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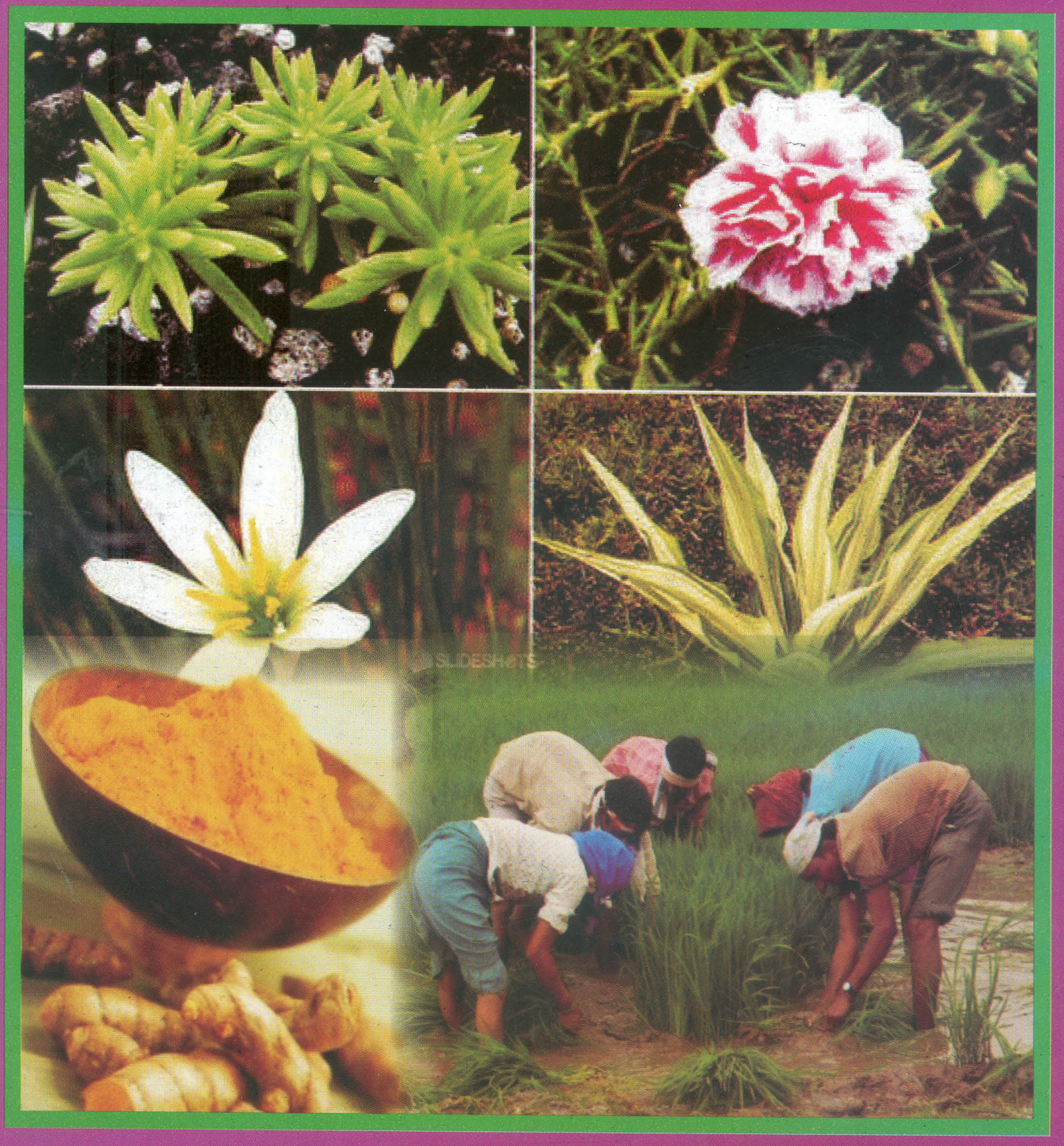
MIP-106
PLANT VARIETIES PROTECTION, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE



Intellectual Property and Biotechnological Inventions

3

"शिक्षा मानव को बन्धनों से मुक्त करती है और आज के युग में तो यह लोकतंत्र की भावना का आधार भी है। जन्म तथा अन्य कारणों से उत्पन्न जाति एवं वर्गगत विषमताओं को दूर करते हुए मनुष्य को इन सबसे ऊपर उठाती है।"

– इन्दिरा गांधी

"Education is a liberating force, and in our age it is also a democratising force, cutting across the barriers of caste and class, smoothing out inequalities imposed by birth and other circumstances."

–Indira Gandhi

Indira Gandhi
National Open University
School of Law

MIP-106
Plant Varieties Protection, Biotechnology, and Traditional Knowledge

Block

3

INTELLECTUAL PROPERTY AND BIOTECHNOLOGICAL INVENTIONS

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BLOCK 3 INTELLECTUAL PROPERTY AND BIOTECHNOLOGICAL INVENTIONS

This Block consists of four units, **Unit 9** of the course deals with Genetic Resources and Biotechnology. The convention on Biological Diversity defines biotechnology as "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products pr processes for specific uses". This Unit will examine the legal aspects of biotechnology, highlight relationships between biotechnology and IPR and also examine the regulatory framework on Biotechnology in India.

Unit 10 of this course will explain the need for the protection of plant genetic resources. It will also discuss the international framework on PGRs. It will examine the PGRs under the Biological Diversity Act, and under the Plant Variety Act.

Unit 11 of this Course deals with the mandate of TRIPS Agreement. In this unit we will explain the interrelation between IPRs and bio-technology, discuss the background, negotiating history and interpretation of TRIPs obligation for patentability of bio-technology invention.

Unit 12 of course explains the patentability of biotechnological inventions and microorganisms. It also explains the background, negotiating history and interpretation of TRIPs obligation for patentability of biotechnological inventions.

UNIT 9 GENETIC RESOURCES AND BIOTECHNOLOGY

Structure

9.1 INTRODUCTION

The 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 uses" (Article 2). It is used to create new varieties of plants, animals, and microorganisms. Salazar explains, "Biotechnology refers to methods of using plants, animals, and microbes wholly or in part, to produce useful substances or to improve existing species. More specifically, biotechnology is the use of technologies based on living systems to develop commercial products and processes". The new biotechnologies include recombinant DNA (rDNA), gene transfer, embryo manipulation, plant regeneration, and tissue culture.

Biotechnology is one of the fastest growing industries in the world, and its growth is expected to continue accelerating in the near future. Bosselmann explains that between 1985 and 1990, the number of biotechnology patent applications filed in the United States grew by 15% annually. Total product sales for the US biotechnology industry in 1991 reached about $4 billion, a 38% increase over 1990; by 2000, sales had grown to $19.3 billion, about an increase of 400% over 1991.

It is believed that the developments in biotechnology can offer magnificent benefits to humanity particularly in agriculture and health (medicine). For instance, with biotechnology, it is now possible to develop plants with improved resistance to insects and environmental stresses such as drought or cold. It is also possible to improve plants and animals genetically to increase their productivity and quality. The Green revolution and the resultant increase in food production all over the world is a representative example of the potential benefits that biotechnology offers. Bosselman notes, "Since 1930, US yields for potatoes are estimated to have increased by 312 percent, corn by 320 percent, and peanuts by 295 percent. About 50 percent of these improvements are attributed to genetic improvements".

9.2 OBJECTIVES

After reading this unit you should be able to:

- examine the legal aspects of biotechnology;
- explain the ownership issues in relation to biotechnology;
- highlight relationship between biotechnology and IPR;
- examine TRIPS Agreement in relation to biotechnology;
- explain the issue of patentability of life forms in US, EU and India; and
- examine the regulatory framework on Biotechnology in India.

9.3 BIOTECHNOLOGY AND LAW

The interface between biotechnology and law happens in different ways.

First, the progress in biotechnological inventions demands sufficient legal protection for them, through the intellectual property rights regime, against unauthorised use. The underlying rationale is that biotechnological inventions require huge investments and thus, necessitates an opportunity for investors to exercise commercial rights without intervention from others. Furthermore, biotechnological inventions are easy to copy, hence without legal protection, further growth of biotechnological industry will be hampered.

Second, genetic resources constitute a key raw material for biotechnological inventions. Therefore, access to genetic resources is crucial for further developments in this field. Thus, the legal mechanism regulating access to genetic resources forms an important intersection point of biotechnology and law.

Third, the legal framework to regulate the implications of biotechnological inventions is an important aspect of interface between biotechnology and law. An important issue in this regard is the potential impacts of biotechnological

inventions on living beings and the environment. For instance, there is a growing anxiety that the use of hybrid varieties of seeds leads to the elimination of agricultural biodiversity. Another major critique is the environmental and health implications of genetically modified organisms and food. Thus, regulation of biotechnological inventions from the points of view of environment and health is another space where biotechnology and law interact.

Self Assessment Question **(Spend 3 minutes)**

1) What is biotechnology?

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9.4 BIOTECHNOLOGY AND OWNERSHIP ISSUES

Developments in the field of biotechnology led to the realisation of the commercial benefits of genetic resources. This resulted in the emergence of a legal framework defining the ownership of genetic resources. However, the issue of ownership has been addressed differently under different legal regimes in different jurisdictions. Two areas of international law appear to stand out in this respect: national sovereignty and intellectual property rights.

9.4.1 Private Property Rights

Developed countries where most of the biotech industries are situated, supported the legal protection of biotechnological inventions by giving ownership to the inventor or investor. The gradual shifting from the earlier prohibition of ownership over living beings to granting of patents over living organisms proves this. Safrin explains this by noting, "The U.S. Supreme Court handed down its seminal Chakrabrty [***In re Dimond v. Chakrabarty,*** 206 USPQ 193] decision, which allowed the patenting of genetically engineered microbes in 1980. Within a few years, the U.S. Patent and Trademark Office was granting patents on human genes and in 1991, the U.S. Court of Appeals for the Federal Circuit upheld such patenting. Thus, in less than a decade, the United States moved from patenting the microbe to patenting the human gene. Moreover, in the celebrated case of ***Moore v. Regents of the University of California***, the California Supreme Court upheld the University of California's ownership of Moore's cell line".

In 1995, the US Patent and Trademark Office granted US patent number 5,397,696 to the US Department of Health and Human Services on a virus found in the blood of Hagahai tribesmen from Papua New Guinea. This created uproar nationally and internationally with respect to the ownership of the biological matter. The researchers entered into an agreement with the tribe that the latter would receive fifty per cent of the royalties. This type of agreement raised serious questions about property rights, compensation, and exploitation of biological resources.

9.4.2 Sovereign Rights

At the same time, developing countries where much of the genetic resources exist sought to establish sovereign right over genetic resources. The Convention on

Biological Diversity and the Indian national legal framework adopted afterwards assume that sovereigns should exercise rights over the sub-cellular genetic sequences of all nonhuman living things within their jurisdiction. The exercise of such control has been promoted by requiring a potential bio-prospector to seek permission from a government authority constituted for this purpose. For example, in India, the National Biodiversity Authority established under the Biological Diversity Act, 2002 holds the power to grant permit to bio-prospectors.

Thus, it is obvious that the interests of different countries have pigeonholed the legal developments on ownership related to genetic resources. Countries apparently supported and adopted legal regimes, which supported their respective advantages. While the developed countries adopted a liberal approach to patenting of life forms, developing countries adopted a strong legal regime to control access to genetic resources.

9.5 BIOTECHNOLOGY AND FORMS OF INTELLECTUAL PROPERTY PROTECTION

There are different forms of protection that can be used to protect intellectual property developed in biotechnological fields.

9.5.1 Plant Variety Protection

Plant breeders' rights constitute an important form of intellectual property rights as far as the biotechnology inventions relating to plants are concerned. The idea of plant breeders' rights dates back to the early 20th century, particularly the Plants Patents Act, 1930 in the United States. The legal protection of plant varieties has become a feature of domestic laws in most of the countries after the TRIPS agreement came into force. For instance, in India, the Protection of Plant Varieties and Farmers' Rights Act, 2001 was adopted to provide intellectual property right protection for new plant varieties.

Most of the laws for plant variety protection work through a registration mechanism. A certificate of registration will be issued to the plant breeder, which entitles its holder to be the exclusive marketeer of the relevant variety. The Convention for the Protection of New Varieties of Plant (UPOV), adopted in 1961 and revised in 1978 and 1991 constitutes the most important legal mechanism at the international level for the protection of plant varieties.

9.5.2 Patent Protection for Animal Inventions

Traditionally, breeders have mated animals with specific physical traits to produce offspring with certain characteristics. As such, intellectual property rights protection was not available or needed for traditional breeders. The advent of genetic engineering marked significant changes in this scenario because it made possible the extraction and mixing of genes to produce offspring with desired characteristics.

In the US, granting of patents to living organisms began with the US Supreme Court approval of patent for a genetically engineered microorganism that broke up components in crude oil in the famous ***Diamond v. Chakrabarty***, 100 S. Ct. 2208 (1980). The Chakrabarty decision opened the door to the patentability of microorganisms in the United States. The first transgenic animal patent was

granted in 1988 for the Harvard Oncomouse, an animal designed for use in the testing of cancer.

9.5.3 Trade Secret

A trade secret is any kind of information that is not common knowledge and which gives its owner some form of advantage — in business, technology, or trade over competitors. The strength of the protection depends on the ability to keep the information secret. Some forms of biological materials can be easily protected as trade secrets. No formal application procedure is needed for a trade secret and this is the major difference from patents and other IPRs. However, the information must have some commercial value, and an effort is required to keep it secret. As long as these conditions are met, protection can be permanent. An example is hybrid corn. Protecting the parent lines as trade secrets is not seriously affected by selling it to farmers. In addition, reproduction of such varieties without access to parental lines is difficult. However, protection of trade secrets depends upon the subject matter: some subject matters are not suitable to be protected because the enabling information is evident in the product such as in biotechnology and software inventions.

9.5.4 Contracts

Agreements and contracts are another form of protection of intellectual property rights in biotechnological inventions. One of the common types of contract in biotechnology based breeding is the material transfer agreement (MTA), used to exchange genetic materials and information. While the form of an MTA may be different in different jurisdictions, generally it permits the recipient to use the genetic material or information as per certain terms and conditions.

9.6 PATENTING OF LIFE FORMS

The development of biotechnology and patenting of life forms are closely linked to each other. A strong patent protection regime has complemented increasing private sector involvement in the field of biotechnology. Patents on life forms have been recognised as an important legal tool to protect the products of Genetic engineering.

The evolution of patents on life forms can be traced back to developments in the developed world particularly in the US and Europe.

9.6.1 Life Patents in US

The US Supreme Court decision in ***Diamond v. Chakrabarty*** (1980) is considered as the beginning of an era of patenting of life forms. In this case, the issue was patenting of a bacterium, an artificially created living being. The Court approached the case from the perspective of distinction between 'invention' and 'discovery' and approved the patenting of artificially created bacterium. The Court in this case held that Congress, while drafting the US Patent Act, intended to include anything made by man under the sun. The Chakrabarty decision marked the beginning of the granting of patents of microorganisms by the US Patent and Trademarks Office (USPTO).

The issue became more specific with the question whether patenting of life forms is limited to microorganisms, or plants and animals could also be patented. The

issue was settled positively with the granting of the first patent for a transgenic animal by the USPTO in 1998.

Diamond, Commissioner of Patents v. Chakrabarty (1980)

Chakrabarty, a micro-biologist in the United States, filed a patent application with respect to his invention of human made genetically engineered bacteria. He claimed that his invention was capable of breaking down multiple components of crude oil. His patent claims were of three types:

- Process claims for the method of producing the bacteria
- Claims for an inoculum comprising a carrier material floating on water such as straw and new bacteria
- Claims to the bacteria

The patent examiner granted the claims on the first two, but rejected that for the third. This was on the ground that

- Microorganisms are products of nature
- Living things are not patentable subject matter under the US Patent Act

Chakrabarty appealed to the Patent Office Board of Appeals. The Board agreed with the examiner on the second ground. This decision was reversed by the Court of Customs and Patent Appeals. The Supreme Court of the United States granted the writ of certiorari to the Acting Commissioner of Patents and Trademarks.

Findings

The Court rejected the petitioner's contention that the passage of the Plant Patent Act of 1930 and Plant Variety Protection Act of 1970 is proof to the Congress understanding that the terms, "manufacture" or "composition of matter" do not include living things. In the Court's view the Congress had recognised that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. In this case the respondent's microorganism is the result of human ingenuity and research. Similarly, there is nothing to suggest that the 1970 Act was enacted because Section 101 did not include living things.

The second argument of the petitioner is that microorganisms cannot qualify as patentable subject matter until Congress authorizes such protection. This is on the ground that genetic technology was nonexistent and unforeseen when Congress enacted Section 101. The Court agreed that it was for the Congress, not the courts, to define the limits of patentability. It is equally true that once the Congress has spoken, it is the province and duty of the judicial department to say what the law is.

J E M AG Supply v. Pioneer Hi-Bred International (1996)

Pioneer Hi-Bred International, the respondent had 17 utility patents issued under Section 101. These patents provide for manufacture, use, sale, and offer for sale of its inbred and hybrid corn seed products. Pioneer sells its patented hybrid seeds under a limited label licence that allows only the production of grain and/or forage and prohibits using such seed for the production or

development of a hybrid or different seed variety. Petitioner J E M Ag Supply Inc., which was doing business as Farm Advantage Inc., bought patented seed from Pioneer in bags bearing the license agreement, and then resold the bags. Pioneer filed a patent infringement suit against Farm Advantage and its distributors and customers. Farm Advantage filed a patent invalidity counterclaim arguing that sexually reproducing plants such as Pioneer's corn plants are not patentable subject matter within Section 101.

The Court held, the petitioners do not allege that Pioneer's patents are invalid for failure to meet the requirements of a utility patent. Also, they do not dispute that plants otherwise fall within the terms of Section 101's broad description (which includes manufacture or composition of matter). Rather their argument is that:

- PPA and PVPA provide the exclusive means of protecting new varieties of plants
- Awarding utility patents for plants upsets the scheme contemplated by Congress.

Taking note of the two statutes, the Court held that neither of them forecloses utility patent coverage for plants.

9.6.2 Life Patents in Europe

Europe has mostly kept pace with the US regarding the approach to life patenting, albeit with caution. Article 53(b) of the Convention on the Grant of European Patents, 1973 excludes the patentability of plant or animal varieties or essentially biological processes for the production of plants or animals. Exceptions to this general prohibition are microbiological processes and their products.

The Directive on the Legal Protection of Biotechnological Inventions, 1998 is another key development in the legal framework of patenting of life forms. It provides for a broad protection of biotechnological inventions. The Directive provides protection for the products consisting of or containing biological material as well as the processes by which biological material is produced, processed, or used. Article 3 of the Directive explicitly provides for the patentability of biological material isolated from its natural environment or produced by means of a technical process even if it existed previously in nature.

The possibility of patenting of life in Europe has been addressed in the famous Harvard *Oncomouse case* (1992 O.J.E.P.O. 588). In this, the issue was the patenting of a transgenic organism (Oncomouse). The European Patent Office ruled in favour of granting patent. This case shows the positive attitude in Europe in favour of granting patents to engineered biological products.

Novartis case (1999)

The patent application in the suit consisted of claims to transgenic plants comprising specific foreign genes. Under Article 53 (b) of the European Patent Convention, patents shall not be granted in respect of plant varieties or essentially biological processes for the production of plants. This provision does not apply to microbiological processes or products thereof.

The Enlarged Board of Appeal stated: If the second half of Article 53 (b) is assumed to be lex specialis, the conclusion follows that the first half sentence of the provision does not apply to situations covered by lex specialis.

It further clarified that processes of genetic engineering are not identical with microbiological processes. Microbiological processes are synonymous with processes using microorganisms. Microorganisms are different from the parts of living beings used for the genetic modification of plants. The exclusion in Article 53 (b) was for excluding subject-matter eligible for protection (under the plant breeders' system), from patentability. Thus the exception to patentability in Article 53 (b) in the first half of the sentence applies to plant varieties irrespective of the ways in which they were produced.

9.6.3 Life Patents in India

Section 3(j) of the Patent Act, 1970 excludes essentially biological processes for production of plants and animals, or plants and animals in whole or in part other than microorganisms.

There is no agreed definition of the term 'microorganisms' and therefore the real scope of what all things may come under this term is not crystal clear. However, from the Indian stance at the WTO forum, it seems that India is not keen to allow patenting of life forms. India has joined other developing countries and insists on prohibition of patents on life, including the patents on biological processes. This is a probable conclusion in the context of the new Section 3(d) inserted by the 2005 amendment which limited the scope of patentability by excluding '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".

Self Assessment Question **(Spend 3 minutes)**

2) How patenting of life is dealt with under the Indian Patent Act?

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9.7 TRIPS AGREEMENT AND BIOTECHNOLOGY

9.7.1 Living being as Non-patentable

Article 27.3 of the TRIPS Agreement explicitly permits nations to exclude animals, plants, and essentially biological processes for the production of plants and animals from patentability. This is an express authorisation for countries to include a legal prohibition of patenting of life forms in their domestic patent laws. However, the TRIPS Agreement makes it obligatory to provide patents for the following:

- Microorganisms

- Non-biological and micro-biological processes
- Plant variety protection either through patents or *sui generis* system or a combination of both

The TRIPS agreement does not define the terms 'microorganisms' and 'micro-biological processes'. These terms could include the following:

- Microorganisms: any biological material that is self-replicable or replicable via a host organism. Sub-cellular material like genes, gene sequences, plasmids etc. could come under this term.
- Microbiological processes: this includes, for example, (1) processes of producing new microorganisms (2) new microorganisms as produced by defined processes (3) process of cultivation or otherwise using a known or new microorganism.

The indeterminate nature of Article 27.3 is primarily due to the lack of consensus on this issue during the Uruguay Round of Negotiations. For instance, while the US was in favour of a strong patent protection to biotechnological inventions, the European Union had faced strong internal resistance to patenting of living organisms. This indeterminate nature arguably gives flexibility to countries to avoid patenting of life forms. Thus, developing countries have the freedom under the TRIPS Agreement to abstain from following the standards adopted by the US or other technically advanced countries.

9.7.2 Concerns of Developing Countries

IPRs and biotechnological inventions pose a number of issues for developing countries such as transfer of technology, unfair exploitation of genetic resources, and fair and equitable sharing of financial benefits. Developing countries, being the centre of genetic resources, are concerned about the use of their genetic resources by biotech industries in the developed world without sharing the benefit arising out of such use.

A group of developing countries have advanced a proposal for substantive revision of Article 27.3.b of the TRIPS agreement to incorporate their concerns related to biodiversity, equity, and transfer of technology. Developing countries have argued for a clarification in TRIPS that the option to exclude from patentability extend to microorganisms and microbiological processes. Further, developing countries also demand prohibition of patents inconsistent with Article 15 of the Convention on Biological Diversity, 1992. This Article emphasises the issue of fair and equitable benefit sharing. The strong divide between the developed and the developing worlds has diminished the chances of incorporation of these demands.

9.8 REGULATION OF BIOTECHNOLOGY IN INDIA

Keeping in view the global and national expansion of biotechnology, India has adopted regulatory measures mainly in two ways:

India evolved a system to regulate genetically modified organisms (GMOs) and the products thereof, which may be developed within the country or imported.

India has set up a patent facilitation cell under the supervision of the Department of Biotechnology, Government of India.

9.8.1 Biosafety Measures in India

Biosafety refers to the rules, regulations, and procedures adopted to study the impact of GM products on human health and environment. These measures intend to avoid risks from using GMOs in research and trade. A number of laws and regulations exist in India regulating the use of GMOs. These include the following:

- Environment Protection Act, 1986
- Drugs and Cosmetics Rules, 1988
- Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms, Genetically Engineered Organisms or Cells, 1989
- Protection of Plant Varieties and Farmers' Rights Act, 2001
- Seed Policy, 2002
- Plant Quarantine Order, 2003
- Food Safety and Standards Act, 2006

The Department of Biotechnology has issued a number of guidelines from time to time. They are:

- Recombinant DNA Safety Guidelines and Regulations, 1990
- Revised Guidelines for Safety in Biotechnology, 1994
- Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants, and Plant Parts, 1998
- Guidelines for Generating Pre-Clinical and Clinical Data for rDNA Based Vaccines, Diagnostics, and Other Biologicals, 1999
- Guidelines and Standard Operating Procedures for Confined Field Trials of Regulated, Genetically Engineered Plants, 2008
- Guidelines for the Safety Assessment of Foods derived from Genetically Engineered Plants, 2008
- Protocols for Food and Feed Safety Assessment of GE Crops, 2008

A number of committees have been set up under the Cell Rules, 1989 to assess Biosafety. These committees are the Recombinant DNA Advisory Committee, Institutional Biosafety Committee, Review Committee on Genetic Manipulation, Genetic Engineering Appraisal Committee, State Biotechnology Coordination Committee, and District Level Committee.

India is planning to establish a National Biotechnology Regulatory Authority and towards this end, a draft Bill (National Biotechnology Regulatory Bill, 2008) has been prepared.

9.8.2 Patent Facilitation Cell

Keeping in view the value of knowledge created through R & D efforts in biotechnology, India has set up a patent facilitation cell in the Department of Biotechnology in 1999. Apart from creating awareness about IPR among scientists and researchers, it facilitates biotechnologists in the country to file patents in India and in other countries.

Self Assessment Question **(Spend 3 minutes)**

3) What is the role of patent facilitation cell of India in promoting biotechnology?

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9.9 SUMMARY

- The interface between biotechnology and law happens mainly in three ways– 1) protection of biotechnological invention through intellectual property rights particularly patents; 2) regulation of access to genetic resources; and 3) regulation of biotechnological inventions to protect living beings and the environment.
- The development of intellectual property rights has resulted in protection of biotechnological innovations in plants and animals mainly through plant breeders' rights and patents respectively.
- The TRIPS agreement does not require WTO members to provide intellectual property rights protection to animals, plants, and essentially biological processes for the production of plants and animals. Nevertheless, WTO members are required to provide intellectual property rights protection to microorganism, micro-biological processes and new varieties of plants.
- In India, there are a number of rules and regulations applicable to biotechnology. However, a comprehensive legal framework is yet to be adopted with the National Biotechnology Regulatory Bill, 2008 under consideration.

9.10 TERMINAL QUESTIONS

1) Discuss the issue of ownership relating to biotechnology and genetic resources.
2) Examine the legal framework regulating biotechnology in India.
3) Critically evaluate the implication of the TRIPS agreement on biotechnological inventions.

9.11 ANSWERS AND HINTS

Self Assessment Questions

1) Article 2 of the Convention on Biological Diversity defines the biotechnology as "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific uses".

2) Patenting of life is generally excluded under Section 3(j) of the Indian Patent Act. However, patenting of microorganisms is allowed.

3) Patent facilitation cell, established in the Department of Biotechnology, focuses on creating awareness about IPR among scientists and researchers and it facilitates biotechnologists in the country to file patents in India and in other countries.

Terminal Questions

1) Refer to Section 9.4

2) Refer to Section 9.8

3) Refer to Section 9.7

9.12 REFERENCES AND SUGGESTED READINGS

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4) P.K. Vasudeva, 'Patenting Biotech Products: Complex Issues', 35(42) *Economic and Political Weekly* 3726 (2000).

5) Ameen Jauhar and Swati Narnaulia, 'Patenting Life: the American, European and Indian Way', 15 *Journal of Intellectual Property Rights* 55 (2010).

UNIT 10 INTERNATIONAL LEGAL FRAMEWORK RELATING TO PLANT GENETIC RESOURCES (PGRS)

Structure

10.1 INTRODUCTION

Agricultural biodiversity is the basis for all human food consumption and food security of a nation. In addition, agriculture is the major source of income for about half of the world population, particularly in developing countries. Despite this, plant genetic resources (PGRs) for food and agriculture (PGRFA) are fast deteriorating dangerously.

Traditional farmers and farming practices have significantly enriched agricultural biodiversity by creating new varieties. These varieties were suitable for local climatic conditions, and the farmers developed them through cultivation of land races and seed exchanges with other farmers. Being life-and-diversity- driven, diversity sustaining enterprises, traditional agricultural systems have contributed significantly to the agricultural biodiversity and food security.

However, a small number of modern and uniform commercial varieties have replaced a significant proportion of the above plant varieties thus developed over the centuries. Humankind had been using an estimated 7000 species to satisfy basic human needs. However, today no more than 30 cultivated species provide 90 per cent of the human calorific food supplied by plants.

Thus, matters relating to conservation and sustainable use of PGRs are of utmost importance for ensuring food security, promoting sustainable agriculture, and securing farmers' livelihood.

10.2 OBJECTIVES

After reading this unit, you should be able to:

- explain the need for protection of PGRs;
- discuss the international framework on PGRs;
- explain the linkage between PGRs and intellectual property protection;
- examine the PGRs under the Biological Diversity Act; and
- examine the PGRs under the Plant Variety Act.

10.3 PGRS: FROM PUBLIC DOMAIN TO PRIVATE PROPERTY

Farmers across the world, particularly in developing countries, have conserved and improved PGRs (Plant Genetic Resources), over centuries. Since time immemorial, farming communities have shared knowledge and resources. Sharing of seeds among farmers constitutes perhaps the most important part of these traditional practices. There was no well-defined property right over PGRs. The reasons for this could be that, either no need existed for a formal private property right, or the absence of such a regime was considered as beneficial to farmers, farming communities and the entire society. Indeed, the free flow of knowledge and resources has immensely enhanced food production and thereby, food security. Thus, PGRs and related knowledge were freely shared and exchanged at the local, national, and international levels.

The development of agricultural biotechnology has been the main trigger behind the shifting of PGRs from their public domain nature. Developments in the field of agricultural biotechnology have created an unprecedented growth of commercial seed production in the developed countries. This development is marked by the emergence of private sector investments in plant breeding and a decrease in public sector spending.

The emergence of private sector involvement in plant breeding has been essentially complemented by the emergence of private property rights in PGRs. The concept in this context was plant breeders' rights (PBRs). PBRs refer to a form of intellectual property right that provides monopoly right over new plant varieties. The legal consequence of PBRs is that to use genetic resources or seeds protected by PBRs, a proper authorisation of the right holder is mandatory. Any kind of unauthorised use will attract legal action against the user.

The development of commercial breeding industries and the consequent private property system triggered a significant shift from the traditional practice of free exchange of resources and knowledge. The traditional practices of in-farm conservation and development of crop genetic resources have given way, at least to some extent, to the commercial production of seeds complemented by a strong private property rights over such new varieties.

10.4 LEGAL PRINCIPLES

10.4.1 Common Heritage of Mankind

Traditionally, PGRs have been a common heritage of humankind. A major implication of the common heritage status here was that there should be no restriction on availability. In other words, PGRs were considered as a public domain resource; access to PGRs was available to all. Consequently, appropriation under private property right schemes was deemed inappropriate.

The common heritage concept was a cardinal principle of the International Undertaking on Plant Genetic Resources that the 1983 Rome FAO Conference adopted (Resolution 8/83, Twenty Second Session). The International Undertaking on Plant Genetic Resources comprises one of the earliest instruments addressing the issue of legal status of PGRs and access to PGRs. The notion of common heritage has progressively given way to appropriation under the guise of private rights as well as sovereign rights.

10.4.2 Sovereignty Rights

There were two important reasons for revising the International Undertaking: the adoption of the Convention on Biological Diversity, 2002 and the failure of the International Undertaking to establish a concrete system to promote the realisation of farmers' rights. The CBD recognises sovereign rights of states over both biological and genetic resources that fall under their jurisdiction. In this new context, it was necessary to renegotiate the International Undertaking to take into account the new trends towards appropriation and benefit sharing. This resulted in the adoption of ITPGRFA (International Treaty on Plant Genetic Resources for Food and Agriculture) in 2001. The underlying principle of ITPGRFA is the sovereignty of states over their PGRs for food and agriculture.

The development of the legal framework relating to PGRs shows a shift from the concept of common heritage of humankind to sovereignty rights and private property rights. A controlled regime of state sovereignty and private property rights (IPRs-PBRs) has replaced the public domain nature of PGRs.

Self Assessment Question **(Spend 3 minutes)**

1) What is the legal implication of considering PGRs as a common heritage of mankind?

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10.5 INTERNATIONAL AGREEMENTS PERTAINING TO PGRS

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

ITPGRFA is the first legally binding agreement to deal exclusively with PGRFA management. The FAO (Food and Agriculture Organisation of the United Nations) adopted it at its 31st conference session in Rome on 3 November 2001; it came into force on 29 June 2004.

Its main objectives are:

- Conservation and sustainable use of PGRFA
- Fair and equitable sharing of the benefits arising from their use in harmony with the Convention on Biological Diversity (CBD)
- Promotion of sustainable agriculture and food security

10.5.2 Convention on Biological Diversity (CBD)

CBD addresses the conservation, sustainable use, and equitable sharing of benefits from utilising biological diversity in general. It is a comprehensive legal framework for the conservation and management of biological resources, of which PGRs constitute an important part. The choice of agricultural biodiversity as one of the thematic work programmes clearly reflects the importance of PGRs in the CBD framework. The Convention was opened for signature at the United Nations Conference on Environment and Development in Rio in 1992, and entered into force on 29 December 1993.

The main objectives of the CBD are:

- Conservation of biological diversity
- Sustainable use of biological diversity
- Fair and equitable sharing of benefits derived from using genetic resources

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

The TRIPS agreement was adopted (14 April 1994) as one of the basic agreements under the WTO (World Trade Organisation) framework. It came into force on 1 January 1995. The TRIPS agreement provides minimum standards for the protection of intellectual property rights in its members states. It covers intellectual property rights as copyright, trademarks, geographical indications, industrial design, patents and confidential information.

Article 27.3(b) of the TRIPS agreement provides that plants and animals other than microorganisms, and essential biological processes for the production of plants or animals other than non-biological and microbiological processes can be excluded from patentability. However, the members are obliged to 'provide for the protection of plant varieties, either by patents or by an effective *sui generis* system, or by any combination thereof'. Thus, the TRIPS agreement provides for the legal protection of intellectual property rights in new varieties

of plants (generally known as plant breeders' rights) that breeders develop. It is to be noted that, in India, the Protection of Plant Varieties and Farmers' Rights Act of 2001 was adopted to comply with this legal obligation under the TRIPS.

Self Assessment Question **(Spend 3 minutes)**

2) What is the obligation of WTO members under the TRIPs Agreement so far as PGRs are concerned?

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10.5.4 The Convention for the Protection of New Varieties of Plants (UPOV Convention)

The UPOV Convention was adopted in Paris in 1961. It was revised in 1972, 1978, and 1991. It seeks to provide uniform and clearly defined principles for the protection of plant breeders' rights and, for this purpose, it established the Union for the Protection of New Varieties of Plants. The UPOV Convention was first negotiated among the European and OECD (Organisation for Economic Co-operation and Development) countries. Until recently, its membership was small (India is not a party to the UPOV Convention) and its importance was limited. Several developing countries, including India, refused to be part of the UPOV framework.

However, the importance of the UPOV convention has increased tremendously after the adoption of the TRIPS agreement. This is mainly because the TRIPS agreement does not require any particular kind of intellectual property protection for new plant varieties. It gives flexibility to countries to formulate their own legal mechanisms. Since there is no other available model for countries to adopt, the UPOV Convention has become a default model of *sui generis* protection for new plant varieties.

The different agreements have different objectives. The ITPGRFA, emerged through the initiatives of the FAO, focuses on agricultural production and food security. The CBD, emerged from an initiative by the World Conservation Union (IUCN), is based on an environmental rational. The TRIPS Agreement and the UPOV Convention mainly provide private incentive structures to promote economic development. Thus, the legal framework relating to PGRs is comprised of more than one international agreement and their approach to the management of PGRs is significantly different.

10.6 PGRS AND INTELLECTUAL PROPERTY RIGHTS

10.6.1 Access to PGRs

The ITPGRFA provides a multilateral system to facilitate access to PGRs and distribution of benefits from using them. The facilitated access to PGRs envisaged

under the multilateral system does not apply to all PGRs for food and agriculture. ITPGRFA specifies these limits or restrictions:

1) Limits access to PGRs enlisted in Annex I of ITPGRFA.
2) Limits access to species that are under the management and control of contracting parties and in the public domain.
3) Restricts access to certain purposes - research, breeding, and training for food and agriculture.
4) Use of PGRs accessed through the multilateral system excludes chemical, pharmaceutical, and/or non-food/feed industrial purposes.
5) Prohibits intellectual property rights over PGRs accessed through multilateral system.

Facilitated access to PGRs under ITPGRFA has two notable characteristics. First, PGRs in the control and management of private individuals and companies, even if they are in Annex I, are not subject to the rules of the multilateral system. This means, such PGRs are outside of a 'facilitated multilateral access regime' and will remain in private control. Second, facilitated access (and benefit sharing) is further effectuated through a material transfer agreement between a provider and a recipient of PGRs. The Standard Material Transfer Agreement (SMTA) is a key tool for translating the language of ITPGRFA into contractual obligations for recipients of materials from the multilateral system. To this effect, the governing body has developed an SMTA through Resolution 1/2006 (16 June 2006). The SMTA is mandatory to access PGRs in the multilateral system. Third, the exclusion of purposes unrelated to food and agriculture implies that, access to PGRs for such purposes (such as chemical and industrial uses) is completely prohibited. It only excludes such uses from the benefit of 'facilitated multilateral access regime'. Principles and procedures to access PGRs for such purposes are available under the CBD regime.

Access to biological resources (including PGRs) is treated in a different way under the CBD. The CBD envisages a bilateral mode of regulation. It means that the countries providing and receiving the PGRs will decide between them the conditions of access and benefit sharing. This bilateralism is evident in the key norms and procedures (such as prior informed consent and mutually agreed terms). This is significantly different from the mechanism provided under ITPGRFA where a multilateral system facilitates access to genetic materials included in Annex I of the treaty. The treaty and the SMTA mention the basic conditions to follow. This means that ITPGRFA provides a multilateral access regime for access to PGRs for food and agriculture, whereas CBD provides for bilateralism in regulating access to PGRs for other purposes.

10.6.2 Benefit Sharing

Paradigms of claims over biological resources (including genetic resources), related knowledge, and the strengthening of intellectual property rights are undergoing rapid change; the concept of benefit sharing developed because of these changes. The concept of benefit sharing emerges in a context where there is no legal mechanism to recognise the rights of communities or people who have conserved and improved these resources and knowledge for centuries. Such legal protection was not an issue earlier as the system was not on an incentive basis; also, there were no legal restrictions on the use of such resources and knowledge.

The emergence of a strengthened intellectual property rights regime mainly through the TRIPS agreement has changed the 'non-restrictive and open access' system. It provides monopoly rights over products (such as high yielding plant varieties) which used the resources and knowledge from the 'non-restrictive and open access' system. In the context of the PGRs, benefit sharing seeks to correct or mitigate the injustice caused by protecting exclusively the plant breeders' rights: permitting the breeders to access freely existing PGRs and knowledge to create new varieties, while restricting farmers' access to these new varieties.

Fair and equitable benefit sharing is an important objective of the legal framework relating to PGRs. CBD is the basic treaty concerning the fair and equitable sharing of benefits from biological resources. The CBD Parties have adopted the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (CBD tenth Conference on 29 October 2010, in Nagoya, Japan). The Protocol is yet to come into force. Under it, each party is obliged to take legislative, administrative, or policy measures to ensure that benefits arising from the utilization of genetic resources as well as subsequent application and commercialization, are shared fairly and equitably with the providing party. Benefits listed under the Nagoya Protocol include monetary and non-monetary benefits. It re-asserts the norms of prior informed consent and mutually agreed terms and conditions as basic norms to ensure benefit sharing. Because the Nagoya Protocol is yet to come into force, the ITPGRFA is the major legally binding agreement at the international level addressing the issue of benefit sharing. Fair and equitable benefit sharing is a key objective of the ITPGRFA. As per the ITPGRFA, there are several means through which fair and equitable benefit sharing may be achieved. They are exchange of information, access to and transfer of technology, capacity building and sharing of monetary and other benefits of commercialization. However, the norms on benefit sharing are subject to intellectual property rights. For instance, it is provided that access to technologies shall be provided by respecting applicable property rights

The mechanism of sharing of monetary benefits is designed in such a way that a recipient who commercializes a product with the help of material(s) accessed from the multilateral system is required to pay under the mechanism. This means, ITPGRFA does not envisage a system of benefit sharing directly between parties. Benefits are intended to reach in various other forms such as conservation measures and capacity building assistance from the mechanism. This benefit sharing mechanism seems to have borrowed from the International Undertaking. The International Undertaking considered the ensuring of conservation, management and use of PGRs for the benefit of present and future generations of farmers as "the best way to implement the concept of farmers' rights".

Notably, in this context, the benefit sharing mechanism under the ITPGRFA has started functioning recently with the help of a voluntary contribution mainly from Norway, Spain, Italy, and Switzerland. The Governing Body in its third session held in Tunis during June 1-5, 2009 approved eleven projects from different regions (including one from India) for funding.

10.6.3 Farmers' Rights

The farming communities across the world have been following, since time immemorial, the practice of sharing of knowledge and resources. Sharing of seeds

among farmers is perhaps the most important part in these traditional practices. Until now, there was no legal interference with this practice of free flow of knowledge and resource, both at the national and international level. There was no well-defined property right regime for regulating PGRs. Either there was no need for a formal legal articulation of private property rights or absence of such a regime was deemed beneficial to farmers, farming communities, and the society. Indeed the free flow of knowledge and resources is claimed to have produced immense results in enhancing food production and achieving food security.

The term farmers' rights found a place in a legally binding international agreement for the first time in ITPGRFA. Article 9 of ITPGRFA bases farmers' rights on their contributions to the conservation and development of PGRs. It defines farmers' rights in an illustrative manner. The illustrated measures to protect and promote farmers' rights are:

- Protection of traditional knowledge relevant to PGRs
- Right to equitably participate in sharing benefits arising from the utilization of PGRs
- Right to participate in decision making on matters related to the conservation and sustainable use of PGRs

In addition to the illustrated measures, ITPGRFA further recognises the rights of farmers to save, exchange, and sell farm saved seeds. It does this by prohibiting the interpretation of the treaty provisions to limit the rights of farmers to save, use, exchange, and sell farm saved seeds.

10.7 LEGAL FRAMEWORK IN INDIA

Legal framework relating to PGRs in India comprises the Biological Diversity Act, 2002, and the Protection of Plant Varieties and Farmers' Rights Act, 2001. Both are relevant in the PGRs context — the former addresses the conservation and management of biological resources, the latter provides for the rights of plant breeders' and farmers' and addresses benefit sharing.

10.7.1 Biological Diversity Act, 2002

In view of India's rich reserves of biological resources and CBD's recognition of the sovereign rights of countries over their biological resources, India enacted the Biological Diversity Act in 2002. The Act aims to undertake and implement India's obligations in accordance with CBD provisions.

a) Access to biological diversity and its regulation

The Act classifies users of biological diversity into two, based on the involvement of foreign partners or institutions in the utilization of resources of India.

For the first category, the Act provides for prior approval of the NBA if their uses are for research, commercial utilization or bio-survey and bio-utilization. The persons referred to in this category may belong to any of the following:

- A person who is not a citizen of India
- A citizen of India, but a non-resident according to the Indian Income Tax Act, 1961

- A body corporate, association or organisation that is
  - Not registered or incorporated in India, or
  - Registered or incorporated in India under any law but has a non-Indian participation in its share capital or management.

Prior approval from the NBA is necessary where any person from India intends to transfer the results of research, using biological resources obtained from India or is occurring in India, for monetary consideration or otherwise to any other person:

- Who is not a citizen of India, or
- A body corporate, association or organisation that is not registered or incorporated in India or has non-Indian participation in its share capital or management.

Publication of research papers or dissemination of knowledge in a seminar or workshop does not constitute transfer if the publication is in accordance with the Central Government guidelines.

An exemption from the prior approval requirement is provided for collaborative research projects. The nature of collaboration may be transfer or exchange of biological resources or information thereto. Institutions including government sponsored institutions in India and those in other countries may undertake the collaborative research. Projects of this kind shall conform to the central government guidelines and be approved by the central government.

Those collaborative research projects, which were concluded based on agreements before the Act came into force, to the extent of the provisions in contravention with the Act, shall be void. All applicants seeking intellectual property protection for their inventions based on the research or information based on biological resources obtained from India shall require prior approval from NBA. In the case of patents, there is no requirement for prior approvals; rather the person can seek permission from NBA after acceptance of the patent but before patent sealing by the patent authority. A 90 days' period is provided for NBA to dispose of the application. While granting approval, the NBA may impose any of the following:

- Benefit sharing fee
- Royalty
- Both of the above
- Conditions including sharing financial benefits in cases of commercial utilization of rights

No such approval or permission is required in the case of an applicant seeking protection under the law relating to protection of plant varieties. A copy of the document granting such right shall be endorsed by the NBA.

Persons in the second classification (any citizen of India, body corporate, undertaking or organisation registered in India) shall give prior intimation to the State Biodiversity Board. The following categories who are citizens of India are exempted from this requirement:

- Local communities or people of the area
- Growers and cultivators of biodiversity
- Vaids and hakims practicing indigenous medicine

b) National Biodiversity Authority

NBA is constituted under the Act, which has the conservers, creators and knowledge holders of biodiversity as its non-official members. The functions of NBA are:

- Regulation of research, commercial utilization, bio-survey, and bio-utilization involving biological resources of India or knowledge relating thereto
- Issuing guidelines for access to biological resources and fair and equitable benefit sharing
- Advising the central government on matters relating to conservation, sustainable use, and equitable sharing of benefits from the utilization of resources
- Advise state governments about selection of areas of biodiversity as heritage sites and measures to be adopted for management of those sites
- Take measures on behalf of the central government to oppose the grant of IPRs in any country outside India on any biological resource obtained from India or knowledge associated with that resource.

c) Procedure before NBA

On receipt of the application for prior approval or permission, the NBA may conduct enquiries and consult the expert committee constituted for that purpose. It may grant approval with such terms and conditions as it deems fit. It may reject an application with reasons recorded in writing. A right of hearing shall be provided to the affected person before rejection of the application. Every approval by the NBA shall be publicly notified. Similar provisions exist with respect to transfer.

The NBA is vested with the responsibility to ensure that the persons seeking approval and the local bodies and benefit claimers arrive at equitable sharing of benefits based on mutually agreed terms.

d) State Biodiversity Board

State Biodiversity Board advises the State Government on matters like conservation and sustainable use of biological resources; equitable benefit sharing measures; and regulate the grant of approvals for commercial utilization, bio-survey and bio-utilization of resources by Indians.

e) Benefit sharing mechanism

The Act identifies, among others, the following ways of benefit sharing:

- Grant of joint ownership of IPRs to NBA or in the case of benefit claimers identified, then to such claimers
- Transfer of technology

- Location of production, research, and development units in such areas which will facilitate better living standards for benefit claimers
- Association of Indian scientists, benefit claimers, and local people in research and development in biological resources and bio- survey and bio-utilization
- Setting up of venture capital fund for supporting the cause of benefit claimers
- Payment of monetary compensation and non-monetary benefit to the benefit claimers

In the case of monetary compensation, the money shall be deposited in the National Biodiversity Fund. Where biological resources or associated knowledge was accessed from individuals or organisations, NBA may direct the amount to be paid to them directly in accordance with an agreement.

10.7.2 Protection of Plant Varieties and Farmers' Rights Act, 2001

The Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPVFR Act) was enacted primarily to comply with India's obligations arising from the Agreement on Trade Related Intellectual Property Rights (TRIPS). Article 27.3(b) of the TRIPS casts an obligation upon the states parties to provide plant variety protection either through patents or through a *sui generis* system. The PPVFR Act was enacted with a clear twin mandate:

1) To recognise and protect the farmers' rights in respect of their contribution made in conserving, improving, and making available PGRs for the development of new plant varieties; and

2) To protect plant breeders' rights to stimulate investment for research and development both in the public and private sector for the development of new plant varieties.

The PPVFR Act provides for registration of plant varieties that are classified into three varieties – new varieties, extant varieties, and essentially derived varieties. Conditions for the registration of a new variety are novelty, distinctiveness, uniformity, and stability. The PPVFR Act confers exclusive rights to produce, sell, market, distribute, import, or export the protected variety. Also conferred are the rights to license them to other persons. The duration of protection has been prescribed as 15 years from the date of registration with the exception of trees and vines, which are protected for 18 years.

The rights conferred under the PPVFR Act can be restricted through the mechanism of compulsory licences. Compulsory licences can be issued to anyone, provided the following two conditions are established:

1) Reasonable requirements of the public for the provision of seeds or other propagating material of the variety have not been satisfied; and

2) Seeds or other propagating materials of the variety are not available to the public at a reasonable price.

The interests and concerns of farmers are recognised in the PPVFR Act in different ways. Foremost among these are the provisions providing entitlements for farmers. These entitlements are mainly under chapter VI of the PPVFR Act:

1) Right to 'recognition and reward': A farmer who is engaged in the conservation of genetic resources and its improvement through selection and preservation is entitled to recognition and reward. Right to recognition and reward is subject to the condition that the genetic material so preserved and improved is used as donors of genes in varieties registrable under the PPVFR Act.

2) Right to claim compensation: The PPVFR Act recognises the right to claim compensation to village or local communities for their contribution in the evolution of a variety registered under the Act.

3) Protection of farmers' privileges: The PPVFR Act recognises the right to 'save, use, sow, resow, exchange, share, or sell' farm produce including seed of a protected variety in the same manner as they were entitled prior to the PPVFR Act. However, farmers are not entitled to sell the branded seed, i.e., seed of a variety protected under the Act.

Besides the above-mentioned entitlements, there are two other main ways in which farmers' interests are recognised and protected under the PPVFR Act. First, special considerations and privileges are provided to farmers by way of exemptions such as exemption from documents to be submitted along with the application for registration of a variety and exemption from fees to be paid in any proceedings before the authority, registrar, or the tribunal or the High Court under the Act. The special consideration could also be seen in the dilution of the principle of *locus standi* by permitting any person or organisation to file claim for compensation on behalf of farmers or local communities.

Self Assessment Question **(Spend 3 minutes)**

3) Mention the ways in which farmers' rights are protected in India?

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10.8 SUMMARY

- Originally, PGRs were considered as a resource in public domain and private property rights were, therefore, not applicable in this regard. The public domain nature of PGRs received formal recognition through International Undertaking on Plant Genetic Resources, 1983 which recognise PGRs for food and agriculture as a common heritage of humankind.
- The public domain nature eventually gave way to appropriation by the state and private parties. On the one hand, state exerted its control over PGRs through sovereign rights and on the other hand, part of the control went into the hands of private parties through intellectual property rights. While the former has been concretised under the CBD, later has received significant momentum after the adoption of the TRIPS agreement.

- The major intersection points were legal regime relating to PGRs and intellectual property rights meet are – access to PGRs, benefit sharing and farmers' rights.
- In India, PGRs are being regulated and controlled through mainly two laws– the Biological Diversity Act, 2002, and the Protection of Plant Varieties and Farmers' Rights Act, 2001. While the former asserts sovereign rights over the PGRs, the later provides a framework for private parties to exercise their control through plant breeders' rights.

10.9 TERMINAL QUESTIONS

1) Write an overview of international agreements relating to PGRS.
2) Discuss the interface between PGRs and intellectual property rights.
3) Discuss the role of the National Biodiversity Authority in regulating access and benefit sharing in the context of PGRs.

10.10 ANSWERS AND HINTS

Self Assessment Questions

1) The most important legal implication of recognising PGRs as a common heritage of mankind is appropriation of PGRs either by the state of by private parties is not allowed. Instead, access to PGRs should be freely available without restriction.
2) As per Article 27.3.b of the TRIPS agreement, all WTO members are required to provide legal protection of intellectual property rights in new varieties of plants. However, the TRIPS agreement does not prescribe any particular form of protection.
3) Major ways in farmers' rights are protected in India include right to claim compensation to village or local communities for their contribution in the evolution of a variety registered and right to save, use, sow, resow, exchange, share, or sell farm produce

Terminal Questions

1) Refer to Section 10.5
2) Refer to Section 10.6
3) Refer to Sub-section 10.7.1

10.11 REFERENCES AND SUGGESTED READINGS

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UNIT 11 MANDATE OF TRIPS AGREEMENT

Structure

11.1 INTRODUCTION

The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) Agreement is a multilateral World Trade Organisation (WTO) agreement and it binding on every member country. The TRIPS Agreement is a legal construct that is complex in the issues that it deals with. The Agreement covers five broad issues:

- how basic principles of the trading system and other international intellectual property agreements should be applied
- how to give adequate protection to intellectual property rights
- how countries should enforce those rights adequately in their own territories
- how to settle disputes on intellectual property between members of the WTO
- special transitional arrangements during the period when the new system is being introduced.

A Council for TRIPS monitors the working of the agreement and governments' compliance with it. Therefore, post WTO globalization of intellectual property has taken on legal form and the TRIPS ensures that all countries party to the

WTO must establish a minimum level of intellectual property protection or face trade sanctions under the rules set forth by the WTO. The technological revolution in the biotechnology industry was one of the major reasons for expanding the IPR regime to include biological subject matter.

The progress in biotechnology has also witnessed unfettered debate about possible risks to individuals, society and the environment. It has affected all levels of political, economic and scientific decision-making. Accompanying the debates about biotechnology itself there has been an argument on extending IPR regimes particularly patents to various products and process derived from biotechnological advances.

11.2 OBJECTIVES

After reading this unit, you should be able to:

- explain the interrelations between IPRs and biotechnology;
- discuss the background, negotiating history and interpretation of TRIPS obligation for patentability of biotechnological inventions; and
- consider the social and ethical concerns involved in biotechnology and its patenting.

11.3 THE TRIPS AGREEMENT

The TRIPS Agreement was a culmination of a long process of international developments, notables among them being the General Agreement on Tariffs and Trade (GATT) of 1947, the Berne Convention for the Protection of Literary and Artistic Works of 1886 and the Paris Convention of the Protection of Industrial Property of 1883. Prior to the establishment of the WTO, the World Intellectual Property Organisation (WIPO) administered practically all the important conventions in the field of IPR. The WIPO, as a United Nations agency, provided the developing countries an equal platform for multilateral rule-making in the IPRs; and many of these countries were opposed to stronger patent regimes. Therefore, the developed countries such as U. S. and European countries that dominated the much smaller organisation chose the multilateral trade negotiations during the GATT as the forum pursuing the agenda of stronger patent regimes. Another advantage of using the trade institutions to strengthen IPRs was that it not only provided comprehensive standards for domestic laws but, perhaps more importantly ensured their enforcement through the "*the most ambitious worldwide system for the settlement of disputes among more than 130 states ever adopted in the history of international law*".

11.4 SYNOPSIS OF TRIPS AGREEMENT

The TRIPS Agreement consist of the Preamble and Parts I to VII containing seventy-three Articles. In the Preamble, it is stated that intellectual property rights are "private rights" which must be enforced by member countries.

Part I of the TRIPS Agreement (Article 1 to 8) contains applicability of general provisions and basic principles. Article 1 sets the implementation framework and

commits the Member States to mandatory compliance to minimum standards. Article 2 provides that earlier treaties on IPR are not abrogated and Members may discharge obligations that they may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Washington Treaty on Intellectual Property in Respect of Integrated Circuits.

The general principles of the GATT Agreement, employed as a framework for the Uruguay Round negotiations, are reflected in the TRIPS general provisions found in Articles 3 and 4, which extend the principles of national treatment and most favoured nation treatment, respectively, to the protection of IPRs. The principle of "national treatment" requires nationals of other countries are to be granted treatment no less favourable than that accorded to the Member's own nationals while the "most-favoured-nation" (MFN) commitment requires that an advantage conferred on any country must be extended to all Members.

Articles 7 and 8 provide express recognition for policy objectives fundamental to international intellectual property (IPR) protection which should aim at promoting technological innovation and the transfer and dissemination of technology. They probably contain most explicit textual expressions of its object and purpose of the Agreement and align with the principle of integration and reconciliation of economic, social and environmental objectives

Part II of the TRIPS Agreement (Article 9 to 40) establishes the standards for availability, scope, use of IPRs. It requires Members to implement in their national laws provisions regarding copyright and related rights (Article 9 to 14), trademarks (Article 15 to 21), geographical indications (Articles 22 to 24), industrial designs (Articles 25 to 26), patent (Article 27 to 34), layout designs (topographies) of Integrated Circuits (Article 35 to 38), undisclosed information (Article 39), and the control of anti-competitive practices in contractual licenses (Article 40).

Part III (Articles 41-61) requires members to develop remedies and procedures under domestic law to ensure that IPR are effectively enforced for both national and foreign right-holders. The implementation requires procedures for effective action against infringement of IPR, ensuring that they are fair and equitable, not unnecessarily complicated or costly, and do not entail unreasonable time limits or unwarranted delays. Further, members must provide for civil and administrative procedures and remedies on evidence of proof, injunctions, damages and other remedies including criminal procedures and penalties at least in cases of wilful counterfeiting or piracy on commercial scale.

Part IV (Article 62) deals with procedural questions concerning acquisition and maintenance of IPR. While no detailed definition of the subject is provided, they are required to be fair, reasonably expeditious, not unnecessarily complicated or costly, and generally sufficient to avoid impairment of the value of other commitments.

Part V (Articles 63-64) includes dispute prevention and settlement procedures and for this purpose the integrated dispute settlement mechanism as laid down in the WTO Agreement shall apply to TRIPS issues.

Part VI (Articles 65 to 67) contains transitional arrangements, during which members are required to bring their national legislation and practices into conformity with its provisions. The length of the period granted to ensure

compliance depends on the level of development of Members as recognised by the United Nations. Accordingly, the dates for WTO Members were: 1996 for developed countries; 2000 for developing countries (as a general rule); 2005 for developing countries who had not introduced patents before joining the WTO; and 2006 for least-developed countries. The transition period has been extended to 2016 for least-developed countries.

Part VII deals with institutional arrangements and establishment of the Council for TRIPS as the compliance monitoring institution of the Agreement. It also provides that the Council for the TRIPS shall review the implementation of the Agreement after five years from coming into force and after every two years thereafter.

11.4.1 Patents and TRIPS Obligations

The TRIPS Agreement encompasses, in principle, all forms of intellectual property including:

- Patent and related industrial design
- Copyright and related rights
- Integrated circuit layout
- Geographical indications of origin.
- Trademarks
- Plant variety protection
- Trade secrets (confidential information)

Among these forms of IPRs, patent and plant variety right are more relevant to the biotechnical innovations and were among the most difficult to negotiate sections of the TRIPS Agreement. The TRIPS agreement adds new standards to those already established by the Paris convention. In addition to complying with Paris convention, it requires parties to provide national treatments with respect to patent protection. It prohibits discriminatory treatment of patent rights as regards to the place of invention, the field of technology, and whether products are imported or locally produced. It mandates that the term of patent protection shall not end before a period of twenty years from the date of filing. It also sets limits and conditions imposed on exceptions and limitations to patents rights and establish disciplines for governments that engage in compulsory licensing. It provides a robust dispute settlement process.

Self Assessment Question **(Spend 2 minutes)**

1) Which part of TRIPS agreement establishes the standards for availability, scope and use of IPRs? Explain

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11.5 MAJOR ISSUES RELATED TO IPR AND BIOTECHNOLOGY

Ethical issues and controversies about biotechnology patents are a significant and growing factors in the development and implementation of biomedical and agricultural technologies. In a few limited contexts, ethical concerns have been translated into legal rules that specify a clear course of conduct, but those situations are the exception. In most cases, ethical concerns about gene patents have not been incorporated into laws, and the ethical issues remain largely unresolved and hotly debated. The major issues that influenced the debates and have an influence on expanding patenting regimes of biotechnology included those related to ethical aspects, the source of biological material obtained for patenting an invention, and how the patent is used.

11.5.1 Ethical Aspects

The development of biotechnology and patentability of biotechnological processes and products has triggered unprecedented ethical and social concerns. Some individuals, groups, cultures, and nations adhere to a position that any patenting of human, animal, or plant genes and tissues is unethical as patenting will lead to greater animal suffering, and that patenting undermines the dignity of humans and other species by making their genes and cells subject to ownership by others. Another argument advanced is that living materials are naturally occurring, and thus isolation and description of "nature's handiwork" should not qualify as patentable subject matter. Concerns have been raised about the cruel treatment of transgenic animals in health research which are bred to suffer from such diseases as AIDS, sickle cell anemia, cystic fibrosis, and cancer. Denying patent protection may not, however, ease their suffering as animals have been research subjects for a very long time, and humans have benefitted immeasurably from their use.

Other ethical concern include fears that patenting and commercialization of biotechnology shall lead to the availability and use of privileged information, and access to new drugs, treatments and plant varieties. However, the counter argument is that eliminating patent protection from biotechnology inventions would make those innovations less rather than more ethical, in part by making new technologies less transparent as companies shall rely more on trade secrets in place of patents and their requirement for public disclosure.

Notwithstanding the arguments against patentability of biotechnological innovations a blanket prohibition on any patents of genes or other biological materials is inconsistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, which requires countries to provide IP protection for most biotechnology products. Therefore, any member state of the WTO is unlikely to incorporate a generic prohibition on biological patents in the national legislations and the political and ethical arguments against them have little or no legal force and relevance. However, the TRIPS agreement permits members states to exclude bioengineered animals from patentability. Thus, each nation must individually decide whether it will extend its patent laws to animals, and these debates generally focus on ethical arguments about animal rights and commodification of life. In jurisdictions that recognize a morality exception to patents, controversial patents are subject to challenge under such clauses, both during initial application, and in subsequent post-issuance challenges.

The Myriad case is a perfect case that highlights issues that have arisen in some significant patent law cases concerning bioethics. It raises questions about patenting genetic inventions, demonstrates how certain bioethical issues go beyond questions of patentability, to the way in which a patent, once granted, is exercised in the marketplace. The U.S. Patent and Trademark Office (USPTO) has granted thousands of patents on human genes – in fact, about 20 percent of our genes are patented.

Myriad was established in 1991 as a spin-off company from the University of Utah by Mark Skolnick, a researcher at the university, and member of an international consortium that sought to find genetic links to breast cancer. The scientists from Myriad, the University of Utah and other institutions succeeded in identifying and sequencing the two genes BRCA1 (in 1994) and BRCA2 (in 1995) that belonged to a class of genes known as tumour suppressors. In addition, they identified that a woman's risk of developing breast and/or ovarian cancer is greatly increased if she inherits a deleterious BRCA1 or BRCA2 mutation. Based on this genetic information, Myriad was able to develop commercial diagnostic tests. To protect the commercial interests, Myriad and its partners filed a number of patent applications in the USA, following these up with applications in other countries. In Europe, they made use of the European Patent Convention (EPC), filing the applications with the EPO. The scope of protection in the patent applications was directed to the genes as such as well as the use of different gene variants to determine the risk of breast and ovarian cancer.

Myriad along with its partners held U.S. patents 5747282 and 5710001 on the isolated DNA coding for a BRCA-1 polypeptide and on a screening method. In 1997, together with the *Centre de Recherche du Chul* in Canada and the Cancer Institute of Japan, they received patent protection on an isolated DNA sequence, asserting rights over a number of mutations in the gene (U.S. Patent 5693473). Further patent applications were filed on the second gene, BRCA-2, in the U.S. and in other countries (US Patents 5837492 and 6033857).

In Europe through three different BRCA1 patents, Myriad was awarded exclusive rights to the isolated BRCA1 gene (European patent, EP, 705 902 B1), to use of the gene in cancer diagnosis in general (EP 699 754 B1), and to some 30 different mutations in the gene that are associated with an increased risk of cancer (EP 705 903 B1). Subsequently, Myriad contacted healthcare providers throughout Europe for licensing the technology at prices that were perceived to be excessively high. Also, the licensing terms prohibited licensees to perform tests themselves, and mandated sending samples to Myriad for analysis.

In the light of the conflicts surrounding Myriad's licensing policy and the general debate on gene patents, oppositions were filed against the isolated BRCA-1 gene. Unlike in most other cases, the opponents in this case were not direct competitors of the patent owner, but organisations and institutes that were eager to question the existing system and included among others, Switzerland's Social Democratic Party; Greenpeace Germany; the French *Institut Curie*; Assistance *Publique-Hôpitaux de Paris*; the Belgian Society of Human Genetics; the Netherlands, represented by the Ministry of Health; and the Austrian Federal Ministry of Social Security.

The opponents challenged the patent on the basis of the EPC's patentability criteria, arguing that the claimed invention lacked novelty, inventive step

and industrial application, and that the patent failed to disclose the invention sufficiently for a person skilled in the art to carry it out. The opposition procedure concerning the first patent – that covering the BRCA1 gene as such – was concluded in 2007, following an appeal procedure. Myriad had lost patent protection for the gene as such in Europe. The proceedings found that errors in the original patent application had not been corrected until the gene sequences were in the public domain. This meant that, according to patentability criteria, the invention had not been fully disclosed in the application as originally filed; and was not novel by the time the invention was fully described in the amended application. It is important to note, however, that the outcome was not the result of a decision that genes cannot be patented, but a consequence of Myriad's failure to satisfy the traditional criteria for obtaining a patent.

The final decision with regard to the oppositions against the two other patents on BRCA1-related inventions was reached in November 2008, also after appeals against the first instance decisions and written decisions were issued by the EPO on 7 March 2009. The broad protection sought by Myriad from the outset – and initially granted by the EPO to some extent – has been severely limited. What remains is patent coverage of one single specific cancer mutation, and of the detection of frame shift mutations in the gene.

The legality of gene patents in the United States was also challenged by the lawsuit, *Association for Molecular Pathology, et al. v. U.S. Patent and Trademark Office, et al.*, filed on behalf of researchers, genetic counsellors, women patients, cancer survivors, breast cancer and women's health groups, and scientific associations representing 150,000 geneticists, pathologists, and laboratory professionals. The lawsuit was filed against the U.S. Patent and Trademark Office, as well as Myriad Genetics and the University of Utah Research Foundation, which held the patents on the genes, BRCA1 and BRCA2. The lawsuit charges that patents on human genes violate the First Amendment and patent law because genes are "products of nature" and therefore can't be patented.

On March 29, 2010, Judge Robert W. Sweet issued a 156-page decision, which declared the patents invalid stating: "*DNA's existence in an 'isolated' form alters neither this fundamental quality of DNA as it exists in the body not the information it encodes. Therefore, the patents at issue directed to 'isolated DNA' containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable under 35 U.S.C. §101.*" The decision also found that comparisons of DNA sequences involved in these patents are abstract mental processes, therefore, also unpatentable. The decision was appealed. Myriad appealed, challenging the court's jurisdiction and its decision. Myriad argued that it had not accused the plaintiffs of infringement, so they lacked standing to file a declaratory judgment suit. Myriad also raised two arguments in favour of patent eligibility.

The U.S. Court of Appeals for the Federal Circuit heard Myriad's appeal of that ruling in April 2011. On July 29, 2011 the Federal Circuit overturned the District Court's finding that the claims covering isolated gene sequences are invalid and also overturned the invalidity of some of the diagnostic claims. The appeals court ruled that companies can obtain patents on the genes but cannot patent methods to compare those gene sequences.

On December 7, 2011, the ACLU filed a petition for a writ of certiorari to the U.S. Supreme Court. On March 26, 2012, the U.S. Supreme Court vacated the decision of the appeals court and instructed: "*The petition for a writ of certiorari is granted. The judgment is vacated, and the case is remanded to the United States Court of Appeals for the Federal Circuit for further consideration in light of Mayo Collaborative Services v. Prometheus Laboratories, Inc.*" The U.S. Supreme Court had unanimously decided for more restrictive rules for patenting on March 20, 2012 in *Mayo v. Prometheus*. The patents at issue in Mayo relate to methods of optimizing the dosage of a particular drug to treat autoimmune conditions such as inflammatory bowel disease. The claimed treatment regimen takes into account the toxicity of the drug and responsiveness of the patient in some cases. To optimize this treatment, the Prometheus patents disclose a method of adjusting a drug dosage based on the level of a metabolite in patients treated with the drug. Prometheus brought an action for patent infringement against Mayo, which had developed its own diagnostic test for a patient's metabolism of the drug. In its review of the case, the Supreme Court found that Prometheus' claims set forth a law of nature — the relationship between a patient's metabolizing of a particular drug and the resulting determination and administration of an effective dose of that drug. The steps to determine the metabolite concentration and administer the drug according to the metabolite concentration were conventional activities used previously by those of skill in the art. In other words, the conventional steps of determining and administering did not present a patentable application of the law of nature.

In addition to the continuing questions about patenting inventions derived from the human genome, the Myriad case raised concerns about the potentially limiting effects of the patents on further research, on the development of new tests and diagnostic methods, and on access to testing. While the considerable medical benefits of the cancer screening technology were not in dispute, there were differing views about how the patent system should recognise such technology, if at all, and about how patents on such technology, once granted, should be exercised.

11.5.2 Obtaining Biological Samples

The ethical debate surrounding the patenting of biological material relates to the manner in which the biological samples used for the patentable discovery were collected. The legal and property rights of local populations and national governments with regard to animal and plant specimens collected within their territory and used for a patented discovery are uncertain and often disputed. At the international level, some of the most inflamed controversies are related to claims of *biopiracy* in which scientists from an industrialized nation seek patents based on human, animal, or plant materials collected from other, less-developed nations. The major concerns related to access to biological samples are prior consent and benefit sharing from commercial utilisation of the material accessed.

a) Prior consent

Treating the human body as a natural resource to be appropriated for the inventive work of researchers has met with some resistance. Concerns have been raised as the prevailing scientific norm is that donors of tissue for research retain no property or other rights in their cells or genes to any patentable discoveries that may result from research using their tissues. Prior consent refers to the

procurement of advance approval from the relevant entities before taking biological samples. One issue relating to prior consent is who is authorised to provide the required consent. The consent may need to be given by the specific individuals from whom the tissue is taken (in the case of human samples), from the local community, tribe, or local government in the region from which the samples would be taken, and from the national governmental authorities.

John Moore's case is regarded as the leading case concerning ownership of human tissue and questioning the ethics of property rights over an individual's body. The case of ***Moore v. The Regents of the University of California*** began when Moore discovered that his cancerous spleen had been used to create a cell line with commercial value without his knowledge.

Moore suffered from hairy-cell leukemia. As part of his treatment for cancer, doctors at the UCLA Medical Centre considered the removal of his diseased spleen essential for his health. The extracted tissue from this spleen was used by doctors at the UCLA Medical Centre to develop a cell line from Moore's T-lymphocytes. The cell line was then patented and commercialized very successfully through a Swiss drug company resulting in a drug worth millions of dollars. The doctors neither took permission of Moore for undertaking research on his unique tissue neither did they inform him of their intention regarding patenting and commercializing his cells without sharing any of the proceeds. Even more annoying was the fact that they affirmatively misled Moore into returning to the hospital on several subsequent occasions to collect additional tissue. When he did find out, he sued the UCLA for breach of fiduciary duty and to establish a property right in his spleen under the tort of conversion.

The California Supreme Court agreed with him that doctor and hospital were at fault in not disclosing their research intentions and by failing to obtain informed consent for their research from him and had committed a breach of fiduciary; and he was entitled to compensation for this failure to disclose such information. However, the Court refused to acknowledge that Moore had a property right in his tissue. Instead, the court found that the California Board of Regents had a property right to Moore's cell line. As Alan Hyde put it, "*Moore's cells were property, but they weren't his. For surely they were the property of the medical researchers after they were removed from Moore's body*." Moore's claim to the products made from his spleen was not tenable as he was in no position to invest the necessary labour to create a product of value from his spleen. It is the labour of the inventor that is important and the patent law rewards this inventive effort, not the discovery of naturally occurring raw materials here, thus the court argued: Human cell lines are patentable because "[l]*ong-term adaptation and growth of human tissues and cells in culture is difficult – often considered an art...*," and the probability of success is low. The Californian court, on policy and ethical grounds, agreed: "*[If the] plaintiff is permitted to have decision-making authority and a financial interest in the cell line, he would then have the unlimited power to inhibit medical research that could potentially benefit humanity. He could conceivably go from institution to institution seeking the highest bid and, if dissatisfied, claim the right simply to prohibit the research entirely.*"

In a related case in the research context rather than the clinical setting, parents of the children with the inherited Canavan disease convinced a medical researcher to attempt to isolate the gene responsible for the disease. The families of affected

children donated their biological tissue under the belief that it would be used solely to help diseased patients and helped to raise funds for the research. The gene was successfully identified and without informing the parents who had donated tissue samples to the research, the researcher's employer (Miami Children's Hospital) patented the gene. The genetic test based on the gene, was licenced to clinics that had starting using the newly discovered genetic test and a modest licensing fee was charged. The families and various support organisations were outraged by these actions and sued the hospital alleging various legal claims including conversion, failure to provide informed consent, unjust enrichment, and breach of fiduciary duty. The federal district court dismissed most of the families' claims, but concluded that the unjust- enrichment claim was sufficiently viable to go forward, and the case subsequently settled.

These cases, underline that even if such disclosure is not legally mandated, a physician or researcher may have a legal duty to inform tissue donors of their intent to pursue patents using the donor's tissue. Any failure to obtain prior informed consent from tissue donors runs the risk of provoking ethical controversies that can result in bad publicity and expensive, time-consuming litigation.

The problem becomes more complex when scientists begin collecting the cells of indigenous people. The Hagahai tribe is an early example of the international controversy over the patenting of human tissue. In a more widely publicised case, attempts were made to challenge a patent sought by the U.S. National Institutes of Health (NIH) for a cell line derived from a member of the Hagahai, an isolated tribe in Papua New Guinea.

The Hagahai lived an isolated existence until 1984, when they sought help because of a disease that was afflicting the community. In return of medical assistance they donated blood samples to NIH. It was found that the members of the tribe carried a unique gene that predisposes humans to leukemia, yet they did not themselves manifest symptoms of the illness. Further analysis of blood samples identified a T-lymphotrophic virus, with potential for development into a vaccine for certain types of leukemia.

The NIH filed a patent in 1991on the cell line, infected with a Papua New Guinea Human T-Lymphotropic Virus (HTLV) variant, and to vaccines for humans against infection and diseases caused by HTLV-I and related viruses that had a high frequency of a gene related to leukemia. Once the patent application became public knowledge, controversy ensued over the nature of informed consent and what ownership should mean. The fact that the genetic material came from an indigenous group made the case particularly sensitive. Many indigenous rights advocates suggested that the patent was a violation of the human rights of the Hagahai and gave rise to accusations of biopiracy. The focus of the international controversy over this patent application, which was subsequently abandoned in response to the pressure, was whether in this case consent should have been obtained by NIH solely from the individual, or from the Hagahai people, or from the Papua New Guinea government.

Another example of an international controversy over the alleged lack of appropriate prior informed consent relates to the Guaymi Indians, the largest indigenous tribe in Panama. Thousands of Guaymi tribal members are infected with an HIV-like virus known as the Human T-Lymphotropic Virus Type 2

(HTVLII). The U.S. Centres for Disease Control and Prevention (CDC) undertook a research project to investigate infection in the early 1990s. Subsequently, in 1993, a patent claim was filed by the U.S. Department of Commerce claiming a cell line–Human T-Lymphotropic Virus Type 2, isolated from blood taken from a 26-year old Guaymi woman being treated for leukemia in Panama. Her cell line is of interest because some Guayami people carry a unique virus and whose antibodies may prove useful in AIDS and leukemia research. The Government of the Solomon Islands has demanded the withdrawal of the patent applications citing an invasion of sovereignty, lack of informed consent, and moral grounds as the reasons for protest. The United States claimed that the woman gave oral consent in the hospital (although the woman was reportedly illiterate, unschooled, and quite sick, which raises questions about the effectiveness of the informed consent). However, the focus of the ensuing controversy was that the tribe was never informed of, nor asked to consent to, the removal of the blood sample to the United States, the establishment of cell lines using those samples, or the patent application. Although United States subsequently dropped the patent application in response to the controversy it nonetheless filed two further indigenous human cell line patent applications that remain controversial

It is evident from these examples that any patent application based on tissues from identifiable populations, such as indigenous tribes, may be subject to significant controversy if prior informed consent is not obtained from the person or persons providing the tissue samples as well as the tribal authorities and, perhaps also, the national government.

The content and form of the information provided in the prior consent has also been controversial. The European Union's Group of Advisers on the Ethical Implications of Biotechnology has endorsed the need for prior consent before using a donor's tissue to develop a patentable invention. In its directive on patenting of biotechnology inventions, the European Union carried forward this recommendation in Recital 26, which provides

"Whereas if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law".

There are also practical problems with a requirement for prior consent in this context— the original researchers, or subsequent researchers who may have access to the tissue, may not have the intent or knowledge at the time of tissue collection that they will be pursuing a patent application based on that tissue. In addition, except for rare cases (including in ***Moore v. The Regents of the University of California*** discussed above), most patentable inventions resulting from human tissue are based on findings using large numbers of samples, complicating and attenuating the requirement for prior consent on future patents from each individual tissue donor.

The ethical issues of consent are being considered in a number of different fora and legal contexts. The focus on biotechnological innovation ranges from use of genetic material of human origin in medical research to bioprospecting of plant and animal resources, linked with community traditional knowledge. The UNESCO Declaration sets prior informed consent in the context of human dignity and autonomy, while the CBD links it to the sovereignty of nations

over their resources. The CBD makes informed consent a condition of access to genetic material of plant or animal origin. Several nations, including India through the Biological Diversity Act, have introduced specific legal measures that draw a direct linkage between prior informed consent and subsequent patenting activities. Several recent international studies and proposals have been published on this subject in recent years, but the legal and ethical status of informed consent requirements for nonhuman biological materials continues to be hotly debated and uncertain issues.

b) Benefit Sharing

Benefit-sharing, along with the prior informed consent, is also a major issue in accessing the biological material, i.e., whether the entities that collect tissue samples that are used to patent a product are ethically obliged to share the economic benefits of their inventions with the individuals or population from whom the samples were taken. In 1997 the twenty-ninth session of the UNESCO General Conference unanimously adopted the Universal Declaration on the Human Genome and Human Rights. The Declaration addresses some of the concerns of indigenous people by setting international standards for genetic research based on respect for fundamental human rights. Article 10 provides a standard by which States Parties can protect Indigenous genetic information:

"*No research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.*"

The Human Genome Organisation (HUGO), conceived in late April, 1988, at the first meeting on genome mapping and sequencing, is an international organisation of over 1300 scientific researchers from more than 50 countries. As a voluntary organisation, HUGO is independent of governments, academic organisations and industries. Its focus is on science rather than medicine or clinical applications. The HUGO ethics committee adopted a Statement on Benefit Sharing with regard to human genetic research in 2000, which states:

- Distribution of benefits of genetic research
- Benefits to those individuals who did not participate in the research
- Discussion about benefit-sharing with groups or communities prior to the research
- The provision of immediate health benefits as determined by community needs
- The distribution of information about general research outcomes to all research participants
- The allocation, by profit-making entities, of a specific percentage (e.g. 1% - 3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts

Similarly, Article 19 of the International Declaration on Human Genetic Data provides that: "*Benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with society as a whole and the international community.*"

An important precedent for benefit sharing in human genetic research is the ill-fated Human Genome Diversity Project (HGDP), which sought to collect genetic samples from as many human populations as possible on the planet. Although the project was never implemented, largely because of ethical critiques and controversies about the project, it did adopt precedent-setting ethical guidelines that recognised an ethical duty for benefit sharing. The guidelines specify that "*a fair share of the financial rewards shall return to the sampled populations*" when the research results in commercial products. The suggested mechanisms for returning such payments to the donors include:

(1) paying "*a set percentage royalty ... for the benefit of the sampled populations*" or (2) negotiating "*a reasonable financial payment with a trustee for the sampled populations, with the proceeds for the population's benefit.*"

With respect access to food and agricultural genetic resources products, the Convention on Biological Diversity addresses primarily issues related to the conservation of biological diversity, and provides for sustainable use of biodiversity components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources. Article 15 specifies that "*the authority to determine access to genetic resources rests with the national government and is subject to national legislation.*" Article 1 establishes the principle of "fair and equitable sharing of the benefits" of biodiversity. Further, the Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), negotiated under the Food and Agriculture Organisation (FAO) of the United Nations, establishes the principles of "facilitated access" and "sharing of benefits" for the commercial or scientific uses of the nation's resources by out-of-country entities. Of course, these treaty obligations are only mandatory for nations that have ratified the treaty and many prominent nations, including the United States and some European nations, have yet to ratify the 2001 treaty.

Despite the endorsement of benefit sharing in the various statements and international agreements described above, benefit sharing remains a controversial and uncertain principle. One practical problem is that many scientific researchers are not provided funds in their research grants for providing economic compensation to individuals or populations providing the tissue samples. Another problem is that there is uncertainty in many cases in identifying who should decide how the benefits are allocated within population.

When the samples are taken from a discrete community or tribe with a recognized governance structure, the allocation of the benefits is usually not problematic as the existing local government can take responsibility for using and distributing the benefits, but when the population is more dispersed or more difficult to clearly define, the distribution of benefits becomes more difficult. Finally, there is an ethical objection that paying significant financial benefits to individual tissue donors may unduly induce some individuals to participate in research.

In sum, while some legal rules and precedents address the issues of prior consent and benefit sharing in certain limited contexts, these issues are primarily ethical issues at the present time, in the absence of applicable laws. At their core, the largely unresolved ethical debates on these issues represent a concern with the fairness and distributional aspects of biotechnology research and commercialization, and are important factors that should be considered in the context of any research project or program involving the collection of biological samples from plants, animals, or human populations.

11.5.3 Use of Patents

Perhaps the most common concern is the availability of the patented inventions and practices that may inhibit access to the benefits associated with the patented technology by entities with limited funding, including public research institutes, patients, farmers, some healthcare providers, university researchers etc.

In the patent case, *Stanford v. Roche Molecular Systems*, the court considered the ownership rights to technology developed by public institution in collaboration with private firm. Dr. Mark Holodniy, a fellow at department of infectious diseases at Stanford University, had been assigned by the University to conduct research at the Cetus Corporation, a private firm. While working on site at Cetus, Dr. Holodniy developed a procedure for measuring the amount of HIV in a patient's blood. Roche Molecular Systems bought Cetus's rights to the procedure and incorporated it developing HIV test kits that became widely used in hospitals and clinics. Dr Holodniy had signed a contract assigning inventions arising from his employment at Stanford to the University. He later signed a contract saying that "I will assign and do hereby assign" to Cetus inventions arising from his time there. Stanford sued Roche for patent infringement in the District Court for the Northern District of California.

Stanford University argued that Dr. Holodniy had no authority to assign his patent rights to Cetus under the federal Bayh-Dole Act, which, among other things, specifies how rights in patents are allocated when federal money is involved. It grants universities and other federal contractors exclusive rights to inventions generated by federally-funded research. Roche said it was entitled to sell the kits in the light of the agreement between Dr Holodniy and Cetus. Although the District Court ruled in Stanford's favour, the Court of Appeals reversed the decision and held that the Bayh-Dole Act did not automatically void Dr. Holodniy's assignment of patent rights to Cetus, which made interpretation of the underlying, competing contractual assignment language relevant. In its 7-2 decision, in June 2011, the Supreme Court affirmed the decision of the U.S Court of Appeals for the Federal Circuit.

This restricted availability could adversely affect, in particular, subsistence agriculture, medical research, and health care. For example, critics allege that when the genetic mutations were first discovered, several labs, including the DNA diagnostics lab at Yale University, offered the BRCA 1/2 mutation testing for $1,600. Soon after Myriad received its patent in 1996 for a comprehensive BRAC analysis, the cost jumped to $2,400. And, while the cost of other comprehensive genetic testing has dropped over the ensuing years as technological capabilities advanced, the cost of the BRAC analysis rose to around $3,340. This monopolising of the patents adversely affects scientific research and health care by preventing some non-profit and other clinical-care units from offering a genetic test for these mutations, particularly for patients without health insurance or the means to pay for such tests, and may also burden or restrict scientific research related to hereditary breast cancer, although the company provides a substantial discount in the license fee to the University and non-profit researchers.

From a legal standpoint, property is considered to be a bundle of rights. The changes in patent regimes over the last three decades have led to large number of patent applications in biotechnology, which raises the question whether biotech

patents are economically efficient. One concern has been what is called as "tragedy of the anticommons". The anticommons property emerges when various owners possess different rights within the bundle and property rights become fragmented between individuals or firms. The "upstream" patenting of research tools and genes will create which will result in excessive and overlapping proprietary hurdles that will impede scientific research. A recent survey of 1,240 university geneticists found that patenting and commercialization of research may be impeding the scientific ideals of openness and sharing, with 73% of respondents claiming that withholding of data by colleagues is slowing progress in their field. Scholars have also used the term "patent thicket" to describe the problem of multiple overlapping rights that can hamper innovation by creating transaction barriers.

In many cases rights provided by the biotechnology patents are exploited by the patent holders to expand market power to things not originally included in the patent claims. The focus on increased profits is often without concern to the interests of patients, farmers, and other potential end users of the patented technologies. For example, Monsanto Company since the 1990s, has been developing and selling Roundup Ready seeds. These genetically engineered crops are resistant to an herbicide Roundup. Roundup is the brand-name of herbicide with the active ingredient glyphosate that itself was patented by Monsanto in the 1970s. Since Roundup Ready plants are resistant to Roundup, so farmers that plant these seeds are obliged to use Roundup to keep other weeds from growing in their fields. Monsanto is exploiting the patents on genetically modified crops to promote sales of its Roundup herbicide through license agreements that requires farmers who buy Roundup Ready seeds to also use Monsanto's Roundup rather than competing brands of the herbicide glyphosate. In several cases, lawsuits have been filed against Monsanto for "patent misuse", but to date these legal claims have been unsuccessful, leaving the issue to be debated in the ethical realm.

In order to address these concerns, the policy approaches that have been suggested include requirements for compulsory licensing, prohibition of exclusive licensing, liability exemptions for clinical uses of patented materials and tests, an expanded experimental-use exemption, the development of patent pools, and open-source approaches to biomedical research.

11.6 TRIPS AGREEMENT AND PATENTABILITY OF BIOTECHNOLOGICAL INVENTIONS

Article 27 of TRIPS Agreement defines "patentable subject matter". It requires Members countries to make patents available for any inventions, whether products or processes, "in all fields of technology without discrimination, provided that they are new, involve an inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively. It is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced (Article 27.1).

More generally, the TRIPS agreement specifically provides (but not mandates) three possible exceptions to patentability that nations may include in their patent laws to deny patents for specific innovations and inventions. These include:

The TRIPS Article 27.2 provides exception for inventions contrary to "*ordre public* or morality". The term "*ordre public*", is derived from French law, and expresses concerns about matters threatening the social structures which tie a society together, i.e., matters that threaten the structure of civil society as such. "Morality" refers to the degree of conformity to moral principles (especially good) and would, therefore, is relative to the values prevailing in a society and shall not be the same in different cultures and countries, and may also change over time. The provision further clarifies, that protection of *ordre public* or morality includes the protection of "human, animal or plant life or health or to avoid serious prejudice to the environment", thereby explicitly allowing for exceptions to patentability when any of these interests may be negatively affected by patent grants. The use of this exception is subject to the condition that the commercial exploitation of the invention must also be prevented and this prevention must be necessary for the protection of *ordre public* or morality. Thus these exceptions can possibly be not applied when, for instance, it would be in the interest of public health to promote the diffusion of a biotechnological invention; as a patent cannot be refused on *ordre public* or morality grounds and, at the same time, its commercialisation is permitted.

The European Union's *ordre public* clause also prohibits patents related to human cloning, modifying human germ lines, using human embryos for commercial purposes, and genetically engineering animals in ways that cause suffering without a substantial medical benefit to humans. In other cases, challenges under the *ordre public* clause to biotechnology patents have failed.

The second exception is that Members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals (Article 27.3(a)).

The third exception provides that Members may exclude plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, plant varieties can be patented and any country excluding plant varieties from patent protection must provide an effective *sui generis* system of protection. Moreover, this provision is subject to review four years after the entry into force of the Agreement (Article 27.3(b)).

The TRIPS Article 28 provides that exclusive rights conferred by a product patent are the making, using, offering for sale, selling, and importing for these purposes. Process patent protection must give rights not only over use of the process but also over products obtained directly by that process. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts (Article 28). According to Article 28.1 (b), if the subject matter of a patent is a process, the rights conferred not only include the process *per se* but also "the product obtained directly by that process". This kind of "Product by Process Claims" give rise to special problem in relation to biotechnology, which enables the right holder to a patent relating to plant or animal biotechnical inventions, through the application of the "process", obtain the patent rights toward the "plant or animal" itself.

However, Members are entitled to provide exceptions to the exclusive rights conferred by a patent, where such exceptions do not unreasonably conflict with the normal exploitation of such rights and do not unreasonably prejudice the

legitimate interests of the patent owner, taking account of the legitimate interests of third parties (Article 30).

Members are committed that the term of protection available shall not end before the expiration of a period of 20 years commencing from the filing date (Article 33).

Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application (Article 29.1).

In an infringement case, if the subject-matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process, where certain conditions indicating likelihood that the protected process was being used (Article 34).

Compulsory licensing and government use without the authorization of the right holder are allowed, but are made subject to conditions aimed at protecting the legitimate interests of the right holder. The conditions are mainly contained in Article 31. These include the obligation, as a general rule, to grant such licences only if an unsuccessful attempt has been made to acquire a voluntary licence from the patentee on reasonable terms and conditions within a reasonable period of time; the requirement to pay adequate remuneration in the circumstances of each case, taking into account the economic value of the licence; and a requirement that decisions be subject to judicial or other independent review by a distinct higher judicial/administrative authority.

Self Assessment Question **(Spend 2 minutes)**

2) What are the possible exceptions to patentability that nations may include in their patent laws as per the TRIPS?

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11.7 REVIEW OF ARTICLE 27.3 (B)

As mentioned above, the TRIPS Agreement requires a review of Article 27.3(b) which deals with the exclusion from patentability of plant and animal inventions, and the protection of plant varieties. The review exercise was initiated in the TRIPS Council since December 1998 but has not been accomplished to this date.

As discussed above, at the time of the Uruguay Round, most of the Contracting Parties did not have any experience on the protection of biotechnological inventions. Therefore, Article 27.3 (b) was accepted, as an agreement in principle, but subject to the review after further experience was acquired on its practical implications.

The debate on the review of Article 27.3(b) was opened in the TRIPS Council in April, 1999. Keeping the review within the scope of the provision's language, the developed countries wanted the focus to be on analysis of information gathered concerning the implementation of Article 27.3 (b). On the other hand, developing countries were resolute that the provisions of the Article 27.3 (b) require a substantive review incorporating the commitments made by WTO Members under the CBD. The two major proposals repeatedly made by developing countries in the course of the review included, one that the new provisions should be added to the TRIPS Agreement specifying the intellectual property rights and the rights of indigenous local communities; and second that the patent applicants should be required to identify clearly the source and the country of origin of biological material.

Doha declaration and the review of Article 27.3(b)

The review of Article 27.3(b) was also one of the TRIPS issues dealt with at the Ministerial Meeting at Doha in 2001. The TRIPS Council through Paragraph 19 of the 2001 Doha Declaration has broadened the discussion by looking into the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore. The Doha Declaration made it clear that work in the TRIPS Council under the reviews and on outstanding implementation issues should cover:

- the relationship between the TRIPS Agreement and the CBD
- the protection of traditional knowledge and folklore;
- and other relevant new developments that member governments raise in the review of the TRIPS Agreement.

It adds that the TRIPS Council's work on these topics is to be guided by the TRIPS Agreement's objectives (Article 7) and principles (Article 8), and must take development issues fully into account.

During the process of the review of Article 27.3 (b), the discussions thus far revealed that views continue to diverge between developed and developing countries on many issues that have been raised, including:

11.7.1 Disclosure of the Origin of Genetic Material and Associated Traditional Knowledge

The need to harmonise the provisions of the TRIPS Agreement and the CBD has been expressed. The argument is that TRIPS is incompatible with the CBD because as it allows for grant of a patent on genetic material without requiring prior informed consent and benefit sharing, as provided in the CBD. Therefore, group represented by Brazil and India, including Bolivia, Colombia, Cuba, Dominican Republic, Ecuador, Peru, Thailand, and supported by the African group and some other developing countries, want to amend the TRIPS Agreement conditions for patentability to include the requirement to disclose the country of origin of genetic resources and traditional knowledge used in the inventions, evidence that they received "prior informed consent" and evidence of "fair and equitable" benefit sharing. The EU's proposal includes the requirement that all patent applicants disclose the source or origin of genetic material, with legal consequences of not meeting this requirement would lye outside the scope of patent law. The United States has argued that the CBD objectives on access to

genetic resources, and on benefit sharing, could best be achieved through national legislation and contractually regulated by including commitments on disclosing of any commercial application of genetic resources or traditional knowledge.

Self Asssessment Question **(Spend 3 minutes)**

3) Apart from ethical consideration what is the major argument of the countries that want that disclosure of origin of genetic material may be made a precondition for granting patents?

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11.7.2 Patenting Plants, Animals and Biotechnology

The revision of Article 27.3(b) is very important for developing countries, since it has an impact on such different issues as breeders' rights, farmers' rights, patenting of (human) genes and recognition of informal or indigenous systems of innovation, notably with regard to biodiversity. Many ethical arguments have been presented during the discussions with respect to the exceptions from patentability in Article 27.2, including that the very basis of patenting of life forms is unethical, and contrary to *order public* and morality; that commodification of life and commercial exploitation of such inventions should be prevented.

The discussions on applicability of patent protection to plant varieties have centred on how the requirements for patentability should be applied in the case of plant and animal inventions, as well as microorganisms. Defining these criteria has been left to national legislation up until now, meaning that different criteria may be applied in different countries. There were also some concerns about having a low threshold for the criteria of patentability. Patenting of genes, more specifically DNA sequences was also discussed. On the one side views are that genes, if isolated, are patentable; the contrary view is that since they are a part of the living organisms, that they are not patentable under TRIPS.

Arguments in favour of protection by patent protection were that the adequate protection was necessary to promote investment and facilitate transfer of technology and that this protection should be granted at the international level. In this context, the most important issue relates to patenting of naturally occurring products and biotechnology. The current TRIPS text allows the interpretation that substances which already exist in nature are discoveries, not inventions, and cannot be patented, even when produced via bio-technological methods. Applications with specific claims over biological discoveries and naturally occurring genetic resources together with associated traditional knowledge have been granted patents in many countries. Many developing and least developed countries are seeking a formal clarification and/or assurance that plants, animals, micro-organisms and parts thereof are not patentable. Some countries have granted protection to non-naturally occurring living organisms and their parts (including genes). During the review, developing countries should, at the very

least, ensure that the *status quo* is maintained. This may, however not be easy, since a number of developed countries would like to expand the patentability of "life".

11.7.3 Plant Variety Protection and UPOV

Discussion has been there on the provisions for protection of plant varieties. While some countries believe it promotes the development of new plants varieties and is beneficial for agricultural development; others argue that such protection is unfavorable for developing countries. The TRIPS Agreement does not specifically refer to UPOV Convention. One view was that UPOV system is an effective system and that there should be clear reference in TRIPS Agreement to the UPOV system of protection in particular to the 1991 version of the Convention, which provides a stronger patent like protection as compared to previous versions. The opposing view is that the UPOV system is not suitable for developing countries and, therefore, it should not be directly referred to in the TRIPS Agreement. Similarly, the provision of the *sui generis* system in Article 27.3(b) is considered by many developing countries to provide the required flexibility to protect plant varieties, farmers' varieties and farmers' rights. However, the opposing view has been that the *sui generis* system in TRIPS primarily targets the protection of the commercial varieties of plants, and that the Agreement does not prevent Members from protecting farmers' rights within their national *sui generis* system of protection. The protection of farmers' rights has also been seen as broader issue, going beyond the scope of the TRIPS Agreement.

11.8 SUMMARY

- The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) Agreement is a multilateral agreement negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994. It is administered by World Trade Organisation (WTO) and introduced intellectual property law into the international trading system for the first time.

- Specifically, TRIPS agreement requires signatory countries to adhere to minimum standards for many forms of intellectual property regulation along with requiring adherence to the Paris Convention, Berne Convention and other WTO Conventions. It provides for transitional arrangements, during which members are required to bring their national legislation and practices into conformity with its provisions.

- The Agreement contains requirements that national laws must meet for granting most different forms of intellectual property including patents, copyright, trademarks, geographical indications, industrial designs, trade secrets, and exclusionary rights (through patent or sui generis system) over new plant varieties. In addition it specifies enforcement procedures, remedies, and dispute resolution procedures. The Agreement states three exceptions that countries may rely on to exclude otherwise patentable subject matter.

- The patentability of biotechnological processes and products has triggered unprecedented ethical, social, environmental safety have given rise to public interest concerns internationally. The review exercise for the Article

27.3(b) dealing with the exclusion from patentability or non-patentability of plant and animal inventions, and the protection of plant varieties has been underway in the TRIPS Council since December 1998 but has not been accomplished to this date.

11.9 TERMINAL QUESTIONS

1) Write a synopsis of TRIPS Agreement?

2) What are the major issues of social concern related to patenting in biotechnology?

3) What are the major issues of social concern related to Review of Article 27.3 (b)?

11.10 ANSWERS AND HINTS

Self Assessment Questions

1) Part II of the TRIPS Agreement (Article 9 to 40) sets standards regarding the availability, scope, and use of intellectual property rights. It requires Members to implement in their national laws provisions regarding copyright and related rights (Article 9 to 14), trademarks (Article 15 to 21), geographical indications(Articles 22 to 24), industrial designs (Articles 25 to 26), patent (Article 27 to 34), layout designs (topographies) of Integrated Circuits (Article 35 to 38), undisclosed information (Article 39), and the control of anti-competitive practices in contractual licenses (Article 40).

2) The national legislations may specifically provide to deny patents for innovations and inventions that are contrary to "*ordre public* or morality"; diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.

3) The major argument, apart form ethical consideration, is harmonisation of CBD and TRIPS. The CBD provides for regulated access to genetic resources through the instrument of prior informed consent and benefit sharing form the utilisation of such resources. A provision to disclose the country of origin of genetic resources and traditional knowledge used in the inventions, is an evidence that they received "prior informed consent" and "fair and equitable" benefit sharing if incorprotaed in TRIPS would harmonise it with CBD.

Terminal Questions

1) Refer to Section 11.4

2) Refer to Section 11.5

3) Refer to Section 11.7

11.11 REFERENCES AND SUGGESTED READINGS

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UNIT 12 PATENTABILITY OF BIOTECHNOLOGICAL INVENTIONS AND MICRO-ORGANISMS

Structure

12.1 INTRODUCTION

The advances in the field of biological sciences since 1970 particularly in the fields of genomics and proteomics have opened up vast novel avenues of research, on new plants, animals, and microbes. The ability to isolate and

manipulate genes has resulted in the rapid development of genetic engineering and the growth of biotechnology industry. It is estimated that about 40% of the world's market economy is based upon biological products and processes — mainly food, protein and fibre production, and human health. Biotechnology has been perceived to have applications in medicine, agriculture, extraction, processing, and the environment.

In recent years, researchers have succeeded in better understanding the functioning of the human body and its immune system. Biotechnology has already provided life-saving medicaments and it appears to promise cures for conditions currently regarded as untreatable. In agriculture, biotechnology is used to modify the physiology of plants with a view to introducing specific desirable features, such as resistance to disease and herbicides, or achieving higher yields.

The progress in biotechnology has also witnessed unfettered debate about possible risks to individuals, society and the environment. It has affected all levels of political, economic and scientific decision-making. Accompanying the debates about biotechnology itself there has been an argument on extending IPR regime particularly patents to various products and process derived from biotechnological advances.

The controversies about biotechnology patents are a significant and a growing factor in the development and implementation of biomedical and agricultural technologies. Like any other novel technology, biotechnology requires the law to adjust and develop and the concerns in a few limited contexts have been translated into legal rules that specify a clear course of conduct. The vast majority of the innovations in plant biotechnology are subject to patents, although the scope of coverage varies considerably by country and technology. Patents are used to protect biotechnology laboratory tools and reagents, genes and gene sequences, and processes for transformation, regeneration and diagnosis.

12.2 OBJECTIVES

After completing the study of this unit, you should be able to:

- acquire basic knowledge of inventions in biotechnology capable of patent protection;
- explain the background, negotiating history and interpretation of TRIPS obligation for patentability of biotechnological inventions; and
- analyse the applicability of patentability requirements for inventions related to biotechnology and microorganisms.

12.3 DEVELOPMENTS IN BIOTECHNOLOGY

To understand the legal implications of IPR regimes in biotechnology, it is pertinent to understand development of the science of biotechnology. The term "biotechnology" was coined early in the 20th century, but the practice – using living organisms to produce other materials or perform specific industrial tasks – dates back to thousands of years. People have been modifying plants, animals and microorganisms for specific uses for centuries. The improvements

in the controlled pollination of plants gave us many varieties through selective breeding and hybridization. Biotechnology provides a set of tools that aim at utilizing systems and organisms. Appropriately integrating these tools with other technologies, biotechnologists use their knowledge of biological systems to manufacture products or to deliver services that can be applied for the sustainable development of agriculture, natural resources, health and pharmaceuticals, industry as well as protection of the environment. The development of biotechnology can be divided into three main generations.

12.3.1 The First Generation

The first generation biotechnology includes the traditional use and improvement of organisms or biological systems. Harnessing yeast to make bread and wine, or using rennet to turn milk into cheese, are ancient examples of biotechnology. Still today the fermentation process is widely used in industries for production of beverages and medicines. The microbial process is used in agriculture for nitrogen fixation, control of pollution in the environment, bio-mining, biogas production and also in pharmaceutical industries.

12.3.2 The Second Generation

The second-generation biotechnology started during the inter-war period. The process of pure cell culture and manufacturing in a sterile state were used to develop new products such as production of chemicals including acetone, citric acid, butanol, glycerol, Vitamin B_2 etc. The invention of penicillin is another milestone product of this generation. This basic principle endures today and pharmaceutical companies use microorganisms to create antibiotics and a host of other important medicines. The technologies of this generation also include tissue culture, polyclonal and monoclonal antibodies, and DNA-markers techniques. Tissue culture is used in agriculture and livestock for rapid multiplication or micro-propagation and production of pathogen free plants, embryo rescue and artificial insemination. Polyclonal and monoclonal antibodies techniques are used in the production of medicines and for vaccine development as well as diagnostic tools for animal and plant diseases. The DNA markers techniques are used in agriculture and livestock for characterization of animal and plant genomes, selection processes, and as a diagnostic tool.

12.3.3 The Third Generation

The third generation of biotechnology are characterised by the Genetic Engineering or recombinant DNA (rDNA) technology. The invention of DNA in 1953 was the turning point in this era of biotechnology. In 1973 scientists Stanley Cohen at Stanford University and Herbert Boyer at the University of California at San Francisco pioneered a way of combining biochemistry in a technique that led to the beginning of recombinant DNA technology. The technology was patented by the inventers, allows use of molecular cloning methods to bring together genetic material from unrelated organisms and creating DNA that would not otherwise be found in biological organisms. Once transferred, these modified DNA may be passed on to offspring of the modified individual through normal reproductive processes. Genetic engineering has resulted in the production of Genetically Modified Organisms (GMOs).

12.4 COMMON INVENTIONS RELATED TO BIOTECHNOLOGY

The most common and successful application of biotechnology for crop and livestock improvements are in:

12.4.1 Cell and Tissue Culture and Micro Propagation

Plant tissue culture is a technique that has been around for more than 30 years. It involves growing plant cells, tissues, or organs *in vitro* on specially formulated nutrient media to produce uniform individuals. Micropopagation is the practice of rapid multiplication of disease-free, high quality planting material to produce a large number of uniform progeny plants, using modern tissue culture method. These techniques have led to production of clean and uniform planting materials in crops such as in cassava, yams, bananas and plantains, palms, and potato to mention only a few.

12.4.2 Molecular Breeding or Marker Assisted Selection

Molecular breeding or marker assisted selection: The concept behind marker assisted selection (MAS) is that there may be genes with significant effects that may be targeted specifically in selection. The MAS techniques provide for faster and easier identification of genes with specific trait such as disease and pest tolerance, through markers that are located near the DNA sequence of the desired gene. Markers are now routinely being used by plant breeders in crop improvement and the technique is further being developed to study resistance to more complex traits such as drought and heat stress. The MAS is also being increasingly used to read the information contained in the animals' genes as it provides an advantage of reducing the number of years it takes to introduce genetic improvements into a livestock species.

12.4.3 Genetic Engineering

Genetic engineering or gene technology, or genetic modification, or gene manipulation refer to a set of technologies through which the genetic makeup of an organism can be altered and genes can be moved across species that would not readily interbreed to produce novel organisms. There are many genetically engineered crops grown throughout the industrial and developing world, including maize, cotton, potatoes, and soybeans.

With some notable exceptions, it has not been very easy to produce genetically engineered animals but efforts are being made to produce farm animals that grow faster, have healthier meat and flesh, and be less able to feel the pain and suffering often associated with the conditions present in modern factory farms. Most of the applications of genetic engineering in animals have been in finding novel uses for the animal particularly to help medical researchers in their quest to find cures for genetic disease, like cancer. Another application being experimented is cloning of endangered animal species with the aim of preserving their populations.

12.4.4 Molecular Diagnostic Tools

Molecular diagnostic tools based on either the properties of nucleic acid (DNA or RNA) or proteins of the target agents, have improved the efficacy,

accuracy, and speed of detection and identification of disease-causing agents and characterization of the diversity of pathogens and pests. Such tests are now used for a wide range of applications, including detection of pests, and diseases; food contaminants, human and animal molecular diagnostic testing; identity and forensic testing etc. Molecular diagnostics are emerging as an important tool for inherited disorders, cardiovascular disorders, and other disease areas. They not only help in identification of individuals who are at increased risk of developing certain disorders but can be used for rapid screening of apparently healthy populations.

12.5 EARLY HISTORY AND APPROACH TO TRIPS

Development of rDNA technique by Cohen and Boyer at Stanford University, in the early 1970s, is regarded as the most significant discoveries that stimulated patenting in biotechnology. It allows for the useful manipulation of genetic material and is considered the founding technology of the biotechnology industry. The techniques comprised a process patent for making molecular chimeras and two product patents — one for proteins produced using recombinant prokaryote DNA and another for proteins from recombinant eukaryote DNA. The licensing of the Cohen-Boyer patents by Stanford University also represents one of the most successful university technology licenses. Over the 25 years of the licensing program, Stanford and the University of California system accrued US$255 million in licensing revenues (to the end of 2001), much of which was subsequently invested in research and research infrastructure.

As regards the first patent concerning a micro-organism, Louis Pasteur's patent – US Patent 141,072, claiming 'yeast, free from organic germs of disease, as an article of manufacture' in 1873, is considered to be an early example of patenting living organisms.

However, it was in 1980 the decision by the U.S. Supreme Court in ***Diamond v. Chakrabarty*** started a new jurisprudence with respect to biotech patentability. In this case a patent application was filed relating to the invention of a genetically engineered bacterium capable of breaking down crude oil, a property which is possessed by no naturally occurring bacteria. Chakrabarty's 1972 patent application contained three groups of claims directed to: (i) the method of producing the bacterium; (ii) an inoculum composed of a carrier material and the bacterium, and (iii) the genetically engineered bacterium itself. While allowing the first two groups, the patent examiner rejected the claims directed to the bacterium as unpatentable on the basis of US patent law under 35 U.S.C. § 101 as product of nature and living things are non patentable. The same was affirmed by the Patent Office Board of Appeals. However, the Court of Customs and Patent Appeals reversed the Board's decision ruling that living organisms are patentable subject matter. The PTO then filed a petition for writ of certiorari to the Supreme Court. The US Supreme Court considered whether the claimed microorganism constituted a "manufacture" or "composition of matter" within the meaning of the US Patent Act and in a 5–4 ruling, ruled that the respondent's micro-organism do constitute a "manufacture" or "composition of matter" under the statute. The Court went on to say that the test for determining whether an invention falls within the scope of product of nature is whether the invention in question involves a hand of man and asserted the principle for which the case

is best known, that "*anything under the sun that is made by man*" is eligible for patenting.

Thus, since the 1980s in many developed countries it was an accepted principle that the fact that an invention consisted of, or based on, or employed living matter, was not a sufficient reason to exclude it from patentability; and included biological material pre-existing in nature (provided that the latter were claimed in an isolated or purified form). Despite this trend, considerable divergent views remained and still remain, among countries with regard to the scope of patentability of biotechnology – related inventions.

Self Assessment Question **(Spend 3 minutes)**

1) Explain briefly as to why the *Diamond v. Chakrabarty* is considered as a landmark case?

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12.5.1 Early Negotiations

The TRIPS negotiations, witnessed primarily a North-South confrontation with the developed countries such as United States, most of the European Countries, Japan, Switzerland, forming one block that favoured higher levels of intellectual property protection in each countrty, whereas the developing countries especially, India and Brazil, advocated for weaker IP Regime. The European Community, Japan, Switzerland and US had each submitted separate drafts during the several rounds of the negotiations. However, as the negotiations progressed and the precise minimum intellectual property standards particularly pertaining to providing a patent protrection for living organisms were being debated, the European Community adopted a stand against patent regime for plant varieties while accepting IP Protection to plant varieties, thus the debate also becàme a "North-North" debate.

The divergent views were reflected in the heavily bracketed provision of the Anell Draft Text (W/76), under negotiation in July 1990. The text mentioned the possible exclusion from patentability of:

"1.4.4 *[Any] plant or animal [including micro-organisms] [varieties] or [essentially biological] processes for the production of plants or animals; [this does not apply to microbiological processes or the products thereof]. [As regards biotechnological inventions, further limitations should be allowed under national law].*"

The issue of patent protection for plants and animals remained outstanding even during the Brussels negotiations, of December, 1990. The Brussels Text provided, in bracketed language, that parties could exclude from patentability:

"[(b) A. Animal varieties [and other animal inventions] and essentially biological processes for the production of animals, other than microbiological processes or the products thereof. PARTIES shall provide for the protection of plant varieties

either by patents or by an effective sui generis system or by any combination thereof. This provision shall be reviewed [. . .] years after the entry into force of this Agreement.]

[b) B. Plants and animals, including microorganisms and parts thereof and processes for their production. As regards biotechnological inventions, further limitations should be allowed under national law.]"

The views of developed countries were essentially reflected in paragraph A, and those of developing countries in paragraph B. The adopted Article 27.3(b) shows, the developed countries' approach finally prevailed to a large extent.

12.6 TRIPS PROVISIONS FOR PATENTING IN BIOTECHNOLOGY AND MICROORGANISMS

As stated above the broad international minimum standard for the subject matter of patent protection is established by Article 27.1 of TRIPS. It obliges Members States to provide patent protection for any invention, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application. However, Articles 27.2 and 27.3 of TRIPS create important subject-matter exceptions to the broad rule of Article 27.1.

Article 27.2 permits member countries to exclude from patentability any

"*inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including the protection of human, animal, or plant life or health or the avoidance of serious prejudice to the environment.*"

Though stated broadly, this exception is in fact subject to two important limiting conditions: First, it applies only if a prohibition against the commercial exploitation of the invention is necessary to protect *ordre public* or morality. Second, the exception applies only if the exclusion from patentability will likewise contribute to the protection of *ordre public* or morality.

Article 27.3 further permits WTO members countries to exclude two specific classes of subject matter from patentability: 1) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals; and 2) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. In contrast to the exclusions permitted in Article 27.2, the two exclusions from patentability permitted by Article 27.3 are not subject to any limiting conditions.

The Article 27.3(b) of TRIPS (Box 1) is often referred as the "biotechnology clause" and was among the most intensely debated Articles of TRIPS. It is also the only Article in the Agreement which incorporates the condition of an early review. The Article 27.3(b) describes the specific obligations of Members States with respect to the patentable subject matter; explicitly requiring protection of microorganisms and certain biotechnological processes through patents. It, however, provides considerable flexibility for Members States to include in their legislations exclusions from scope of patentability and adopt different approaches

to patentability of inventions relating to plants and animals. Further, it clearly distinguishes between plant and plant variety. While a plant may be excluded from scope of patentability, plant varieties have to be provided protection through patent or a *sui generis* system or by any combination thereof. The present Unit shall focus only on patentability of inventions relating to plants and animals and microorganisms as related to biotechnology, and not on protection of plant varieties which is discussed in another Unit.

Box 1:

Article 27.3(b) Patentable Subject Matter

Members may also exclude from patentability: Plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

12.7 AMBIGUITY AND INTERPRETATIONS OF THE TERMS

The TRIPS Article 27.3(b) (Box 1) includes the terms, such as, a "plants and animals", "microorganism" or an "essentially biological process" but does not define them. It is also not explicit whether or not genes should be patentable, whether derived from plants, humans or animals; and also if genetic material identified in nature is patentable on the grounds that isolating and purifying it differentiates it from an unpatentable discovery. There is, therefore, ample scope for members countries to determine for themselves how strictly the common standards under TRIPS should be applied. The possible legal interpretations of these terms in relation to biotechnological inventions are discussed below:

12.7.1 Plants and Animals

As per the Article 27.3(b), national legislations ***may*** (emphasis added) exclude from patentability "plants and animals". In the absence of any distinction, and in the light of the second sentence of the same Article that introduces an exception for one particular classification (plant varieties), the scope of the exception under Article 27.3(b) is to be interpreted in broad terms. Consequently, Members States may exclude plants as such (including transgenic plants), plant varieties (including hybrids), as well as plant cells, seeds and other plant materials. They may also exclude animals (including transgenic) and animal races. Members States may opt to exclude from patentability only certain categories of plant and animal inventions. Thus, in European countries the prohibition to patent a plant "variety" does not prevent the patenting of plants as such. Similarly, the granting of a patent by the European Patent Office on the "Harvard oncomouse" (a mouse genetically modified to facilitate the testing of anti-cancer drugs) was also based on the judgment that it was not a "race" but a specifically altered "animal". These issues have been resolved differently by the patent authorities of different countries.

12.7.2 The "OncoMouse" Case

The debate surrounding the patenting of higher life forms has largely been centred on one particular patent application which relates to what has been colloquially termed the "Oncomouse" or the "Harvard mouse". In the mid-1980s, Harvard geneticists Phil Leder and Timothy Stewart at Harvard University inserted cancer-causing genes, known as 'oncogenes' into a mouse. The resulting "oncomouse" and its offspring were useful because they offered a living model by making the animal vulnerable to human cancers using which researchers could study the onset of cancer and test the efficacy of treatments.

The US Patent

A patent application covering the Oncomouse was filed in 1985 based on a US priority application in 1984. The very broad first claim of the US Oncomouse application reads:

"*A transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said animal, or an ancestor of said mammal, at an embryonic stage.*"

The USPTO was the first to grant a patent to the Oncomouse in 1988. The patent has never been judicially reviewed for validity as patentable subject-matter in court. Although in the mid-eighties there has been public concern on patenting animals in the US as well, this is no issue anymore today; it is largely accepted. The patent has expired in April 2005.

The European Patent

The oncomouse case was considered in the European Patent Office (EPO) at length at various levels. The two key relevant provisions of European Patent Convention, that were tested included: Article 53(a) that excludes patents for inventions "the publication or exploitation of which would be contrary to *ordre public* or morality"; and Article 53(b) that excludes patents on "animal varieties or essentially biological processes for the production of…animals."

The patent application was rejected at the first step by the Examining Division of the EPO excluding it under Article 53(b) as an "animal variety" interpreting that it excludes not only certain groups of animals from patentability but, in fact, animals as such. In decision T 19/90, the Board of Appeal did not accept the interpretation. The appeal decision contained two important conclusions. First, it stated that "the question under Art. 53(b) was not whether the claims embraced an "animal", but whether the claims embraced an "animal variety" within the meaning of Article 53(b)". Although the Technical Board of Appeal did not make a ruling on this specific point and remitted the case to the department of first instance for further prosecution, the Examining Division finally decided that the subject-matter of the application did not constitute an "animal variety" within the meaning of that provision.

The other important argument was that the EPO developed a utilitarian balancing test for exclusion in the EPC on granting patents for inventions which are contrary to morality or *'ordre public'* as contained in Article 53(a). This aimed to assess the potential benefits of a claimed invention against negative aspects, in this case weighing the suffering of the oncomice against the expected medical

benefits to humanity and any possible risk to the environment against the benefits to mankind said to be conferred by the invention. The EPO concluded that the usefulness of the oncomouse in furthering cancer research satisfied the likelihood of substantial medical benefit, and outweighed moral concerns about suffering caused to the animal. However, while the claims in the original application referred to animals in general, in the course of the proceedings, the patent was amended and finally maintained with claims limited to mice.

Opposition notices were filed by 17 different parties; the most controversial matter was the European morality provision Article 53(a). In 2001, the Opposition Division decided that the patent as amended during the opposition proceedings by introducing auxiliary request for restricting the patent to transgenic rodents meets the requirements of the EPC. The interest in developing anticancer treatments was again balanced to overall animal suffering, and rodents were found to comprise representative animal species useful for allowable animal testing. Finally, notices of appeals were filed in 2003 by several former opponents based on wrong interpretation of Article 53(a). In July 2004, after 19 years of proceedings, the ultimate decision by the Board of Appeal held that the patent meets the requirements of the EPC if it is further restricted to mice instead of rodents, it is interesting to note that the patent term ended in June 2005.

The Canadian Patent

Canada is the only country where the Oncomouse patent has been litigated in court and has finally been revoked. The granting of patents is governed by the Commissioner of Patents pursuant to the Canadian Patent Act. The Act indicates that a patent will only be granted for an "invention," which Section 2 defines as: "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter".

Harvard filed its Canadian patent application in June 1985. Following a lengthy prosecution battle, the patent examiner issued a Final Action on March 24, 1993, rejecting claims for a product patent while allowing claims for the process of making the transgenic mammal. The premise for rejection was that the product claims did not fall within the definition of "invention" under Section 2 of the Canadian Patent Act. It was noted that, had Parliament intended to include animals as patentable subject matter, it would have expressly included animals in the definition of "invention". Moreover, the examiner relied on the Manual of Patent Office Practice wherein there was express exclusion of animals as statutory subject matter. The Commissioner of Patents confirmed the examiner's decision in August 1995, allowing claims to the process, the cells and plasma containing the oncogene and method for making the mouse, but not the mouse itself. The Commissioner held that an invention being a 'manufacture or composition of matter' was something the inventor could control, and on this point he separated the gene construct from its animal host. The mouse, by comparison, had been gestated in utero and was the work of nature and it was not man that made the final product. When Harvard appealed the Commissioner's decision to the Federal Court of Canada Trial Division, the same was dismissed. However, in August 2000, the Federal Court of Appeal, in a split 2-1 decision, allowed Harvard a patent on the mouse itself. The appeal court ruled that "*The oncomouse is both unobvious and a new and useful 'composition of matter'; therefore it is an 'invention' within the meaning of Section 2 of the Act*". The ruling was that the

Patent Act was silent on the patentability of non-human animals and therefore did not exclude such organisms. The oncomouse was a combination of human ingenuity and laws of nature but would not exist in nature. It required human ingenuity to bring it into being and was therefore appropriately a composition of matter.

In October 2000, the Government of Canada filed an application to appeal the "Oncomouse" decision to the Supreme Court of Canada. On December 5, 2002, in a 5-4 majority decision, the Supreme Court of Canada decided that a patent could not be granted for a higher life form. The majority decided that the wording of section 2 of the Canadian Patents Act should be strictly construed and that higher life forms were not implicitly incorporated within the definition of an invention. Although the Supreme Court of Canada's rejection of the application was based on the definition of the "invention" in question rather than a morality exception, the court acknowledged that it was influenced by the controversial nature of the subject-matter when opting for a narrow interpretation.

The oncomouse case, therefore, highlights how different jurisdictions have dealt with the basic question of whether a transgenic animal – provided it complies with the patentability requirements – should be considered patentable subject matter; and how they have then weighed the ethical dimension of this particular technology.

Self Assessment Question **(Spend 3 minutes)**

2) The basic question of patenting transgenic animals has been dealt differently in different jurisdictions. Explain in the light of the "oncomouse" case.

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12.7.3 "Essentially Biological Processes" and "Biological Processes"

Another possible exclusion from patentability relates to "*essentially biological processes for the production of plants or animals*". This provision of TRIPS Agreement reflects the exclusion clause in Article 53(b) of the European Patent Convention. The Technical Board of the European Patent Office (TBEPC) gives a negative definition of what does not constitute an "essentially biological process", i.e., a process for production of plants comprising at least one essential technical step which cannot be carried out without human intervention and which has a decisive impact on the final result. Under this premise, the term "*essentially biological*" may be construed as a process that is performed without the application of any external technical skills, making human intervention as the decisive criterion.

Nevertheless, a "*biological process*" would by definition exclude manipulation of an independent natural process. Human intervention as a criterion, therefore,

seems to fail in the distinction between an "essentially biological process" and a "*biological process*". However, a "*biological process*" would require a further qualification, namely the criterion to be "essential", to the given exception to patentability. According to this definition, conventional breeding methods are generally not patentable, while methods based on modern biotechnology (e.g., tissue culture, insertion of genes in a plant) where the technical intervention is significant, would meet the criteria of patentability. However, various biotechnological applications are multi-step processes, in which natural processes and technical manipulation are intrinsically linked, would be subject to legal clarifications. The question arises as to which of the steps carried out in an experiment is an essential biological process or, in interlinked multiphase processes, where to establish the decisive step to determine patentability.

Different approaches have been taken by national patent legislation towards this issue. Some European countries, such as Switzerland, Hungary, Bulgaria, Iceland, Norway, and Canada, Korea, Thailand and South Africa excluded the patentability of "essentially biological process": Nevertheless, Australia, Japan, New Zealand and Romania regard "essentially biological processes" as patentable subject matters. In U.S., "naturally occurring essentially biological processes" cannot obtain patent protection. In China "animal and plant varieties" are not patentable. However, processes producing animal and plant varieties are patentable.

In 2010, the EPO's Enlarged Board of Appeal (the highest instance in the EPO's judiciary) decided that methods used for conventionally breeding plants are not patentable. The decision was based on patent on broccoli (EP1069819) and on tomatoes (EP1211926), both derived from conventional breeding. These patents claimed the process for breeding as well as the seeds, plants and edible parts of the plants. In G1/08, the EPO's Enlarged Board of Appeal decided that the process for breeding had to be regarded as 'essentially biological' and therefore could not be patented because of Article 53(b) of the European Patent Convention and Article 4(b) of EU Directive 98/44/EC, which exclude patents on 'essentially biological processes for the production of plants or animals'.

However, the decision of the Enlarged Board of Appeal does not solve the legal questions or the underlying problems regarding conventional breeding. For example, in May 2011, the EPO granted a further patent on melons derived from conventional breeding (EP 1 962 578). The products such as plants and fruits were regarded as an invention. This interpretation of Directive 98/44/EC on the legal protection of biotechnological inventions implies that conventional ('essentially biological') breeding would be patentable, even if the process for breeding was excluded.

12.7.4 "Microorganism" and "Microbiological Process"

Conventionally a "microorganism" is an organism that is too small to be normally perceptible to the naked human eye and viewed only under a microscope, usually, an ordinary light microscope. In the scientific context "microorganism" are referred to "a Member of one of the following classes: bacteria, fungi, algae, protozoa or viruses." One of the major concerns is distinguishing the man-made from the natural leading to the question if microorganisms as found in nature should qualify as patentable subject matter under this provision. It is generally

accepted that "to be patentable, a microorganism cannot be as it exists in nature". However, in some jurisdictions it is sufficient to isolate a microorganism and identify a use therefore to obtain a patent.

A significant component of biotechnological research is directed towards production of naturally existing biological materials as proteins, DNA sequences, genes, receptors, etc. These materials may have valuable direct use in different medical treatments, and they are also prone to various "improvements" to possess somewhat different characteristics. In addition they can be used as valuable inputs in the production of other medical or agricultural products. An important practical issue relates to the patenting of cells, genes and other sub-cellular components. Though these materials are not visible to the naked eye, they do not constitute "microorganisms" and, therefore, are not subject to the obligation under Article 27.3. Nevertheless the patenting of these materials has become common practice in many jurisdictions.

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions defines 'biological material' as "*any material containing genetic information and capable of reproducing itself or being reproduced in a biological system*"; and 'microbiological process' as "*any process involving or performed upon or resulting in microbiological material*". According to Article 3 "*Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature*". In accordance with the EPC, the patenting exclusion specifically does not apply to microbiological processes and the products made by such means. This refers to procedures for extracting, transforming, and using microorganisms, but also the fields of cell and molecular biology, which in accordance with the practice of the EPO are assigned to the category of microbiological processes. Furthermore patent protection is available for inventions, which relate to genes or proteins; plant and animal cells as such, which can be cultivated more or less like bacteria and yeasts, are not covered by the patenting exclusion.

In the United States, patents have been granted for the pure cultures of an isolated or purified form of specific microorganism as well as medically important proteins. The concept of "new" under the novelty requirement does not mean "not preexisting" but "novel" in a prior art sense, so that the unknown but natural existence of a product does not preclude the product from the category of statutory subject matter. Some of the products of nature, which are generally patentable under US patent law, include pure microbial culture, isolated virus, specific purified proteins, purified nucleic acid sequences (indulging isolated genes) and other purified biomolecules (e.g. antibiotic, vitamin etc.). Similarly, in Japan the Enforcement Standards for Substance Patents stipulated that patents can be granted on chemical substances artificially isolated from natural materials, when the presence of the substance could not be detected without the prior isolation with the aid of physical or chemical methods.

Members may also opt for a narrower scope of patentability, confining it to microorganisms that have been genetically modified. TRIPS, in effect, does not define what an "invention" is; it only specifies the requirements that an invention should meet in order to be patentable (Article 27.1).

12.8 THE INDIAN SCENARIO

12.8.1 The Changing Patent Regime

The Indian State policy with regard to patents had focused on balancing developmental concerns with the need for promoting innovations. Patents were perceived as a tool for economic development and restricted the scope and term of patents.

The Indian Patents Act, 1970 has been hailed as a model legislation for developing countries, balancing the need for granting rewards for inventors and ensuring that the developmental needs are not ignored. The Indian philosophy towards patenting regimes had fundamentally been as an economic policy question, in contrast to the industrialised nations which conceive patents as a fundamental right comparable to the right of physical property. This was reflected in the Indian Patent Act of 1970 which *inter alia* provided only process not product patents in food, medicines, chemicals; and excluded several areas from patentability (including method of agriculture, any process for medicinal surgical or other treatment of humans, or similar treatment of animals and plants to render them free of disease or increase economic value of products). These differences in patent systems were reflected in the GATT negotiations on the issue of inclusion of IPRs in the WTO. The type of patent system established by India was clearly in contrast to the global IP regime promoted by the developed countries. However, India's negotiating position within TRIPS and its policy on patents have undergone enormous shifts in the recent years.

India has amended the Patent Act, 1970, three times in a span of five years (between 1999 and 2005). The first was in the year 1999, to give effect to some of the provisions of the TRIPS with retrospective effect from 1995. The second amendment was in 2002 to meet its TRIPS obligations which came into force on 20 May 2003. The third amendment of the Patents Act, 1970 – initially enacted by way of the Patents (Amendment) Ordinance 2004 that was replaced by the Patents (Amendment) Act 2005 which is in force now having effect from the 1 January 2005.

Under the amended Act, Section 5 of the Patents Act, 1970 which envisaged that with respect to inventions relating to food, medicine, drugs or chemical substances, only patents relating to the methods or processes of manufacture of such substances could be obtained was deleted, thereby introducing a product patents regime in the area of pharmaceutical and other chemical inventions in India. In compliance with TRIPS, the Patents Act 1970, as amended in June 2002, gives patent rights for new microorganisms. The 2002 Amendment Act also provides an explanation for chemical process, which states: chemical processes include biochemical, biotechnological and microbiological process.

12.8.2 Examination of Patent Application

The primary step of examination, before application is accepted for awarding patent rights, deals with eligibility of invention and determining what types of inventions can be considered for patent protection. The eligible inventions are not, however, automatically entitled to protection and are thereafter examined under the well-known set of requirements of novelty, non-obviousness, industrially applicable and disclosure. This specific examination determines

whether the claimed invention is a sufficient advance over the existing state-of-art and is supported by a sufficient disclosure to the public and merits the protection of the State.

The Patents Amendment Act, 2002 has changed the definition of 'invention' as in Section 2(1)(j) which reads as "*a new product or process involving an inventive step and capable of industrial application*". The term "inventive step" is defined in Section 2 (1) (ja), which states that "*inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art*". This entails that the requirement for patentability are basically, that it should be new (novelty); involve an inventive step (non-obviousness of the invention), and capable of industrial application.

Considering that the patenting of biotechnology and microorganism *per se* is still in early stages, it is, therefore, natural that the Indian patent practice and jurisprudence with respect to the patenting of biological material are not so well-settled and/or uniform and will need some time to stabilise.

12.8.3 Subject Matters of Patentability

As stated above, product patents on substances capable of use as medicine, drug, or food were considered patentable subject matter only with the implementation of the TRIPS compliant amended Patent Act form January 1, 2005. Also the definition of potentially patentable "chemical processes" explicitly include "biochemical, biotechnological, and microbiological processes" only after the India's patent laws were amended in 2002. These legislative changes in the earlier anti-product patent regime coupled with the government's policy shift for encouraging patenting witnessed an increase in investments and expansion of biotechnology industry.

This paradigm shift under India's post-TRIPS patent regime was witnessed when first chemical product patent was granted to F-Hoffmann-La Roche AG (Roche) for Pegasys (pegylated interferon alfa 2a) – a key drug used to treat Hepatitis C (Hep C or HCV). Roche's patent for Pegasys involves combining interferon alfa 2a – a naturally occurring protein with known antiviral effects – with a structure called polyethelyene glycol (PEG), a known inert substance that prevents interferon from being broken down by the body, thus allowing it to remain in the bloodstream longer.

The patent was challenged by a post grant opposition in May 2007, by Sankalp Rehabilitation Trust, a Mumbai-based NGO. The grounds of challenge included that the patent was wrongly granted because given the existing knowledge at the time Roche filed its patent application, the "invention" that Roche was claiming was neither new nor inventive; and that the pegylated form of interferon claimed by Roche is only a "new form of a known substance" without increased efficacy as compared to other known interferon conjugates and therefore is not patentable under Section 3(d) of the Patents Act. However, in a decision delivered on 17 March 2009, the Indian Patent Office dismissed the oppositions and upheld the grant of patent to Roche.

Since the pre-1995 product patents do not apply in India, this has left many drugs that were patented prior to 1995, marketable in India as generics. Furthermore, the innovators have not sought patent protection for some drugs in India, thereby

creating a strong opportunity for Indian companies. Many Indian firms that make "bio-generics" or "bio-similars" have developed proprietary processes to manufacture first-generation biologics no longer under patent protection globally, such as recombinant human insulin, erythropoietin, interferon, and granuloctye colony-stimulating factor.

12.8.4 Invention v. Discovery

The most important question with reference to patents involving biological subject matter is whether substances isolated or derived from naturally occurring living organisms are "inventions" or "discoveries". The initial premise has been that product that occurs in nature in essentially the same form cannot be patented.

The product of nature doctrine appears as early as 1889, when the move to patentability was blocked by the U.S. Commissioner of Patents in *Ex parte Latimer*, case by rejecting an application for a patent to cover a fibre identified in the needles of a pine tree, declaring that it would be "unreasonable and impossible to allow patents upon the trees of the forest and the plants of the earth." The ruling constituted formal enunciation of the "product-of-nature" doctrine that the Patent Office would invoke in the Chakrabarty case which paved the way for patenting of living materials.

The Indian Patent Act in Section 3(c) states that, "*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*" It is, therefore, obvious that any invention which is the result of human intervention, where living beings have been used initially for conducting experimentation is not prohibited from patenting.

The Draft Patent Manual of India explains that there is a difference between discovery and invention, as "*the discovery adds to the amount of human knowledge by disclosing something, which has not been seen before, whereas an invention also adds to the human knowledge by suggesting an act, to be done and is not patentable*". It further adds that "*a claim for discovery of scientific principle is not considered patentable, but such a principle when used with process of manufacture resulting into a substance or an article may be patentable*".

The question of whether a DNA sequence is a discovery or an invention has to be addressed based on the assumption that genes are naturally occurring and thus are discoveries, and not inventions. The Draft Patent Manual of India states that when a genetically modified Gene Sequence/ Amino Acid Sequence is novel, involves an inventive step and has industrial application, the following can be claimed.

a) Gene sequence / Amino Acid sequence

b) A method of expressing above sequence

c) An antibody against that protein / sequence

d) A kit made from the antibody / sequence

All of these claims are, however, linked by the inventive concept if the genetically modified sequence is new, inventive and has industrial application.

12.8.5 Patenting of Microorganisms

The TRIPS compliant Patents Act 1970, as amended in June 2002, provides patent rights for new microorganisms. Section 3(j) of the Act excludes from patentability "*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*." As per this sub-section, while plants and animals or any part of the plant or animal is not patentable, an exception is made in the case of micro-organisms. However, any discovered micro-organism from the nature is not patentable.

The Calcutta High Court decision in ***Dimminaco AG v. Controller of Patents and Designs***, 2002 relating to patentability of biotechnological process with living end product is another milestone decision in Indian context.

Dimminaco A.G., a Swiss company had filed a patent application for an inventive process for patenting the process for preparation of a live vaccine for Bursitis, an infectious poultry disease and the invention involved a live (attenuated) vaccine to combat the disease. The Controller of Patents turned down the application on the ground that the vaccine involved processing of certain microbial substances; this was only a natural process devoid of any manufacturing activities and hence not patentable. This was in consonance with the prevailing practice that grants patents only to non-living and tangible inventions, even though the Patent Act imposed no such limitation. It concluded that the process did not constitute an invention under the Act and thus refused to allow the application.

However, on appeal, the Calcutta High Court diverted from the above position. The Patent Office argued before the Court that an inventive process must lead to an article or a substance. An article according to the Patent Office implied a material thing, item, a thing of a particular class or kind as distinguished from a thing of any class or kind. It was further argued that only an inanimate object can be denoted as a thing or item and not a living one. It was therefore concluded that a vaccine with the living organism could not be considered substance. Hence, the process of preparing a vaccine having a living entity cannot be considered 'manufacture'. The appellant argued that the terms 'manufacture' and 'substance' had not been defined in the Act and therefore one would have to rely on the meaning provided in a dictionary. The appellant also brought to the notice of the Court that the Patent Office on earlier occasions had accepted applications in respect of new processes which included cells, virus and other microorganisms.

The Calcutta High Court held that the Indian statute on patents does not put any restraints on patentability of microorganisms developed in a controlled environment in the laboratories. The Court also held that the process for creating a vaccine leads to a vendible product even if the end product contains live material. The court said that if the invention results in the production of some vendible items or improves or restores formal conditions of vendible item, it is patentable. Therefore since the claim process for patent leads to a vendible product, it is certainly a substance after going through the process of manufacture.

The court concluded that a new and useful art or process is an invention, and where the end product is a new article, the process leading to its manufacture is an invention. This decision of the Calcutta High Court was in line with the position in US, most of the European countries as well as Japan, since most

processes in the biotechnology field will be patentable, irrespective of whether resultant product is living or non-living. After the Dimminaco decision, the Indian law kept pace with the needs of flourishing biotechnology industry.

Other areas involving microorganisms are also patentable in India. For example, a synergistic composition containing the microorganism, which is either new or known, and a process using microorganisms to produce a substance can both be patented. Also, the process of biosynthesis of a new microorganism is patentable. Microorganisms that are lyophilized as an end product are patentable.

The expression "any part thereof", in the wording of Section 3(j) ought to be defined – preferably with an explanation appended to the section. The apprehension – which is not unfounded – is that this expression is so open ended that it is liable to be interpreted in a manner that almost any biological material (for example DNA, RNA, protein sequences, antibodies, hybridomas, etc.) would be caught within its ambit. However, the IPO has yet to observe a situation where an invention has been rejected merely because it was claimed to be a genetic material (even though the patenting of tissues or cells of human beings or animals can be objected to under the foregoing section).

12.8.6 Biological Deposit

The Indian Patent Act under Section 10 provides the requirements for contents of specifications. This, *inter alia,* provides for conditions specific to applications mentioning biological material in specifications as given below:

10(4) Every complete specification shall –

a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;

b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and

c) end with a claim or claims defining the scope of the invention for which protection is claimed;

d) be accompanied by an abstract to provide technical information on the invention:

(ii) if the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty and fulfilling the following conditions, namely:

A) the deposit of the material shall be made not later than the date of filing the patent application in India and a reference thereof shall be made in the specification within the prescribed period;

B) all available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit of the material at the institution;

C) access to the material is available in the depository institution only after

the date of the application of patent in India or if a priority is claimed after the date of the priority;

D) disclose the source and geographical origin of the biological material in the specification, when used in an invention.

If the invention is using biological material, such a material shall be deposited for the completion of the application when such material is not available to the public and cannot be described adequately as per the provisions of the Act. The deposition shall be made with the International Depository Authority under the Budapest Treaty, on or before the date of filing/priority. The International Depository Authority in India is Microbial Type Culture Collection and Gene Bank (MTCC) – Chandigarh. Further, Section 10 (4) of the Patents (Amendment) Act, 2002 also links with requirements of Section 6 (1) of the Biological Diversity Act which states:

> *"No person shall apply for any intellectual property right by whatever name called in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application:*
>
> *Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned."*

Accordingly, the Draft Patent Manual of India defines the steps involved in substantive examination, which include *inter alia* disclosure of geographical origin of the biological material and permission from National Biodiversity Authority.

Self Assessment Question **(Spend 3 minutes)**

3) As per the Indian Patent Act, what additional requirements are to be fulfilled if the application for patent mentions biological material?

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12.9 SUMMARY

- Biotechnology or use of living systems and organisms to develop or make useful products had been practiced by humankind for thousands of years. However, recent developments in molecular biology and genetic engineering have opened up new avenues for application of biotechnology which has impacted research and industry related to medicine, agriculture, extraction, processing, and the environment.

  The TRIPS negotiations, witnessed unprecedented debates between the developed countries and the developing world; the latter advocating for

a weaker IP Regime particularly providing a patent regime protection for living organisms. The major issues that influenced the debates on patenting were the application of IPR regimes to biotechnology and these included those related to ethical aspects, the source of biological material obtained for patenting an invention; and how the patent is used.

- The TRIPS Article 27.3(b) describes the specific obligations of Members States with respect to the patentable subject matter; explicitly requiring protection of microorganisms and certain biotechnological processes through patents. It includes the terms, such as, a "plants and animals", "microorganism" or an "essentially biological process" but does not define them providing ample scope for members countries to determine for themselves how strictly the common standards under TRIPS should be applied. The patent system allows protection to be obtained for products, processes and methods of use, while the same holds true for biotechnology related inventions and microorganisms there are certain specific subject matter restrictions in certain jurisdictions.
- The scope of eligible patentable subject matter in the Indian Patents Act includes any product or process irrespective of the technology, However, the Act also provides a list of inventions that are excluded from patentable subject matter and those related to biotechnology inventions include discovery of any living thing occurring in nature, plant and animals in whole or any part thereof including seeds; varieties, species and essentially biological processes for production or propagation of plants and animals. Nevertheless, microorganisms and microbiological processes are patentable subject matter.
- In addition to other statutory requirements, the applicant for patent which mentions biological material should, disclose the source and geographical origin of the biological material in the specification, deposit the sample with the International Depository Authority and obtain permission from National Biodiversity Authority for filing the application

12.10 TERMINAL QUESTIONS

1) What are the common inventions related to biotechnology?
2) What are the provisions in TRIPS related to patenting in biotechnology and microorganisms?
3) What are the provisions for patent protection of inventions related to biotechnology and microorganisms?

12.11 ANSWERS AND HINTS

Self Assessment Questions

1) Ananda Chakrabarty, a microbiologist, filed patent application on an invention for treating oil spills in 1972. Chakrabarty developed genetically engineered bacterium capable of breaking down oil spills at a much faster rate than naturally occurring bacteria. The application contained three groups of claims:

i) The method of producing the bacterium

ii) An inoculum composed of a carrier material and the bacterium

iii) The genetically engineered bacterium itself

Chakrabarty's claims to the bacteria were rejected by the USPTO on two grounds, first that microorganisms are "products of nature" and second that living things are not patentable subject matter under the statute 35 U.S.C. Section 101. Following two levels of appeals, the case was heard by the U.S. Supreme Court, which, in a five to four ruling, held that a live, human-made microorganism is patentable subject matter under Section 101 as a "manufacture" or "composition of matter." The court held that Chakrabarty's microorganism was a product of human ingenuity having a distinct name, character, and use. This ruling opened the door to patents on living organisms and genetically modified organisms.

2) In April 1988, Philip Leder and Timothy Steward of Harvard University were successful in inserting cancer-causing genes, known as 'oncogenes' into a mouse to serve as a more effective model for studying how genes contribute to various forms of cancer. A patent application covering the transgenic Oncomouse was filed in different countries. The granting of patents on transgenic organisms is no longer an issue in the United States and inventors were granted an American patent for an animal genetically engineered.

The European Patent Office (EPO) Examining Division rejected in 1989 Harvard's initial application for a patent holding that patents for animal and plant varieties were prohibited. However, after an appeal to the EPO's Technical Board of Appeal in 1990, Harvard's oncomouse was granted a European Patent. In their decision, it was concluded that the benefit to humankind of this transgenic system outweighed other factors. Despite such a decision, the public interest groups and political parties had opposed the patent and the EPO resumed opposition proceedings that lasted nine years. Further, the EPO narrowed the Harvard Oncomouse patent to transgenic rodents (in place of mammals as claimed originally) containing an additional cancer gene. Finally, in July 2004, after 19 years of proceedings, the ultimate decision by the Board of Appeal held that the patent meets the requirements of the EPC if it is further restricted to mice instead of rodents It is interesting to note that the patent term ended in June 2005.

Yet though Harvard ultimately prevailed in both its American and European patents, things turned out differently in Canada. In 1985, Harvard College applied for a patent in Canada. In March 1993 the Canadian Patent Examiner allowed a patent for the process claims but claims for the transgenic animal itself as the invention or the subject or a patent, were denied. In the Examiner's opinion a transgenic mouse was not an "invention" as defined in the Canadian Patent Act. Harvard appealed this decision to the Federal Court of Canada, which allowed claims for the Oncomouse. However, the Harvard oncomouse case was further appealed to Canada's highest court and on December 5, 2002, the Supreme Court of Canada in a 5-4 majority decision, decided that higher life forms, such as mammals, were not patentable subject matter.

This case highlights that there is no absolute standard or approach for defining what is patentable subject matter as regards to patenting transgenic animals. It varies from country to country. This reflects the controversial nature of patenting life form as an invention which very much depends on the prevailing community views or policy on this issue by each country.

3) In addition to other statutory requirements ,the applicant for patent which mentions biological material should:

   a) disclose the source and geographical origin of the biological material in the specification, when used in an invention.

   b) Deposit the sample with the International Depository Authority under the Budapest Treaty, on or before the date of filing/priority; which in India is Microbial Type Culture Collection and Gene Bank (MTCC) – Chandigarh; and

   c) Obtain permission from National Biodiversity Authority for filing the application.

Terminal Questions

1) Refer to Section 12.4
2) Refer to Section 12.6 supplemented with information in Section 12.7
3) Refer to Section 12.8

12.12 REFERENCES AND SUGGESTED READINGS

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Notes

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