounding GIs as a potential deal-breaker).

See Urgent ACTA Communique, supra note 64.

See Press Release, Eur. Comm'n, supra note 63.

See ACTA Draft—July 1, 2010, supra note 58, art. 2.X (stating that parties

may exclude "certain rights other than trademarks, copyrights and GIs" from the

definition of "goods infringing an intellectual property right."). In the ACTA draft

that leaked after the Washington, D.C. round of negotiations, the text remains

unchanged from the July text version. See ACTA Draft—Aug. 25, 2010, supra

note 59, art. 2.X.

ACTA Text—Dec. 3, 2010, supra note 60, art. 13, n.6. The October

2010 version already contained similar language stating “for the purpose of this

Agreement, Parties agree that patents do not fall within the scope of this Section.”

See ACTA Draft—Oct. 2, 2010, supra note 60, art. 2.X n.6.

See ACTA Text—Dec. 3, 2010, supra note 60, art. 5(h).

See id. art. 13; see also discussion infra Part III(A)(4) (providing a more

detailed analysis of this provision).

See Kur & Grosse Ruse - Khan, supra note 35, at 8-14 (explaining that

typically, once rights have become part of a convention, they remain part of the

convention while new rules and rights are added on top of them, strengthening

rights and protections).

See ACTA Text—Dec. 3, 2010, supra note 60, art. 2(1) (emphasis added).

This provision mirrors TRIPS Article 1(1), which is discussed in detail in Part

II(B) above and Part IV below.

Press Release, Eur. Comm’n, supra note 63.

See ACTA Text—Dec. 3, 2010, supra note 60, art. 13.

See discussion supra Part II; see also discussion infra Part IV (discussing

the trade interests in generic drugs and Article 41(1) of the TRIPS Agreement).

See ACTA Text—Dec. 3, 2010, supra note 60, art. 6(1).

This version defines “in-transit” goods as those under “customs transit,”

defined as the “procedure under which goods are transported under customs

control from one customs office to another,” or “transshipment,” defined as the

“procedure under which goods are transferred from the importing means of

transport to the exporting means of transport within the area of one customs office

which is the office of both importation and exportation.” Id. art. 5(f), (i), (n).

See id. art. 16 (“A Party may adopt or maintain procedures with respect to

suspect in-transit goods or in other situations where the goods are under customs

union control.”).

See, e.g., ACTA Draft—Apr. 21, 2010, supra note 57, art. 2.X (extending

to goods “imported, exported, in-transit or in other situations where the goods are

under customs supervision.”); see also id. art. 2.6, ¶ 1 (revealing other

permutations of similar draft language).

Compare id. (“1. Each Party shall provide procedures for import [and intransit]

shipments and [may] [shall] provide procedures for export shipments, by

which right holders may request the competent authorities to suspend release of

suspected counterfeit trademark goods and suspected pirated copyright goods

[goods suspected of infringing an intellectual property right] into free

circulation.”), with id. art. 2.X, ¶ 3 (“[Parties shall provide for the provisions

related to border measures to be applied [at least]in cases of trade mark

counterfeiting and copyright piracy. [Parties may provide for such provisions to be

applied in other cases of infringement of intellectual property rights.]]”). In the

July ACTA text, however, the brackets around the term “in-transit” under Option 1

are removed. See ACTA Draft—July 1, 2010, supra note 58, art. 2.6, ¶ 1 (citing

option 1). The July text contains a new Option 2, favored by the majority of the

negotiating parties, which is limited to counterfeit trademark and pirated copyright

goods, but applies to transit. Id.

ACTA Text—Dec. 3, 2010, supra note 60, art. 16(1)(a)-(b).

Art. 5(i). The current definition of “in-transit goods” appeared first in the

publicly released April 2010 ACTA draft text. See ACTA Draft—Apr. 21, 2010,

supra note 57, art. 2.6, n.23 (referring to the bracketed inclusion of “in-transit”

goods under Option 1 of draft Article 2.6). This definition of “in-transit goods”

also appeared in the July ACTA draft text and the leaked draft text following the

Washington, D.C. round of negotiations. See ACTA Draft—July 1, 2010, supra

note 58, art. 2.6 (defining “in-transit” goods in footnote 18); ACTA Draft—Aug.

25, 2010, supra note 59, art. 1.X (placing the definition of “in-transit” goods in

Article 1.X: Definitions, located in Chapter One, Section B).

ACTA Text—Dec. 3, 2010, supra note 60, art. 5(f).

See ACTA Draft—Jan. 18, 2010, supra note 56, art. 2.6 n.10 (revealing

that Canada, New Zealand, and the United States proposed the inclusion of

"customs transit" and "transshipment" as defined by the Kyoto Convention).

It was doubtful whether all negotiating parties who used the term "intransit"

or referred to goods in transit in more general terms—as the E.U. did in

Art.2.X:1-2 of the April 2010 ACTA Draft—relied on the same definition of

transit in their proposals. See, .e.g., ACTA Draft—Apr. 21, 2010, supra note 57,

art. 1.X:1-2.

See ACTA Draft—Aug. 25, 2010, supra note 59, art. 1.X. However, a

careful reading of the October 2010 ACTA text reveals that the definitions of "intransit

goods," "Customs transit," and "transshipment," contained in Article 1.X,

General Definitions, are not exactly the definitions used in the agreement itself.

See ACTA Draft—Oct. 2, 2010 supra note 60, art. 1.X. Instead, the draft language

in Article 2.X:2 regarding Border Measures uses the phrase "goods in transit or in

other situations where the goods are under Customs control." Id. art. 2.X, ¶ 2

(emphasis added). The December draft addresses the discrepancy, which was most

likely the result of poor legal drafting, by aligning the terminology in Article 16 to

the definitions in Article 5. ACTA Text—Dec. 3, 2010, supra note 60, arts. 5, 16.

See ACTA Text—Dec. 3, 2010, supra note 60, art. 5(n).

ACTA Text—Dec. 3, 2010, supra note 60, art. 16(2). TRIPS, on the other

hand, states: “It is understood that there shall be no obligation to apply such

procedures to imports of goods put on the market in another country by or with the

consent of the right holder, or to goods in transit.” TRIPS Agreement art. 51 n.13;

see also Grosse Ruse - Khan & Jaeger, supra note 48, at 534-35 (opining that

while this may be viewed as some form of implicit allowance to extend border

measures to goods in transit, this view is contested); Kumar, supra note 26, at 515-

17 (discussing the conflicting scholarly interpretation of footnote 13 to TRIPS

Article 51).

ACTA Text—Dec. 3, 2010, supra note 60, art. 2(1).

Art. 6(1); see also discussion infra Part III(A)(3) (discussing the

operation of Article 6(1)).

ACTA Text—Dec. 3, 2010, supra note 60, art. 16(2).

Suggested Readings

51. Terenee P. Stewart(ed.) : The GATT Uruguary Round : A Negotiating History
52. Iver P. Cooper : Biotechnology and Law (1998), Clerk Boardman

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53. David Bainbridge : Software Copyright Law (1999)
54. Sookman : Computer Law (1998)
55. Carlos M. Correa(ed.) : Intellectual Property and International Trade (1998)
56. Sweet and Maxwell : Patent Co-operation Treaty Hand Book (1998)
57. Christopher Wadlow : The Law of Passing-Off (1998)
58. W.R. Cornish : Intellectual Property Law (1999)
59. Special attention should be given to literature of the U.N. System, WIPO and the UNESCO.

7.8 SELF ASSESSMENT QUESTIONS

1. What is a patent infringement? What are the elements of patent infringement?
2. What do you understand by 'In-Transit Goods'? Discuss the Indian position on border measures?
3. What is the scope of ACTA border measures? Discuss the ACTA provisions on border measures?
4. Discuss the relationship between the TRIPS Agreement and free trade?
5. What do you understand by passing off? Why passing off is necessary?
6. How the passing off action arises? Discuss the evidentiary problems in a passing off action?

LL.M. Part-1

Subject: Intellectual property Law

Block-III- Special Problems of Proof of Infringement

Unit-8-THE PROOF OF NON-ANTICIPATION, NOELTY OF INVENTIONS PROTECTED BY PATENT LAW; EVIDENTIARY PROBLEMS IN PIRACY: TRIPS OBLIGATION – REVERSAL OF BURDEN OF PROOF IN PROCESS PATENT

STRUCTURE

8.1 INTRODUCTION

In the previous unit you have learned about the territorial nature of patent rights**,** the infringement of Intellectual Property Rights (IPRs), particularly patent infringements, different elements of patent infringement and the relationship between TRIPS agreement and Free trade. You have also learned about the status of 'Intellectual Property in transit', TRIPS obligations and Indian position regarding the same. Further, you have known about the evidentiary problems in action of passing off.

In the last decade, the application of modern biotechnology for agricultural, ecological and medical purposes has sparked great hopes for the extent to which man can explore and exploit biological resources for his well-being. Simultaneously, the commercial use thereof has led to intense international and multicultural conflicts and debates. These conflicts and debates hinge on the conflicting claims concerning two of the most important 'resources of biotechnology' - genetic material and knowledge. These claims have a proprietary character. The way in which these claims are awarded or rejected determines, to a large extent, the overall freedom of access to and use of genetic material, whether modified or not. These perspectives are interconnected and interactive. This is exemplified by the manner in which they are dealt with in the Convention on Biodiversity (CBD) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The implementation of these treaties determines to a large extent the manner in which the 'global commodity' genetic material, and the knowledge pertaining thereto, can be exploited commercially. Also, it directs the role of the global public domain in innovation, traditional usages of genetic material and sustainable development.

In this unit we will discuss about the proof of non-anticipation and its legislative basis. We will also discuss about the novelty of inventions protected by patent law under the European Patent Convention, TRIPS

obligations, the Convention on Biodiversity (CBD) and procedure regarding onus and burden of proof. Further, we will also discuss the definition and meaning of piracy and national legislation to prevent piracy.

8.2 OBJECTIVES

After reading this unit you will be able to:

- ✓ Understand the concept of non-anticipation and its legislative basis.
- ✓ Understand the meaning of novelty of inventions.
- ✓ Write the different protections of novelty by patent law under the European Patent Convention and TRIPS obligations.
- ✓ Discuss the definition and meaning of piracy and national legislation to prevent piracy.
- ✓ Describe the procedure regarding onus and burden of proof in process patent.
- ✓ Discuss the Initiatives to reconcile TRIPS and the CBD

8.3 THE PROOF OF NON-ANTICIPATION

8.3.1 The Legislative Basis

A patent is valid in the absence of evidence to the contrary. Under the statutory presumption, the party attacking the patent has the onus of proving that the patent is invalid, no matter what the ground of attack may be, on the balance of probabilities. The attributes of novelty, utility and inventive ingenuity or lack of obviousness are all presumed to be present in an invention for which a patent has been granted until the contrary has been shown.

8.3.2 Anticipation

Patent invalidity based on lack of novelty or newness is often called “anticipation”. The statutory definition of “invention” requires that it be “new”. As discussed in greater detail below, an invention is not “new” if the same thing has been done before or described before, publicly. The invention, if not new, is said to have been “anticipated” by the prior art reference.

In Sanofi, Justice Rothstein endorsed a two part test for anticipation. In order to be anticipatory, a single piece of prior art must both:

(a) disclose the invention of the patent in question; and

(b) enable a skilled reader to make the invention using the prior art reference and common knowledge, allowing for some trial and error (non-inventive) experimentation to make it work.

Justice Rothstein stated that the following (non-exhaustive) factors should normally be considered, in accordance with the evidence in each case:

- ✓ "1. Enablement is to be assessed having regard to the prior patent as a whole including the specification and the claims. There is no reason to limit what the skilled person may consider in the prior patent in order to discover how to perform or make the invention of the subsequent patent. The entire prior patent constitutes prior art.
- ✓ 2. The skilled person may use his or her common general knowledge to supplement information contained in the prior patent. Common general knowledge means knowledge generally known by persons skilled in the relevant art at the relevant time.
- ✓ 3. The prior patent must provide enough information to allow the subsequently claimed invention to be performed without undue burden. When considering whether there is undue burden, the nature of the invention must be taken into account. For example, if the invention takes place in a field of technology in which trials and experiments are generally carried out, the threshold for undue burden will tend to be higher than in circumstances in which less effort is normal. If inventive steps are required, the prior art will not be considered as enabling. However, routine trials are acceptable and would not be considered undue burden. But experiments or trials and errors are not to be prolonged even in fields of technology in which trials and experiments are generally carried out. No time limits on exercises of energy can be laid down; however, prolonged or arduous trial and error would not be considered routine.
- ✓ 4. Obvious errors or omissions in the prior patent will not prevent enablement if reasonable skill and knowledge in the art could readily correct the error or find what was omitted."

8.4NOVELTY OF INVENTIONS PROTECTED BY PATENT LAW

Novelty is a patentability requirement. An invention is not patentable if the claimed subject matter was disclosed before the date of filing or before the date of priority if a priority is claimed, of the patent application.

In some countries, such as the United States, Canada, Australia and Japan, a grace period exists for protecting an inventor or their successor in title from authorized or unauthorized disclosure of the invention before the filing date. That is, if the inventor or the successor in title publishes the invention, an application can still be validly filed which will be considered novel despite the publication, provided that the filing is made during the grace period following the publication. The grace period is usually 6 or 12 months. This type of novelty bar is sometimes known as a relative novelty bar. In other countries, including European countries, any act that makes an invention available to the public, no matter where in the world, before the filing date or priority date has the effect of barring the invention from being patented. Examples of acts that can make an invention available to the public are written publications, sales, public oral disclosures and public demonstrations or use. This is known as an absolute novelty requirement.

Local novelty (as is currently the requirement in New Zealand) only regards publications, uses or sales that have taken place within that jurisdiction to be novelty destroying. Local novelty by publication is now largely extinct under New Zealand practice. This leaves only “local novelty by use”, which is rather limited, even to the point of irrelevance. Therefore, to all intents and purposes, New Zealand patent law already appears to operate on a de facto absolute novelty basis. The grace period should not be confused with the priority year defined by Paris Convention for the Protection of Industrial Property. The priority year starts when the first filing in a Contracting State of the Paris Convention is made, while the grace period starts from the pre-filing publication.

8.4.1 Novelty under the United States

In the United States the four most common ways in which an inventor will be barred under Section 102 are:

- ✓ by making the invention known or allowing the public to use the invention; or

- ✓ having the invention published in a fixed medium (such as in a patent, patent application, or journal article); or
- ✓ if the invention was previously invented in the U.S. by another, who has not abandoned, suppressed, or concealed the invention, or
- ✓ if the invention was described in a patent application filed by another, where the application later issues as a US patent.

In U.S. patent law, anticipation occurs when one prior art reference or event discloses all the features of a claim and enables one of ordinary skill in the art to make and use the claimed invention; the claim is then said to lack novelty. The term "features" in this context refers to the elements of the claim or its limitations.

8.4.2 Novelty under the European Patent Convention

Under the European Patent Convention (EPC), European patents shall be granted for inventions which inter alia are new. The central legal provision explaining what this means, i.e. the central legal provision relating to the novelty under the EPC, is Article 54 EPC. Namely, "an invention can be patented only if it is new. An invention is considered to be new if it does not form part of the state of the art. The purpose of Article 54(1) EPC is to prevent the state of the art being patented again."

When assessing novelty, a generic disclosure (in the state of the art, i.e. for instance in a prior art document) does not normally take away the novelty of any specific example falling within that disclosure. On the other hand, "a specific disclosure does take away the novelty of a generic claim embracing that disclosure". For instance, the prior disclosure of the subset "vegetables" takes away the novelty of the wider set "fruits and plants". Or, as two other examples, "a disclosure of copper takes away the novelty of metal as a generic concept, but not the novelty of any metal other than copper, and one of rivets takes away the novelty of fastening means as a generic concept, but not the novelty of any fastening other than rivets."

8.4.3 Novelty

Novelty or newness is the sine qua non of every invention. “Anticipation” is a patent law term of art that means disclosure in the prior art of something substantially identical to the claimed invention.

Conditions for Patentability; Novelty and Loss of Right to Patent

A person shall be entitled to a patent unless ---

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

(d) the invention was first patented or caused to be patented, or was the subject of an inventor’s certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent or inventor’s certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by applicant for patent, or on an international application by anther who has fulfilled the requirements paragraphs (1), (2), and (4) of 35 U.S.C. 371(c) of this title before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant’s invention thereof the invention was made in this country by anther who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

While every proviso of 35 U.S.C. 102, i.e., (a) through (e), recites a condition or circumstance under which a right to patent is lost, provisos (b), (c), and (d) each recite a different circumstance under which a once existing right to a patent is lost. These three provisos are sometimes referred to collectively as "statutory bars". Proof of the existence of a statutory bar in order to invalidate a patent must be clear and convincing evidence. The judgment that something is old or that it is new is subjective or extrinsic. By objective or intrinsic is meant those qualities or attributes which are absolute and do not vary from observer to observer. Novelty is a question of fact.

Prior Art

Determination of anticipation and novelty are made in light of the prior art. Prior art is that fund of information which is available or accessible to the public. "Prior art" is knowledge that is available, including what would be obvious from it, at a given time, to a person of ordinary skill in the art. An inventor is assumed to have full and comprehensive knowledge of the prior art, in legal contemplation. To determine precisely what the law regards as being prior in the prior art, one must return to the requirements imposed by 35 U.S.C 102.

The wording of 35 U.S.C. 102(a) distinguishes an invention between "the applicant" and "others", knowledge in any form possessed only by the applicant or use made only by the applicant not being prior art against such applicant under 35 U.S.C. 102(a). The availability of earlier work as prior art against later-filed patent application can be obviated under the following circumstances:

(1) Where it can be demonstrated that the portion of the disclosure relied upon in the earlier-filed application as "prior art" in the later-filed application is in fact the work product of the identical entity in whose name the later application has been filed, the prima facie art effect of such earlier-filed application can be obviated by the submission of a declaration pursuant to 37 C.F.R 1,131.
(2) Where the earlier-filed and later-filed applications, although they have different inventorship entities, have both been assigned to the same entity and a difference exists between the claims of two applicants which is deemed to be obvious, the issue reduces itself to a question of obviousness double patenting which can be

obviated by the filing of a terminal disclaimer.

8.4.4 Physical Novelty Required for Anticipation.

The physical object or embodiment of that which is sought to be protected by a patent must itself be new, and not merely previously unknown. One who merely explain why or even how a prior art process or apparatus works is not deemed the inventor thereof. The simultaneous application of two fundamental principles, which are that: (1) once subject matter enters the public domain, it remains there forever after and (2) patenable subject matter must distinguish over that that already in the public domain by more than a mere advantage, that is, there must be a physical difference between what already in the public domain and what is sought to be patented. All advantages are inherently in and are incidents of the physical embodiment. One who performs the steps of a process must necessary produce all of its advantages, for these naturally flow from it and are inseparable part of it.

8.4.5 Doctrine of Inherency

Anticipation may be based upon an inference of inherency. Thus a disclosure need not be express but may anticipate by inherency where it would be appreciated by one of ordinary skill in the art. If a claimed invention is inherently disclosed in a prior art reference, that reference can anticipate a claim.

In order for something to be “inherent” in a disclosure it must be the necessary and only reasonable construction to be given to the disclosure, that is, the result claimed must inevitably occur. The mere fact that a certain thing may result from a given set of circumstances is insufficient to prove anticipation. A patent claiming a process inherently performed by old apparatus, and the product inherently produced, is invalid for want of novelty. Inherency is a question of fact.

It should be noted that the inherency of an advantage and its obviousness are entirely different questions. Obviousness cannot be predicted on what is unknown. While structure that differs only slightly from the prior art may not be obvious because of an advantage inherent in such difference,

recognition of a new property of or application for a previously known composition, even when that property or application is unobvious from the prior art, cannot impart patentability to claims to the known composition, because in such case there is no structural difference whatever between the prior art and what is being claimed. Inherency is not established by possibility or probability; for a result to be deemed inherent, it must invariably happen.

The doctrine of inherency frequently comes into play where a mathematical equation to quantitative relationship is claimed. Another application of the doctrine of inherency involves properties inherent in known or existing materials.

To rely on the doctrine of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. The Examiner having doing so, the applicant may be required to show that the prior art lacks the functional characteristics of the subject matter claimed where rejection is made under 35 U.S.C. 102 but not under 35 U.S.C. 103 unless the Examiner has made a case of prima facie obviousness.

8.4.6 Novelty and Anticipation

Patent invalidity based on lack of novelty is often called “anticipation”. To avoid anticipation and satisfy the novelty requirement, the degree of physical difference which must exist between that which is sought to be patented and the prior art need be only slightly. Any degree of physical difference, however slight, invalidates claims of anticipation. As is the case for inventions in any field of technology, assessment of a claimed computer-related invention for compliance with 102 and 103 begins with a comparison of the claimed subject matter to what is known in the prior art.

If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or non-functional descriptive material. Functional descriptive material is a limitation in the claim and must be considered and addressed in assessing patentability under 103. Thus, a rejection of the

claim as a whole under 103 is inappropriate unless the functional descriptive material would have been suggested by the prior art.

Non-functional descriptive material cannot render non-obvious an invention that would have otherwise been obvious. Common situation involving non-functional descriptive material are:

- ✓ a computer-readable storage medium that differs from the prior art solely with respect to non-functional descriptive material, such as music or a literary work, encoded on the medium,
- ✓ a computer that differs from the prior art solely with respect to non-functional descriptive material that cannot alter how the machine functions (i.e., the descriptive material does not reconfigure the computer), or
- ✓ a process that differs from the prior art only with respect to non-functional descriptive material that cannot alter how the process steps are to be performed to achieve the unity of the invention.

Thus, if the prior art suggests storing a song on a disk, merely choosing a particular song to store on the disk would be presumed to be well within the level of ordinary skill in the art at the time the invention was made. The difference between the prior art and the claimed invention is simply a rearrangement of non-functional descriptive material. Any rejection be imposed in an Office action, the Office action should clearly communicate the findings, conclusions and reasons which support them.

8.4.7 Utility

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. The words “useful” and “utility” encompass a spectrum of concepts. The question of utility is considered as a question of fact.

“Useful” versus “How to Use”

The first paragraph of 35 U.S.C. 112 (application for patent --- specification) states:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. Section 112 incorporates with 101.

"Useful" as used in 101 has been construed to include a certain minimum level of safety. A rejection under 35 U.S.C. 101 for lack of utility has been said to be tantamount to a rejection under the how-to-use provision of the enablement clause of the first paragraph of 35 U.S.C. 112. Lack of utility because of inoperativeness (a question of fact) and absent of enablement (a question of law) are closely related grounds of unpatentability. Thus, in a cerebrated opinion, Justice couched the utility requirement in the form of a negative rule.

By useful invention, in the statute, is meant such a one as may be applied to some beneficial use in society, in contradiction to an invention, which is injurious to the morals, the health, or the good order of the society. It is not necessary to establish, that the invention is of such general utility, as to supercede all other inventions now in practice to accomplish the same purpose. It is sufficient, that it has no obnoxious or mischievous tendency, that it may be applied to practical uses, that that so far as it is applied, it is statutory. If its practical utility be very limited, it will follow that it will be of little profit to the inventor; and if it be trifling, it will sink into utter neglect. The law, however, does not look to the degree of utility, it simply requires, that it shall be capable of use, and that the use is such as sound morals and policy do not discountenance or prohibit.

Justice Story's discourse touches upon the shades of meaning implicit meaning in the word "useful". Useful means merely operative, that the invention is capable of some benefit. As far as "technical progress" is concerned, advancement in the art is an indication of non-obviousness. Where utility is proved to exist in any degree, a sufficiency of invention to support the patent must be presumed. The fact that a process may not be advancement in the art may be a simpler process that a prior art process does not necessary make it obvious.

One who appropriates the teachings of a patent may not deny the utility of the invention. Use of a patented device by an accused infringer has long been recognized as an admission of its utility and as creating an estoppel upon the infringer to deny such utility. The commercial success of an invention has been taken as evidence, but not conclusive evidence, of its utility.

8.5 EVIDENTIARY PROBLEMS IN PIRACY

8.5.1 Definition and Meaning of Piracy

Piracy is an act of robbery or criminal violence at sea. The term can include acts committed on land, in the air, or in other major bodies of water or on a shore. It does not normally include crimes committed against persons traveling on the same vessel as the perpetrator (e.g. one passenger stealing from others on the same vessel). The term has been used to refer to raids across land borders by non-state agents.

Piracy is the name of a specific crime under customary international law and also the name of a number of crimes under the municipal law of a number of States. It is distinguished from privateering, which is authorized by national authorities and therefore a legitimate form of war-like activity by non-state actors. Privateering is considered commerce raiding, and was outlawed by the Peace of Westphalia (1648) for signatories to those treaties.

Those who engage in acts of piracy are called pirates. Historically, offenders have usually been apprehended by military personnel and tried by military tribunals.

In the 21st century, the international community is facing many problems in bringing pirates to justice. Two circumstances are supposed to enable the North to conduct its piracy. First, current patent law does not readily allow the recognition of different types of knowledge used in arriving at an invention. Also, the origin of the biological material and the manner in which it was acquired are irrelevant to the patentability of an invention or the rights related to a patent granted. Second, TRIPS has rendered the Northern patent regimes into a global regime, also where biotechnological inventions are concerned.

8.5.2 Traditional knowledge and genetic resources

The claim of cultural piracy is established on the following basis. For a variety of reasons, traditional knowledge can hardly be recognized, let alone rewarded, in present patent procedures. Recognition of traditional knowledge in a patent procedure is hampered by the fact that it is usually not codified, categorized and structured in manners that are common in the Western world. Languages and methodology are completely different from the languages and methods of 'modern science' with which scientists creating biotechnological inventions work.

Hence, it is almost impossible for patent examiners to 'translate' traditional knowledge concepts into those of Western science - and subsequently recognize them in a patent application. Although some traditional knowledge has been described, both by indigenous communities themselves and by Western scientists, it is not yet done in a coherent and structured fashion. The same applies to most databases that contain traditional knowledge.(26) Hence, the information patent examiners would want to investigate is fragmentized and often not reliable. However, even if such information would be more readily accessible, it may just as well not bear any light on the patentability of an invention. There may be a causal relation between the use of traditional knowledge and the invention for which a patent application is filed, but it is likely not to show from the invention. Not only the translation of concepts 'hides' traditional knowledge, but also the fact that highly technical products, such as biopharmaceuticals, are the sum of the parts, and traditional knowledge may be the most indirect one of them.

Therefore, even if traditional knowledge contributed directly to the development of a biopharmaceutical product, it is likely that it would not be recognized as such during the patent procedure. It is likely that the patent office will grant a patent for the invention involved, while it should not, or restrictively, do so because part of it lacks novelty and/or is obvious.

The so-called appropriation of traditional knowledge by means of patenting certain products that partially derive from that knowledge is one side of this problem. Clearly, indigenous communities and representative organizations seem to have possibilities to fight outright unjustified patents. They may act defensively. The other side of the problem may be that they cannot adequately protect their knowledge and the tangible manifestations thereof. They lack offensive measures to protect their interests, as their knowledge and the products deriving there from are either not suited for patenting or are considered to have fallen into the

public domain. The public/private domain paradigm and the manner in which certain information or goods are considered to be public or private is, at least in the field of intellectual property, determined mostly by the notion of 'communication'. This can be exemplified by the definition of 'novelty' in Article 54(1) and (2) of the EPC, according to which publicly communicated information belongs to the state of the art and cannot be patented. This implies that Northern bioindustry generally keeps its knowledge, and certain inventions, secret until it applies for a patent. It is very conscious of the danger of losing its claims, and pursues to make effective use of the law of trade secrets and, ultimately, patent law to safeguard its interests.

Traditionally, indigenous communities have treated their knowledge differently. Although traditional knowledge is often held exclusively as well, that exclusivity does not hinge on the Western concept of communication or secrecy, but rather on attributes of the keeper of the knowledge. For example, shamans and traditional healers may hold and apply particular knowledge exclusively, though not because they themselves developed it or held it secret from other community members, but because they fulfil certain spiritual or cultural requirements.

Therefore, much of the traditional knowledge relevant for the development of biopharmaceuticals has fallen into the public domain. However, even if it has been kept secret and is first communicated publicly upon filing a patent application, it would still not be eligible for patent protection. Traditional knowledge has been developed over generations and in communities over prolonged periods of time. Therefore, it is impossible to identify the individual inventor - which is necessary for patent protection. Often, the communities concerned do not even wish to appoint a representative as such since they feel that the knowledge involved belongs to all and cannot be attributed to an individual. A community patent does not exist, however. Also, other patent requirements prevent traditional knowledge, and certain products deriving there from, from being patented for example, most of the time the innovations concerned are not immediately industrially applicable. It is important, however, that some indigenous communities do not only endeavour to prevent others from appropriating their traditional knowledge through patent law, but do not want to make use of that exclusive proprietary right themselves either. Many indigenous communities do not recognize the concepts of individual ownership, exclusion and competition that underlie Western property law regimes.

The diverse origin of traditional knowledge makes the protection thereof even harder. Cultures and their manifestations - whether they are scientific, spiritual or artistic - are generally accessible, open and dynamic. Like human beings from all cultures, indigenous communities have exchanged much knowledge and many customs over time. Therefore, it is difficult to identify the communities to which the knowledge should predominantly be attributed. The fact that many communities, sharing similar knowledge, reside in different countries further complicates the matter.

A similar situation exists in regard to genetic resources and reflects upon the claim of biopiracy. As stated above, most genetic resources are found in the South - in developing countries with a tropical climate. Presently, the origin of the material used in the development of an invention or the manner in which the inventor acquired it is irrelevant for patentability. Indication of the origin of the material used is only required if it concerns a rare material, which the patent examiner needs to acquire himself to check whether the invention can be repeated (enablement). Consideration 27 of the European Biotechnology Directive states that the geographical origin of biological material must be disclosed in the patent application if the invention deals with such material.

However, this consideration has not been repeated and included in the Directive itself, and can therefore not be applied. Also, Consideration 27 explicitly states that the obligation to disclose the origin of biological materials used in the development of the invention does not affect the examination of patent applications or the validity of the rights related to patents granted. The origin of the tangible materials used in the development of an invention is irrelevant for the patentability of the invention since the latter focuses on the novel intellectual effort, contributing to technological progress. The societal aspects of a particular technological step forward, for example the behaviour of the patent applicant when acquiring the material used in the invention or the danger of application of a certain invention, are deemed irrelevant and are to be regulated by other regimes.

However, even if one is inclined to include considerations about the origin of the material and the manner in which a patent applicant has acquired such in the examination procedure, the legal ramifications thereof would be hard to determine. Should the provider of such material benefit from the invention? If so, how should this be accomplished? One may doubt the basis therefore as the provider did not actually contribute intellectually to the invention. Also, his exclusive claim to the tangible material concerned

may be controversial. The same genetic material is present in many countries. Giving preference to a benefit-sharing claim from one or the other country may lack a legitimate basis.

8.5.3 National legislation to prevent piracy

In the past few years, many developing countries have implemented sui generis regimes for both the offensive and the defensive protection of their genetic resources and the traditional knowledge of their indigenous communities. For example, Costa Rica, Brazil, Peru and India have implemented legislation for that purpose. These statutes have in common that they condition access to genetic resources and traditional knowledge upon the fulfillment of certain requirements, such as prior informed consent of a national office governing the country's biological resources and the indigenous communities involved.

Furthermore, biological samples and knowledge can only validly be transferred if proper benefit-sharing agreements are concluded, allowing the source country and the indigenous communities involved to share in the proceeds deriving from the commercial exploitation of the material or knowledge concerned. The statutes presuppose the existence of intellectual property rights in the materials and knowledge concerned, and often negate the existing public/private domain paradigm. Even the transfer of biological samples or of traditional knowledge does not exhaust the proprietary rights pertaining thereto - the provider usually remains entitled to exploit the object of transfer regardless of any subsequent intellectual property rights of the acquirer. Most importantly, these statutes generally indicate that within the countries concerned no intellectual property rights can be obtained if the aforementioned requirements, such as benefit sharing, are not fulfilled. Sometimes, violating the requirements of these statutes amounts to a criminal offence and may be prosecuted accordingly.

Obviously, these statutes violate TRIPS in various manners, most importantly by negating the distinction between the public and the private domain, adding additional requirements to the patentability of inventions and apparently providing for continuous licenses to the transferors by operation of law. However, these statutes seem to correspond more or less with another treaty which existed before the conclusion of TRIPS - the Convention on Biodiversity (CBD).

8.6 TRIPS OBLIGATION – REVERSAL OF BURDEN OF PROOF IN

PROCESS PATENT

8.6.1 Globalization of intellectual property

The TRIPS was concluded in 1994, in the course of the establishment of the World Trade Organization (WTO). Ratification of TRIPS is a prerequisite for membership of the WTO. Of course, developing countries practically had no choice but to adhere to TRIPS. Their economic development made it absolutely necessary to join the WTO, which allows them to freely trade their products around the world. Hence, they were forced to implement TRIPS in their national legislations. The North insisted on the connection between TRIPS and the WTO as it would enable it to effectively enforce the intellectual property rights pertaining to some of its most important export products, i.e. technology and artistic creations such as medicines and films. At the same time, it is clear that developing countries do not have the means to participate in the 'race to innovation'. The state of their technological and economic development does not allow them to compete with equal arms.

Therefore, the South feels that it is not only confronted with cultural piracy and biopiracy, but that it is even forced to collaborate. It not only finds that its genetic and knowledge resources are appropriated, but that it must even legitimize the 'theft' through granting and enforcing intellectual property rights. In view of this, some of these countries have made national legislation providing measures against the appropriation of those resources through intellectual property law.

8.6.2 Onus & Burden of Proof

The pre-1988 Patent Act provided that a patent is prima facie valid. The presumption was redrafted in the 1985 version of the Patent Act (which came into effect on December 12, 1988) to provide that, "in the absence of any evidence to the contrary", the patent shall be considered valid. It was merely a stylistic change and did not change the substance of the presumption. As with its English counterpart, this section "deals only with the incidence of proof, not with the standard of proof. It shows on whom the burden lies to satisfy the court, and to the degree of proof which he must attain". The presumption applies to all forms of attack on the validity of a patent.

The burden of proving invalidity rests upon the party alleging invalidity. The statutory "presumption" adds little to the onus already resting, in the usual way, on the attacking party. In the context of PM (NOC) proceedings however, the presumption the applicant would otherwise have to prove that its patent is not invalid may shift, due to the statutory presumption, to the respondent to prove that the patent is invalid.

Once the party attacking the patent has introduced evidence, the Court, in considering this evidence and in determining whether it establishes the invalidity of the patent, must not take the presumption into account. The threshold of proof of invalidity is on "the balance of probabilities". It is not the "clear and convincing standard" as it is under US law.

The onus is on the party attacking the patent to put such facts into evidence from which the Court might conclude on the balance of probabilities that the patent is invalid.

Some Courts have said it is not an easy burden to discharge, or that the evidence must be very clear. It cannot be said that the statutory presumption of validity is, as a rule, either easy or difficult to overcome; in some cases, the circumstances may be such that the presumption will be easily rebutted, while, in other cases the same result may be very difficult or even impossible to obtain. The more correct statement of the burden of proof is that it depends on the strength of the evidence in each case. If the evidence proves on a balance of probabilities that the patent is invalid, the presumption is rebutted and is no longer relevant. The question of anticipation is one of fact.

8.6.3 The Convention on Biodiversity: Connecting innovation with conservation

The Convention on Biodiversity (CBD) was concluded in 1993, one year before the conclusion of TRIPS. Its main goals comprise the conservation of biodiversity, sustainable exploitation of its components and the equitable and fair sharing of the benefits deriving there from. Referenced national sui generis regimes are mostly based on a few provisions in the CBD. Most importantly, Article 3 of the CBD states that states have sovereign rights over their biological resources. Article 8(j) of the CBD obliges states to:

Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation

and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

Article 8(j) is related to Articles 15 and 16 of the CBD, which are generally considered to be the 'heart' of the convention. Article 15(1) and (2) repeat that states have sovereign rights over their biological resources insofar as they are the country of origin or have acquired them in compliance with the CBD. Pursuant to Articles 15(4) and (5), access to biological resources is conditioned upon prior informed consent of the source country. Furthermore, Article 15(7) states that the countries involved should provide for a mechanism that allows fair and equitable sharing of the benefits arising from the commercial and other utilization of genetic resources. Article 16 of the CBD concerns access to and transfer of technology. Article 16(2) states that developing countries are to have access to technology under 'fair and most favourable terms', albeit consistent with the 'adequate and effective protection of intellectual property rights'.

Clearly, both bioprospecting activities and the commercialization of the products resulting therefrom - among other things by means of intellectual property law protection - are subjected to both TRIPS and the CBD. It is the interface between these treaties that determines the manner in which various commercial and other interests in genetic resources and various types of knowledge can be safeguarded. Nevertheless, it is clear that the CBD and TRIPS are not easily implemented fully at the same time. Some of their provisions do not seem to correspond or are even outright in conflict with each other. For example, in principle, the exclusive rights of the patentee (Article 28 of TRIPS) would not allow 'fair and equitable' benefit-sharing (Articles 15 and 16 CBD).

Nevertheless, and on a general level, both the CBD and TRIPS allow the consideration of interests that, strictly speaking, fall outside their scope. Hence, Article 16 of the CBD explicitly states that intellectual property rights should be recognized and respected. Similarly, Article 7 of TRIPS emphasizes one of the underlying aims of the global intellectual property law regime:

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.

Moreover, Article 31 of TRIPS provides for granting compulsory licenses if the potential licensor has unsuccessfully made reasonable efforts to acquire such a license from the patentee, or a situation of national emergency exists. In my opinion, it is from these ambivalent and unclear interfaces that a fully integrated international bioprospecting regime should be developed.

8.6.4 Initiatives to reconcile TRIPS and the CBD

Several international governmental organizations ('IGOs') have taken initiatives to that extent; however, to discuss them falls outside the scope of this paper. Briefly, the characteristics and aims of the most relevant initiatives - those taken by the World Intellectual Property Organization (WIPO) and the Secretariat of the CBD - will be considered. WIPO and the Secretariat of the CBD - through its working groups and expert panels - work closely together in pursuing to integrate the two instruments and to reconcile some of the interests involved.

WIPO has conducted an extensive fact-finding mission, to inquire into possible means for the protection of the interests of traditional knowledge holders. Clearly, most manifestations of traditional knowledge cannot be protected pursuant to current intellectual property law. Therefore, WIPO suggests to develop of a sui generis regime. Its most important requirements would be that it concerns documented and concrete knowledge with which the applying community has a cultural association. Rightholders would have the right to prevent the reproduction and fixation of literary and artistic expressions, and the exploitation of technical elements.

Although sui generis protection for traditional knowledge may solve some of the conflicts, many problems remain, and further study is required. It would be good to clarify the relation of such a regime with existing intellectual property law, delineate the subject matter, develop methods to identify the proper communities, monitor infringements and mechanisms for enforcement and provide sufficient legal certainty given the dynamic nature of the knowledge protected. Also, the proposed sui generis regime would not address non-economic interests in the subject matter, which, as was noted above, is of great importance to the communities involved.

Another part of the WIPO initiative is aimed at allowing patent examiners to consider traditional knowledge when they inquire into the novelty and non-obviousness of inventions. For this purpose, WIPO has started an experiment with the Traditional Knowledge Digital Library, which in the future could be integrated in its Intellectual Property Digital Libraries. The Traditional Knowledge Digital Library is to provide concise, categorized and standardized information on prior traditional knowledge and to allow patent examiners to apply the novelty and non-obviousness requirements accurately. Whilst increasing the chance that appropriation of traditional knowledge will be noticed during patent procedures, this initiative has one important downside. It puts the traditional knowledge concerned in the public domain, disabling the communities concerned even more in their attempt to obtain protection offensively.

Also the working groups and expert panels of the CBD, pursuing to pave the road for implementation, have made considerable efforts. A major achievement is the conclusion of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization in 2002. The Bonn Guidelines may give providers of genetic material and/or knowledge and the acquirers and users thereof directions in the drafting of agreements that comply with both the CBD and TRIPS. These so-called Material Transfer Agreements are to safeguard ethical and users' interests of indigenous communities, to regulate the acquisition and enforcement of intellectual property rights in common consent, provide accurate descriptions of the genetic material and related traditional knowledge concerned and to specify the ways in which such may be exploited commercially (Articles 42-44 A). Pursuant to Articles 44-50 A, Material Transfer Agreements are also to provide specified ways of benefit-sharing.

However, the Bonn Guidelines go further than providing suggestions for the contents of Material Transfer Agreements only. They also propose to link directly the patentability of an invention consisting of or made by using of genetic material and/or traditional knowledge, to prior informed consent of provider countries and/or indigenous communities and fair and equitable benefit-sharing (Articles 1 and 2 C). Clearly, several of the referenced sui generis regimes in the South already provide for these additional requirements for patentability.

Despite the steps made by the promulgation of the Bonn Guidelines, several key problems remain. The competence of indigenous communities and provider countries with respect to the traditional knowledge and genetic material subjected to the Material Transfer Agreements remains

uncertain. As indicated above, this uncertainty derives from the diverse origin of both genetic material and traditional knowledge. This will directly affect the validity of the agreements and raises the question whether courts of law will be inclined to uphold and enforce them. Also, the manner in which the ethical interests of communities should be aligned with the enforcement of intellectual property law pursuant to TRIPS remains unclear.

Furthermore, although the rights and obligations in regard to the initial knowledge and material may be specified in the agreements, the legal ramifications thereof for derived inventions and products are not articulated. In regard of the purported additional requirements for patentability - prior informed consent and benefit sharing - questions remain as well. What would be the extent of these requirements in view of the indirect relation between initial material and knowledge, and the eventual invention (end product)? When are the rights of the provider countries and communities exhausted? And what is the legal status of these requirements? Are they formal or substantive ones, i.e. affecting the validity of patents?

Nevertheless, several botanical gardens, controlling a lot of the ex situ genetic material originating in developing countries, adhere to the Common Policy Guidelines for Participating Botanical Gardens that correspond with important elements of the Bonn Guidelines.

Also, collaborations between public and private participants in bioprospecting activities have led to grassroots initiatives through which some of the interests concerned may be reconciled. For example, the projects of the International Cooperative Biodiversity Group (ICBG) aim to conduct bioprospecting activities in a variety of developing countries, among which Peru and Surinam, in compliance with Articles 8(j), 15 and 16 of the CBD. The ICBG consists of universities, companies, indigenous communities' representative organizations and national governmental institutes, both from the North and the South. By means of a combination of contractual instruments, such as prospecting, transfer of know-how, and trade secret agreements, and the sharing of intellectual property rights eventually obtained, the ICBG pursues to integrate both the CBD and TRIPS.

Nevertheless, the ICBG projects are severely criticized, mostly because they do not address the non-economic importance of traditional knowledge. Also, from a commercial perspective the relatively low royalty

rates and other financial benefits awarded to developing countries and indigenous communities have led to complaints.

8.7 SUMMARY

In this unit we have discussed about the proof of non-anticipation and its legislative basis. We have also discussed about the novelty of inventions protected by patent law under the European Patent Convention, TRIPS obligations, the Convention on Biodiversity (CBD) and procedure regarding onus and burden of proof. Further, we have also discussed the definition and meaning of piracy and national legislation to prevent piracy.

8.8 SUGGESTED READINGS/REFERENCE MATERIAL

References

Apotex Inc. v. Sanofi-Synthelabo Canada Inc., 2008 SCC 61 at para. 28.

Synthon B.V. v. SmithKline Beecham plc, [2006] 1 All E.R. 685, [2005] UKHL 59 per Hoffmann L.J.

s. 45, Patent Act R.S. 1985, c. P-4 (Every patent granted under this Act shall be issued under the signature of the Commissioner and the seal of the Patent Office, shall bear on its face the date on which it is granted and issued and shall thereafter, in the absence of any evidence to the contrary, be valid and avail the grantee and his legal representatives for the term mentioned therein.)
(Beloit Canada Ltd. v. Valmet OY (1986), 8 C.P.R. (3d) 289
Apotex Inc. v. Sanofi-Synthelabo Canada Inc., 2008 SCC 61 at para. 37.

This happened with the notorious neem tree patents of W.R. Grace Inc. It concerned the Indian plant Azadirachta indica, locally known as the Sarva-roga nivarini. This plant has been used by Indian farmers and traditional healers for thousands of years, and seems to have characteristics that are useful both agriculturally and medically. W.R. Grace received several patents on the plant and certain of its compounds and derivative products, and enforced its patent proactively. Several groups of 'traditional users' in India were threatened with infringement suits and ordered to halt the commercial exploitation of the plant. Only after prolonged battles in the media and before the EPO, one of W.R. Grace's European patents (no. EP 436 257 B1) was revoked because of lack of novelty. The corresponding US patent, no. 512,4349, however, was sustained. See

hereon G. Dutfield, Intellectual Property Rights, Trade and Biodiversity, London: Earthscan, 2000, pp. 65-67.

In Europe, for example through Article 99 EPC, opposition to the patent, among other things for lack of novelty.

P. Drahos and J. Braithwaite, 'Intellectual Property, Corporate Strategy, Globalisation: TRIPS in Context', Wis. Int'l L.J. (20) 2002, p. 451. Drahos and Braithwaite analyse the manner in which large Western corporations have become dependent on intellectual property law and tailor their commercial activities and conduct accordingly.

On the difficulties of offensively protecting traditional knowledge and related products through patent law, see generally N. Roht-Arriaza, 'Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities', Mich. J. Int'l L. (17), 1996, pp. 919-965 and F.W. Grosheide and J.J. Brinkhof (eds.), Intellectual Property Law: Articles on the Legal Protection of Cultural Expressions and Indigenous Knowledge, Antwerp [etc.]: Intersentia, 2002 (Molengrafica Series, 13).

See The Crucible Group II, Seeding Solutions: Options for National Laws governing Access to and Control of Genetic Resources, vol. 2, Rome: IPRC-IPGRI, 2001; J. Boyle, Of Shamans, Software and Spleens ,Cambridge, Mass.: Harvard University Press, 1996; D. Posey and G. Dutfield, Beyond Intellectual Property, Ottawa: International Development Research Centre, 1996. This is also expressed in various statements made by indigenous communities and their representatives. See the Statement from the International Workshop on Indigenous Peoples and Development, 1997; the Sabah Statement on the Protection and Conservation of Indigenous Knowledge, 1995; the Suva Statement on Indigenous Peoples' Knowledge and Intellectual Property Rights, 1995; the Statement from the COICA/UNDP Regional Meeting on Intellectual Property Rights and Biodiversity, 1994; the Julayinbul Statement on Indigenous Intellectual Property Rights, 1993; Kari-Oca Declaration and Indigenous Peoples Earth Charter, 1992; Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples, 1992; the Declaration of Principles of the World Council of Indigenous Peoples, 1984; availabe at <http://users.ox.ac.uk/~wgtrr/decin.htm>. These declarations have in common that they consider knowledge, land and natural resources, such as genetic material, to be inseparable. Indigenous communities have responsibilities for their natural environment which relate to 'guardianship' or 'custodianship' and are not considered to be

rights that could be alienated or otherwise exploited for one's individual benefit, like a property right.

On the natural exchange between cultures, see R.J. Coombe, 'The Properties of Culture and the Possession of Identity: Postcolonial Struggle and the Legal Imagination' in: B. Ziff and P.V. Rao (eds.), Borrowed Power: Essays on Cultural Appropriation, New Brunswick: Rutgers University Press, pp. 74 ff. Attempts to solve these problems have been made, for example by the establishment of representative organizations, which would be entitled to decide upon transfer and the future commercial use of the knowledge and would divide the proceeds thereof to the communities they represent; supra note 31.

See, e.g., Article 27 TRIPS. Patents can be granted for inventions in all areas of technology, and regardless of the location of invention and whether components thereof are imported or not.

WIPO/GRTKF/IC/4/11, p. 27; WIPO/BIOT/99/1; WIPO/SCP/3/11, §208.

European Council Directive 98/44/EC, 1998 OJ L 213, pp. 13-21.

See, e.g., the Convention on the International Trade in Endangered Species of Wild Fauna and Flora, 1973 (CITES). CITES regulates the import and export of endangered species; available at <http://www.cites.org>. On the stance that patent law is not the appropriate instrument to deal with all sorts of societal aspects of inventions, see e.g. R. Crespi, 'Patenting and Ethics: A Dubious Connection', J. Pat. & Trademark Off. Soc'y (85) 2003, p. 47; U. Schatz, 'Patentability of Genetic Engineering Inventions in EPO Practice', Int'l Rev. Indus. Prop. & Copyright L. (1) 1998, p. 2. But see, e.g., Roht-Arriaza, 'Of Seeds and Shamans', supra note 30, pp. 942-944.

Cf. J. Vogel, 'The Successful Use of Economic Instruments to Foster Sustainable Use of Biodiversity: Six Case Studies from Latin America and the Caribbean', Biopolicy Journal (2) 1997, pp. 5-7. Vogel analyses among other things the relation between the lack of scarcity of genetic resources and the economic valuation thereof in benefit-sharing agreements.

The grace periods that were granted to certain developing countries pursuant to Articles 65 to 67 TRIPS are expired now, or about to expire, or are, for most countries, not applicable given the exclusion of pharmaceuticals in Article 70(8) and (9). The Declaration on the TRIPS Agreement and Public Health ('Doha declaration'), allowing further

postponement to 2016, is only applicable to the least developed countries. WT/MIN(01)/DEC/2, 20 November 2001.

For an extensive overview of the circumstances leading to the conclusion of TRIPS, see, among others, Drahos and Braithwaite, 'Intellectual Property', supra note 29, and S. Sell, 'Post-TRIPS Developments: The Tension between the Commercial and Social Agendas in the Context of Intellectual Property', Fla. J. Int'l L. (14) 2002, pp. 193 ff.

Machlup already concluded that developing countries should not implement intellectual property law regimes. See F. Machlup, An Economic Review of the Patent System, Washington: US Government Printing Office, 1958. See also C. Juma, 'Intellectual Property Rights and Globalisation: Implications for Developing Countries', Center for International Development, Harvard University, 1999 (Science, Technology and Innovation Discussion Paper No. 4), and J. Lerner, 'Patent Policy Innovations: A Clinical Examination, 53 VNLR (53) 200, pp. 1841 ff.

Costa Rica implemented the Ley de Biodiversidad, A.L. No. 7788 (1998), available at <http://www.grain.org/brl/costarica-leybiodiversidad-1998.cfm>; Brazil implemented its Ley PM 2.186-16, 2001, available at <http://www.planalto.gov.br>; Peru implemented the Ley sobre la conservación y approvechamiento sotenible de la diversidad biológica, C. no. 26839, 2002, available at <http://www.indecopi.gob.pe>; India implemented the Biological Diversity Act, B. 93/2000, 2002, available at <http://www.nifindia.org>.

The Brazilian statute illustrates this. Recently, a German national was suspected of committing biopiracy, and was arrested in Brazil. M. Astor, 'German Man Arrested in Brazil Accused of Biopiracy', Associated Press, 4 September 2003.

See, generally, on the interface between the CBD and TRIPS S.R. King et al., 'Biological Diversity, Indigenous Knowledge, Drug Discovery and Intellectual Property Rights: Creating Reciprocity and Maintaining Relationships', Journal of Ethnopharmacology (51) 1996; Ch. McManis, 'The Interface between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology', WAULQ (76) 1998, pp. 255-279.

Also, the Preamble and Article 8 of TRIPS emphasize the importance of social and public interests and show that this instrument is not narrowly

tailored to trade issues only. It is noted, however, that these provisions may factually not offer developing countries means to redress certain effects of TRIPS. Past conflicts about the implementation of TRIPS caused the US to consider the imposition of severe trade sanctions on the developing countries that allegedly were not fulfilling their international obligations, e.g. Argentina, Brazil, Thailand and South Africa. See, e.g., K. Maskus, Intellectual Property Rights in the Global Economy, Institute for International Economics, 2002, p. 178, available at <http://www.iie.com> and E. 't Hoen, 'TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha', Chi. J. Int'l L. (3) 2002, p. 2. The North thus has an effective tool enabling it to force developing countries to comply with its wishes, perhaps sometimes even when the latter do not have to comply strictly pursuant to TRIPS or other international instruments.

Other IGOs addressing the issues related to the interface between CBD and TRIPS are (with reports and keywords): WTO (IP/C/W/195; IP/C/W/228; WT/GC/W/233; IP/C/M/32 (§128); IP/C/M/33 (§121); IP/C/W/347/Add.1; IP/C/W/370; trade, medicines); UNCTAD (TD/B/COM.1/EM.13.3 (§17); trade, development); FAO (CPGR/91/12' CPGR-6-95/8; CGRFA-Ex3/96/LIM/2; CGRFA-Ex5/98/inf.1Annex; CGRFA-Ex8/99/8'CPGR-BSP1,2,4 and 8; food, agriculture, genetic resources); UNESCO (CLT-2002/CONF.203/5; CLT-2002/CONF.203/3 (and Rev.); CLT-2002/CONF.205/5; CLT-2003/CONF.205/5; culture, natural sciences, traditional knowledge); WHO (EB111.R12/2003; WHO/EDM/TRM/2002; EB87.R24/1991; WHA41.19/1988; traditional medicine).

See WIPO, Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge (1998-1999), Intellectual Property Needs and Expectations of Traditional Knowledge Holders, Geneva, April 2001. See also UNEP/CBD/WG-ABS/1/4, p. 8.

WIPO, Report on Fact-Finding Missions, p. 226.

WIPO/GRTKF/IC/4/8, pp. 22-31.

WIPO, Report on Fact-Finding Missions, p. 217.

WIPO/GRTKF/IC/2/6, p. 26. The database is available at <http://www.wipo.int/globalissues/databases/tk/index>.

See UNEP/CBD/COP/6/20 and COP Decision VI/24, available at <http://www.biodiv.org/decisions/default.asp?m=cop-06&d=24>.

For a national initiative to reconcile both treaties in the user country Belgium, see G. Van Overwalle, 'Belgium Goes Its Own Way on Biodiversity and Patents', EIPR 2002, p. 233.

Available at <http://www.kew.org/conservation/principles.html>. Botanical gardens from around the world followed these guidelines. Thus far, however, no Dutch botanical garden participates.

See <http://www.nih.gov/fic/programs/icbg.html> and J.P. Rosenthal, The International Cooperative Biodiversity Program: A Benefit-Sharing Case Study for the Conference of the Parties to the Convention on Biological Diversity, available at <http://www.biodiv.org./doc/case-studies/default.aspx>.

See, e.g., interview with J. Martínez Alier, Deuda ecológico y biopiratería, 2002, available at <http://www.grain.org/sp/publications/biodiv32-5-entrevista.cfm>.

The King v. Uhlemann Optical Co., 11 C.P.R. 26 at p. 45, [1950]

Diversified Products Corp. v. Tye-Sil Corp. (1991) 35 C.P.R. (3d) 350 (F.C.A. per Decary J.A.) at pp. 357-358.

Blyth v. Blyth, [1966] 1 All E.R. 524 at p.535, per Lord Denning; quoted in Rubbermaid (Canada) Ltd. v. Tucker Plastic Products Ltd. (1972) 8 C.P.R. (2d) 6 (F.C.T.D. per Pratte J.) at p.14.

McPhar Engineering Co. of Canada Ltd. v. Sharpe Instruments Ltd. (1960), 35 C.P.R. 105 (Ex. Ct. per Thorsen P.) at p. 129; Unipak Cartons Ltd. v. Crown Zellerback Canada Ltd. (1960), 33 C.P.R. 1 (Ex. Ct. per Thorsen P.); Lovell Manufacturing 60 v. Beatty Bros. Ltd. (1962) 41 C.P.R. 18 (Ex. Ct. per Thorsen P.) at p. 44; quoted with approval in Diversified Products Corp. v. Tye-Sil Corp. Ltd. (1987), 16 C.P.R. (3d) 207 at para. 42, p. 229 (F.C.T.D.), affirmed (1991), 35 C.P.R. (3d) 350 (F.C.A.).

McPhar Co. v. Sharpe Instruments (1960), 21 Fox Pat. C. 1 at p. 28;

Beecham Canada Ltd. v. Procter & Gamble Co. (1982) 61 C.P.R. (2d) 1 (F.C.A. per Urie J.A.) at p. 24; Wellcome Foundation Ltd. v. Apotex Inc. (1991) 39 C.P.R. (3d) 289 (F.C.T.D. per McKay J.) at p. 336.

Merck Frosst Canada Inc. v. Canada (Minister of National Health and Welfare) (1994), 55 C.P.R. (3d) 302 (F.C.A. per Hugessen J.A.) at p. 319.

DeFrees and Betts Machine Co. v. Dominion Auto Accessories Ltd. 25 Fox Pat. C. 58 (Exchequer Court of Canada per Noel J.) at p. 79 ; Windsurfing Int'l Inc. v. Les Entreprises Hermano Ltée (1982), 69 C.P.R. (2d) 176 (F.C.T.D.) at p. 181.

Diversified Products Corp. v. Tye-Sil Companies Ltd. (1987),16 C.P.R. (3d) 207 per (F.C.T.D. Cullen J.) at p. 229; Diversified Products Corp. v. Tye-Sil Corp. (1991) 35 C.P.R. (3d) 350 (F.C.A. per Decary J.A.) at p. 359.

Windsurfing Int'l Inc. v. Les Entreprises Hermano Ltée (1982), 69 C.P.R. (2d) 176 (F.C.T.D.) at p. 181; Hy Kramer Canada Ltd. et al. v. Lindsay Specialty Products Ltd. (1986) 9 C.P.R. (3d) 297 (F.C.T.D. per Rouleau J.) at p. 303.

Diversified Products Corp. v. Tye-Sil Corp. (1991), 35 C.P.R. (3d) 350 (F.C.A.) at p. 359 quoting Rubbermaid (Canada) Ltd. v. Tucker Plastic Products Ltd. (1972) 8 C.P.R. (2d) 6 (F.C.T.D. per Pratte J.) at p.14.

DeFrees and Betts Machine Co. v. Dominion Auto Accessories Ltd. 25 Fox Pat. C. 58 (per Noel J.) at p.79 (Exchequer Court of Canada)

Suggested Readings

60. Terenee P. Stewart(ed.) : The GATT Uruguary Round : A Negotiating History
61. Iver P. Cooper : Biotechnology and Law (1998), Clerk Boardman
Callaghan, New York
62. David Bainbridge : Software Copyright Law (1999)
63. Sookman : Computer Law (1998)
64. Carlos M. Correa(ed.) : Intellectual Property and International Trade (1998)
65. Sweet and Maxwell : Patent Co-operation Treaty Hand Book (1998)

66. Christopher Wadlow : The Law of Passing-Off (1998)
67. W.R. Cornish : Intellectual Property Law (1999)
68. Special attention should be given to literature of the U.N. System, WIPO and the UNESCO.

8.9 SELF ASSESSMENT QUESTIONS

9. What is non-anticipation? Discuss the legislative basis for the proof of non-anticipation?
10. What is novelty of invention? Discuss the novelty under the European Patent Convention?
11. What do you understand by doctrine of inherency?
12. Explain the meaning of piracy? Discuss the provisions of national legislation to prevent piracy?
13. Describe the TRIPs obligations pertaining to the reversal of burden of proof in process patent.
14. What do you understand by CBD? Discuss the initiatives to reconcile TRIPS and the CBD?

LL.M. Part-1

Subject: Intellectual property Law

Block- III- Special Problems of Proof of Infringement

Unit-9- : NEED AND SCOPE OF LAW REFORMS

STRUCTURE

9.1 INTRODUCTION

In the previous unit you have read about the proof of non-anticipation and its legislative basis. You have also discussed about the novelty of inventions protected by patent law under the European Patent Convention, TRIPS obligations, the Convention on Biodiversity (CBD) and procedure regarding onus and burden of proof. Further, you have also discussed the definition and meaning of piracy and national legislation to prevent piracy.

Before the TRIPS agreement, intellectual property protection laws were covered under a patchwork of legislation varying from country to country. Under TRIPs, a uniform set of patent and copyright criterion relating to intellectual property protection has been established throughout the world. But the TRIPs agreement fails to strike a balance between the rights of the IPR holders and the rights of the users (society), with disproportionate weighting on the former. Furthermore, there is an inherent contradiction

between the philosophy of free and low-cost movement of goods and services – upon which the multi-lateral trading system is based – and the monopolistic restrictions imposed under the TRIPs.

In this unit we will discuss about the need and scope of law reforms in intellectual property rights particularly patent law in India.

9.2 OBJECTIVES

After reading this unit you will be able to:

- ✓ Understand the concept of Intellectual Property Rights Regimes
- ✓ Explain need of law reforms in Intellectual Property Rights laws
- ✓ Describe the wealth of nature, biodiversity and Food Security in Asia
- ✓ Understand relation between food security and the TRIPs
- ✓ Discuss the 2005 Amendments to Indian Patent Act, 1970
- ✓ Describe the sweeping changes to the Patent Prosecution System
- ✓ Ambiguities in the new law

9.3 NEED OF LAW REFORMS

9.3.1 Intellectual Property Rights Regimes

Before the TRIPS agreement, intellectual property protection laws were covered under a patchwork of legislation varying from country to country. During the recession in the late 1980s, and facing increasing technological competition from South East Asian countries, the US government placed IP issues at the forefront of their agenda in approaching the GATT Uruguay Round negotiations. The US even threatened to boycott these negotiations if its demands for some kind of international legislation governing intellectual property rights were not met. The US favoured inclusion of IP issues into the World Trade Organization (WTO) because

this was the only mechanism that would ensure member states could be effectively sanctioned if they failed to comply with international IPR laws.

Developing countries were initially very reluctant to develop any internationally-binding IPR agreement. Their primary concern was, and still is, that these legal devices would enable industries from the North to appropriate and privatize the wealth of biodiversity that constitutes the basis for food security and health care for millions in their countries. They were also concerned that such measures would disrupt the cultural and economic fabric of traditional societies.

Under TRIPs, a uniform set of patent and copyright criterion relating to intellectual property protection has been established throughout the world. This system currently obliges WTO members to grant titles to "inventors" of micro-biological processes, micro-organisms and plant varieties. Under article 27.3(b) of the TRIPs, countries must "…provide for the protection of plant varieties either by patents or by an effective sui generis system or any combination thereof". This sui generis system would be based upon an internationally recognized system of PBRs — plant breeders rights; or PVPs — plant variety protection measures. There is, however, a clause under Article 27.2 which makes allowances for patent exclusions where necessary to protect "…human, animal or plant life or health or to avoid serious prejudice to the environment…".

The United States is trying to get Southern governments to accept the sui generis guidelines lain down by the Geneva-based Union for the Protection of New Varieties of Plants (UPOV) as the best way to fulfill their obligations under TRIPs. The UPOV system operates under two conventions –one set up in 1978 and the other established in 1991. Under the original UPOV statement, the South's biodiversity was understood to be part of the heritage of mankind, and therefore freely available to all for scientific or commercial use. This allowed private interests such as multi-national pharmaceutical and agri-business enterprises to plunder the South's genetic material without compensation. These corporations could then develop an "improved" variety and claim property rights on the basis of having made an "invention". Having done this, the "free heritage of mankind" plundered from the fields and forests of local communities could be sold back to them as a commodity.

Both UPOV conventions effectively give protection only to the commercial breeding sector, and ignore the rights of the millions of farmers who have been engaged in seed breeding and development for generations. The innovative contribution of local communities is ignored altogether. Unlike its predecessor, UPOV 1991 also gives exclusive rights of sale and reproduction to the patent holder, denying farmers the rights to replant and exchange seeds. In fact, many critics point out that the entire regulatory process under UPOV reflects a trend of ever-greater protection of the interests of commercial plant-breeders and fewer and fewer rights for traditional farmers. Critics argue that if developing countries enter into the UPOV 1978 convention they will, according to the Crucible Group, be entering "…a political and policy treadmill leading inevitably to UPOV 1991 and then onward until UPOV is indistinguishable from the most monopolistic elements of the utility patent system".

There have been attempts to redress the imbalance between plant breeders rights versus farmers' rights, namely under international institutions such as the FAO and the Convention on Biological Diversity. These bodies have sought to ensure that local communities role as developers and conservers of plant genetic resources is recognized, and have stated that farmers should share in the benefits of new varieties developed from plants in their fields. Still, though, the role of indigenous peoples as nurturers of plant biodiversity is generally not appreciated. In the words of the Crucible Group Crucible Group: "That indigenous peoples inhabit the most diverse fields and forests of the world are sometimes viewed as both coincidental and unfortunate. That a correlation could exist between the uses made by people of biological diversity and the availability of that diversity is seldom considered." This all too common perspective means that the sentiments expressed within the Biodiversity Convention are by and large overridden by other international agreements, such as UPOV, that favour commercial interests, under the misguided and frankly arrogant notion that in the modern world, it is private companies that are the true innovators of plant diversity.

9.3.2 The Need of Reforms

The TRIPs agreement fails to strike a balance between the rights of the IPR holders and the rights of the users (society), with disproportionate weighting on the former. Furthermore, there is an inherent contradiction between the philosophy of free and low-cost movement of goods and services – upon which the multi-lateral trading system is based – and the monopolistic restrictions imposed under the TRIPs.

Many DNGOs are therefore calling for the removal of article 27,3(b) from the TRIPs, or for entire the TRIPs agreement to be removed from the WTO. At a very minimum, the following reforms must be addressed in order to give developing countries the ability to address the interests of small farmers and food security:

A freeze in any further tightening of standards within the TRIPs agreement, and an extension to the conversion period allotted to developing countries under the initial agreement. This will allow countries time to consider a range of ideas related to developing sui generis legislation that would be inclusive of the rights and needs of small farmers and indigenous peoples.

Under the principle of national sovereignty, no country should be obliged to adopt an externally-imposed IP system affecting rights to their own plant-genetic resources. Instead they should be free to develop alternative approaches for the stimulation of innovations that are most appropriate to the country's needs, capacities and priorities. To ensure the full and fair participation of farmer and people's organizations in the review of the TRIPs agreement, and in the design of any subsequent sui generis IPR systems. To bring the Agreement into line with international objectives under the Convention on Biological Diversity (these are: the conservation of biological diversity; the sustainable use of its components; and the fair and equitable sharing of the benefits arising out if the utilization of genetic resources).

9.4 SCOPE OF LAW REFORMS

9.4.1 The Wealth of Nature

Most of the world's plant biodiversity is found in the South. Genetic resources are primarily found in developing countries with a tropical climate, such as Brazil, Peru and Costa Rica. They are commonly referred to as **'the South'**. Biodiversity is largest in these countries - the variety of genes, organisms and ecosystems. Throughout history, this wealth of flora has been regarded as the common property of local communities. Traditional societies have both thrived on and nurtured this diversity, relying upon it as the basis for their food, medicine, clothing, tools and building materials. Thus, while less then 1% of this enormous biological diversity has been documented by modern science, a tremendous pool of information has been accumulated through the cultural knowledge of indigenous peoples.

The wealth of genetic material and the intimate cultural knowledge of the properties of plant species amongst local populations has meant that an estimated 83% of efforts to locate and exploit new species — a process known as bio-prospecting — occurs in the South. Of the active ingredients in modern prescription drugs, approximately three-quarters came to the attention of researchers because of their use in traditional medicines in the Majority World. The current value of the world market for medicinal plants derived from materials utilized by indigenous communities is estimated at $43 billion annually. Similarly, the value of crop varieties developed by indigenous communities to the modern seed industry is estimated at $15 billion a year. There are also enormous profits generated from the use of countless other plants found in indigenous communities which now go into the manufacturing of fabrics, perfumes, sweeteners and cosmetics.

9.4.2 Food Security and the TRIPs

The implications of the TRIPs agreement and article 27.3(b) in particular, are very worrying in terms of food security. At the moment, between 15%-20% of the world's food is grown by small farmers, feeding at least 1.4 billion people. These farmers save their seeds after each harvest for replanting the following season. If developing countries adopt a plant breeder's rights system such as UPOV 1991 under the TRIPs agreement, they will effectively be criminalizing the practice of seed saving. Legal contracts drawn up by the seed company will force farmers to purchase their seed year after year, a requirement that would raise farmers' costs and drive millions off the land. In a statement to EU Ministers, a coalition of Southern NGOs warned that such restrictions would "… create dependency where there was previously independence; force farmers to pay for what was previously free and theirs; and reduce farmers increasingly to the status of contracted labourers for corporations".

With new genetic technologies being developed apace, sweeping claims to patents for "invented" life forms are constantly emerging over both high-value commercial crops and staple food varieties. The patenting of certain traits — such as disease resistance or increased yields — or plant genes may subject the production and marketing of important crops to monopolistic controls. A plant protection system such as UPOV 1991 will allow seed companies to exact high royalties, and could mean that traditional farmers lose their rights to cultivate their own landraces. An international IP system for plant breeders is therefore certain to increase corporate control over agriculture in the South, and over the world food system as a whole.

The plant variety protections under TRIPs will also ban breeding based on protected varieties, and would discourage the kind of innovation that generally takes place at the farm level. This is because under UPOV, protection can only be given where new varieties are proven to be "distinct, uniform and stable." Any farmer using a PVP in crop experimentation must therefore prove that the genotype of the variety they have bred is significantly different from the original plant, otherwise it will

be classified as ‘essentially derived’ from the PVP variety and thus cannot be grown or sold without the license holder’s permission.

Challenging these patent systems require sophisticated arguments in a field that is extremely specialized and technical — as well as being notoriously pockmarked with legal grey areas. Bureaucratic issues therefore pose a major obstacle to the ability of local communities to contest patent claims. The expense involved in a legal challenge becomes prohibitive, particularly where the challenging parties do not themselves seek large profits from their intellectual property.

Even apart from these difficulties, the evidence suggests that farmers’ rights to their germplasm and knowledge could not be effectively protected through a conventional patenting system. This is because patents cannot be applied to pure knowledge or folkways. The idea that an indigenous community could, for instance, claim a patent on their use of a particular root for insecticidal purposes is unrealistic under a conventional PVP system. This point was reinforced by the Keystone International Dialogue on Plant Genetic Resources in 1991, which in its conclusions stated that if a TRIPs agreement was adopted, the only IP in the world that would not be protected would be that of indigenous communities.

This brings us to the heart of the problem. Plant variety protection regimes have generally been developed for commercial breeders in industrialized countries, where farmers are a small percentage of the population, farming is commercial, seeds are bought from corporate suppliers and products are sold through commodity markets. But in developing countries, agriculture has a completely different complexion. Seeds from harvested crops are usually saved from year to year and traded with other farmers in the vicinity. These seeds are constantly being experimented upon and bred with other locally adapted varieties. This lack of uniformity and stability means that they are not eligible for protection under a conventional PVP system, meaning that farmers would still have no claim to their own landraces. This would lead to a gradual replacement of

indigenous seeds with PVP varieties, accelerating genetic erosion in farmers' fields.

Worries over the loss of genetic diversity are not limited to ecological concerns. Most small farmers in the South produce a number of crop types and varieties, much of which is either consumed by the household or traded on local markets. These farmers rely on the diversity of plant varieties in their fields as insurance policies against crop failure, pest outbreaks, and other eventualities. On-farm diversity is maintained by the practice of seed exchanges amongst farmers. PVP systems such as UPOV 1991 would, in theory, grant the patent holder the right to prohibit the re-use of saved seeds by farmers. This would be almost certain to disrupt the free exchange of seeds preventing farmers from spreading their risks through on-farm diversification.

A related problem is that patenting would contribute to further crop standardization and reinforce the trend towards monoculture, both of which erode biodiversity. Because of the potentially huge financial rewards, the UPOV system promotes varieties geared towards intensive farming systems. PVPs will focus research and development on commercial agriculture, with an emphasis on products and methods most suited to large-scale farming. In addition, many new varieties are being marketed in tandem with a particular set of chemical inputs, allowing agri-businesses to sell their seeds as part of a "package" of technologies. Many small farmers in the Majority World are financially unable to undertake the conversion to intensive farming systems, and face the choice of either selling their land or entering into a contract growing agreement with a multi-national company – an arrangement which often leads them into poverty and debt. By pushing farmers towards specialized commercial production, PVPs will undermine the basis of small-scale mixed subsistence and local market farming production systems, pushing millions off the land and into overcrowded cities.

The plant protection systems initiated under TRIPs are also likely to encourage the spread of genetically modified crops, putting a premium on food re-production through biotech methods. This might mean that varieties traditionally grown in developing countries may be genetically changed, and that these new varieties will end up substituting the plants from which they were derived. While we won't get into a long discussion on the issue of biotechnology, we will say that there are many reasons to be believed that this trend has grave implications for future food security. The first and most important thing to bear in mind here is that control over new seed varieties rests in the hands of a few large companies investing vast sums into research and development. The development of genetically engineered crops is therefore not being driven by the needs of poor and vulnerable farmers, but by large multinational companies with two essential motives:

1) to generate profit; and

2) to ensure the continuation of that profit by consolidating their control over the international agriculture sector.

This is plain enough when one looks at the trends in crop research and development. Rather then focusing on improving yields in marginal lands, nearly all research into GM crops is going into improving food processing qualities, transport durability, appearance and shelf-life – traits favouring sales in Northern consumer niche markets rather than meeting food needs in the South. Even where research has been geared towards developing countries, the emphasis tends to be on export crops at the expense of subsistence crops.

Furthermore, most GM crops are geared towards intensive agriculture unsuited to the diversified farming systems practiced by millions of resource-poor cultivators. Like the hybrid varieties pioneered at the international crop research centres during the 1960s, GM crops generally require intensive farming methods; necessitating a departure from traditional techniques such as multiple cropping, intercropping, and

nutrient recycling. This trend will further disempower and marginalize farmers in the local and national food production process.

There is also a fundamental cultural displacement that will occur under the TRIPs. For centuries, farmers have seen themselves as the stewards of seeds and the products of those seeds. These plants were not seen as 'genetic resources' to be expropriated and privatized, they were embedded within a framework of indigenous knowledge systems which related to culture, technologies and the world views of local people. Private ownership of seed varieties is therefore antithetical not only to the values of most agrarian societies, but also to the very idea what it means to be a farmer. A quote from one farmer who said that a patent on seed is a patent on freedom – if you've patented a seed its like being forced to purchase your own freedom. Farmers now face a future where their role as harbourers and developers of these seeds is being undermined by the commodification of their knowledge and resources.

Finally, it must be remembered that in many non-industrial societies the idea of private ownership of a living organism is an anathema. These cultures are based on a holistic view of and respect for life, which Western technologies and property systems fundamentally disregard. Innovations in these societies are seen as belonging to the community – the inherited wealth of crop varieties and other resources which have been nurtured and passed down from previous generations. A multilateral regime of private intellectual property rights therefore poses a grave threat to the knowledge systems and cultural, social and economic lifestyle of farmers and indigenous communities.

9.4.3 Biodiversity, Rice and Food Security in Asia

Asia produces 90% of the world's rice, over an area of about 150 million hectares. In aggregate terms, rice accounts for nearly 50% of Asia's farm incomes and makes up nearly 80% of people's daily calories intake. Over the centuries, Asian farmers have developed over 140,000 rice varieties. These varieties have numerous different properties, including resistance

to drought, flooding, salt levels, pests or disease. Some varieties have medicinal qualities, whiles others are valued for their aromatic, sticky, or slow cooking qualities. Some produce short round grains, others long sleek ones, etc. etc. Much of this diversity, however, has been lost from farmers' fields over the past thirty years. The various Green Revolution programmes in the region have contributed to a drastic reduction in the numbers of rice varieties grown in most countries, as high-yield varieties were introduced along with mechanization, irrigation and chemical fertilizers and pesticides. Apart from many of the well-documented social and ecological problems this process triggered, the loss of on-farm diversity has led to a succession of serious outbreaks of pests such as the brown plant-hopper. Today, in Thailand and Burma, 40% of the total rice area is planted to only five varieties. In Pakistan, the top five varieties account for 80% of total rice farming. In Cambodia, just one variety – IR66 – accounts for 84% of the country's dry land rice production.

With TRIPS, this level of uniformity will be enhanced by the aggressive promotion of biotechnology, leading to an increase in food insecurity. Already, some 160 biotech patents on rice are held by biotechnology companies, with more then half these varieties owned by the top 13 companies alone. Under TRIPs, Asian farmers will be forced to purchase their rice seed year after year, and will be selecting from an increasingly narrow range of commercial varieties. These patented plants will have been developed and bred from genetic material cultivated in farmers' own fields for generations. Because GM varieties are bred to be tolerant to chemical inputs, farmers' dependency on a limited number of varieties will also force an ever-increasing use of toxic fertilizers and pesticides. The promotion of biotechnology through TRIPs will further increase dependency on corporate agri-business, concentrate land-ownership, pollute the environment and impoverish millions of small farmers. The TRIPs agreement therefore runs completely counter to the ethics and principles of sustainable agriculture and food security in Asia.

In summary, there are several serious concerns regarding the implementation of an internationally binding IP system on plant varieties. These are:

- ✓ The concern that PVPs will prevent the free exchange of seed varieties amongst farmers, disrupting a practice that forms the basis for on farm-diversity and thus food security for Majority World farmers
- ✓ That these farmers will also lose the right to breed their own varieties on their land, and that local landraces could disappear as a result
- ✓ That patenting represents another step towards the consolidation of corporate control over agriculture, forcing farmers to purchase both seed and chemical inputs on an annual basis and thereby squeezing out economically marginal farmers
- ✓ That this increased corporate control will also accelerate the trend towards monocultural production systems, displacing small-scale diversified farmers, reducing the genetic diversity of food crops and placing strains on local agro-ecosystems
- ✓ That the patent system acts as an incentive to investment in biotechnology, the spread of which could have disastrous implications for food security in the Majority World by replacing traditional varieties with commercial GM crops in farmers' fields, and by tightening the stranglehold of TNCs over food production.

9.5 INDIA - CHANGES IN PATENT LAW

As a developing country, India was given until January 1, 2005 to effect full implementation of its obligations under TRIPS. This implementation was effected by two separate pieces of legislation. The first was the Patents Act 2002 which for the most part came into effect on May 20, 2003. It had been intended that the second would be enacted in 2004. However, a change of government in 2004 led to a delay. In order to meet the TRIPS deadline of January 1, 2005, a presidential ordinance (The Patents Ordinance 2004) was proclaimed in December 2004. Subsequently, Parliament passed the Patents Act 2005 that was similar to but, as a result of political pressure by left wing parties forming part of the

government coalition, not identical with the presidential ordinance. The Act specifically states that most of its provisions are “deemed to have come into effect on January 1, 2005”, but it also ratified and maintained the validity of acts taken under the presidential ordinance.

Probably the most important change effected by the 2005 legislation was the repeal of the provision barring the grant of patents for chemical or pharmaceutical products. As a consequence of this change, provisions relating to exclusive marketing rights for pharmaceutical products that have existed for the previous ten years were repealed on the basis that full patent protection has become available. Changes in the law to make it easier to obtain protection for computer-related inventions were included in the presidential ordinance but did not survive in the Act as enacted by Parliament.

Other significant changes included:

Provisions for establishment of an Appellate Board that could possibly be the precursor of a special patents court. The creation of the Appellate Board was provided for in 2002, but it has not yet come into operation. It will have jurisdiction not only over appeals from the patent office in pre-grant matters but will also have original jurisdiction with respect to post-grant petitions for revocation of a patent if these arise otherwise than as a counter-claim to an action for patent infringement.

Provisions relating to compulsory licensing of pharmaceutical products which have been expanded to make it clear that such licenses can be granted for manufacture and export to “any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided that compulsory license has been granted by such country.”

“Bolar-type” exclusions from patent infringement for steps reasonably relating to development of data required for marketing approval were added to the law in 2002. In 2005, it was made clear that the exemption extends to the import of products for carrying out such testing.

India has traditionally had a pre-grant opposition system. The 2005 presidential ordinance replaced this by a post-grant opposition coupled with the possibility of third parties making comments on pending applications after they had been published. The final legislation as passed by parliament provides for both pre- and post- grant oppositions. As with the prior law, not all grounds of possible invalidity can be raised in

opposition proceedings, a few being reserved for consideration by the new Appellate Board or the courts only during revocation proceedings.

Pre-grant oppositions may be filed at any time between publication of the application and its grant. Post grant oppositions can be brought within one year of the grant of the patent.

The grounds on which an application or patent may be opposed are:

a) that the applicant or patentee wrongly obtained the invention from the opponent or a person from whom the opponent derives title;

b) that the invention was previously published, subject to the limitations on anticipation discussed above;

c) that the invention was previously claimed in an Indian application having an earlier priority date;

d) that the invention was publicly known or publicly previously used in India, again subject to the qualifications on “anticipation” discussed above;

e) lack of inventive step over any prior publication or over any prior use in India;

f) that the application or patent claims unpatentable subject matter;

g) lack of sufficient and clear description of the invention or the method by which it is to be performed;

h) failure of the applicant to provide the Controller with details of corresponding foreign applications as required;

i) in the case of a convention application that it was not made within twelve months of “the first application for protection of the invention in a convention country by the applicant or a person from whom he derives title”;

j) failure to provide information or including wrong information on the source or geographical origin of biological material used in the invention; and

k) that the invention is anticipated by knowledge “oral or otherwise available within any local or indigenous community in India or elsewhere”.

Under the new procedure for oppositions, a three person opposition board will be set up to make recommendations on the disposition of the opposition after receipt of the statements and evidence from both sides but prior to the final hearing on the opposition which shall take place before a Controller.

The main patent rights law in India is the Patent Act of 1970. It gives inventors sole rights over their innovations for a defined period of time. Although innovations in all industries are covered under the Patent Act of 1970, the law was said to offer too little protection over innovations from inventors in India's pharmaceutical industry. In 2005, India passed a change to its patent law to comply with guidelines of the World Trade Organization further safeguarding innovations in medicines.

Rights

- ✓ Under the Patent Act of 1970, a patent holder or patentee has sole rights over the development, trade or sale of the innovation. Pursuant to state laws of India, the patentee has the authority to protect his innovation and safeguard it from unauthorized distribution or sale. If a patentee feels as though his rights under the Patent Act of 1970 have been compromised, he may take legal action and accuse the alleged offender with violating his rights as the patent holder.

Innovations

- ✓ One key difference of patent law in India from similar laws in other countries is that India's patent law distinguishes between patentable and non-patentable innovations. In other words, India law recognizes there's a difference between the person who invented something and someone who invented the process that yielded the invention. Only the inventor of the actual innovation applies for and may receive a patent.

Patentees

- ✓ Inventors apply for patents either individually or jointly in India. In addition, a representative of a deceased inventor may file an application for a patent on the deceased inventor's behalf. The application process requires a number of forms to be filled out and accompanying information clearly documenting the authenticity of the innovation and

verifying it's the sole creation of the inventor. Most inventors rely on the help of patent attorneys to complete the application.

Time Period of Patent

- ✓ Inventors of innovations in industries, such as manufacturing, food or prescription drugs receive sole rights over their products for a period of seven years as patentees. Inventors granted patents in other industries get rights over their products for as long as 20 years.

9.5.1 2005 Amendments to Indian Patent Act, 1970

- ✓ In 2005, the government of India enacted a change to its patent law pertaining to the pharmaceutical industry. India's pharmaceutical industry produced the 4th highest volume of generic medicines and served as a leading world supplier. However, its global position in the pharmaceutical market was achieved, because of its lax patent laws on pharmaceuticals, which allowed generic drugs to be manufactured and sold cheaply while undercutting the original inventor's profits. The new law extends rights from seven years to 20 years for patentees of prescription drugs. In addition, a generic drug can't be manufactured and sold unless and until the manufacturer obtains a license---a provision that withstands the entire patent time period.

Indian patent attorneys, patent examiners and other IP rights professionals will have to remove several expressions from their daily lexicon in light of the recently promulgated Patent (Amendment) Rules 2005. The age-old prosecution steps of putting an application in order for acceptance, notice of acceptance, advertisement of notice of acceptance, opposition before grant and sealing of a patent no longer have a place in Indian patent practice.

The rules make substantial changes to the Indian patent prosecution system. Until 10 years ago it used to take several years for an application to come up for examination and reach the stage of grant. Now a patent is granted within approximately two years of filing an application.

The amendments are not only procedural. Rather, the Indian patent regime has undergone a paradigm shift. The principal reason behind the recent changes is India's obligation as a World Trade Organization member country to meet the January 1 2005 deadline set by the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement. The national patent law was amended in three phases to make it compliant with the TRIPs norms. These changes have brought the Indian patent system up to world standards - from an anti-monopolistic perspective to a new vision of patents as an investment-friendly, research and development-encouraging institution of property.

The Patents Act 1970 was amended first in 1999 and then again in 2003. The Third Amendment Bill has been pending consideration by Parliament. However, with a view to complying with the TRIPs deadline of January 1 2005, the president promulgated an ordinance on December 27 2004 making sweeping changes to patent legislation. This ordinance has recently been substituted by the Patents (Amendment) Act 2005. This update analyzes the procedural amendments introduced by the act.

The Patents (Amendment) Rules 2005 came into force on January 1 2005. The rules were amended pursuant to the promulgation of the Patents (Amendment) Ordinance 2004 and the Patents (Amendment) Act 2005. The new set of rules introduced major changes in the Indian patent prosecution system.

Foreign Filing Permit

The amended patent law requires an Indian resident to obtain a foreign filing permit before filing a patent application outside India. The foreign filing permit is not required if a corresponding Indian patent application has been filed not less than six weeks before filing the foreign application. This requirement will have a direct bearing on the patent prosecution strategies of major companies with research and development facilities in India. Previously there were no restrictions on making a first filing outside India for inventions originating in India. Many companies (including Indian companies) have made their first filings at the US Patent and Trademark Office and the European Patent Office for inventions originating from their

Indian research and development operations. While companies can continue to do so, they will first have to obtain a foreign filing permit.

An interesting aspect of this requirement relates to Patent Cooperation Treaty (PCT) international applications. Does this provision require an applicant to obtain a foreign filing permit even for a PCT international application filed with the Indian Patent Office as the receiving office? If so, does the position change even if the applicant has designated India in the international application? The Patent Office is asking applicants to file a request for foreign filing even in the case of PCT international applications designating India.

Working Statements

The requirement to file a working statement (a statement providing information regarding the commercial working of the invention in India) has always been set out in the Patents Act (Section 146). However, very few patentees have voluntarily complied with this requirement. The fine for not filing a working statement was Rs1000 as per Section 122(1). The rules framed under the Patents (Amendment) Act 2002 introduced Form 29, prescribing the information to be provided by the patentee. A patentee must file the working statement every six months throughout the term of a patent. The Patents Rules 2003 increased the fine from Rs1,000 to Rs20,000. The ordinance and the latest amendment have substantially hiked the fine to Rs1 million. The major increase in the penalty has brought the slightly neglected working statement provisions to the centre of attention. Consequently, patentees have been carefully analyzing the contents of Form 27, introduced by the Patents Rules 2005. Form 27 requires a patentee to provide the following information:

- ✓ whether the patented invention is utilized in India;
- ✓ if not utilized, the reasons for this;
- ✓ if utilized, the quantum and value of patented product manufactured in India or imported;

- ✓ the licences and sub-licences granted; and
- ✓ whether public requirements have been met.

It is difficult for a patentee to provide a clear answer to the last requirement - patentees are expected to state whether the requirements of the Indian population (1 billion people) have been met by commercially utilizing the invention in India. In addition, the requirements assume that the invention is always a standalone product - the form seems to have been drafted with drug patents in mind. In many fields of engineering (eg, telecommunications) it is at times impossible for the patentee to utilize inventions individually - frequently a portfolio of patented inventions is put to commercial use. Therefore, the quantum of the patented product is very difficult to estimate.

The requirements of Form 27 reflect the fact that importation amounts to local utilization, as set out in Article 27 of the TRIPs agreement. However, it has been argued that importation does not amount to local utilization, and this is the legislative intent behind Section 83(b). This is yet another provision that requires judicial scrutiny.

Requests for Examination

The timeline for filing a request for examination has also been changed. Under the Patents (Amendment) Act 2002 the request for examination had to be filed at any time after the publication of an application, and within 48 months of the date of filing of the application. Publication took place 18 months after the date of filing the application in India. For PCT national phase applications the 48-month period started on the international filing date.

However, under the Patents (Amendment) Act 2005 the deadline to file a request for examination is any time after publication and within 36 months of the priority date. In the case of PCT national phase applications, the deadline is now 36 months from the international priority date. India has a 31-month deadline to enter the national phase. Therefore, an applicant that enters the national phase in India in the 31st month will have only five months to file a request for examination.

An important issue is the difficulty in calculating the timeframe for PCT national phase applications. There is no provision in the act making the PCT international publication equivalent to the publication for Indian purposes. As such, a PCT national phase application must be published in India 18 months from the filing date of the application in India. However, the 36-month deadline to file a request for examination is calculated from the international priority date. In light of this, how can an applicant that enters the national phase in India in the 31st month wait for the 18th month after publication to file a request for examination, if the filing deadline is 36 months from the international priority date?

9.5.2 Sweeping Changes to the Patent Prosecution System

Assignment

Previously there was a requirement to register all transactions concerning a patent with the Patent Office within six months of the date of execution of the document concerning such transactions. Typically these transactions included assignments, mortgages, licences, share in a patent or creation of any interest in a patent. This position has now changed. Although the law continues to require that such transactions be in writing, it does not require that an assignment be registered for them to be valid and enforceable.

Annuity payments

The amended rules provide for a six-month time extension to pay the first annuity, which is payable at the expiration of the second year from the date of the patent. To seek such an extension a request must be filed on Form 4 with a fee of Rs1,200 per month.

Grace period

The grace period for patent applications filed in anticipation of prior display of the invention in an exhibition, description of the invention in a paper read by the inventor before a learned society or publication in the transactions of a learned society has been increased from six months to one year.

Filing documents

If a document is electronically transmitted to the Patent Office it is deemed to have been filed. However, the rules stipulate that "the electronic transmission must be duly authenticated". The expression 'duly authenticated' has been left undefined, making this important provision unclear (especially considering that the Patent Office is about to go fully online).

Statement and undertaking for foreign applications

The statement and undertaking regarding foreign applications must be filed within three months of the date of filing of the Indian patent application. In the case of PCT national phase applications in India, this period is three months from the date of filing the national phase application in India. Regarding the applicant's continuing obligation to furnish information regarding corresponding applications, there is a change in the timeframe. Previously the time limit was 30 days from the date of receipt of the office action, but this has now been increased to three months.

Inventor's declaration

Form 5 requires the filing of a declaration as to inventorship. Typically this is to enable the applicant for a provisional patent application to add the names of the subsequent inventors while filing the complete patent application. As such, all patent applications with complete specification (eg, convention priority applications and PCT national phase applications) fall outside this requirement. The rules now clarify that, even in the case of PCT national phase applications, the inventor's declaration is not required.

Application form

In the past, two separate forms were used to file a PCT national phase application and a convention priority or ordinary patent application. Form 1 was used for convention or ordinary patent applications, and Form 1-A was used for PCT national phase applications. This system has been changed, and Form 1 is now used for all types of patent applications.

Translation of PCT applications

In the case of PCT national phase applications that were not filed or published in English, an English translation of the application is acceptable if it is verified by the applicant or a person authorized by the applicant.

Early examination of national phase applications

Early examination of PCT national phase applications is now possible by filing a request on Form 18, along with a fee of Rs14,000 (if the applicant is a legal entity).

Priority documents

If a PCT national phase application does not meet the requirements of Sections 17.1(a) and (b) of the regulations under the PCT, the applicant must file a verified English translation of the priority document within three months of the date of invitation. The new rules prescribe that such verification can also be carried out by the duly authorized patent agent.

Publication of applications

All patent applications (although certain exceptions on the grounds of secrecy are set out) will be published on the expiry of 18 months from the date of application or the date of priority, whichever is earlier. An early publication (before the expiry of 18 months) is possible by filing a request on Form 9.

Rights of patent applicant

An applicant for patent in India enjoys the same privileges and rights as if the patent has been granted. However, the applicant cannot institute proceedings for infringement until the patent is granted. Regarding the World Trade Organization and mail box applications, a patentee's rights accrue only from the date of grant.

Timeframe for examination of applications

The timeframe for the examination of patent applications has substantially changed. Previously the Patent Office had 12 months from the date of the first office action to consider the application. In the meantime, the first office action had to be replied to within four months of receipt. The new rules prescribe a total time period of six months to consider the application, with this period being extendable by three months. Upon filing the request for examination, the controller of patents will refer the application to an examiner. The law does not prescribe a time limit in which to do so. The examiner, on receipt of such reference, must issue an office action within one month of, and not later than three months from, the date of reference.

Comment

The recent amendments to the Patents Rules were dependent on the promulgation of the ordinance, and the amendments made a number of progressive changes to the patent prosecution system. However, when the ordinance was substituted by the Patents (Amendment) Act 2005, the rules remained the same. Therefore, yet another revision of the rules seems likely.

9.5.3 Ambiguities in the New Law (INDIAN PATENT ACT, 2005)

The 2005 amendments to the patent law have many ambiguities that need to be addressed. To illustrate a few: under the new law, a maker of generics can apply to copy a patented drug, but only after it has been marketed for three years. The generic's maker however must pay a "reasonable" royalty. The new law does not define what can be considered to be "reasonable". This can result into unwarranted complications and needless litigation. Further, the amendments have sparked fears that with the new law, prices on patented breakthrough drugs would most likely rise to nearly the level in the United States, while prices on more commonly used drugs would most likely rise only moderately. The Indian government has said it would step in if price rises were excessive but has not said how that would be determined. In fact, the new law bars the government from over-riding any patent for at least

three years - a provision not required under the TRIPS Agreement. Further, the new law states that the Controller of Patents has a series of wide-ranging discretionary powers to determine all kind of criteria like "reasonable affordability," "reasonable pricing," and "reasonable royalty." As Subbaraman Ramkrishna, senior director for corporate affairs at Pfizer India Ltd. noted, the word "reasonable" appears 42 times in the bill, giving the impression that royalty rates would be imposed subjectively. Lastly, with the removal of Section 5 of the law, it is not clear if chemical processes continue to be defined to include biochemical, biotechnical and microbiological processes.

The amendments made to the patent law by India have been ostensibly to comply with its WTO obligations on intellectual property, the amended law represents a compromise between opposing interests. This compromise has resulted in a complicated and confused law with potential negative consequences that could have been avoided. The new law at times seems to exceed the requirements of the Agreement on TRIPS, or has provisions unique to India, and at other times, appears to be in conflict with the TRIPS Agreement. It is also believed that India, ironically, has swung from one extreme to another, moving from 1970 law that was clearly anti-patent to a law that is pro-patent applicant but not necessarily pro-innovation.[24] At a time when there is increasing skepticism around the world over the patent-system as it has evolved so far, particularly in the United States, it remains to be seen whether the hybrid Indian patent-system stands the true test of time. The works of founders of states, law givers, tyrant destroyers and heroes cover but narrow spaces, and endure but for a little time, while the work of the inventor though of less pomp is felt everywhere and lasts forever.

9.6 SUMMARY

In this unit we have discussed about the concept of Intellectual Property Rights regimes and need of law reforms in Intellectual Property Rights laws. We have also discussed about the wealth of nature, biodiversity and Food Security in Asia and relation between food security and the TRIPs. Further, we have also discussed the 2005 Amendments to Indian Patent Act, 1970, the sweeping changes to the Patent Prosecution System and Ambiguities in the new law.

9.7 SUGGESTED READINGS/REFERENCE MATERIAL

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Julian A. Oram, The TRIPs Agreement and its Implications for Food Security, International Famine Centre, University College, Cork, September, 1999

See The New York Times, March 24, 2005, Section C , Page 6 , Column 5

Couple of years ago, U.K.- based GlaxoSmithKline demanded 40 percent of the sales proceeds of an AIDS drug it licensed to a South African company. However, under pressure from South African regulators and activists, it later licensed it to three rival companies for only 5 percent.

See The New York Times, March 24, 2005, Section C , Page 6 , Column 5

Section 5 of The Patent Act, 1970 states, inter alia, "In the cases of inventions - (a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or (b) relating to substances prepared or produced by chemical processes .... no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

A Confusing Patent Law for India, Economic and Political Weekly, April 16, 2005

See Jaffe, Adam and Josh Lerner, Innovation and its Discontents, Princeton University Press, 2004

Francis Bacon, quoted in Mainly on Patents at page 1, edited by Felix Liebesny, Butterworths

Suggested Readings

69. Terenee P. Stewart(ed.) : The GATT Uruguary Round : A Negotiating History
70. Iver P. Cooper : Biotechnology and Law (1998), Clerk Boardman Callaghan, New York
71. David Bainbridge : Software Copyright Law (1999)
72. Sookman : Computer Law (1998)
73. Carlos M. Correa(ed.) : Intellectual Property and International Trade (1998)
74. Sweet and Maxwell : Patent Co-operation Treaty Hand Book (1998)
75. Christopher Wadlow : The Law of Passing-Off (1998)
76. W.R. Cornish : Intellectual Property Law (1999)
77. Special attention should be given to literature of the U.N. System, WIPO and the UNESCO.

9.8 SELF ASSESSMENT QUESTIONS

1. What is need of law reforms in the area of IPR?
2. Discuss the scope of law reforms in IPR laws?
3. Discuss the major changes brought about by the 2005 amendments in the Indian Patent Act, 1970?

4. Describe the ambiguities of Indian Patent Act, 2005?

LL.M. Part-1

Subject: Intellectual property Law

Block- IV : Intellectual Property of Human Right

Unit-10:**Freedom of speech and expression as the basis of regime of intellectual property; right copy right protection on internet (WIPO copyright treaty, 1996)**

STRUCTURE

10.1 INTRODUCTION:

Today we are in the 21st century and things are changing for India. With the rapid growth of trade and industry in the era of globalization, liberalization, increasing use of internet, e-commerce and convergence of technologies have opened new vistas of opportunities for the people of India. The information and communication revolution is taking place all over the world and it has left the common man bewildered to even comprehend what is happening. The social, economic, political, cultural and educational system is undergoing changes on an unprecedented scale. It is making the life of an ordinary man difficult as he is unable to keep pace with the changing time and especially with regard to matters pertaining to knowledge sector.

Today technology is evolving fast as result of which the computers have found place in every home, every office and in all important departments. With the touch of a finger the whole world of knowledge, information is available just like magical lamp of Allauddin where an individual would get any information which one desires. A person living in India can communicate with a person in U.S.A. or Australia thousands of miles away. This is done in Cyberspace.

The advancement of science and technology has made a tremendous impact and change almost in all walks of life. The paper highlights the impact of information technology on library science. The libraries are considered to be storehouse of knowledge and information which-h is acquired with the help of books. But now with the help of virtual world the scenario has changed. With the easy accessibility to information and knowledge the students of library science will have to equip themselves with information technology and they will be required to learn the cyber language. They will also have to be acquainted with the computer security system. As potential users of information technology it will be imperative for library science professional to prepare themselves to handle the new and exciting world of cyberspace.

Cyberspace is a world of virtual reality. It has netizens and not citizens. Cyber world is not like physical world. The laws of physical world are

different and they cannot be applied to Cyberspace. Physical laws have limitations and are defined. But laws of Cyber space are dynamic, undefined and limitless and they have to keep pace with technological advancements.

Cyberspace is a space where entry is not bound by geographical boundaries. Today a person sitting in the Chennai can access the information through Internet anywhere in the world. In the light of this librarians and information scientist should know about:-

1) The right to information and right to freedom of speech and expression,
2) Crimes related to internet, and
3) Intellectual property rights.

The Indian people are governed by the Constitution of India which gives the fundamental rights to the people. The Constitution of India does not specifically guarantee the right to information, but since long it has been recognized by our Supreme Court as fundamental right necessary for democratic functioning of our country. Our Supreme Court has specifically recognized the right to information as an integral part of the right to freedom of speech and expression guaranteed under Article 19(1) (a) of constitution and it can also be read within the purview of Article 21. The right to information is not an absolute right some information can be held back where giving of the information would harm the interests which need to be protected.

Article 19(1) (a) gives the right of freedom of speech and expression including the freedom of press to the citizens of India and the same article 19 sub clause (2) gives the reasonable restrictions which can be imposed by the government on the grounds of sovereignty and integrity of India, security of state, friendly relations with foreign states, public order, decency or morality, or in relation to contempt of court, defamation or incitement to an offence. But today the information which is available on the internet, the access is unlimited and person is free to get the information which under the law is prohibited. To give an example the viewing of pornographic and obscene material or any matter which affect the unity and integrity of the nation can be accessed by the people easily. The question to be answered here is "what happens to the reasonable restrictions given in article 19(2)? What control does the government have to restrict the right to information? These are questions which will have to be considered and determined by the government as well as the people of India while making laws for cyber space.

The advent of technology has brought with it unknown dangers and threats and in the hands of unscrupulous people it could mean a weapon mightier than any other weapon known to mankind so far. Internet crimes can be committed with considerable ease against anyone in the world from any part of the world and even from within the comfort of ones home. There is likelihood for more crimes to be committed in future in India.
Anonymity makes Internet a preferred weapon of choice for committing crimes. Technological perfection makes it very easy for these crimes to be committed. India has adopted a legislation to facilitate and safeguard electronic transactions and computer related crimes and it is the Information Technology Act 2000 which is applicable to the users of technology. This law is based on the Model Law on Electronic Commerce prepared by the United Nations Commission on International Trade Law (UNCITRAL) which was adopted by the UN General Assembly on 30th January 1997. The aims and objectives of the Act include enabling or facilitating the use of electronic commerce and providing equal treatments to users of paper-based documentation and to users of computer-based information. It is to promote efficient delivery of government services by means of reliable electronic records.

10.2 Objective

The aim of this unit it to aquent the reader about the intellectual property right releated to freedom of speech and expression and to sec how individual commercial interest and social interest are protected of the individual under the copyright Act.
The main objective of the copy right law it to promote the access and the use fo information an for protecting the works from the infringements and for encouraging the author in pursuit of knowledge. The Technological developments, the increasing number of electronics publication and digital libraries pose challenge to the right holder as well as law enforcing agencies.

10.3.1 Intellectual property

"Intellectual property" is an intellectual work, produced by the intellect of human brain. For example, literary work produced by the author’s, musical work produced by the musicians, inventions invented by the inventors, coining of trade marks used in the course of business or trade, design of

industrial products, etc. are intellectual properties as they are created by the human intellect. Computer programming is also an intellectual property as it is also the creation of human intellect. The person who creates an intellectual piece of work owns it like any other tangible property like land or movable goods. "Intellectual property" like tangible property is owned by its owner to the exclusion of all others. The owner of intellectual property has exclusive right over his intellectual property. No one can make use of intellectual property without the consent of the owner of the intellectual property. For example, no one can copy literary, musical piece of work, work an invention or apply a design to an industrial product without the consent of the author, musician, or the inventor, as the 'case may be, who has created this piece of creative work. Similarly, no one can make use of the trade marks without the consent of its proprietor. However, the owner

of intellectual property may assign intellectual property itself or any interest in the intellectual property in the favour of any other person in consideration of monetary gain. For example, an. author may assign the copyright in his literary work in the favour of any other person in consideration of lump sum amount of royalty. Similarly, a musician may assign a composition compose by him to any other person in consideration of monetary gain. Similarly, an inverttor may assign his invention or grant a licence to work his invention in the favour of any other person in consideration of commercial gain to him.
Thus, a person enjoys exclusive rights with respect to his intellectual property which he has created by the intellect of his brain.

10.3.2Intellectual property law

The exclusive rights which a person enjoys with respect to his intellectual property are his 'intellectual property rights' (hereinafter referred to as IPRs). The law that protects the 'intellectual property rights' is known as 'intellectual property law'. For example, copyright law protects the copyright of authors, musicians, etc. with respect to literary or musical work, etc. The law of patents protects the inventions of the inventors. The law of trade marks protects the trade marks used in the course of trade by the traders or businessmen for their goods or services. .
According to agreement on Trade Related Intellectual Property Rights (TRIPs), agreement between the members of the World Trade Organisation (WTO) intellectual property law includes law relating to;

(i) Copyright and related rights;

(ii) Trade marks, trade names and service marks;
(iii) Geographical indications;
(iv) Industrial Designs;
(v) Patents;
(vi) Layout Designs of Integrated Circuits;
(vii) Undisclosed Information.

10.3.3Intellectual property law relating to copyright.

Two important conventions relating to intellectual property law relating to copyright are: .

(i) Bern Convention, 1886; and
(ii) Universal Copyright Convention, 1952 as revised in 1971

10.3.4(i) BERN CONVENTION, 1886

The Bern Convention is the first international convention which was convened in 1886 in Switzerland with the main objective to protect the literary and artistic work. The Bern Convention came. into force on 5th December, 1887 and was revised several times. It was revised at Berlin in 1908; at Rome in 1928; at Brussels in 1948; at Stockholm in 1967; and in Paris in 1971.

The Bern Convention consists of 38 Articles. According to Article 35 of the Bern Convention, "the Bern Convention shall remain in force without limitation as to time."

10.3.5 Works protected

Article 2 of the Bern Convention provides for the works which are protected under the Convention. The works protected under the convention are as follows :

(i) "Literary and artistic work";
(ii) Possible requirement of fixation;
(iii) Derivative works;
(iv) Official texts;
(v) Collections;
(vi) Obligation to protect; beneficiaries of protection;

(vii) Works of applied art and industrial designs;
(viii) News

The Bern Convention protects the works of the authors not only in the country of their origin but also in the countries of Union.
Article 5(1) of Bern Convention provides as follows :
"Authors shall enjoy, in respect of works for which they are protected under this Convention, in countries of the Union other than the country of origin, the rights which their respective laws do now or may hereafter grant to their nationals, as well as the rights specially granted by the Convention." Article 9 of the Convention provides that authors of literary and artistic works protected by Bern Convention have exclusive right to authorising the reproduction of these works, in any manner or form.
Term of protection According to Article 7 of the Bern Convention, the term of protection granted to the literary and artistic work by this Convention is during the lifetime of the author and of fifty years after his death.

10.3.6(ii) UNIVERSAL COPYRIGHT CONVENTION, 1952 AS REVISED IN 1971

Universal Copyright Convention, 1952 (hereinafter referred to as UCC, 1952) was signed at Geneva on 6th September, 1952. The UCC, 1952, that came I into force in 1952 was revised at Paris in 1971 and is administered by UNESCO,
I which is a specialised agency of United Nations. .

The objective of UCC, 1952 as revised in i971 (hereiriafter referred to as 1971 Convention) is to ensure in 'all countries copyright protection of literary,I scientific and artistic works. As the preamble of the UCC, 1952 Convention as revised in 1971 reads as follows :- .

"The Contracting States moved by the desire to ensure in all countries copyright protection of literary, scientific and artistic works, Convinced that a system of copyright protection appropriate to' all nations of the world and expressed in a universal convention, additional to, and without impairing international system already in force, will ensure respect for the rights of individual and encourage the development of literature, the science and the arts, Persuaded that such a universal copyright system will facilitate a wider dissemination of works of the human minds and increase international understanding.
Have resolved to revise the Universal Copyright Convention, 1952."

10.3.7 Works protected .

Article 1 of the revised UCC, 1952 as revised in 1971 ptovides as follows:

"Each Contracting State undertakes to provide for the adequate and effective protection of the rights of authors and other proprietors in literary, scientific and artistic works, including writings, musical, dramatic and cinematographic works and paintings, engravings and sculpture."

Thus, according to Article 1 of the 1971 Convention, the works protected under the 1971 Convention are as follows :

(i) literary;
(ii) scientific;
(iii) artistic works, including writings;
(iv) musical;
(v) dramatic and cinematographic works;
(vi) paintings;
(vii) engravings; and
(viii) sculpture.

UCC, 1952 as revised in 1971 consists of 20 Articles. The 1971 Convention does not abrogate multilateral or bilateral conventions ,or arrangements in effect between two or more contracting states of the 1971 convention. However, in the event of any difference between the provisions of such existing conventions or arrangements and the provisions of 1971 convention, the provisions of this 1971 convention prevail.

Article XVII of the 1971 Convention provides that 1971 Convention shall not in any way affect the provisions of the Bern Convention for the protection of Literary and Artistic works or membership in the Union created by that Convention.

10.3.8 WORLD INTELLECTUAL PROPERTY ORGANISATION (WIPO)

The World Intellectual Property Organization (WIPO) was created by the "convention" establishing the World Intellectual Property Organisation popularly known as "WIPO convention". WJPO Convention was formally signed at Stockholm on July 14, 1967 and c"ame into force in 1970. WIPO was created with the objective "to encourage creative activity, and to

promote the protection of intellectual property throughout the world through cooperation among States." Wipo became the specialised agency of United Nations in 1974. The

headquarter of WIPO is situated in Geneva, Switzerland. WIPO has succeeded to the "United International Bureau for the Protection of, Intellectual Property."
"United International Bureau for the Protection of Intellectual Property" that preceded WIPO was set up in 1893 to administer the "Berne Convention for the protection of literary and artistic works, 1886" and "Paris Convention for the protection of industrial property, 1883". At present WIPO administers 24 international treaties relating to intellectual property.

10.3.9 International treaties administered by WIPO

Following are the 24 international treaties relating to intellectual property which are administered by WIPO.
(i), Berne Convention
(ii) -Brussels Convention
(iii) 'Budapest Treaty
(iv) Film Register Treaty
(v) Hague Agreement
(vi) Libson Agreement
(vii) Locamo Agreement
(viii) Madrid Agreement
(ix) Madri4 Agreement (Marks)
(x) Madrid Protocol Nairobi Treaty
(xi) Nairobi Treaty
(xii) Nice Agreement
(xiii) Paris Convention
(xiv) Patent Law Treaty
(xv) PCT
(xvi) Phonograms Convention
(xvii) Rome Convention
(xviii) Singapore Treaty on the Law of Trade Marks
(xix) Strasbourg Agreement
(xx) Trademark Law Treaty
(xxi) Vienna Agreement
(xxii) WashingtonTreaty

(xxiii) WCT
(xxiv) WPPT

10.3.10 Copyright

'Copyright 'is an 'exclusive right' exercised over a work produced by the intellectual labour of a person, As in **Sulmanglam R. Jayalakshmi v. Meta Musica1**,[1] the Madras High Court held that "the right which a person acquires in his literary or artistic work which is the result of his intellectual labour is v called his "copyright","

'Copyright' is not restricted to literary or artistic work, "Copyright" applies to different other kinds of works also like dramatic, musical, cinematographic film, computer programme, work of architecture and sound recording and any other woz:k which is produced by the intellectual labour of a person, In other words, different kinds of works which are the results 'of intellectual labour of person fall within the purview of the "copyright". As the subject-matter of copyright is the work produced by the intellectual labour of a person, therefore, the right to "copyright" is a right to "intellectual property of a person."

The 'exclusive right' to copyright exercised by a person includes his right to assign the copyright either wholly or partially in the favour of any other person. The owner of the copyright may also grant any interest in the copyright by licence in the favour of any other person. The 'exclusive right' to copyright also entitles the owner of the copyright to restrain any person from doing any unauthorised act with respect to the work in which his copyright

1. AIR 2000 mad 454

subsists. As in Bharat Law House, **Messrs v. M/s Wadhwa Co. Ltd**.,[1] it was observed that! "Copyright is the exclusive right to do and to authorise others to do and restrain others from doing certain acts in relation to a literary work". "Exclusive right" to copyright in a work also includes the right to reproduce the work. As in Penguin Books Ltd. v. **M/s India Book Distributors,2** the Delhi High Court observed that "anything with respect to the intellectual work in its most" elementary form means exclusive right to multiply copies of a book."

10.3.11 Copyright Law prevents the reproduction, sale or any other act with respect to a work if it is done without the consent of the owner of the copyright in that work. Because any act done with respect to a work in

which a copyright subsists without the authority of the owner of such copyright is deemed to be an infringement of the copyright.

'Copyright Law' provides for the civil as well as 'criminal' remedies against the infringement of copyright. 'Copyright Law' provides for civil remedies in the from of injunctions, damages or accounts against the infringement of copyright. Similarly, Copyright Law provides for the punishments in the from of imprisonments and fines as a criminal remedy for the offence of infringement of the copyright. As in **Associated Electronics v. MIs, Sharp Tools[3],** the Karnataka High Court observed as follows:

"The Copyright Law is in essence concerned with the negative right of preventing the copying of physical material, existing in the field of literature and -art. Its object is to protect the writer and artist from the unlawful reproduction of his material."

Similarly, in **Sulmanglam R. Jayalakshmi v. Meta Musica1,[4]** the Madras High Court observed that "the primary function of copyright law is to protect the fruits of a man's work, labour, skill or test from annexation by the other people."

Copyright Law protects copyright of a person in a work produced by his intellectual labour irrespective of his status. Thus, a saint who has renounced the world has copyright in the work produced by his intellectual labour like any other person. As in **Sulmanglam R. Jayalakshmi v. Meta Musical,[5]** the Madras High Court observed as follows:

"The Law of copyright has to protect a man's copyright irrespective of his status as a family man or saint. Merely because a person has renounced the world, he cannot be compelled to renounce his copyright too."

Thus, if a saint writes certain lyrics in the praise of God, he has copyright over those lyrics under the Copyright Law.

10.3.12 Protection of individual commercial interest.

No person other than the owner of ' the copyright can do anything with respect to the work in which the copyright subsists. However, the Copyright Law permits the owner of the copyright to assign the copyright either wholly or partially to any other person. The Copyright Law also permits the owner of the copyright to grant any interest in the copyright by granting licence in the favour of any other person. The owner may assign the copyright or grant licence

1. AIR 1988 del 68
2. Air 1991 Kant 406
3 AIR 2000 mad 454
4. Ibid

in the favour of any other person in consideration of monetary gain. Thus, copyright law not only protects the creative genius of human mind, but also entitles a person to earn monetary gain from a work produced by his intellectual labour. As in **Garware Plastics and Polyster Ltd., Bombay v. M/s. TelelinJ ,**[1] the Bombay High Court observed as follows:

"The Copyright Act is meant to protect the owner of the copyright against unauthorised performance of his work, thereby entitling him monetary gain from his intellectual property."

Similarly, in **Sulmanglam R. Jayalakshmi v. Meta Musical,**[2] the Madras High Court observed that "primary function of the Copyright Law is to protect the fruits of a man's work, labour, skill from annexation by other people."

Lord Atkinson in Macmillan & Co. Ltd. v. K & J.'[3] quotes Lord Halsbury as follows:

"I shall very much regret if I were compelled to come to conclusion that the state of law permitted one man to make the profit and to I appropriate to himself what has been produced by labour, skill and capital of another."

Whereas Lord Atkinson in **Macmillan & Co. Ltd. v. K. & J.,**[4] explains the basis of Copyright Law as follows:

"The moral basis on which the principle of the protective provisions of Copyright Act rests is the Eighth Commandant-

I i.e., "Thou shall not steal".

Emphasising the importance of Copyright Law in protecting the commercial interest of an 'artist' or an 'author' in his work, Hon'ble Justice V" R. Krishna Iyer in Indian Performing Rights **Society Ltd. v. Eastern India' Motion Pictures Association**[5], observed as follows:

"The creative intelligence of man is displayed in multifarious ways of aesthetic expression but it often happens that economic system so operates " that the priceless divinity which we call artistic or literary creativity in man is exploited and masters, whose works are valuable are victims of pitfalling payment. World opinion in defence of human rights to intellectual property led to international conventions and municipal laws, commission codes, and organisations calculated to protect works of art. India responded to '~ this universal need by enacting the Copyright Act, 1957."

10.3.13 Protection of social interest.

Copyright Law not only protects the commercial interest of a person in the work produced by his intellectual labour, but also protects the interest of the society. Because art and literature are the essential constituents of culture of any society. Maturity and excellence in the art and literature

1. AIR 2000 Mad 454.
2. AIR 1924 PC 75, at page 81
3. Ibid
4. AIR 1977 SC 143

means maturity and excellence in the culture. Thus, by protecting the copyright of the authors and artists in their artistic or literary work, the copyright law protects the culture of the society. As the Delhi High Court in **Penguin Books Ltd., England v. Indian**[1] **"**Copyright is a property right and throughout the world, it has been regarded as a form of property working for special protection in the ultimate public interest."
Similarly, in Smt. **Mannu Bhandari v. Kala Vikas Pictures Pvt. Ltd**., the Delhi High Court highlighted the social interest served by the Copyright Law as follows:
"The hallmark of any culture is excellence of arts and literature. Quality of creative genius of artists and authors determine the maturity and vitality of any ,culture. Art needs healthy environment and adequate protection. The protection which law offers is thus not the protection of the artist or author alone. Enrichment of culture is of vital interest to each society. Copyright Law protects this social interest."

10.3.14Copyright Law in India .

Copyright law existed in India even prior to its independence. The Copyright Law in India can be traced to Indian Copyright Act, 1847. The Indian Copyright Act, 1847 was enacted during East India Company's regime. Later the Imperial Copyright Act, 1911 of United Kingdom was extended to India as part of His Majesty's dominion. Then in 1914, Indian legislature passed the Indian Copyright Act of 1914. To this Act was annexed the modified version of the Imperial Copyright Act, 1911 for its application in India. Thus, prior to its independence, the copyright law applicable in India consisted of Indian Copyright Act, 1914 and the Imperial Copyright Act, 1911 of United Kingdom as modified in its application to India by the Indian Copyright Act, 1914.

10.3.15The Copyright Act, 1957

After Independence, the Indian Parliament enacted the Copyright Law, 1957 to be applicable in India. The Copyright Law, 1957 of India repealed

the Indian Copyright Act, 1914, and the Copyright Act of 1911 passed by the Parliament of United Kingdom as modified in its application to India by the Indian Copyright Act, 1914.
The Copyright Act, 1957 came into force on 21.1.1958 and extends to the whol~ of India:~ Sec;. 1 of the Copyright Act, 1957 reads as follows:

1. Short title, extent and commencement.

(A) This Act may be cadies. the Copyright Act, 1957.
(B) It extends to the whole of India.
(C) It shall come into force on such date as the Central Government may"by notification in the Official Gazette, appoint.

Important features of the Copyright Act, 1957

Following are the important features of the Copyright Act, 1957.

10.3.16 Different works in which copyright subsists.

The Copyright Act, 1957 specifies and defines different kinds of works in which copyright' subsists. These different kinds of works include literary,

(ii) in the case of an unpublished work other than work of architecture, the author is at the date of the making of the work a citizen of India or domiciled in India; and
1. AIR 1985 Del 68.
2. AIR 1987 Del. 13.
(iii) in the case of work of architecture,
the work is located in India.
Explanation.-In the case of a work of joint authorship, the conditions conferring copyright specified in this sub-section shall be satisfied by all the authors of the work.
(3) Copyright shall not subsist
(a) in any cinematograph film if a substantial part of the film is infringement of the copyright in any other work;
(b) in any sound recording made in respect of a literary, dramatic or musicai work, if in making the sound recording, copyright in such work has been infringed.
(4) The copyright in a cinematograph film or a sound recording shall not affect the separate copyright in any work in respect of which or a substantial part of which, the film, or, as the case may be, the sound recording is made.
(5) In the case' of work of architecture, copyright shall subsist only in the artistic 'character and design and shall not extend to processes or methods of construction.

10.3.17 II. MEANING OF COPYRIGHT (Sec. 14)

"Copyright" means the exclusive right to do or authorise the doing of any I of the acts in respect of a work or any substantial part thereof as provided in Sec. 14 of the Copyright Act, 1957.

Sec. 14 provides for different kinds of works and different kinds of acts which may be done or authorized to be done with respect to these works so as lot aft within the definition of "copyright".

Sec. 14 gives a comprehensive definition to the term "copyright". Sec. 14 different meaning to "copyright" with respect to the following different kinds of works as follows:

1. Literary, dramatic or musical work [Sec. 14 (a)]
2. Computer programme [Sec. 14 (b)]
3. Artistic work [Sec. 14 (c»
4. Cinematographic film [Sec. 14 (d),
5. Sound recording [Sec. 14 (e)

10.3.18 Literary, dramatic or musical work [Sec. 14 (a)]

according to sec. 14(a), in the case of literary, dramatic or musical work, not & mega computer programme, copyright means to do or authorise to do any of, the following acts in respect of a work or any substantial part thereof, namely :- .

(a) in the case of a literary, dramatic or musical work, not being a computer programme,

(i) to reproduce the work in any material form including the to issue copies of the work to the public not being copies . already in circulation;

(iii) to perform the work in public, or communicate it to the .

(iv) to make any cinematograph film or sound recording in respect of the work;

(v) to make any translation Of the work;

(vi) to make any adaptation of the work;

(vii) to do, in relation to a translation or an adaptation ot" the work, any of the acts specified in relation to the work in sub-clauses (i) to (vi)..

10.3.19 Computer programme [Sec. 14(b)]

According to sec. 14(b), in the case of 'computer programme', "copyright" . ' means to do or to authorize :
(i) to do any of the acts which include acts with respect to literary, dramatic or musical work;
(ii) to sell or give on coercial rental or offer for sale or for commercial rental any copy of the computer programme:
Provided that such commercial rental does not apply in respect of ; computer programmes where the programme itself is not the essential object of the rental.

10.3.20. Artistic work [Sec. 14(c) !

According to sec. 14(c), with respect to 'artistic work', copyright means do or authorize to do any of the following acts: .
(i) to reproduce the work in any material form including depiction in three dimensions of a two dimensional work or in two dimensions of athree dimensional work;
(ii) to communicate the work to the public;
(iii) to issue copies of the work to the public not being copies already in circulation;
(iv) to include the work in any cinematograph film;
(v) to make any adaptation of the work; .
(vi) to do in relation to an .adaptation of the work any of the acts specified in relation to the work in sub-clauses (i) to

10.2.21 Cinematograph film [Sec. 14 (d)]. .

According to sec. 14 (d), with respect to "cinematograph film", copyright means to do or authorise to do any of the following acts :
(i) to make a copy of the film including a photograph of any image forming part thereof.
(ii) to sell or give on hire or offer for sale or hire, any copy of the I film, regardless of whether such copy has been sold or given on hire on earlier occasions; .
iii) to communicate the film to the public;
In Raj Video Vision v. K. Mohana Krishna,1 the Madras High Court held that sec. 14(d)(ii) of the Copyright Act, 1957 gives a right to the producer to sell or give on hire, or offer for sale or hire, any copy of the film

regardless of whether such copy has been sold or given on hire on earlier occasions.

10.3.22 Sound recording [Sec. 14 (e)).

According to sec. 14(e), with respect to 'sound recording', copyright means to do or authorise to do any of the following acts:
(i) to make any other sound recording embodying it;
(ii) to sell or give on hire, or offer for sale or hire, any copy of the sound recording, regardless of whether such copy has been sold or given on hire on earlier occasions.

10.3.23Copyright and electronic publishing

All forms of works can be stored and transmitted or made available electronically. Most types of literary, dramatic, musical and artistic works can be represented in digital from, as can films and sound recordings. It is not surprising that the growth of multimedia and networks is now posing considerable challenges to copyright law and the traditional role of copyright. Already there areclaims that copyright law is doomed in this arena, quickly to be overtaken by contractual means of controlling the use and dissemination of copyright works 16°. Already there are serious issues emerging in relation to the Internet, copyright and freedom of speech. In the USA, copyright infringement action has been taken by the Church of Scientology against an ex-member who placed some of the Church's materials on the Internet'61. Even the act of digisation, converting a conventional work to digital form, has wide-ranging implications.

10.3.24 What is electronic publishing?

The term 'electronic publishing' lacks precision, but it could include publication by one of the following methods:
the sale, rental or lending. of a physical carrier containing a copy of the work or works in question, for example, CD:-ROM, magnetic disk or magnetic tape by means of commw1ications networks, for example, the Internet or on-line facilities, or by means of a broadcast, whether or not encrypted, for example, Prestel and CEEFAX.
All these forms of electronic publishing are capable of copyright subsistence. In all cases, the individual works so made available may be subject to copyright and, in some cases, there will be other copyrights,

such as that in the broadcast or cable programme. Additionally, there may be an additional copyright in the form of a compilation.
The word 'electronic' has a particularly wide meaning by s 178 of the Act, being 'actuated by electric, magnetic, electro-magnetic, electro-chemical or electro-mechanical energy', an9 the term 'in electronic form' means in a form usable only by electronic means. However, even this may be incapable of keeping up with technological change. Would the above definitions be appropriate in relation to a liquid DNA computer?162 Nevertheless, it is clear that these definitions apply to CD-ROM, laser and magnetic disk technology, and this is important as, by s 17(2), copying includes storage in any medium by electronic means. Some forms of on-line publishing would be deemed to be cable programme services.

10.3.25 Multimedia

A CD-ROM disc typically may contain a whole range of works. For example, a multimedia i product on the topic of heavy metal music may include:
the music shown in conventional notation and/or waveform the sound of
the music being plaited, perhaps by different performers and/or in different styles
an oral and/or textual description of background material relating to the composers and performers
film sequences showing the music being performing in studios or at live concerts
photographs or films showing the composers birthplaces, childhood days, homes and acquaintances and
title sequences, trade marks, background music and so on.
A feature of multimedia is the freedom that the person using it has to move about at will. The information is therefore structured and may have hypertext links. In terms of copyright subsistence, all the works above may be subject to copyright in addition to .the whole as a compilation. There may also be copyrights in the non-literal elements relating to structure and cross-referencing of items. A major difficulty for a company producing a multimedia work is making sure that all the necessary permissions have been obtained. This may be made more
difficult by the spectre of revived copyright resulting from the planned extension of the. term of copyright to life plus 70 years163. '

10.3.26 The Internet

The Internet is made up of interlinked public telecommunications networks to which computers are connected. Anyone can gain access by use of an appropriate modem, usual1y with an appropriate agreement with an access provider, a person who provides a 'gateway' link to the Internet. Material can be accessed, viewed, retrieved, printed and downloaded from all over the world and a vast and growing amount of information is available. Virtually any type of work can
. be made available via the Internet. At the present time, there is no one person who is in overall control ofthe Internet; it could be described as information technology communications anarchy. While copyright still subsists in materials on the Internet (individual1y or colkctively, as compilations), there is a view held by some that placing material on the Internet is equivalent to placing it **in** the public domain. Nothing couJd be further from the truth. Even if the owner of the work does not mind others freely copying the material, that fact does not prejudice the
subsistence 'of copyright. In any case, a person who abandons his economic rights under copyright might feel aggrieved if another later claims he was the author or makes a derogatory treatment of the work. Abandonment of the economic rights does not necessarily mean that the moral rights under copyright law have also been waived'64.

Apart from any copyright in the individual works and compilations of works, there may be separate copyrights in works as cable programmes included **in** a cable programme servicel65. The Copyright, Designs and Patents Act 1988 s 7(1) defines a cable programme service as a service consisting whol1y or mainly in sending visual images, sounds or other information by means of a telecommunications system, otherwise t~an by wireless telegraphy, for reception:

(a) at two or more places (whether for simultaneous reception or at different times **in** response
to requests by different users); or

(b) for presentation to members of the public.

It would seem that information available through the Internet will fall within the first meaning above. There are a number of exceptions (including systems which are predominantly interactive, such as electronic mail). There are, however, difficulties with applying cable programme copyright to the Internet. This forn1 of copyright was intended to be the equivalent to the broadcast copyright for providers of cable television. In this sense it works well, but by s 9(2)(c) the author of a cable programme is the person providing the cable programme service in which the programme is included. But who is providing the service here? The access provider who arranges connection to the Internet does not, in reality, provide the service

in which the programmes (or works) are included. Rather, the access provider is a facilitator. To this, some other problems for copyright in 'cyberspace' can be added. For example, it is impossible to control copying and unauthorised use of works (copies can be made on disk virtually instantaneously - much cheaper and quicker than photocopying). Also, the international dimension is a nightmare in terms of policing and acting against infringers.

10.3.27 Legal liability of facilitators

A facilitator is a person who acquires copies of works or subscribes to on-line services and makes those copies or services available to end users. A library is a good example. In terms of electronic publishing, facilitators are in a vulnerable position. If a person gains access to electronically stored information and makes a copy of it or a substantial part of it (or does any other act in reiation to it) beyond the scope of the licence agreement under which it is made available, then the facilitator, depending on the circumstances, could be liable for infringement of copyright directly or by authorising the infringement. Under the Copyright, Designs and Patents Act 1988 s 16(2), copyright is infringed by a person who, without the licence of the copyright owner does, or authorizes another to do, any of the acts restricted by the copyright. The relative ease of copying electronically stored works is the reason why facilitators are in a more dangerous position here than they are in relation to works stored on paper.

We-have seen that the issue of authorising infringement of copyright was raised in a case involving the sale of Amstrad home music centres having dual cassette tape players. The way the machines were advertised did nothing to reassure the industry, using phrases such as 'You can even make a copy of your favourite cassettes'. Undoubtedly the great majority of purchasers of these machines use them to make unauthorised copies of sound recordings and computer games. However, in Amstrad Consumer Electronics pic v The British Phonograph Industry Ltd'66 it was held that supplying machines which would be likely to be used unlawfully to copy pre-recorded cassettes subject to copyright protection was insufficient to make the manufacturer or supplier an infringer of copyright. Neither could Amstrad be said to be authorising infringement of copyright because it had no control over the way its machines were used once sold. Libraries or Internet access providers, on the other hand, do have some control over how works are accessed or used. Also, access providers can

control, by contractual means, the use that their clients make of the Internet.

Facilitators must fully understand the law of copyright in terms of electronic publishing and make sure that the electronic information they hold or subscribe to is not misused. One way they can minimise the risk of legal liability is to post warning notices near computer terminals or on screen, monitor the access of electronic materials and generally educate the end users about the copyright position and the need to respect copyright materials. Where the facilitator or access provider is in a contractual relationship with the us of the material, the inclusion in the contract of appropriate indemnity clauses should be considered.

10.3.3.28 World Intellectual Property Organisation

Geneva Diplomatic Conference on Certain Copyright and Neighbouring Rights Questions

(Geneva, December 2 to 20, 1996)

WIPO Copyright Treaty

(Adopted by the Diplomatic Conference on December 20, 1996)

(WIPO is an international body under the United Nations responsible for promoting the protection of intellectual property throughout the world through co-operation among States, and in collaboration with other related international organisations. WIPO plays a particularly important role in educating intellectual property officials worldwide about the importance of establishing and implementing strong intellectual property laws. The U.S. creative community looks to WIPO treaties to establish a basic standard of intellectual property protection worldwide. This organization, and the new WIPO Copyright Treaty in particular, represent, a fundamental step in promoting grth and protecting our nation's precious technology assets in the new digital era.

Preamble

The Contracting Parties,

Desiring to develop and maintain the protection of the rights of authors' in their literary and artistic works in a manner as effective and uniform as possible,

Recognising the need to introduce new international rules and clarify the interpretation of certain existing rules in order to provide adequate

solutions to the questions raised Ly new economic, social, cultural and technological developments,
Recognising the profound impact of the development and convergence of information and communication technologies on the creation and use of literary and artistic works,
Emphasising the outstanding significance of copyright protection as an incentive for literary and artistic creation,
Recognising the need to maintain a balance between the rights of authors and the larger public interest, particularly education, research and access to information, as reflected in the Berne Convention,
Have agreed as follows:

Article 1 - **Relation to the Berne Convention**
(1) This Treaty is a special agreement within the meaning of Article 20 of the Berne Convention for the Protection of Literary and Artistic Works, as regards Contracting Parties that are countries of the Union established by that Convention. This Treaty shall not have any connection with treaties other than the Berne Convention, nor shall it prejudice any rights and obligations under any other treaties.
(2) Nothing in this Treaty shall derogate from existing obligations that Contracting Parties have to each other under the Berne Convention for the Protection of Literary and Artistic Works.
(3) Hereinafter, "Berne Convention" shall refer to the Paris Act of July 24, 1971 of the Berne Convention for the Protection of Literary and Artistic Works.
(4) Contracting Parties shall comply with Articles 1 to 21 and the Appendix of the Berne Convention Readme 3

Article 2 - Scope of Copyright Protection
Copyright protection extends to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such.

Article 3 - Application of Articles 2 to 6 of the Berne Convention
Contracting Parties shall apply mutatis mutandis the provisions of Articles 2 to 6 of the Berne Convention in respect of the protection provided for in this Treaty.

Article 4 - Computer Programs
Computer programs are protected as literary works within the meaning of Article 2 of the Berne Convention. Such protection applies to computer programs, whatever may be the mode or form of their expreSSIOn.

Article 5 - Compilations of Data (Databases)

Compilations of data or other material, in any form, which by reason of the selection or arrangement of their contents constitute intellectual creations, are protected as such. This protection does not extend to the data or the material itself and is without prejudice to any copyright subsisting in the data or material contained in the compilation.

Article 6 - Right of Distribution

(1) Authors of literary and artistic works shall enjoy the exclusive right of authorising the making available to the public of the original and copies of their works through sale or other transfer of ownership.

(2) Nothing in this Treaty shall affect the freedom of Contracting Parties to determine the conditions, if any, under which the exhaustion of the right in paragraph (1) applies after the first sale or other transfer of ownership of the original or a copy of the work with the authorisation of the author.

Article 7 - Right of Rental

(1) Authors of:
(i) computer programs;
(ii) cinematographic works; and
(iii) works embodied in phonograms as determined in the national law of Contracting Parties, shall enjoy the exclusive right of authorising commercial rental to the public of the originals or copies of their works.
(2) Paragraph (1) shall not apply:
(i) in the case of computer programs where the program itself is not the essential object of the rental!; and
(ii) in the case of cinematographic works, unless such commercial rental has led to widespread copying of such works materially impairing the exclusive right of reproduction.
(3) Notwithstanding the provisions of paragraph (l), a Contracting Party that, on April 15, 1994, had and continues to have in force a system of equitable remuneration of authors for the rental of copies of their works embodied in phonograms may maintain that system provided that the commercial rental of works embodied in phonograms is not giving rise to the material impairment of the exclusive rights of reproduction of authors.

Article 8 - Right of Communication to the Public

Without prejudice to the provisions of Articles 11 (l)(ii), 11 bis (l)(i) and (ii), II ter (l)(ii), 14(1)(ii) and 14 bis(l) of the Berne Convention,
authors of literary and artistic works shall enjoy the exclusive right of authorising any communication to the public of their works, by wire or wireless means, including the making available to the public of their works

in such a way that members of the public may access these works from a place and at a time individually chosen by them.

Article 9.- Duration of the Protection of Photographic Works

In respect of photographic works, the Contracting Parties shall not apply the provisions of Article 7(4) of the Berne Convention.

Article 10 - Limitations and Exceptions

(1) Contracting Parties may, in their national legislation, provide for limitations of or exceptions to the rights granted to authors of literary and artistic works under this Treaty in certain special cases that do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the author.

(2) Contracting Parties shall, when applying the Berne Convention, confine any limitations of or exceptions to rights provided for therein to certain special cases that do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the author.

Article 11 - Obligations concerning Technological Measures

Contracting Parties shall provide adequate legal protection and effective legal remedies against the circumvention of effective technological measures that are used by authors in connection with the exercise of their rights under this Treaty or the Berne Convention and that restrict acts, in respect of their works, which are not authorised by the authors concerned or permitted by law.

Readme 3

Article 12 - Obligations concerning Rights Management Information

(1) Contracting Parties shall provide adequate and effective legal remedies against any person knowingly performing any of the following acts knowing or, with respect to civil remedies having reasonable grounds to know, that it will induce, enable, facilitate or conceal an infringement of any right covered by this Treaty or the Berne Convention:

(i) to remove or alter any electronic rights management information without authority;

(ii) to distribute, import for distribution, broadcast or communicate to the public, without authority, works or copies of works knowing that electronic rights management information has been removed or altered without authority.

(2) As used in this Article, "rights management information" means information which identifies the work, the author of the work, the owner

of any right in the work, or information about the terms and conditions of use of the work, and any numbers or codes that represent such information, when any of these items of information is attached to a copy of a work or appears in connection with the communication of a work to the public.

Article 13 - Application in Time

Contracting Parties shall apply the provisions of Article 18 of the Berne Convention to all protection provided for in this Treaty.

Article 14 - Provisions on Enforcement of Rights

(1) Contracting Parties undertake to adopt, in accordance with their legal systems, the measures necessary to ensure the application of this Treaty.

(2) Contracting Parties shan ensure that enforcement procedures are available under their law so as to permit effective action against any act of infringement of rights covered by this Treaty, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements.

Article 15 - Assembly

(1) (a) The Contracting Parties shall have an Assembly.

(b) Each Contracting Party shan be represented by one delegate who may be assisted by alternate delegates, advisors and experts.

(c) The expenses of each delegation shan be borne by the Contracting Party that has appointed the delegation. The Assembly may ask the World Intellectual Property Organisation (hereinafter referred to as "WIPO") to grant financial assistance ,to facilitate the participation of delegations of Contracting Parties that are regarded as developing countries in conformity with the established practice of the General Assembly of the United Nations or that are countries in transition to a market economy.

(2) (a) The Assembly shall deal with matters concerning the maintenance and development of this Treaty and the application and operation of this Treaty.

(b) The Assembly shall perform the function allocated to it under Article 17(2) in respect of the admission of certain intergovernmental organisations to become party to this Treaty.

(c) The Assembly shall decide the convocation of any diplomatic conference for the revision of this Treaty and give the necessary instructions to the Director General of WIPO for the preparation of such diplomatic conference.

(3) (a) Each Contracting Party that is a State shall have one vote and shall vote only in its own name.

(b) Any Contracting Party that is an inter-governmental

organisation may participate in the vote, in place of its Member States, with a number of votes equal to the number of its Member States which are party to this Treaty. No such inter-governmental organisation shall participate in the vote if anyone of its Member States exercises its right to vote and vice versa.

(4) The Assembly shall meet in ordinary session once every two years upon convocation by the Director General of WIPO.

(5) The Assembly shall establish its own rules of procedure, including the convocation of extraordinary sessions, the requirements of a quorum and, subject to the provisions of this Treaty, the required majority for various kinds of decisions.

Article 16 - International Bureau

The International Bureau of WIPO shall perform the administrative tasks concerning the Treaty.

Article 17 - Eligibility for Becoming Party to the Treaty

(I) Any Member State of WIPO may become party to this Treaty.

(2) The Assembly may decide to admit any inter-governmental organisation to become party to this Treaty which declares that it is competent in respect of, and has its own legislation binding on all its Member States on, matters covered by this Treaty and that it has been duly authorised, in accordance with its internal procedures, to become party to this Treaty.

(3) The European Community, having made the declaration referred to in the preceding paragraph in the Diplomatic Conference that has adopted this Treaty, may become party to this Treaty.

Article 18 - Rights and Obligations under the Treaty

Subject to any specific provisions to the contrary in this Treaty, each Contracting Party shall enjoy all of the rights and assume all of the obligations under this Treaty.

Article 19 - Signature of the Treaty

This Treaty shall be open for signature until December 31, 1997, by any Member State of WIPO and by the European Community.

Article 20 - Entry into Force of the Treaty

This Treaty shall enter into force three months after 30 instruments of ratific~tion or accession by States have been deposited with the Director General of WIPO.

Article 21 - Effective Date of Becoming Party to the Treaty

This Treaty shall bind

(i) the 30 States referred to in Article 20, from the date on which this Treaty has entered into force;

(ii) each other State from the expiration of three months from the date on which the State has deposited its instrument with the Director General of WIPO;

(iii) the European Community, from the expiration of three months after the deposit of its instrument of ratification or accession if such instrument has been deposited after the entry into force of this Treaty according to Article 20, or, three months after the entry into force of this Treaty if such instrument has been deposited before the entry into force of this Treaty;

(iv) any other inter-governmental organisation that is admitted to become party to this Treaty, from the expiration of three months after the deposit of its instrument of accession.

Article 22 - No Reservations to the Treaty

No reservation to this Treaty shall be admitted.

Article 23 - Denunciation of the Treaty

This Treaty may be denounced by any Contracting Party by notification addressed to the Director General of WIPO. Any denunciation shall take effect one year from the date on which the Director General of WIPO received the notification.

Article 24 - Languages of the Treaty

(1) This Treaty is signed in a single original in English, Arabic, Chinese, French, Russian and Spanish languages, the versions in all these lang~ages being equally authentic.

(2) An official text in any language other than those referred to in paragraph (1) shall be established by the Director General of WrpO on the request of an interested party, after consultation with all the interested parties. For the purposes of this paragraph, "interested party" means any Member State of WIPO whose official language, or one of whose official languages, is involved and the European Community, and any other inter governmental organisation that may become party to this Treaty, if one of its official languages is involved.

Article 25 - Depository

The Director General of WIPO is the depository of this Treaty.

10.4. Question for self assessment

1. What do you mean by IPR?
2. What do you mean by Copy right?
3. What works are protected under copyright Act?

10.5Suggested reading

1. Intellectual property laws by Menu Paul
2. Law relating to intellectual property by B.L. Wadhera
3. The law of Intellectual property Rights: In prospect and Restrospect by A.K. Kaul and V.K. Ahuja

LL.M. Part-1

Subject: Intellectual property Law

Block- IV :Intellectual Property and Human Right
Unit-7- Legal Status of hazardous research protected by the regime of intellectual property

STRUCTURE

11.1. Introduction

Of all entire living creature only man has been endowed with intellectual mind and the same has been effecting utilized by him in improving his standard of living right from the time immemorial. Intellectual property is the property which has been created by the exercise of intellectual faculty. India has a long and creditable record of protection of intellectual property right through a system of well developed substantive laws and established legal and administrative infrastructure for the inforcement of Intellectual property rights (IPR)

Intellectual property law within its scope covers patent, trade secret, copyright, knowhow, industrial design trademarks and so on. Intellectual property legislation relates to the acquisition and use of a range of right covering different types of creations including creations of an aesthetic character (artistic works and industrial designs) technologies (patent) as well as information and signs of a purely commercial value (e.g. trademarks) Every law must have some public oriented goals and on this point intellectual property law is not an exception.

Ideas and knowledge are ever increasingly important part of trade. Most of the value of new medicines and other high technology of products lie in the amount of invention innovation, research, design and testing. Research is the basis of all the inventions. IPR gives protection to all the invention. Now the question raises research whether IPR give protection to hazardous researches also The filed of IPR is very vast where it gives protection to the inventions it also gives a shield to the researches also buton the other hand there are certain regulations and rules have also been laid down patent biodiversity and plant variety protection are areas where provision for research have been mentioned whose Along with intellectual property rights the states of hazardous research has also been discussed in environmental law.

11.2 Object

The object of this study to bring the students aware with the scope of IPR in the field of research which is beneficial and at some extent be disadvantages for human beings, animals and also to the plant life along with this there are certain legal aspect with the help of which we can regulate the hazardous aspect of research and make it favorable to whose mankind and environment.

11.3.1Hazards Research and IPRs

Those research which directly or indirectly adversely affects the life of humans, plants, animals or in the whole to the ecology or the environment can be consider as hazardous research. Today is the world where research ha not been remained confined to a particular field. But in this chapter we have to confined our study to those fields of IPRs which are getting attention easily, Patent, and biotechnology are the main aspects of IPRs which need to be discussed here-

Patent Law:

In legal parlance the patent is a legal grant of a monopoly right for some fixed term to the creator of new invention in return of his disclosing the invention. In M/s Bishwanath Prasad Radhey Shyam V. Hindustal Metal Industries has explained the object of patent law in the following words:

"The object of patent law is to encourage scientific research of 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 new inventions of commercial utility. The price of grant of the monopoly is the disclosure of the invention at the patent office, which after expiry of fixed period of monopoly, passes into public domain."

The patent rights do not impede protection of public health and nutrition and should act as instrument to promote public inters. Specially in sectors of vital importance for socio-economic and technological development of India.

Where on one hand patent grants a monopoly right to the inventor on other hands it also puts a cheek to those inventions the primary entended use or commercial exploitation of which could be contrary to public order morality or which causes serious prejudice to human, animal or plant life or health or to the environment.

The patent Law in its non patentable invention firstly includes those inventions which are frivolous or which claims anything abvious contrary to well establishment natural laws. Secondly plants and animals in whole or in part there of other than microorganism but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.

Along with this patent shall not be granted in respect of envention relating to atomic energy for security and safety purpose.

Indian Patent Act 1970 defines patentable inventions as: a new product or process involving an inventive step and capable of industrial application.

Since IPR protection is granted only for invention and not for discoveries, incase of bio technology innovation, it is difficult to say whether the new life from in the form of gene, DNA, cell etc is a scie4ntific discovery or a technological invention. Discovery is merely making available what

already exist in nature. A substance freely occurring in nature, if merely found or discovered, it not patentable. However if the substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is considered as invention and hence patentable.

The consideration of industrial application it yet another obstacle for securing patent for inventions in biotechnology. However in India there are several ethical issues too related to patenting of life forms, the most important being extent of private ownership that could be extended to life forms. One of the major causes of uncertainties and controversies releted with IPR protection of life forms is lack of an established practice in protecting not only such living materials, but any forms of intellectual property.

11.3.2 Patent in the Sphere of Biotechnology with Specific Reference to Micro-Organism

Various aspects of intellectual property protection in the sphere of biotechnological invention are emerging as a subject matter of fierce debate at national and international level. The inventions in biotechnology cut across issues related to science, technology policies, ethics, economics, legal regulations and complexities of international trade. Grant of patent to a genetically engineered living organism by U.S. Supreme Court in 1980 and subsequent establishment of WTO-IPR regime making provision of patenting of invented living organism has raised several socio-legal and ethical issues regarding f'..lture of researches in bio-sciences.

2.3.3 Emerging Trends in: Biotechnology

The traditional biotechnology which was largely confined to three major areas, viz., (i) plant breeding, (ii) animal breeding, and (iii) industrial microbiology has made a paradigm shift. Recombinant DNA technology, Protopast fusion technology and Hybridism technology have changed the whole complexion of plant, animal and human life. These technologies have been employed in production of genetically engineered organisms and altered genes DNA falling in the area of genetic engineering, protein engineering, cell fusion, tissue culture, gene therapy and fermentation technology.

Human Genome Project (HGP) launched in 1990 is one of the biggest breakthrough in the realm of science of genetics. Successful discovery of human genome by Craig Venter is a hurculean task completed in an international cooperative effort involving 18 countries and 250 laboratories.

Yet another landmark in the field of biotechnology is successful cloning of mammals. Recent claim of human cloning has taken the whole world by surprise and disguise. Cloning of human beings is still a gray area of creative genius of bio-scientist surrounded by host of ethical and legal issues.

11.3.4Patenting of Life Form [Micro-organism]

Micro-organisms as per classical definition are organisms too small to be visible to the naked eye; organisms include all the living things which may be a single cell or a group of differentiated but-inter-dependent cells. Micro-organisms include viruses which depend entirely upon the machinery of reproduction of the host cells and which could be visible only under electron microscope.

Micro-organisms ordinarily do not include various tumor forming cell lines and monoclonals as these are not natural organisms but are produced under abnormal stress conditions or under human interventions. Moreover, most of the transformed cell lines and all the monoclonals are not considered as micro-organisms. Therefore, while defining micro-organisms the cell and tissues of higher life forms including vertebrates and non-vertebrates may be kept out of definition.

11.3.5Budapest Treaty-Creation of the International Depository

In Biological invention, it is not possible to adequately describe the living substance nor it is possible to reproduce the invention without the biological material. Consequently, the world community has accepted that all biological materials be deposited in recognized international depositories. Thus came the Budapest Treaty on the International Recognition of Deposit of micro-organisms for the purposes of patent procedure.2 The treaty provides for recognition of culture collection as International Depository Authorities (lDAS) in anyone of which a new stain of micro-organism can be deposited for the purposes of a patent application in any.member-State.

11.3.6Patenting of Micro-organism in India

The exclusionary provision of Section 3(j) permits grant of patent to micro-organisms. As such the Patent Act, 1970 a:s amended in 1999 and 2002 makes provisionfor patenting of micro-organism.

11.3.7Judicial initiative

Calcutta High Court on 15th January, 2002 has given a landmark decision4 allowing claim for grant of patent to genetically engineered micro-organism called infectious bursitis vaccine.

The appellant had filed a patent application for an inventive process of preparing infectious bursitis. vaccine. The application was rejected by the Patent Authorities on the ground that-

(i) the process of preparing a vaccine having living entity cannot be considered as manufacture;

(ii) the abovementioned process is not an invention according to Section 2(1) of the Patent Act 1970; and

(iii) a process to be covered under invention must result in a substance and a vaccine with a living organism cannot be considered as a substance.

Contention of the appellant was that the preparation of infectious bursitis vaccine is an invention because

(i) the process involves inventive steps and the invented vaccine protects poultry against infectious bursitis;

(ii) there is no bar in present Indian law against patenting of end product, the manufacture of which involves live virus; and

(iii) The patent claimed in the present case is only for process for preparation of vaccine itself.

Taking into consideration the contentions of both sides, the High Court held as under.

(i) Controller erred himself in law by holding that merely because end product contains live virus, process involved is not an invention.

(ii) The claim of patent should have been considered by Controller on principles of Section 3 of the Patent Act. No objection was raised by examiners under Section 3.

(Hi) Applying the Vendibility test the vaccine was treated as substance.

The Court directed Controller to reconsider the application for grant of patent to appellant. It is submitted that this judgment has opened new opportunities for obtaining patents in India on micro-organism-related inventions which wer.e hitherto not granted.

11.3.8Patent application in India for cloning methods

A South Korean scientist seems to be active in this area and perceives that such inventions have potential in India as well. July and August issues of Gazette of India 2001, Part III, Section 2 have reported that 3 PCT applications on cloning methods have been filed in India in the National phase. All these applications are based on the inventive work of Hwarng-Koo-Suk of South Korea. These applications are:

1. A method for producing clone cows (IN/PCT/2000/00572)
2. A method for producing clone tigers by employing enter species nuclear transplantation technique (IN/PCT/2000/00603)
3. A method for producing human clone embryos by employing inter species nuclear transplantation technique (IN/PCT/2000/00064) The fate of all these applications will be decided by the Indian Patent Office after thorough examination, which would entail determining the patentability of cloning methods under the Indian law.

11.3.9 Ethical Dilemma

Patenting of life form (micro-organism) raises host of ethical issues. They can be formulated as under:

1. Is life a patentable commodity?
2. Is patenting of life forms subserve the animal and human welfare?
3. Is majority of world population living in developing countries andleast developed countries going to be benefited by patent of biotechnological invention?
4. Should invention leading to cruelty on animals without bringing any advantage to human welfare be patented?
5. What yardstick should be applied to patentable and not patentable invention?
6. Do developing and underdeveloped countries have capabilities and resources to reap the benefit of new age biotechnological invention?

Recently, on 12th May, 2003 the "UN Panel on Medical Ethics in the Age of Genetic ngineering"l discussed the human and social implication of the biomedical researches conducted during the past 50 years. The

panel attempted to explore as to how these researches will benefit human beings.

A great debate is going on around the world about the functioning pattern of WTO and TRIPs Agreement. Partisan attitude of its dispute settlement body in favour of developed nations, especially USA, raises thedoubts about the so-called fair and equitable justice dispensation system.Jayshree Watal who had the distinction of participating in formative Uruguay rounds of talks in her scholarly book on IPR has aptly commented that, monopoly sans humanism, is the essence of patents without fear of loss or control over their use.l. It is not easy to find answer to the above raised ethical issues. In this age of technology and commerce the human values have been relegated. It is only through enlightened global debate and firm political stand that the image likely to be caused to the interests of developing nations can be litigated.

11.3.10 Biotechnology:

Modern biotechnology is found to offer the mankind the potential of enormous benefit-including healthier and longer life with plenty of water and food. Modern day biotechnology deals generally with molecular biology and specifically with genetic engineering. Basically biotechnology concerns 'techniques' for using the properties of living things to make products or services. Thus the aCED defines biotechnology to be "the application of scientific and engineering principles to processing of materials by biological agents to produce food and services. According to the CBO biotechnology "means any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use. The Indian 1989 Hazardous

Microorganisms Rules defines biotechnology as to mean "the application of scientific andengineering principles to the processing of materials by biological agents to produce goods and services". Thus the modern biotechnology involves scientific techniques on living things for commercial exploitation. The technique include:

a) Selecting natural strains of organisms that carry desirable traits;
b) Making hybrids by fusing cells from different parental sources;
c) Using chemicals and radiation to create mutant strains or genetically engineered plants, animal, and microorganisms to produce specific phenotype characteristic.

Like most modern technologies, biotechnology cannot be confined within the borders of a single state. Indeed the techniques of genetic manipulation are so simple and relatively inexpensive that the Third World countries may easily claim a share of the important discoveries that are certain to result. The next decade is therefore, likely to witness intense competition among nations of leadership roles in the development of new biotechnologies.

11.3.11 Advantages:

'Agriculture: Perhaps the most immediate benefits from biotechnology will flow from its agricultural uses. Through relatively simple genetic engineering techniques, scientist can create biological pesticides that are highly selective and therefore not as likely to cause adverse environmental side effects as G)1emical pesticides. Genetic modification techniques can also be applied directly to plants to improve yields. For example, scientists should soon be able to create plants that have a higher resistance to diseases and drought. In addition to increasing yields, genetic engineering can increase crop quality by enhancing nutritional value, flavor and process ability. The development of agricultural biotechnologies will be of particular interest to developing countries, where agriculture is often a mainstay of the economy and where the pressure of past land use is rapidly reducing the capacity of existing technologies to increase yields. Biotechnology has the potential greatly to improve the productivity of land by reducing the quantities of water and energy necessary to raise a given crop while at the same time preserving essential soil nutrients. It may well be that new products of biotechnology will become essential to the survival of some 3rd world countries as population pressures relentlessly demand greater agricultural production from fewer natural resources.

11.3.12 'Public Health:

Genetic engineering techniques can be used to manufacture live animal vaccines to protect human beings from vector borne diseases. Scientist are also attempting genetically to modify mosquitoes to make them incapable of transmitting diseases such as malaria and yellow fever.

'Mineral Development: Genetically altered microorganisms are capable of leaching metals from low / grade ores and thereby enhance recovery of such metals such as copper etc. Unlike traditional metal recovery techniques, biotechnology does not require high temperatures and

pressures, and it is significantly less polluting. Similar technologies might also be used to mine deposits that are otherwise unreachable. Bioengineered microorganisms might also be used to facilitate crude oil recovery from marginal wells. Microorganisms could be designed to lower viscosity of the oil in place and to increase underground pressure by generating carbon dioxide.

'Pollution Control: The very first genetically engineered microorganisms to receive a patent in the US was designed to digest crude oil into less toxic substances. Microorganisms already playa prominent role in water pollution control technology, and genetic engineering techniques have an enormous potential both for enhancing the efficiency of the existing pollution destroying bugs and for producing new microorganisms that are capable of rendering toxic pollutants in drinking water harmless.
As with many modern technological developments, the enormous benefits of biotechnology will not come without corresponding social and environmental risks. Biotechnology has a dualistic character. On the one hand, it offers developing countries new ways of solving a number of major constraints and it also can contribute to their economic independence. On the other hand, its application and use can cause social, economic and ecological problems.

'Substitution of traditional commodities: Using biotechnology it has become possible to produce substitutes for some traditional commodities. This development threatens those countries that depend heavily on the export of few commodities. As commodities become extremely interchangeable, the processing companies (which are mainly located in the industrialized countries) have a wider choice of material. Because of their economically weak position and narrow export base, developing countries will suffer from the loss of export markets for one or more commodities, and this can have serious adverse consequences for their development.

Industrialization of Agriculture: Much of the current biotechnological plant research is carried out by multinationals and is aimed mainly at large scale, commercial agriculture. The technology developed is adapted to the needs of this type of agriculture. More than 75% of agricultural production in developing countries, however, is on a small scale. The currently available biotechnology is not adapted to the needs of the small producers

or their limited ability to invest and is thus unsuitable for them. The large commercial producers will be able to make use of the technology, thus increasing their productions, but that of the small farmers would remain the same. Increased production will lead to lower prices, which is good for the general public but bad for small farmers.
This may lead to even more migration to the over crowded cities, where there is no prospect for work.
Another problem associated with the industrialization of agriculture is that more and more crops are being sown with the same genetic base. The narrowing of the genetic base of the main commercial and food crops increases the risk from diseases and pests because the whole plant population becomes equally susceptible to disease and environmental stresses. This genetic erosion threatens the world supply of food and plant improvement research, which is based on genetic diversity.

'Privatization of Knowledge and Technology: The idea of patents on products and processes in microorganisms goes against the principle of free availability of natural genetic resources. At both the national and international level there is still no clear definition of which new developments might be covered by patent law. Patenting in advanced countries will jeopardize these countries export markets and small scale food production, and that as a result the gap between he third worlds countries and the west and between the developing countries themselves will widen. Moreover, biotechnological research in industrialized countries ignores any possible consequences for developing countries.
'Effects on People and the Environment: In many cases the application of biotechnology will involve the introduction of new or modified organisms into the areas where they were not found in the same form or to the same extent. The effect of this might include the following:
1: disease in people, animals and plants;
2: disturbance of ecosystem;
3: transfer of new genetic properties to other species; and
4: decrease of genetic diversity.

Very little is known about the possible risks of introducing genetically modified organism (GMO'S) into the environment. Living organisms reproduce and, once released, they are hard to control. The effects may be irreversible. In developing countries, the infrastructure is not strong enough for effective production of biotechnology-generated products. A further constraint is the weak distribution and marketing networks. The problem of mass poverty in the 3rd world is essentially one of rural poverty. Biotechnology applications in rural areas can contribute to

poverty alleviation if they are accompanied by widespread gains in the purchasing power of the poor through the creation of increase employment opportunities in rural areas.

11.3.13 Regulating Biotechnology: The Basic Issues:

The need for regulating biotechnology has been felt a decade ago. However currently there is not a single particular institution created for the exclusive purpose of regulating biotechnology and products of biotechnology. It is simply because biotechnology issue is not simply one issue at all but a complex matrix of issues that touch upon scientific, political, social, ethical and economic concerns and hardly any international institutions has the scope, the resilience, the political support or expertise to provide and support a comprehensive framework for the regulation of biotechnology. The various concerns expressed regarding biotechnology and biotechnology products essentially revolve around 2 basic questions: "Is it safe?" and "Is it good?". It has been found that the question
"is biotechnology safe?" further breaks down into 2 sub questions:
1. How does one regulate biotechnology to protect human health and plants and animals for human consumption?
2. How does one regulate biotechnology to protect against threats to environment; and the question "Is biotechnology good" also breaks into two parts:
How does one regulate biotechnology to balance socio-economic interest?
Need we establish some ethical boundaries for manipulating life?
Thus with respect to the second aspect "Is it safe"? question the biosafety regulations assume greater significance. In other words the biosafety regulations/rules provide the necessary answer to the question, from the environmental perspective how one can regulate biotechnology?

11.3.14Bio safety:

Generally speaking 'Biosafety' is an all embracing term referring to safety measures relating to potential or actual adverse effects on the conservation and sustainable use of biological diversity including risks to human health, arising as a consequence of the application of the modern biotechnology. Thus incidentally biosafety measures can operate so as to

regulate the biotechnology and its products. The safety measures may, for example, include a ban on the biotechnology product or its import, based on the risks assessment- risk assessment for releasing genetically modified organisms (GMO's) into the environment and the risk management requirements once the GMO is in the environment; the Bio labeling (to indicate that the product is a product of biotechnology).

11.3.15 Indian 1989 Hazardous Micro Organisms Rules (Bio Safety rules):

In exercise of the powers conferred by the Environment Protection Act, 1986 and with a view to protect the environment, nature and health in connection with the application of gene technology and micro organisms, the Govt. of India has made the Rules for the manufacture, use, import, expor and storage of hazardous micro-organisms, genetically engineered organisms or cells. The rules cover biotechnology products developed using techniques like cell hybridization and genetic engineering or by any such other gene technologies (Rules 2(3)). Various competent authorities have been created to ensure and supervise the compliance of the safety measures like Recombinant DN advisory Committee; Review Committee on Genetic Manipulation; Institutional Bio safety Committee; Genetic Engineering Approval Committee; State Biotechnology Co-ordination Committee; District level committee.

11.3.16 The implications of biotechnology and biotechnology products are alarming.

Biotechnology, like any other branch of science brings both good and evil. To curb these evil effects and at the same time to derive benefits to the mankind, biotechnology has to be regulated because it may even pose threat to our own survival. In this context only bio safety measures to some extent assume significance. The Bio safety measures basically address the environmental concerns of the biotechnology and bioproductsj GMO's LMO's. At the international level the Bio-safety Protocol governs the transboundary movements of GMOs. At the national level by the 1989 Hazardous Microorganisms Rules, an attempt is made to regulate the manufacture, import and storage of LMO's. The import, export, transport manufacture, process, uses or sales of LMOs can only be dome with the approval of the Genetic Engineering Approval

Committee. The discharge of the GMOs can be prohibited in specific areas. Deliberate and unintentional release of the GMOs even for the experimental purposes except in special cases is totally prohibited. Food products containing LMOs cannot except with the approval of the above-mentioned committee (GEAC)

11.3.17 New Threats To Biodiversity And Related Rights

Biotechnological processes use life forms or derivatives thereof, to make or modify products or processes for specific use. Under IPR's, transformed microorganisms, plants and animals can be patented and become exclusive private property. The North has always used Third World Germplasm as a freely available resource and modified it. The advanced capitalist nations wish to retain free access to the developing worlds storehouse of genetic diversity, while the South like to have the proprietary varieties of the North's industry declared a similarly public good.

The TRIPs agreement of the WTO requires member states to accept IPRs over microorganisms, micro-biological processes and plant varieties. This core requirement and provision is antithetical to India's cultural and economic interests. It also puts at risk the community-based public domain knowledge of biological resources. Article n.3(b) ofTRIPs is of particular concern to developing countries, in as much as it to mandatorily requires for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. This article was a major coup for biotechnology and agrotech corporations in that it provides broad international patent protection for engineered bioresources.

Another sector of biodiversity that has been vulnerable to the change in patent law and policy is that of agricultural biodiversity. The Indian agriculture sector has been opened up to international trade as per the dictates of the WTO. This has meant, among other things, reorientation of cropping patterns for export markets, entry of global corporations in the seed, food processing and packaging sectors and industrialization of agriculture with the introduction of potentially hazardous technologies, such as genetic engineering.

India issued its first ever National Agriculture Policy in 2000. On the one hand, the policy expressly remarks how the situation for Indian farmers would deteriorate in the wake of integration of agricultural trade in the global system. On the other hand, however, it continues to focus on promoting "value addition" and accelerating the growth of agrobusiness. This policy also does little to address the problem of the economic marginalization of small-scale, diverse food production systems that conserve farmers' varieties of crops, which form the genetic pool for food and agriculture in the future. On the contrary the policy inter alia seeks to give special attention" . . . to development of new crop varieties, particularly of food crops, with higher nutritional value through adoption of biotechnology particularly, genetic modification.

Genetically modified organisms and intellectual property go together. The law of patents allows private ownership at the level of the gene. In other words, IPR law under TRIPs legitimizes the patenting of life forms and biodiversity. Today transgenic crops are the "intellectual property" .of the multinational corporations, such as Monsanto, which are marketing the technology to countries in the Third World. Monsanto has been very loud and public in its claims against farmers who used its patented seeds, even if this use was accidental. Multinational agro-business firms such as Monsanto have been aggressively pushing their products into India not only through the regular trade route, but also by dumping food and seeds with GMOs as food aid in disaster areas, as well as in nutritional programmes.

"Meanwhile there has been as increase in the spending in developed countries on research and

development in crop biotechnologies for application in agricultural practices in the developing countries. The lack of technical knowledge in developing countries is a matter of grave concern when dealing with potentially hazardous technologies. The most pressing concern, however, is the imbalance of negotiating strength between the corporations that pioneered transgenic crops on the one hand, and farmers, scientists and governments in poor countries on the other.

There is the concern that wide use of transgenics in agriculture would reduce the diversity of crop species grown and so reduce the gene pool. The gene pool has already been reduced to some extent by modern farming techniques and it is feared that the availability of GE crops would aggravate the problem.

Many Indian farmers--generally the small and marginal--never adopted the intensive practices used in many developed nations, such as heavy reliance on pesticides and chemical fertilizers. These farmers still use traditional seeds that can be saved from one crop to plant the next. Those

farmers may get smaller yields and profits than their corporate counterpart, but because they use free seeds--and, often, little or no chemical fertilizers or pesticides--they rarely take on debt. If GE seeds become the norm traditional seeds might become hard to find, or the latter could get contaminated by GE crops in neighboring fields due to possible crosspollination. Then the big multinationals would control the market for seeds--the most basic source of a farmer's livelihood and, indeed, his/her life. In this scenario, Indian agriculture would increasingly become a subsidiary of agro-business corporations in the North.

11.3.18 Biopiracy:

By 2050, the world is expected to have 9 billion people - as against 6 billion today. The tragedy is that while the biggest sources of biodiversity are in tropical countries, they are the least informed about what they possess, leading to charges of "bio-piracy" against industrial countries which plunder these resources and make extortionate profits on them.
'Biopiracy' can refer to
1. Unauthorized use of biological resources e.g., plants, animals, organs, microorganisms, genes;
2. Unauthorized use of traditional communities' knowledge on biological resources;
3. Unequal share of benefits between a patent holder and the indigenous community whose resource and/or knowledge has been used;
4. Patenting of biological resources with no respect to patentable criteria (novelty, non-obviousness and usefulness).
In under-developed countries, farmers breed crop varieties adapted to their local soil/climate conditions over several decades. Local plant breeders improve varieties through a circular model: selective breeding, release of the variety, and use of the seeds for further selection. Traditional varieties are not fixed genetic structures, but rather dynamic structures, resulting from collective efforts over generations. Most of the time, improvement and use of crops cannot be separated.
An interesting variety may be locally known for its particular properties and identified by a local name, but rarely patented. This may be explained by several facts: the crop does not show the quality of stability and homogeneity required, patenting is a long and expensive process, the selection of the crop is a community work, hence no single holder can be identified, etc.

11.3.19 Research costs and benefit sharing

Some companies argue that under-developed countries are themselves guilty of piracy. They believe that the southern countries do not have adequate and efficient intellectual property protection laws, and say they are losing millions of dollars per year because of lack of respect of patents. These companies have been applying pressure for the strengthening of intellectual property issues within the WTO.
Companies say access to biological resources allow them to develop new products that could help solve food and health essential issues. They also argue that research; development and commercialization authorizations have a cost that must be balanced by the protection of the resulting product. Patents offer this much needed revenue and favour innovation
One of the solutions suggested to solve this North-South disagreement was to define bilateral contracts between source-country and pharmaceutical or seed companies. These contracts of bioprospecting lay down the 7s of benefit sharing, and can potentially bring substantial royalties to southern countries.

11.3.20What defense is there against biopiracy

practices?

The agreement can result in high potential benefits for the source-country. However, there are several reasons why this usually does not happen:
1. Bilateral contracts are not always respected, or they do not propose a fair trade. By admitting that the principle of compensation of the populations is retained, which amount could be an equitable and realistic remuneration? How could the rights be redistributed?
2. Lack of awareness of the potential value of the products;
3. Very few of the samples collected actually lead to a new profitable product;
4. Lo~t ownership in case of genetic modification;
5. Majority of concerned species to be found in several countries at the same time, thus preventing some of them from taking advantage of the product, or diluting the benefits for all;
6. Protection of collective knowledge doesn't fit within the legal systems of IPR protection (e.g. patents, copyrights, trademarks);
7. Finally, most bioprospecting is made by directly using the genetic resources stored in seed banks.

Some options considered by southern countries include:
1. Documentation of traditional knowledge;
2. Registration and innovation system;
3. Easier and less expensible patenting system;
4. Development of a sui generis system;
5. Development of own research;
6. Creation of alliances of source-countries.

In 1993, 500,000 Indian farmers demonstrated against the General Agreement on Tariffs and Trade. In a Charter of Farmers' rights, they stated their wish to protect their right to produce, reproduce and modify seeds and plants.

11.4. Question for self assessment

1. What are the types of invention which are non patentable in India.
2. Does India have provision for grant for E.R.R.?
3. Is there patenting of micro-organism in India?
4. What are the advantages and disadvantage of biotechnology.
5. Discuss the Role of IPR in hazardous Research.

LL.M. Part-1

Subject: Intellectual property Law

Block- IV:Intellectual Property and Human Right
Unit-12- Human right of the impoverished masses intellectual property protection of new products for health care and food security.

STRUCTURE

12.5. Suggested Readings

12.1 Introduction:

Human rights are the right which are possessed by every human being irrespective of his or her nationality, race, religion, sex, status etc. We can say human rights may be considered as those fundamental an inalienable rights which are essential for life as human being. Human rights are based on mankind's increasing demand for a life in which the inherent dignity and worth of each human being will receive respect and protection. As human rights are not created by any legislation they very much resembles to natural rights and sometimes called fundamental rights or basic rights or natural rights. The Indian Constitution bears the impact of the Universal Declination of Human Rights. The framers of the Indian Constitution were influenced by the concept of human rights and guaranteed most of human rights contained in the Universal Declaration of human right, Civil, Political Economic, Social and Cultural rights which are contained in Universal Declaration of human right have been incorporated in our Constitution in Part-III and Part IV.

The right to equality and the principal of nondiscrimination is the foundation of international human rights law. Poverty is one of the most related factor in violation of human rights. The poors are usually victims of discrimination based on multiple grounds, such as birth, property national or social origin, ethnic origin, colours, gender and religion. As discrimination causes poverty, poverty also cause discrimination. In addition to other grounds of unequal treatment often suffers discrimination because they are poor. Poor or the impoverished masses are the vulnerable section of the society.

12.2 Objective

Area of human rights and intellectual property rights is very wide in which all the basic rights of human being have been covered. Whereas intellectual rights covered those rights which are essential to protect the interest of individual, on the otherside human rights protects those rights which are fundamental and necessary for the life of a human being.
Human rights and intellectual property rights are at some extent co-relative to each other Here the object of the study is to bring aware students with the aspects of human rights, intellectual property right and

their effects relating to health products specifically the drugs and food security which is a major problem throughout the developing countries.

12.3.1 What Are Human Rights?

Human rights can be defined as the fundamental rights which the humans have by the fact of being human and which are neither created nor abrogated by any government. They were first defined by the UK philosopher John Locke as absolute moral claims or entitlements of life liberty and property. Human Rights can be referred as basic rights and freedom which all humans are entitled.

Human Right are fundamental and universal. They can also be defined as basic standards of treatment to which all people are entitled, regardless of nationality, gender, race, economic status or relgion.Human rights represent claims which individuals or groups make on the society. They also include right to freedom from torture, the right to life, freedom from inhuman treatment, slavery, forced labour, the right of liberty and security, freedom of movement and right of residence, right to fair trial, right to privacy, freedom of thought, conscience and religion, freedom of opinion and expression, right to marry and form a family, right to participate in one's government either directly or indirectly or through freely elected representative, the right to nationality and equality before law.

Human rights is defined in Protection of Human Rights Act, 1993. Human rights means the rights relating to life, liberty, equality and dignity of the individual guaranteed by the Constitution or embodied in the international Covenants and enforceable by courts in India.

Protection Of Human Rights Act, 1993

This Act was passed in the year 1993 with a view to provide for a constitution of a National Human Rights Commission, State Human Rights Commission and Human Rights Courts for better protection of human rights and for matters concerned therein. It lays down provisions for - constitution of National Human Rights Commission, appointment of its chairperson and other members, removal of the members of the Commission, term of office of members, terms and conditions of service of members, procedure to be regulated by the Commission, officers and other staff, functions and powers of the Commission and the method to be followed in case of a complaint. In the same way, these things are laid down in case of State Human Rights Commission. The National Commission is empowered to inquire into and investigate complaints of human rights violations and recommend appropriate relief measures to the Government. At the state level, similar functions are entrusted to State Commissions. The Act had a vowed objective of establishment of Human

Rights Court at district level, apart from establishing Human Rights Commissions at the national and state level.
Chapter VI of the Act deals with the Human Rights Courts. It also states that for every Human Rights Court, the State Government shall, by notification, specify a Public Prosecutor or appoint an advocate who has been in practice as an advocate for not less than seven years, as a Special Public Prosecutor for the purpose of conducting cases in that Court.
The Act also contains provisions for grants and funds by the Central and State Governments as they find appropriate to the National and State Governments respectively. Both Central and State Commissions are required to keep proper accounts and records and is required to maintain annual accounts. The Commission cannot inquire into any matter which is pending before a State Commission or any other Commission duly constituted under any law for the time being in force. The government of India can also constitute special investigating teams if necessary for investigation in the matters of human rights violations. Also no action can be taken against the Central or State government and National and State governments for anything done in good faith or with good intention in accordance with the rules of this Act. The Central and State governments can also make rules by notification to carry out the provisions of this Act. In case of any difficulty, the Central government can make provisions which are not inconsistent with the provisions of this Act and help in removing difficulty.

12.3.2 Human Right's Violations

Today there is universal consensus that all individuals are entitled to certain basic rights under any circumstance. These include certain civil liberties and political rights. The most fundamental of these rights is the right to life and physical safety. The impoverished masses and vulnerable seations of the society is the most exploited in case of human rights violation. human rights are the articulation of the need for justice, tolerance, mutual respect, and human dignity in all the activities. Speaking of rights expresses the idea that all individuals are part of the scope of morality and justice
To protect human rights is to ensure that people receive some degree of decent, humane treatment. To violate most basic human rights is to deny individuals their fundamental, moral entitlements. Examples are acts

typically deemed "crimes against humanity," including genocide, torture, slavery, rape, enforced sterilization or medical experimentation, and deliberate starvation. Because these policies are sometimes implemented by governments, limiting the unrestrained power of the state is an important part of international law. Underlying laws that prohibit the various "crimes against humanity" is the principle of non discrimination and the notion that certain basic rights apply universally.

Over the course bf time, assaults on political rights and the fundamental right to life are typically widespread. Some of the gravest violations of the right to life are massacres, the starvation of entire populations, and genocide. The term "war crime" refers to a violation of the rules of jus in bello (justice in war) by any individual, whether military or civilian. The laws of armed conflict prohibit attacks on civilians and the use of weapons that cause unnecessary suffering or long-term environmental damage. Women and girls are often raped by soldiers or forced into prostitution.

Trafficking in women is a form of sexual slavery in which women are transported across national borders and marketed for prostitution. This is another form of the human rights violation as far as women are concerned. Government forces may carry out programs of torture. Torture can be either physical or psychological. Torture is used in some cases as a way to carry out interrogations and extract confessions or information. Political oppression may also take the form of discrimination. When this occurs, basic rights may be denied on the basis of religion, ethnicity, race, or gender. Apartheid, which denies political rights on the basis of race, is perhaps one of the most severe forms of discrimination. Violations of political and economic rights are the root causes of many crises. When rights to adequate food, housing, employment, and cultural life are denied, and large groups of people are excluded from the society& apposes decision-making processes, there is likely to be great social unrest. Such conditions often give rise to justice conflicts, in which parties demand that their basic needs be met

Human rights are the rights of all to equal opportunity for social, economic, and psychological development, regardless of race, religion, caste, class, or gender or status. It is sad that we have to remind ourselves that all of us are human, and none should assume that some are more human than others.

Sadder still, that we have to lay down laws to protect this natural equality, because some do believe and behave in ways which prove that some humans are more equal than others, meaning entitled to more privileges than others. The situation in our country has deteriorated to such an extent that the majority are deprived of the opportunity to develop themselves. Theirs is a struggle for mere survival. Denied their natural

human rights to personal development, they are fighting to assert simply their right to be human.
Indeed, many conflicts are sparked or spread by violations of human rights. For example, massacres or torture may inflame hatred and strengthen an adversary's determination to continue fighting. In cases where extreme violations of human rights have occurred, reconciliation and peace building become much more difficult. Unresolved human rights issues can serve as obstacles to peace negotiations. This is because it is difficult for parties to move toward conflict transformation and forgiveness when memories of severe violence and atrocity are still primary in their minds.

12.3.3Voilation of Human Rights in Various Vulnerable Section

12.3.4.Children

India has more working children than any other nation. Main reason behind child labour is poverty but everyday news of children dying of starvation, dipping sex ration, child marriage, child trafficking, child abuse, etc. is very common. Violations of children's rights are not limited to poor and downtrodden only. They happen in middle class and elite homes also, though in different forms. Girls in vulnerable situations such as poverty, disablility, homelessness etc. find themselves dubly disadvantaged, by their gender and the physical, economic, political, social situation thet they find themselves in.

It is therefore imperative to take a gender perspective into account in examining the situation of children. Some other examples of violations of children's rights are pre-natal diagnostic techniques to determine the sex, illegal sale of babies, imposition of corporal punishment on the child, children as victims of crimes - sexual abuse, bonded labour, child labour, child prostitution, use by criminal gangs, juveniles, etc. Various legislations like Juvenile Justice (Care and Protection of Children) Act, 2000, Immoral Traffic (Prevention) Act, 1956, Child Marriage Restraint Act, 1929, etc. have been made in addition to the Protection of Human Right Act, 1993, to deal with specific issues.

12.3.5 Scheduled Casts and Scheduled Tribes

The conditionof scheduled castes and scheduled tribes was very bad in the society. The Scheduled castes (lower castes) remained economically dependent, politically powerless and culturally subjugated to the upper caste. The scheduled tibes like the scheduled castes face structural discrimination within the Indian socity. Unlike the scheduled castes, the scheduled Tribes are a product of marginalization based on ethnicity.

In India the population of scheduled tribes is around 8 million and they are socially and economically disadvantaged. They are mainly landless with little control over resources such as land forest and water. They constitute a large proportionof agricultural laborers, casual laborers, plantation laborers, industrial laborers etc. This has resulted inpoverty among them, low level of education and reduced access of health care services.

In rural areas still there is a lot of discriminated practicises are going on. And violation of their human rights is not a new thing to them.

Various rules, regulations and legislation have been passed but enforcement and implementation has been a dismal failure.

12.3.6 Women

Women have low status as compared to men in the Indian society. They have little control over the resources and important decisions related to their lives. During infncy and growing years a girl child fces different forms of violence like infanticide, neglect of nutrition needs, education and healthcare,. As adults they face violence due to unwanted pregencies, domestic violence, sexual abuse at the workplace and sexual violence including marital rape and honor killing.

Even after more than 65 years of our independence, Indian women wear a pathetic look.

Enactment of protection of Human Rights Act 1993 was the enitrative taken by Indian government for preventing the human rights violation in the country. The Preamble of the Act makes it clear that it is an Act to provide for the constitution of National Human Right Commission, States commission and Human Rights courts for better protection of human rights. Though the commissions have been constitute but the constitution of Human Rights court is still awaited.

The performance of a national institution has to be assessed in terms of not only its successes in achieving its stated objectives, but also the constraints within which it has worked. A pertinent question here is whether the NHRC as the requisite powers to fulfill its functions as a

national institution with a statutory basis. Compared to the institutions of similar nature around the world, it has a relatively heavy case-load; that is, it handles a larger number of complaints of violation of human rights, or of negligence in preventing such violation. And dealing with complaints is only one of the 10 major functions assigned to the Commission under Section 12 of the Act. Its ambit ranges from reviewing safeguards for the protection of human rights and performing such other functions as it may consider necessary for the promotion of human rights. However, year after year the NHRC has been complaining of a lack of response from the Union government to its pleas to amend the law so as to realize its objective of "better protection of human rights and for matters connected therewith or incidental thereto".

The State Commissions also work in the same way as the NHRC. The area of their jurisdiction is limited to their respective States. Also in the fourth Annual Meeting held between the NHRC and SHRCs, the SHRCs complained about the lack of infrastructure facilities in the State Commissions and other problems. However, if NHRC has taken cognizance of a particular case, then any SHRC cannot take cognizance of that case again. Also, NHRC can transfer any case to any SHRC if it may deem fit.

Human rights are a sort of special moral entitlement. They belong to an individual as a consequence of being human. Human rights are defined at different places differently. In India, human right now days is a burning issue. The act passed to protect human rights i.e. Protection of National Human Rights Act, 1993 was passed by with a view to prevent human rights violations. But this Act has also proved to be deficient in some cases especially in cases relating to violation of human, rights by armed forces. It is very necessary to protect the interests of people like SC, STs, impoverished etc. because these people form the vulnerable section of the society. Also, the procedure followed in NHRC and SHRCs needs to simplify a bit so that everyone including the vulnerable sections can access it. The concept of separate human rights courts which is coming up nowadays can perhaps help in more efficient protection of human rights of the vulnerable sections of the society.

12.3.7 Poverty Eradication and Human Rights

What does a human rights approach add to efforts to eliminate poverty? answer is that a human rights approach to poverty reduction provides a conceptual framework for the process of sustainable human development.

It is a normative framework derived from intemationally accepted human rights standards and it is one that can be operationally directed towards promoting and protecting the human rights of people living in poverty.
A human rights approach to poverty is about empowerment of the poor. One of the clearest and most persistent themes in the World Bank series Voices of the Poor is powerlessness. crying Out for Change examines the "ten interlocking dimensions of powerlessness and ill-being (that) emerge from poor people's experiences. It concludes: "[T]he challenge for development professionals, and for policy and practice, is to find ways to weaken the web of powerlessness and to enhance the capabilities of poor women and men so that they can take more control of their lives."
Empowerment occurs through introducing the concept of rights. When human rights are introduced in policy making, the rationale of poverty reduction no longer derives' only from the fact that the poor have needs but is based on the rights of poor people entitlements that give rise to obligations on the part of others that are enshrined in law.
The different components of a human rights normative framework can contribute to the empowerment of the poor. The most relevant components are; the concept of accountability, the principles of non-discrimination, equality, and participation, and the recognition of the interdependence of rights.

12.3.8 Equality and non -discrimination

By introducing the dimension of international legal obligation, such as the standards on equality and non- -discrimination, a human rights perspective adds legitimacy to poverty eradication as a primary goal of policy making.
Where discriminatory attitudes result from deeply rooted attitudes of the population, governments should take the lead in inducing change through education and should adopt and enforce laws prohibiting any discrimination by private citizens or groups.
Governments must in addition take special measures in order to provide to their most vulnerable, discriminated and socially excluded groups, including the poor, effective protection against discrimination by governmental authorities as well as by private actors.
The equal relevance of civil and political and economic social and cultural rights to poverty reduction Recognition of the complementary relationships between civil and political rights on the one hand and economic, social and cultural rights on the other, can strengthen as well as broaden the scope poverty. In particular, it helps dispel the misconception that civil and political rights and freedoms are luxuries that are relevant only for affluent

societies. A human rights approach insists that guarantees to ensure civil and political rights are necessary components of poverty reduction strategies.

12.3.9 To Steps to be taken to:-

To reduce or eliminate poverty there is an accountability of policy makers and other actors whose actions have an impact on the right of people. Rights imply duties, and duties demand accountability. It is, therefore, an intrinsic feature of the human rights approach that any poverty reduction stagey should build into it institutions and legal/ administrative provisions for ensuring democratic accountability.

A human rights approach to poverty also requires the active and informed participation of the poor including in for example the formulation implementation and monitoring of poverty reduction Strategies

The enjoyment of the right of participatre is therefore dependent on the realization ofother human rights. For example, if the poor are to participate meaningfully in PRSs, they must be free to organize without restriction (right of association), to meet without impediment (right of assembly) and to say what they want without intimidation (freedom of expression) they must know the relevant facts (right to information) and they must enjoy an elementary level of economic security and well- being (right to a reasonable standard of living and associated rights.

12.3.10 Health

Health is a prerequisite for sustainable human development poverty reduction, social welfare, political stability and economic growth. Health is also a fundamental human right, and a right whose realization is necessary for the exercise of other human rights and freedoms.

The relationship between health and human rights is multifaceted. Disease such as HIV/AIDS, tuberculosis and malaria disproportionately affect people living in poverty, whose living conditions are made worse as a consequence of ill health. Human rights violations, such as violence against children or harmful traditional practices, may have serious health consequences.

As defined by the Economic Social and Cultural Rights Committee of the UN general Assembly, the righ include a wide range of socio-economic factors that promote conditions in which people can lead a healthy life, and extends of underlying determinants of health, such as food and nutrition, housing, access to safe and potable water and adequate sanitations afe and healthy working condtions, and a healthy environment.

In other words, the realization of the right to health depends upont he realization of other human rights. In the Committee'sanalysis these include the rights to food, housing, work, education, non-discrimination and equality, as well as on the implementation of freedom of association,assembly and movement and the right to privacy and access to personal information.

12.3.11 HIV/ADIS

HIV/AIDS provides a striking example of the inter-relationship between health, human rights and sustainable development. AIDS and poverty are now mutually reinforcing negative forces ion many developing countries and are impediments to economic growth in the hardest hit areas. AIDS is the leadingcuase of death in sub-Saharn Africa, where life expectancy is now around 47 years, and is the fourth largest killer world-wide.

Trickling the root causes of vulnerability to HIV/AIDS therefore requires that particular attention be paid to the causes of stigma and discrimination, and of how they reinforce stereotypes and inequalities related to gender, ethnicity, race, sexually and social status. Equally a human rights response calls for freedom of expression and open public discussion to increase public awareness and responsibility towards those affected by the disease.

Hence the violation of human rights is violation of basic rights of a human being. As poverty is the cause of all the difficulties face by a person, it also plays a lead role of exploitation of this section of vulnerably society. Poverty causes many kinds of discrimination which leads to the violation of human rights of the impoverished masses with the enactment and implementation of policies of poverty eradication we could be able to curb the violation of most of the human rights

Introduction

Intellectual property is the creative work of the human mind. The main motivation of its protection is to encourage the creative activities. The

contribution of intellectual property to industrial and economic development of a country cannot be exaggerated. The prosperity achieved by developed nations is the result of exploitation of their intellectual property. The protection of intellectual property is also responsible for the transfer of technology from developed countries to the developing countries.

Intellectual property is defined under Article 2(viii) of the World Intellectual Property Organization (WIPO), 1967 to include right relating to (i) literary, artistic and scientific works; (ii) performance of performing artists, phonograms and broadcasts; (iii) inventions in all fields of human endeavour; (iv) scientific discoveries; (v) industrial designs; (vi) trademarks, service marks and commercial names and designations; (vii) protection against unfair competition; and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields.
Under Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) of 1994, the intellectual property rights have been negotiated under seven broad heads. These heads are copyright; industrial designs; trademarks; patents; geographical indications; layout designs of integrated circuits; and undisclosed information. Council
or TRIFs Agreement to prevent and settle disputes within the WTO settlement of disputes mechanism has been established.

Intellectual property rights have a direct bearing and symbiosis with inventions and technology. Technology can be defined as a systematic knowledge for the manufacture of a product or of rendering of a service in industry, agriculture or commerce whether that knowledge be reflected in an invention, a utility model, an industrial design, a plant variety, or in technical information in the form of documentation or in skills or experiences of experts for the design, installation, operation or maintenance of an industrial plant or its equipment or. for the management of an industrial or commercial enterprise or its activities. Today, science and technology is the key to the progress of mankind and the intellectual capital formed by scientific resources and the aptitude for the technological innovations as expressed in proprietary knowledge constitutes the major assets of any country. and a new patent regime emerged from process patent to product patent in India, the Indian pharmaceutical industry was impacted.

12.3.12 Role of IPRs in Pharmaceuticals

The TRIPS Agreement deals not only with patents but also with other films of IPR such as copyright, trademark, industrial designs, geographical

indications and others. Among them three intellectual. property which play important role in development and commercialization of pharmaceutical industry are patents, trademarks and trade secrets.

Patent: First and foremost area which deals with pharmaceuticals is patent laws. Patent specifically deals with protection and monopoly rights for inventions to the inventor to grant patent rights 3 essential requirement are there which are

(i) Novelty
(ii) Inventiveness
(iii) Industrial application

After the amendment Act of 2005 the product patent has been granted which have a deep impact on pharmaceutical product.

Trademarks: The widest and largest use of IPR in Pharmaceutical industry is in use of trademarks. In pharmaceutical industry the registration of trademarks helps brand building for value creation. Branded queries or medicines help the patients and medical profession to identify the manufactures and potentially reliable quality inherent in the branded product. Trademarks in medicines help to build trust and confidence in the minds of the doctors and patients.

Section 13 of Indian Trademark Act, 1999 states that words which are declared by the W order Health Organization and notified in the prescribed manner by the Registrar from time to time as international proprietary Names shall not be registered; this prohibition stands against the generic names registration as trademark. In a recent case, where Dr. Reddy' Challenged Torrent Pharmaceutical against the registration of dopamine, the Intellectual Property Appellate, Bo~d held that Dopamine con not be registered as it is an international non-proprietary name allotted by WHO.

Copyright: Copyright protects the literary, artistic, dramatic or musical and cinematographic creations of author for an exclusive period of time. In pharmaceutical industry documents recording the researches instruction manuals, dossiers & literature texts are protected through copyright. In case of non-prescription drugs and over the counter (OTC) drugs, various slogans or one-liners (Jingles) are also protected through copyrights. As copyright also protect the artistic creations, different drawings pictures, graphic or colour combination used on cations, tubes, labels of pharmaceutical products are copyright protected.

12.3.13 Industrial Designs:

Designs Act protects shape or appearances applied to an article for commercial or industrial purpose. Design protections are . available for

outer packaging of bottles, shapes of medical instruments designs over the tablet cover etc. Use of design protection in Indian phanna .sector is comparatively low. Though medical devices, syringes, inhaler etc have increasingly acquired protection under the Designs Act 2000.

Trade Secret Data Exclusivity

Though there is no specific Act for providing protection, trade secret protection is conferred to any formula, pattern, device, consumer lists etc. which are crucial information for trade and commerce through common law. India still lacks a legislation to protect confidential information. Presentlyhowever, trade secrets continue to have to seek protection through law of contracts and tort.

One of the most controversial and widely debated topics, presently in India related indirectly to confidential information is the 'data exclusivity'.

Data exclusivity refers to a practice whereby for a fixed period of time, drug regulatory authorities do not allow the dossier or regulatory documents of an originator to be referred or used to register a therapeutically equivalent generic version of that product. TRIPS Agreement under article 39 (3) also talks about protection of undisclosed test data against unfair commercial uses.

12.3.14 Indian Patent Act and TRIPS Agreement On 15 April 1994

India become party to the TRIPS Agreement that time India's existing enactment of the patent Act 1970 directly contravened Article 27 of the TRIPS Agreement. And being the member of WTO India has to make their patent provisions compliant to the TRIPS Agreement: TRIPS gave the transitional period for WTO members to introduce legislation complying with the obligations.

For developing countries like India the deadline given was 2000 ,but for those countries that do not grant product patents an additional period of 5 years was also given to introduce product patent protection India has the advantage of this extra transition period. Where the TRIPS itself deals with the pharmaceutical aspect, the Indian patent Act also works in the light of the provisions of the TRIPS Agreement.

12.3.15 TRIPS Agreement & Pharma

Article 27 of the TRIPS Agreement is most relevant provision relating to pharmaceutical industry. Article 27.1 give a wide definition of patentable inventions it says that patent shall be available for any inventIon whether

product or processes, in all fields of technology, provided they, are new, involve an inventive step and are capable of industrial application. It also says that patent is available and its right is enjoyable without any discrimination of place of invention or field of technology or whether products are imported or locally produced but subject to Para 4 of Article 65, Para 8 of Article 70 and Para 3 of this Article 27.2 describe where the exclusion can be given to the patentable inventions, the prevention within their territ01Y of the commercial exploitation of which is necessary to protect public order or morality, including to protect
human, animals or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. Apart from this members have been given some more exclusion from patentability. Article 27.3 (a) diagnostic therapeutically and smgical methods for the treatment of humans or animals may also be excluded from patentability. Article 27.3 (b) again gives a chance to exclude from patentability plants and animals other than microorganism. But further grant of patents for product or processes for microorganisms have made compulsory. Members shall provide for the protection of plant varieties either by patent or by an effective sui-generis system or by any combination there of. A unifonn patent tenn extinction of 20 years in retmn for disclosing the invention to the public in the patent application with sufficient details to enable a person skilled in the relevant technology' to practice the claimed invention is also provided by TRIPS.18 TRIPS also include those exceptions to exclusive rights which have been conferred by the patent. In case of process patent the bmden of proof is to be made available by the member countries under Article 34. Provision of Data Exclusivity is also available in the agreement. Aprovision relating to protection of undisclosed information has been given under Article 39.3 except to that extant where it is necessary to protect public or against unfair commercial use. To extend the protection to product patent a transitional period of 5 years should be given to the developing country and for least developed countries it is 10 years periodl9. Transitional arrangement and protection of existing subject matter dming the transition phase are also dealt with under Article 70.8 of the TRIPS Agreement.

India's commitment to implement the Agreement on TRIPS required about three sets of amendments to its patent law. The first amendment of the Patent Act, 1970 introduced requirements under the transitional arrangements through sections 5(2). The amendment of 1999 introduced ,exclusive Marketing Rights provisions on 1, January 1996. Section 5 of the ;atent Act. 1970 was linked to newly introduced chapter IV A, Section 24 A to 24F of exclusive marketing rights. The Act of 1970 talks about only of process patent and those countries who have no provisions for product

patent in that law, has to alter their patent Regime to be in conformity with the provisions of TRIPS agreement.
India also avails the transitional phase of 10 years, during this phase all applications for the product patent was kept in the mail box till 2005. Some expense predicted that all 8500 applications filed for EMR in India will become EMR and will cause harm to Indian pharmaceutical industry. But contrary to that only 14 were filed out of which majority of them got rejected.

12.3.16 EMR Grant in India

In most cases appropriate tests were conducted prior to 1st January 1995 and in other cases there have been non-matching of applicant or subject matter or lack of convention status of the country of research or other technical grounds. One of the EMRs granted was stayed by Calcutta High Court and related product patent (mailbox application) was rejected thereafter, in post 2005, product patent examination (on pre-grant Opposition), fin other EMR which had been granted to an Indian company for a topical composition of known substances has also lapsed. Thereafter, the composition (product) patent application has been ~anted on the pre-grant Opposition. A third EMR application filed by a Swiss based Pharmaceutical Corporation led to the grant of an EMR. The Swiss Pharmaceutical Corporation thereafter successfully obtained an injunction against majority of other Indian companies, post 2005, when the product patent (mailbox) application was taken up for examination a large number of pre-grant opposition were filed and product patent applications were rejected leading to the extinction of the EMR thereof. An EMR for pesticides has been granted to an Indian company and was replaced by the grant of a product patent post 2005, Parliament again amended the Patent Act in 2002 to set in turn with the provisions of the TRIPS agreement to a greater however not to a fullest extent. The key issues included in the second amendment were redefining patentable subject matter, extension of the term of patent protection to 20 years and amending the compulsory licencing system, deleted the provision of licence of right. Reversal" of burden of proof under section 104-A had been inserted. The Patents (2nd Amendment) Act 2002 incorporated the research exemption under section 107-A.
The TRIPS Agreement also under the heading exceptions to rights conferred, give liberty "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 patent owner taking account of the legitimate interests of third parties." 20 The Patent Act of

1970 also gives certain exemptions. Section 47(3) says that any person can use patented product or process for the purpose of experiment or research including imparting of instructions to pupils. Section 107A (a) states that any act of making, constructing, using selling or importing a patented invention solely foruses related to the development and submission of information does not amount to infringement of patent. By going through these two sections it can be considered that these sections enable the pharmaceutical companies to conduct further research & experimental work over the patented product. This exemption is specifically useful for generic manufacturers to prepare generic version in advance of patent expiry. These research exemptions are also known a Bolar Provision. Beside these provision section 3 (g)21 was also deleted bythe Patent (Amendment)Act 2005) elation of this section widened the scope of patentability of testing methods or processes which can be also useful for the manufacturing of drugs in pharmaceutical industry.

The New Patent Regime of Product Patent came with the 3rd amendment of Patent Act 1970. Inclusion of clause (ja) was there anddefmes 'inventive step' as a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that make's :the invention not obvious to a person skilled in the art. Product patent have now been made available to all fields of inventions including pharmaceuticals food and chemical. Another section 92-A has inserted provisions for Compulsory License for the export of patented pharmaceutical products. This is meant to facilitate the Indian industry to continue supplying chapreI' generic versions of patented drugs to those Least Developed Countries (LDCs) that do not have adequate domestic manufacturing capabilities.

The Patent (Amendment) Act 2005 has also omitted section 24A to 24F of chapter IV A of the Patent Act of 1970. Before amendment of the Act 1970, there was provision for opposition of an accepted patent application by anyinterested person under the Patent Act, 1970 but after the amendment there was insertion of the additional provision for pre-grant opposition along with the provision for filing post grant opposition. Section 25 (1) of the Patent Act,1970 lays down the grounds on which a patent application can be opposed in India. It also stresses that provisional specifications should be updated with complete specification 'Within 12 months with no provision for further grace period.

While making the necessary Amendments to the Indian Patent Act (passed by the parliament on 22 March 2005), the Indian Government hasstrived to ensure that not only is India's commitment to the WTO community for providing strong intellectual property protection is taken care of but also the protection of the domestic industry, the consumers and the economy at large is ensured.

Pre-grant oppositions by pharmaceutical companies in India have been in news in recent time as per various induce and legal sources it is believed that till date. Indian pharma companies have flied 148 pre grant oppositions in to patent applications. Indian drug companies such as Ranbaxy Labs, Cipla and Torrent pharma are believed to have filed around 15 and 50 pre-grant oppositions, respectively. With regard to such pre-grant oppositions, MNC; pharma companies feel that the same are used by domestic pharma companies, such as a strategy to delay the grant of their patents. However, a pre-grant opposition regime accretion of information, which otherwise the patent office would not have been aware of it, also helps the patent office in rejecting frivolous and non patentable invention. And now when pre as well as post grant opposition has come into existence the doubts of these 'Big' multinational pharma companies will be removed.

12.3.17 National Pharmaceutical Policy, 2006

The Pharmaceutical policy of 2002 was controversial as it reduced the span of price control which in turn would have resulted in increase of essential life saving dmgs. It has been replaced by national pharmaceutical policy 2006 which aimed an strengthening of dmg regulatory system the formulae proposed for fixing equitable prices for bulk dmgs and their formulations include cost plus margins models negotiated prices, differential prices, reference prices bulk purchase prices etc. The policy provided for 'Rastriya Swasthya Beema Yojana' for the 'Below Poverty Line' (BPL) families and other schemes. The maximum allowed post marketing expenses have been increased to 150 percent from 100 percent as provided WIder Drug price control order, 1995 with an extra 50 percent for products of R & D intensive companies. In April 2008, the Health Ministry expressed strong reservations against the proposals in the draft policy. One of the major reasons in that the chemical ministry wants to establish a separate pharmaceutical department. 36

12.3.18 Sawant Reddy Report

Indian has emerged as one of the important producers of generic medicines in the world. There has been a prolonged debate on the likely impact of data protection provisions on the growth of pharmaceutical industry and on availability of cost genenc medicines India does not have a data protection law like the Hatch & Waxman Act. TRIPS agreement Art 39.3 seeks to give protection to the originator for the investment in time and money in the generations of registration data. The Sawant Reddy

panel as constituted by the central government submitted its report on steps to be taken by government of Indian in the context of data protection provision of TRlPS Agreement Art 39.3 on 31st May 2007. The panel has come out with following recommendations:3?

During the period of Data exclusivity the government would ensure prevention of leakage of data or unauthorized use of research material. During the transitional period, the millennium requirements under Art 39.3 that is, nondisclosure of test data and non acceptance of fraudulently obtained data of Trips may be implemented.

The office of drug regulator must work for up gradation of physical infrastructure and technical skills. Pharmaceuticals as well as traditional medicines must be provided with five years of DE.

Drugs for life threatening diseases like HIV / AIDS may be exempted from the provisions of fixed period data protection by the drug regulator by placing reliance on the data submitted by the first applicant and grant market approval to the subsequent applicants for the same products in India.

DE will be protected under the provisions of common law, Law of Torts and the Indian Contract Act, 1872.

In order to ensure confidentiality of data, additions must be made to the Drugs and Cosmetics Act, 1940 to specify third party liability for unauthorized use and make data protection enforceable through courts.

In world health conference Mrs. Indira Gandhi Said, "AjJluent societies are spending vast sums of money understandably on the search for new products and processes to alleviate suffering and to prolong life. In the process drug manufactures have become a powerful industry. My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death."

The Government of India has taken many initiatives for the growth of pharmaceutical industry. The union budget of 2007-08 incorporated many provisions pharma sector. That is weighted deduction on in house R&D expenditure extended for a period five more years until March 31.2012, service tax exemption to DCG 12 approved CR03s offering trial for technology testing and analysis services for testing of new drugs peak customs duty reduced to 10% etc.

Before the advent of product patent regime Indian Pharmaceutical industry (IPL) has shown its strongest performance. The IPI improved not only in the area of production but also has performed as a foreign exchange earner. Total production of the industry expanded more than four fold in value terms (in domestic currency). The dollar value exports too had a similar increase. The first indicator for analyzing the performance of the pharmaceutical industry is the net worth of the firms which is a reflection of their respective market values.

Introduction

Food security is a major problem/ 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.

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 ofIPRs in agriculture is directly linked to the realization of basic of food needs.

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.

12.3.19 Food Security

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 world wide 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 situation 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 of often more linked to the problem of lack of access of food and misdistribution 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. The indicates that food security must be analyzed 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.

At present, the potentialof modem 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 defmed social or economics objectives. To date, commercialized genetically modified crops have generally.

There have been various attempts at the .international level to define food security. At present, the most widely accepted defmition is that adopted at the 1996 world food summit (WFS) The WFS plan of Action acknowledge that food security must be achieved from the individual and household levels up to the globalleveLIt 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 question of food security can also be looked at from a right 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. This includes measures such as land reform enduring physical and

12.3.20 Intellectual Property Rights and Food security

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.

IPRs have progressively been introduced in agriculture in two main phases. Firstly, a number of

developed coutries adopted over time a form of intellectual property protection for plant varieties. Plant breeders rights which id 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 patentablity of micro-organisms and a form of intellectual property protection for 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

private4 sector in the development of improved plant verities. 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 fertilizers, pesticides and water. From a food security point of view, another potentially interesting feature of agro-biotechnology is the possibility to modify verities to improve their nutritional value, such as in the case of the pro-vitamin Arice. Other arguments include the potential of the introduction of IPRs in developing countries to increase foreign direct investment, increase technology transfer and R&D foreign companies while at the same time giving domestic actors incentive to be more innovative.

12.3.21 The Trips Agreement

The Trips agreement is today the most important intellectual property treaty for all WTO member states.

The Trips Agreement is a general tartly whicp. covers different types of IPRs such as patents, copyright and geographical indications. It seeks to introduce minimum standards if IPRs in all member states. The TRIPS Agreement imposes the patentability of micro-organisms it also requires all member states to introduce intellectual property protection for plant verities. Article 27 (3) b framed as an exception to the general rule of Article 27 (1). It provides that all members states, shall provide for the protection of plant veritiesieither by patents or by an effective sui generis system or by any combination therefore.

Article 27 (3) b is, however, an interesting provision within the TRIPS context because it does not impose the patentability of plant verities but give member states liberty to introduce an alternative system.

Article 27 (3) b is of further significance io tbe context of tbe broader leagal regime for food security IPRs environmental management and human rights. It provides members 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 PGRF A Treaty and their environmental management obligations under the Biodiversity Convention.

12.3.22The International; Convention for the Protection of New Varieties of Plants

The International Convention for the Protection of New Varieties of Plants (upOV Convention) is any 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 results, the UPOV Convention proposes the adoption of plant breeders rights The DPOV Conventions' main aim is to protect new varieties of plants in the interest of both agricultural development and commercial plant breeders.

12.3.23 Human Right related Legal framework.

The reahsation 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 analyzed 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 ,md 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 intemationallevel a better distribution of world food supplies in relation to the needs of each country. **The** practical terms, the right to food is rea]ised when all individuals have physical and economic access at all times to adequate food or means for its procuremcnt. 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 detennine 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, tlle realisation of the right to food requires the availability of food in a quantity and quality that is sufficient to satisfy

The dietaly 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 right.

The link between IPRs and human rights surfaces at different levels. The ESCR Covenant rccognises everyone's right to take cultural life and the right 'to enjoy the benefits of scientific progress and its apphcation, 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 PRs holder does not prevail over everyone's right to the enjoyment of scientific and technological development.

The Act clearly seeks to establish both plant breeders rights and farmers rights. The proposed regime for plant breeders' rights largely follows the model provide by the UPOV Convention. It introduces rights which arc meant to provide incentives for the further development of a commerc1al seed industry in the country. The criteria for registration arc thus the same as those found in UPOV. namely novelty. distinctiveness. uniformity and stabdity.121 The Act incorporates a number or elements from the 1978 version of UPOV and also includes some elements of the more stringent 199 J version, like the possibility of registering essentially derived varieties. The section on farmers' rights constitutes the most intestine part of the legislation from the point of view of the development of S1l1 gelleris regimcs. This part was completely changed by the Parliamentary Committee which added a whole chapter on farmers' rights where the first draft dealt with the issue in a single short provision.122 The Act now seeks to put farmers' rights on par with breeders rights. It provides, for instance, that farmers are entitled, like commercial breeders, to apply to have a variety registered. Farmers are generally to be treated like commercial breeders and are to receive the same kind of protection for the varieties they develop. However, it is unsure whether these provisions will have a significant impact in practice since the Act accepts the registration criteria of the UPOV Convention which cannot easily be used for the registration of farmers varieties. The Act incorporates other provisions which are directly related to food security concerns. These include, for instance, a section which specifically bars the registration of plant varieties with genetic restriction use technologies.

The Act further seeks to foster benefit sharing in the interest of farmers in cases where registered plant varieties Overall, the Act is noteworthy for making a real attempt at balancing breeders and farmers rights.

Apart from adopting plant variety legislation, India has passed substantial amendments to its patent legislation. Among the major changes required is an increase in the general patent term from 14 years to 20 years and from 7 years to 20 years in the case of process patents on food related inventions., the Amendment Act takes into account some of the concerns

that have been voiced in recent times, in particular with regard to biopiracy or the unwarranted use of traditional. It now obliges inventors to disclose the geographical origin of any biological material used in an invention. Further, there is a specific exclusion on patents that are anticipated in traditional knowledge.

Besides the plant variety and patents legislation the Biodiversity Act is also important because the regulation of biodiversity management has direct impacts on food security and because the Act directly links biodiversity management and IPRs.

The biodiversity Act effectively condones the introduction of IPRs in the management of biological resources provided for in the TRIPS Agreement but does not specifically seek to ensure the IPRs are supportive of the goals of the Biodiversity Convention.

On the whole, the Indian legal framework constitutes a good starting point for a regime seeking to comply with all relevant international obligations in the field of food security and IPRs. However, it remains inadequate in important areas like farmers right and the protection of traditional knowledge.

12.3.24 PLANT VARIETY PROTECTION AND FARMERS' RIGHTS - NATIONAL PERSPECTIVES:

After the fonnation of WTO in mid 1990s all WTO member states are committed through TRIPS agreement to promote effective protection of Intellectual Property Rights in all the field of technology. Art. 27 (3) (b) of the TRIPS Agreement requires tpat its members shall provide for the Protection of Plant Varieties (herein after PVP) either by patenting or by an effective suigeneris system. The clause in the TRIPS agreement leaves room to the member countries. This led to a heated debate as to the system of protection to be adopted for plant varieties breeders

right provide incentive only to the seed industry without taking into consideration the interests of

the farmers. The seed sector wanted that the plant breeders protection system should be adopted that is modeled on the lines of the UPOV Convention without considering the farming community but being an agrarian economy it was not considered to being the interest of the country and India opted for the sui-generis system. Hence Indian plant variety protection system covers certain issues in protecting plant variety rights which International Union for the Protection for New Varieties' of Plants (herein after UPOY) model does not cover. Indian government acceded to the Convention but included some provisions, which are essential for the protection of farmers.,

12.3.25 Sui-Generis System and plant Variety protection

After ratifying the TRIPS agreement India become bound to follow the provision of the agreement one hand the agreement exclude plants and animals other than micro-organisms and essentially biological processes for the production of plants and animals other than non biological and microbiological processes on the other hand the agreement is also concerned for the protection of plants and ask to protect the plant varieties either by patent or by an effective sui-genesis system, 5 or by combination of both.

Though the TRIPS agreement neither defmes sui-generis nor elaborates what makes the suigeneris effective, it does not suggest any existing plantvariety protection system such as International Union for the Protection of Plant Varieties (DPOY) as a model. The Latin word sui-genersis means generated by one self and hence also meaning 'of its own kind' or 'unique ,.6

According to the TRIPS agreement member countries can make their own rules to protect new plant varieties and that protection must be effective. Member country can opt to develop their own sui-generis law or any system or evenupov model.

This flexibility of the sui-generis system is important for developing countries like India for three major reasons. First it will facilitate in striking a balance between promotion of private interest in national plant breeding and safeguarding the vital public interest good role being served by plant varieties in enhancing the livelihood opportunities of farming communities, in poverty alleviation, in promoting food security and in conserving the agro biodiversity and associated traditional knowledge the second aspect is the conflict between.

TRIPS Agreement and other legally and morally binding international declaration, treaties and

Conventions concerned with poverty alleviation econoffiIc development human

Rights protection and bio-resources conservation. The third important aspect is that as an IPR protection device the sui-generis system is equivalent to the patent system in the stringency of offered protection. This is explicit form the TRIPS Agreement Article 27 (3) (b) which affirms that plant and animals other than micro-organisms are excluded from patentability. Having made such affirmative exclusion, TRIPS Agreement avers that protection to plant varieties may be provided by patent or by an effective sui-generis system or by any combination there of the option is left to the Member states and those states which chose - to disallow the stringency of patent on plant varieties, shall opt for an effective sui-generis system;

The very first initiative taken to develop Indian legislation on plant varieties protection occurred in late 1980s. The first draft of the bill was produced in

1993 by the ministry of agriculture, the nodal ministry through the bills development. Three drafts have since followed in 1997, 1999 and 2000, although only the latter two were introduced in parliament. The last but one draft was tabled in the Lok Sabha in December 1999, and referred to a Joint Parliamentary Committee (JPC). From January to August 2000 JPC held public consultation at various locations through out India and tabled its report along with a revised draft in the Lok Sabha on August 25.2000. After almost a decade the bill was passed in August 2001 in the form of Protection of Plant arieties and Farmer's Rights Act 2001. development of new plant varieties of plants in conformity with the TRIPS Agreement. Protection is essential for the research in the area of plant varieties. This will facilitate the growth of seed industry in the country and will ensure the availability of high quality seeds and planting material to the farmers. The preamble of the Act states that the protection of plant breeders is essential for this agricultural development of the country. The Act primarily extends to protect the rights of the farmer while at the same time protecting the rights of the plant breeders. The contribution of the farmers in conserving improving and making available the plant genetic resource for the development of new plant varieties is also protected by the Act. If

12.4 Q.1. Discuss the areas of IPR realted to pharmaceutical products.

2. What are the essential requirements for patenlability
3. What is the importance of new product palant regime.
4.Discuse role of IPR in the area of food security
5. What are the enactments made by the government, in India in IPR dealing with food security.
6. How we can define human rights.
7. How far the poverty is respossible for the violation of human right.
8. What kindof measurement should be taken for impoverished masses to avoid violation of human right.

12.5 Suggested Redding

1. Trade relate aspect of intellectual property right agreement
2. Law relating to IPR by B.L. wedhera
3. International Law and Human Right by Kapoor
4. Law of IPR, in prospect and Retrospect by A.K.Kaul and V.K.Ahuja
5. Law Relating to IPR by M.K. Bhandari
6. Law relating to IPR by Meenu Paul

LL.M. Part-1

Subject: Intellectual property Law

Block- IV:Intellectual Property and Human Right
Unit-13-Traditional knowledge protection- biodiversity convention, right of Indigenous people

STRUCTURE

13.1 Introduction

We are living in an age where the world is ruled by power of knowledge. Today we are having better opportunities and facilities to acquire knowledge and transform it into wealth. But the knowledge which we are exploiting today has been created by people who had rebuts commonsense, great understanding of native, rich experience and selpless attitude. These knowledge i.e. which has been created generation over generations is called as Traditional knowledge. These local communities still are great reservoir of traditional knowledge.

13.2 Objective

In this competitive global era the progress and development of any nation depends upon the capability and potential to convert the knowledge into wealth. Countires such like India has commons of knowledge remains with indigeneous people local communities, tribals and nomedics These people because of illiteracy, prevnt isolable habitat, lack of information are unable to convert their knowledge into wealth Fen developed countries try to exploit the traditional knowledge with out giving the due advantage to the holders of the knowledge.

13.3.1 Meaning of Traditional Knowledge:

Knowledge which envolved through generations over generations with the passage of time is considered as traditional knowledge Indigenous people of world possess an emeses knowledge for their environment based on centuries of living close to nature. Living in land full of richness and variety of complex ecosystem, they have and understanding of the properties of plants and animals the functioning of ecosystem and the techniques using and managing them that is particular and often detailed. In rural communities of developing countiress locally occurring species are relied on many, sometimes for foods, medicines, fuels, building material and other products, equally peoples knwoeldge and perceptions of

environment and their relationship with it are often important elements of cultural identity.

You have understood that what is traditional knowledge. A question can be raise in any persons mind how can a threat be their for traditional knowledge. Here we can observe the development of new technology and the nee use of traditional knowledge based products today are the major threats to the surrival of many of these communities. The modern cultural industriese as well as the manufacturing industries now commercially exploit the traditional knowledge based products using new technology without the permission and sharing of profits with the communities. It is possible today to bring out new products or find out new use of existing products based on traditional knowledge utilizing the technological developments in the field of biotechnology. The development of new product or new use of existing products stables the claim of patient The striking case of threat to traditional knowledge is patenting of neen and turmeric by United States of America But this was fortunately challenged by CSIR with USPatent office and ultimately it was revoked by the European Patent office (EPO).

13.3.2 Need to Protect the Traditional Knowledge

There is an urgent need to protect the traditional knowledge of our country so that outsiders may not exploit our TK and take benefits on it. India is a country hich is having immense of TK this TK has potential of being transformed into wealth by providing leeds for development of useful practices and processes for the benefit of mankind. These valuable cluse provided by traditional knowledge can save time, money investment in modern biotechnology and other industries into research and product development. This needs protection though IPR system is their but it is based on individual private property rights. But TK is incompatible with IPR (Intelletual property Rights) because TK is specifically emphasized on collective creation and ownership.

We can classified the traditional knowledge Information into four groups-

1. Information known to society with or without documentation and is in constant use by people e.g. common use of Neem and Turmaric.
2. Information is well documented and available to the public for examination and use e.g. ayurvedic text, information in the palm leaves.
3. Information that is not documented or commonly known outside small group of people and not revealed outside the group e.g. tribal knowledge.

4. Information known only to individuals and members of families e.g.cure of asthama by Guad family of Hyderabad using specific fish variety as a means of a dispensing antiasthematic drug.To bring traditional knowledge with in the ambit of IPR it has to satisfy the criteria of IPR i.e. newness non obviousness and innovativeness whereas traditional knowledge is a knowledge carried on generations over generations which can not be covered by IPR. For the protection of traditional knowledge a new legislation is required. Only a separate system for the protection of traditional knowledge can provide are effective mechanism to protect the TK along with benefit shating concept.
5. The new legislation will be able to contest false claims of IPR you have understood why it is necessary to protect the traditional required. Initiatives are required to be taken not only at national level but also at international level or global level. At national level certain initiatives have been taken by the government of India in which preparing a traditional knowledge digital library is remarkable one.This digital library not only contains the records of 35000 Ayurvedic medicinal formulations based on traditional knowledge, discriptions methods of preparation, claim botanical name of plants and desease which can be cured but also eliminate the problem of grant of wrong patent. This digital library will be made available to almost all patent office over the world.Contain legislature efforts have also been made at national level such as passing of ertain laws and enactments. Patent law, Biodiversity law protection of Plant verities laws and forest Law are among them.

At some level these measurements have protect the traditional knowledge even them there is a vast area of traditional knowledge which still requires a strong protection.

Along with this at global level also WIPO and UNESCO jointly look the initiative for developing model legislation for protection of folklore. Another attempt was made by the United Nations. UN draft Declaration of Right of Indigineous People 1994 though agreed that prior approval of the Community should be obtained before using traditional knowledge, but the claim of ownership was not accepted.

The TRIPS agreement did not make any significant provision for protecting traditional knowledge. No unifom normas were laid down for protection of traditional knowledge. This led WIPO to set UP enter governmental committee on intellectual property and genetic resources, traditional knowledge and folklore The committee was established as an international forum to debate and dialogue concerning inter play between

IPR and traditional knowledge genetic resources and traditional cultureal expression.

The WIPO inter Governmental Committee indentified issues of traditional knowledge, folklore, access to genetic resources and benefit sharing.But till fifth session of Inter Governmental Committee legal framework at an international level could not be formulated.

Convention on Biological Diversity (CBD) 1992 has also recognized contributions of local and indigenous community to the conservation and sustainable utilization of biological diversity through traditional knowledge practices and innovation.

13.3.3 Biodiversity & Conservation

Introduction:

The most dynamic feature of the earth is the existence of life and the most striking feature of life is its diversity. Biodiversity refers to the variability amongst the species population communities and ecosystem both wild and domestic, that constitute life of an area or eventually of the entire plamnet or biodiversity ancompasses the variety of all life on earth. Biological diversity means the variability among living organisms from all sources and the ecological complexes of which they are part and includes diversity within species or between species and of eco system.

A question may be raise in your mind that what is the importance of biodiversity? We have read what is biodiversity we can also understand its importance.

Biodiversity performs two important functions: Firstly, it regulates and mainlines the stability of climate, water, regimes, soil fertility, quality of air and overall health of the life support system on earth. Secondly biodiversity is the source from which human race derives food, fodder, fuel, fiber, shelter medicine and raw material for other multifarious requirements. Thus it acts as the biological capital of the planet and forms the foundation upon which human civilization exists.

Conversion on Biological Diversity (CBD) All over the world legal strategies at global, regional and local level have been developing for ensuring protection to biodiversity and its relating interests The UN Convention on Biological Diversity was signed at Rio de Janerio in June 1992 and came into force on 29th December 1993. CBD is a legally binding agreement between countries from all over the world Its aims are to conserve biological diversity, to use its components in a suitable way and to show fairly and equitably between all people the benefits that can

arisefrom the use of genetic resource. It is the firstr agreement to address all aspects of biological diversity (Species, ecosystems and genetic resources) and has become are of the most widely ratified international tretes on environmental rises.it is indeed for the first time that genetic diversity is specifically convered in a global treaty.

It was in the year 1984 that the need to have a global converntion on biological diversity started gaining momentum, In response, the United Nations Environment Programme (UNEP) in the year 1987 recognized the need to streamline international efforts to protect biodiversity. It was observed that the existing creaties were inadequate to address the issues of conservation and sustainable use a new global treaty on biological diversity was urgently needed. Organization such as the World Conservation Union and Food and Agricultural Organization (FAO) contributed draft articles in addition to specific studies commissioned by the UNEP. On May 22n, 1992 the nations of the world adopted the CBD in Nairobi and on June 5, 1992 the CBD was tabled at the UN Conference on Environment and development the Earth Smmit in Rie De Janerio where 150 countires signed the convention.The Convention entered into force on 29 December 1993, 90 days after the 30th ratification as stated in its article 36. It has now been ratified by 180 parties (179 counties and European Community)

Satient Fatures of the convention on Biological Diversity.

13.3.4 Objectives:

The conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising out of the utilization of genetic resources including appropriate access to genetic resources, appropriate transfer of relevant technologies taking into account all rights over those resources and to technologies and appropriate funding.

Recognition of the intrinsic value of biological diversity and the need for its conservation in natural habitats, that these genetic resources will be available through generations, that nations have sovereign rights over their genetic resources, that conservation efforts need to be compensated, and that communities share the benefits that accrue from the use of these resources,

Countries have the sovereign rights to exploit their own resources while pursuing their own environmental policies. They also have the responsibility to ensure that the activities within their jurisdiction do not

cause damage to the environment of other countries or of areas beyond the limits of national jurisdiction.

13.3.5 Conservation and Sustainable use:

Countries, in accordance with their capabilities, shall develop national programmes for the conservation and Sustainable use of biological diversity, or adapt existing plans or programmes for this purpose, and integrate the conservation and sustainable use of biodiversity into relevant sectoral or cross sectoral plans, programmes and policies.

13.3.6 Identification and Monitoring:

Countries shall identify important components of biodiversity and monitor them through sampling and other techniques, with particular attention to those which require urgent conservation measures identify activities likely to have significant adverse impact on conservation and sustainable use of biological diversity and monitor their effects, and maintain and organize data derived from activities undertaken following the above.

13.3.7 In-situ Conservation:

Measures to promote the conservation of biological diversity outside their natural habitat, require countries to establish a system of protected areas, and develop guidelines for their management establish means to regulate, manage or control risks associated with the use and release of biotechnology which are likely to have adverse environmental effects, also taking into account risks to human health subject to national legislation, preserve and maintain knowledge and practices of indigenous and local communities. The application of such knowledge and innovations must also be promoted and the equitable sharing of benefits arising from the utilization of such knowledge, innovations of practices must In encouraged and cooperate in providing Particularly to developing countries.

Financial and other support, Ex-situ Conservatism: To promote the conservation and maintenance of ecosystems and the recovery of viable population of species in their natural surroundings, countries shall establish and maintain facilities for ex-situ Conservation and research, preferably in the country of origin of genetic resource and cooperate in providing financial and other support for maintenance of ex-situ conservation facilities in developing countries.

13.3.8 Sustainable use:

Countries shall integrate conservation and sustainable use of biological resource into national decision- making, and adopt measures to avoid or minimize adverse impacts on biodiversity encourage customary use of bioresearches in accordance with traditional culture practices, and encourage cooperation between government authorities and private sector in developing methods for sustainable use of resources.

13.3.9 Access to genetic resources:

National governments and national legislation have the authority to determine access to genetic resources, each country must endeavor to create condition facilitate access to genetic resources for environmentally sound uses to other countries and not impose restrictions that run counter to the objectives of the convention.

This article recognizes the sovereign rights of countries over the natural resources and gives the authority to determine access of genetic resources to the respective national government. This access is subject to national legislation, prior consent and should be encouraged for environmentally sound uses. The scientific research coming out on these genetic resources will be with the participation of the nation that has provided these resources. Benefits accruing out of these resources are to be shared with the contracting party that supplied these resources.

13.3.10 Access to and transfer of technology:

This article recognizes that technology includes biotechnology and that achieve the provisions of the convention, it is important that technology be transferred on favorable terms ,to the countries that provide the genetic resources. However, the Convention states that in areas where the technology pertains to intellectual property rights and patents, the tenns should be in line with intellectual property rights protection. N ationallaws or policies should be in place so that the private secto~ also facilitates exchange of infonnation and technology.

13.3.11 Handling of biotechnology and distribution of its benefits:

Each contracting country has to take measures to ensure that biotechnological research based on genetic resources is with the participation of the country that has provided the genetic resources and

the results and the benefits are shared. Countries also have to consider the need for and the modalities of a bio-safety protocol which include prior infonned agreements relating to safe handling and use of genetically modified organisms.

Financial resources: This article states that based on its capability, each country will provide financial support to national activities engaged in meeting the objectives of the convention. The developed countries will need to pay the incremental costs incurred by developing countries in conserving biodiversity and provide financial assistance to developing countries in their attempts to meet the convention objectives.

Financial mechanism: This article states that the mechanism for Providing [mancial resources will function under the authority of and be accountable to the Conference of Parties {COP).

Dispute settlement: In the event of any dispute, the countries involved will first attempt to seek solutions through negotiations. Only when regotiations fail will they seek the mediation of third party. In the case that both options do not work, it becomes mandatory for the countries to either the case to the International Court of Justice, or to an arbitrationtribunal. The tribunal will consist of three members, two of which will be appointed by the disputing parties.

Voting rights: While contracting parties are entitled to one vote, regional economic organizations can also exercise their right to vote, with the number of votes equaling the number of their member countries.

Relation between CBD and its protocols: A country may become party to a CBD protocol only if it is party to the convention. Decisions under any protocol shall only be taken by those countries that arc party to the protocol concerned .

13.3.12 Financial interim arrangement:

The Global Environment Facility shall be the institutional structure on an interim basis, for the period between the conservations entry into force and the first CoP or until CoP designates the institutional structure.

According to its meaning in common usage in English the word indigenous refers to some particular region or location During the late tweintieth century the term indigenous peoples evolved into a legal category that refers to culturally distinct groups that had been affected by the processes of colonization These are usually collective that have preserved some degree of cultural and political separation from the mainstream cultural and political system that has grown to surround or dominate them

economically, politically culturally or geographically Or in simple words we can say the indigenous people are those who have preserved traditional ways at living, such as pastoral, horticultural, hunting and gathering techniques self medicating ways and district forms As you have come to know about who are indigenous people you must also know what kinds of rights they are having or should be given?

Till today many legislations have been passed but still not as ingle legislation is able to camletely protect the rights of the indigenous people. Among these legislation CBD is a significant international instrument in the development of rights of indigenous people and aims to provide for the equitable sharing of the benefits derived from them The importance of CBD is that of a tool for indigenous and local communities to the conservation of biodiversity.

Along with this UN has made an attempt to protect the rights of Indigenous people a declaration was made in New York City on 13 September 2007, Declaration on the Rights of Indigenious peoples by United Nations General Assembly. Though its is not a legally binding instrucment under international law, the UN describes it as setting an important standard for the protection of rights of indigenous people. The provisions of declaration are mentioned here-

Article 1

Indigenous peoples have the right to the full enjoyment, as a collective or as individuals, of all human rights and fundamental freedoms as recognized in the Charter of the United Nations, the Universal Declaration of Human Rights and international human rights law.

Article 2

Indigenous peoples and individuals are free and equal to all other peoples and individuals and have the right to be free from any kind of discrimination, in the exercise of their rights, in particular that based on their indigenous origin or identity.

Article 3

Indigenous peoples have the right to self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development.

Article 4

Indigenous people, in exercising their right to self-determination, have the right to autonomy or self-government in matters relating to

> their internal and local affairs, as well as ways and means for financing their autonomous functions.[4]

Self-determination is recognized by the United Nations and indigenous peoples alike as a pre-existing condition for the ability to exercise any additional human rights. It is seen as an inherent right and a fundamental necessity towards a democratic system. Without self-determination, a political body is unable to work towards and achieve a desirable and consensual goal

Article 5

> Indigenous people have the right to maintain and strengthen their distinct political, legal, economic, social and cultural institutions, while retaining their right to participate fully, if they so choose, in the political, economic, social and cultural life of the State.

Article 6

> Every indigenous individual has the right to a nationality

The right to a nationality, or legal citizenship in at least one state, ensures that indigenous peoples do not experience the difficulties of statelessness. This reaffirms the right in Article 7 of the Convention on the Rights of the Child for indigenous people.

Article 7

> Indigenous individuals have the rights to life, physical and mental integrity, liberty and security of person. Indigenous peoples have the collective right to live in freedom, peace and security as distinct peoples and shall not be subjected to any act of genocide or any other act of violence, including forcibly removing children of the group to another group.

Article 8

Article 8 guarantees "the right not to be subjected to forced assimilation or destruction of their culture" to each indigenous people and to indigenous individuals. It requires states to effectively prevent the following actions:

- "depriving [indigenous peoples] of their integrity as distinct peoples, or of their cultural values or ethnic identities"
- dispossession of "lands, territories or resources"
- "forced population transfer" which violates or undermines indigenous rights;
- "forced assimilation or integration"

- "propaganda designed to promote or incite racial or ethnic discrimination" against indigenous peoples

States must also provide effective redress when such actions occur.[4] Scholar of law Siegfried Wiessner argues that Article 8 introduces a "novel prohibition of ethnocide against indigenous peoples" into international law.

Article 9

> Indigenous peoples and individuals have the right to belong to an indigenous community or nation, in accordance with the traditions and customs of the community or nation concerned. No discrimination of any kind may arise from the exercise of such a right

Article 10

> Indigenous peoples shall not be forcibly removed from their lands or territories. No relocation shall take place without the free, prior and informed consent of the indigenous peoples concerned and after agreement on just and fair compensation and, where possible, with the option of return.

Article 11

This article has two parts. The first addresses the rights of indigenous peoples to maintain and to further their own cultural practices and traditions specifically their cultural and intellectual property. The second part says that states should attempt to make reparations for all the cultural property and knowledge that was taken from indigenous peoples forcefully or without their consent

Informed consent is a voluntarily and decisional capacitated consent. Consent is known to be entirely acquainted when a fully competent party to whom entire disclosures and have been clarified and to whom fully grasps what has been disclosed voluntarily agrees to the terms.

Article 12

Article 12 addresses the rights of indigenous individuals and peoples regarding religious and ceremonial practices. It asserts their right to:

- "manifest, practice, develop and teach their spiritual and religious traditions, customs and ceremonies"
- "maintain, protect, and have access in privacy to their religious and cultural sites"
- "use and control their ceremonial objects"
- "repatriation of their human remains"

"States shall seek to enable the access and/or repatriation of ceremonial objects and human remains in their possession" through just, explicit, and efficient methods developed through consultation with indigenous peoples involved.

Article 13

This article discusses the rights of indigenous people to

- "Revitalize, use, develop, and transmit to future generations their histories, languages, oral traditions, philosophies, writing systems, literatures, and to designate and retain their own names for communities, place, and persons"
- "States shall also take effective measures to ensure that this right is protected and understood in legal and administrative proceedings"

Article 14

1. Indigenous peoples have the right to establish and control their educational systems and institutions providing education in their own languages, in a manner appropriate to their cultural methods of teaching and learning.

2. Indigenous individuals, particularly children, have the right to all levels and forms of education of the State without discrimination.

3. States shall, in conjunction with indigenous peoples, take effective measures, in order for indigenous individuals, particularly children, including those living outside their communities, to have access, when possible, to an education in their own culture and provided in their own language.

Article 15

1. Indigenous peoples have the right to the dignity and diversity of their cultures, traditions, histories and aspirations which shall be appropriately reflected in education and public information.

2. States shall take effective measures, in consultation and cooperation with the indigenous peoples concerned, to combat prejudice and eliminate discrimination and to promote tolerance, understanding and good relations among indigenous peoples and all other segments of society.

Article 16

1. Indigenous peoples have the right to establish their own media in their own languages and to have access to all forms of non-indigenous media without discrimination.

2. States shall take effective measures to ensure that State-owned media duly reflect indigenous cultural diversity. States, without prejudice to ensuring full freedom of expression, should encourage privately owned media to adequately reflect indigenous cultural diversity.

Article 17

1. Indigenous individuals and peoples have the right to enjoy fully all rights established under applicable international and domestic labour law.

2. States shall in consultation and cooperation with indigenous peoples take specific measures to protect indigenous children from economic exploitation and from performing any work that is likely to be hazardous or to interfere with the child's education, or to be harmful to the child's health or physical, mental, spiritual, moral or social development, taking into account their special vulnerability and the importance of education for their empowerment.

3. Indigenous individuals have the right not to be subjected to any discriminatory conditions of labour and, inter alia, employment or salary.

Article 18

Indigenous peoples have the right to participate in decision-making in matters which would affect their rights, through representatives chosen by themselves in accordance with their own procedures, as well as to maintain and develop their own indigenous decisionmaking institutions

Article 19

States shall consult and cooperate in good faith with the indigenous peoples concerned through their own representative institutions in order to obtain their free, prior and informed consent before adopting and implementing legislative or administrative measures that may affect them

Article 20

1. Indigenous peoples have the right to maintain and develop their political, economic and social systems or institutions, to be secure in the enjoyment of their own means of subsistence and development, and to engage freely in all their traditional and other economic activities.

2. Indigenous peoples deprived of their means of subsistence and development are entitled to just and fair redress.

Article 21

1. Indigenous peoples have the right, without discrimination, to the improvement of their economic and social conditions, including, inter alia, in the areas of education, employment, vocational training and retraining, housing, sanitation, health and social security.

2. States shall take effective measures and, where appropriate, special measures to ensure continuing improvement of their economic and social conditions. Particular attention shall be paid to the rights and special needs of indigenous elders, women, youth, children and persons with disabilities.

Article 22

1. Particular attention shall be paid to the rights and special needs of indigenous elders, women, youth, children and persons with disabilities in the implementation of this Declaration.

2. States shall take measures, in conjunction with indigenous peoples, to ensure that indigenous women and children enjoy the full protection and guarantees against all forms of violence and discrimination.

Article 23

Indigenous peoples have the right to determine and develop priorities and strategies for exercising their right to development. In particular, indigenous peoples have the right to be actively involved in developing and determining health, housing and other economic and social programmes affecting them and, as far as possible, to administer such programmes through their own institutions.

If the draft declaration of UN is imposed as a legally binding instrument for all the member countries as a model instrument for the enactment of laws at national level the rights of indigenous people would not be curtailed at large The rights of indigenous people are directly related to the human rights. The adoption of the declaration should similarly be given an importance of Universal Deelaction of Human Rights.

13.4 Question-

Q.1. What is Traditional Knowledge?

Q.2. Why traditional knowledge is required to be protected?

Q.3. What kind of efforts have been made for protection of traditional knowledge?

13.5 Suggested Readings

1. Law relating to Intellectual Property by B.L. Wadehra
2. Law relating to IPR by Dr. M.K. Bhandari
3. Intellectual property Law by Meenu Paul