Semester -I

18BTP105A BIODIVERSITY, BIOSAFETY AND IPR 4H-4C

Total hours/week: **L:4 T:0 P:0** **Marks:** Internal:**40** External:**60** Total: **100**

Course Objectives:

To expose the students on the biosafety aspects to follow in their work and research, need of IPR components of transgenic products and transgenic research guidelines and rules.

Course Outcomes:

Knowing the biosafet, IPR and biodiversity aspects would help the student in carry out their research in basic and advanced biotechnology.

UNIT -I

Biodiversity: Introduction, types, Concepts. Values, uses, Measures of biodiversity. Vegetation types of India. Hotspot biodiversity areas in India, Red Listed plants and RED Data Book, Threatened plants and animals of India. Role of biotechnology; Conservation biodiversity - In situ and ex situ methods. Molecular markers and their application in plant conservation.

UNIT –II

Biosafety: Introduction; Background; Biological Safety Cabinets; Primary Containment for Biohazards; Biosafety Levels; Biosafety Levels; Recommended Biosafety Levels, Cartagena protocol on biosafety.

Biological risk assessment: Biosafety guidelines for Genetically Modified Micro organisms (GMM) and Plants (GMP)-Risk assessment, guidelines for research activities, Guidelines for environmental release of GMM, GMP and GLP. GATT and World Trade Organizations. Establishment and functions of GATT, WTO and WIPO.WTO Guidelines and Summits. Physical and Intellectual Property. Tangible and Intangible property. Roles of IBSC, RCGM and GEAC.

UNIT –III

Intellectual Property Rights: Types of IP: Patents, Trademarks, Copyright and Related Rights. **Agreements and Treaties :** History of GATT and TRIPS Agreement; Madrid Agreement; Hague Agreement; WIPO Treaties; Budapest Treaty; PCT; Indian Patent Act 1970 and recent amendments.

UNIT – IV

Patent application: Rules governing patents. Patent related cases. Licensing - Flavr Savr™ tomato as a model case. Biopiracy and case studies on patents (Basmati rice, Turmeric, and Neem). Biotechnological examples of patent, trademark, trade secret, copy right. Traditional Knowledge.

UNIT – V

Bioethics-Introduction. Animal Rights. General issues related to environmental release of transgenic plants, animals and microorganisms. Ethical issues related to research in embryonic stem cell cloning. Ethical, Legal and Social Implications (ELSI) of Human Genome Project.

References

Martin. M.W., & Schinzinger, R. (2003). *Ehics in engineering* (3rd ed.). New Delhi: Tata McGraw-Hill,.

BAREACT, (2007). *Indian Patent Act 1970*. Acts and Rules, Universal Law Publishing Co. Pvt. Ltd.

Kankanala, C. (2007). *Genetic Patent Law and Strategy* (1st ed.). India: Manupatra Information Solution Pvt. Ltd.

Biosafety issues related to transgenic crops. DBT guidelines, New Delhi: Biotech Consortium Ltd,.

http://www.actahort.org/members/showpdf?booknrarnr=447_125

http://www.biomedcentral.com/content/pdf/1472-6939-2-2.pdf

http://www.wipo.int/portal/index.html.en

http://www.ipr.co.uk/IP_conventions/patent_cooperation_treaty.html

KARPAGAM ACADEMY OF HIGHER EDUCATION

(Deemed to be University Established Under Section 3 of UGC Act 1956)

Coimbatore – 641 021.

LECTURE PLAN
DEPARTMENT OF BIOTECHNOLOGY

STAFF NAME: Dr. R S. SARANYA

SUBJECT NAME: BIODIVERSITY, BIOSAFETY AND IPR SUB.CODE: 18BTP105A

SEMESTER: I CLASS: I M.Sc. (BT)

S.No	Lecture Duration Period	Topics to be Covered	Support Material/Page Nos
UNIT-I			
1	1	Biodiversity: Introduction, types, Concepts. Values, uses, Measures of biodiversity	W1
2	1	Vegetation types of India	W1
3	1	Hotspot biodiversity areas in India	W1
4	1	Red Listed plants and RED Data Book	W1
5	1	Threatened plants and animals of India	W1
6	1	Role of biotechnology; Conservation biodiversity	W1
7	1	In situ and ex situ methods	W1
8	1	Molecular markers and their application in plant conservation	W1
	Total No of Hours Planned for Unit I =08		
UNIT-II			
1	1	Introduction; Background; Biological Safety Cabinets	T1:67-104
2	1	Primary Containment for Biohazards	T1:67-104
3	1	Biosafety Levels	T1:67-104
4	1	Biosafety Levels for infectious agents	T1:67-104

5	1	Recommended Biosafety Levels	T1:67-104
6	1	Cartagena protocol on biosafety	T1:67-104
7	1	Biosafety guidelines	T1:67-104
8	1	Genetically Modified Micro organisms (GMM)	T1:67-104
9	1	Risk assessment, guidelines for research activities	W2
10	1	Guidelines for environmental release of GMM, GMP and GLP	W2
11	1	GATT and World Trade Organizations	W2
12	1	Establishment and functions of GATT, WTO and WIPO	W2
13	1	WTO Guidelines and Summits	W2
14	1	Physical and Intellectual Property	W2
15	1	Tangible and Intangible property	W2
16	1	Roles of IBSC, RCGM and GEAC	W2
	Total No of Hours Planned for Unit II = 16		
UNIT-III			
1	1	Types of IP	R1:19-78
2	1	Patents	R1:19-78
3	1	Trademarks, Copyright and Related Rights	R1:19-78
4	1	History of GATT	R1:19-78
5	1	History of TRIPS	R1:19-78
6	1	Madrid Agreement	R1:19-78
7	1	Hague Agreement	R1:19-78
8	1	WIPO Treaties- PCT	R1:19-78
9	1	Budapest Treaty	R1:19-78
10	1	Indian Patent Act 1970 and recent amendments	R1:19-78
	Total No of Hours Planned for Unit III = 10		

UNIT-IV			
1	1	Rules governing patents. Patent related cases	J1,J2
2	1	Licensing - Flavr Savr™ tomato as a model case	J1,J2
3	1	Biopiracy and case studies on patents Basmati rice, Turmeric	W3, W4
4	1	case studies on Neem	W4
5	1	Biotechnological examples of patent, trademark	W5
6	1	Trade secret, copy right	W5
7	1	Traditional Knowledge	W5
	Total No of Hours Planned for Unit IV = 07		
1	1	Bioethics-Introduction. Animal Rights.	J3
2	1	General issues related to environmental release of transgenic plants	W6
3	1	Transgenic animals, microorganisms	W7,J2
4	1	Ethical issues related to research in embryonic stem cell cloning	J4,J5
5	1	Ethical, Legal issues in HGP	W8
6	1	Social Implications in HGP	W8
7	1	Discussion on ESE questions	
	Total No of Hours Planned for Unit V = 07		
Total Planned Hours	**48**		

TEXT BOOK

1. Lboratory Biosafety Manual (WHO)

REFERENCE BOOKS

1. Bioethics and Biosafety in Biotechnology, 2007. V.Sree Krishna New Age Int.ltd.publishers.

WEBSITE

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2. www.uabc.ac/sites
3. www.sdpi.org>w37-Biopiracy
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6. http://nepad-abne.net/environmental-biosafety/gmos-and-environment/
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JOURNALS

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2. http://www.planetnaturals.com/
3. http://nuffieldbioethics.org/wp-content/uploads/The-ethics-of-research-involving-animals-full-report.pdf
4. Biosafety of Genetically Modified Organisms
5. https://watermark.silverchair.com

UNIT-I

SYLLABUS

Biodiversity: Introduction, types, Concepts. Values, uses, Measures of biodiversity. Vegetation types of India. Hotspot biodiversity areas in India, Red Listed plants and RED Data Book, Threatened plants and animals of India. Role of biotechnology; Conservation biodiversity - In situ and ex situ methods. Molecular markers and their application in plant conservation.

Types of Biodiversity

Biodiversity can be studies at three different levels :

1. Species diversity
2. Genetic diversity
3. Ecosystem diversity

Species Diversity

In general a species is a group of similar organisms capable of interbreeding with each other. Members of the same species generally have many similar physical or morphological (structural) characteristics. Species biodiversity refer to the different species in a particular region.

How is species diversity measured?

Species diversity can be measured in many ways. Ecologists generally use the terms species richness, species abundance or species evenness to estimate species diversity. Species diversity is generally measured by estimating the species richness. Species richness refers to the total number of individuals of a species in a given area. Thus, if there are 20 daisy plants in an area of 10 square kilometers then the species abundance will be 20. Many ecologists also use the concept of species evenness in measuring species diversity. Species evenness is a measure of the relative abundance of the different species making up the richness of an area.

Importance of species diversity:

The more the species diversity in an area is, the healthier the ecosystem will be. We must realize that every organism performs some functions in the ecosystem. Such functions could range from decomposition to keeping the population of herbivores under control. What would happen to the ecosystem if any one species got extinct? Who would then perform that functions? In such a case species diversity helps in the survival in an ecosystem. They could be bacteria, fungi or insects. What if one of these got extinct? The others would still be able to decompose and so the ecosystem would survive. This is only one example where species diversity helps ecosystems survive. There are many more.

Genetic Diversity

Genetic diversity refers to the existence of a variety of genes in a population of a particular species. All human belong to the same species (Homo sapiens). Yet there are so many differences in the colour, features and other traits between humans. This is due to genetic diversity. Individual members of a particular species have some broad similarities. It is due to genetic diversity that individual members show some distinct characters. For example all humans will have some common characters like the presence of hair or eyes. But due to genetic diversity the colour of eyes or hair in humans differs in different individual humans.

Why is genetic diversity important?

High genetic diversity ensures better survival of the species. Nature has a system called natural selection. The natural selection concept was stated by Charles Darwin. Natural selection means that nature decides whether an organism will survive or not. Nature is dynamic and keeps undergoing changes. These changes in the environment of an organism will obviously affect the organism. Those organisms that are able to adapt to these changes will survive while those that cannot adapt will not. In this process of natural selection genetic diversity plays a very important role. The more the genetic diversity, the more are the chances of survival of a species.

Ecosystem diversity

Diversity which results because of different ecosystem (Example, desert, forest, marine, grassland etc.) is referred as ecosystem diversity. Ecosystem diversity is the assemblage and interaction of species living together and the physical environment present there. In a broader way, it is also called landscape diversity which includes placement and size of various ecosystems. For example, landscapes like forests, grasslands, deserts, mountains etc. As well as aquatic ecosystems like rivers, lakes and seas—all show ecosystem diversity. Thus, there is a large variety of different ecosystems on Earth, each having its own complement of distinctive interlinked species based on the differences in the habitat. Ecosystem diversity involves different

part of ecosystem like niches, trophic levels, energy flow, food chain and recycling of nutrients.

Ecological role of Biodiversity

All the species in ecosystem participate in the numerous ecological processes that occur within and between the ecosystems. Each of the species has a specific role to play in the ecosystem. *Some of these are:*

1. *Cycling of water and nutrients:*These are done mostly by the plants, animals and microbes. Not only this, non-living components like air, water and solar energy are also attached with this.
2. *Food production:* Plans are directly or indirectly related with food production. They are the sole source of food. Hence they are called primary producer. Though food chain and food web, this food is transferred from one organism to other.
3. *Climatic stability:* Vegetation and plantation of an area are mostly responsible for the climate of that area. A forest is one of the main sources of rain which in turn control climate. Thus rich plant- diversity has a better control of climatic stability.
4. *Reduction in pollution:* There are some natural ays for controlling pollution. Some micro-organisms as well as some plants and animals have the capacity to breakdown pollution, thus helping in pollution reduction.
5. *Soil generation and reduction in soil erosion:* Diverse living organisms both plants and animals in a long run help in the formation of soil. Abiotic factors help in this process.
6. *Production of energy or producers:* Though energy is the prime requirement of all the-living organisms, sun is the sole source of energy. Green plants or producers are the only medium which can convert solar energy into chemical energy. This energy in turn is used by all the living organisms in the biosphere.
7. *Consumers:* All the other animals which are directly or indirectly take plants as their food resources are consumers. All the herbivores and carnivores are called consumers.
8. *Reduction in natural calamities:* Natural calamities like drought, flood, earthquake etc. are often the result of loss or destruction of biodiversity. Healthy ecosystem has the capability of quick recovery from any natural calamities. Rich biodiversity also lessen the occurrence of natural calamities.
9. *Decomposers and decomposition:* Micro-organisms decompose the dead plant and animal body or organic material and thus help in the recycling of materials. This process is known as decomposition and the micro-organisms are called decomposers.

Values of biodiversity can be categorized as follows: Biodiversity or biological diversity simply means the variety and variability among living organisms and the ecological complexes in which they occur. Such variety refers to the variety at the species, genetic and ecosystem level.

Direct values

These are those ways by which we can directly use biodiversity for our benefit. For example we can use plants as food of for deriving medicines in the laboratory. Economic value and recreational value comes under this category.

Direct values are further classified into:

- ***Consumptive use Value:*** Consumptive use value is the value put on the products of nature which are consumed directly without passing through a market. For example, if we use firewood by cutting down a tree or consume an animal after hunting it.
- ***Productive use value:*** Productive use value is the value put on the products of nature hich are consumed after passing through a market. For example, if we buy fish from the market then it will have productive use value.

Indirect values or Non-Consumptive value

These are those ways by which we don't physically use a plant or animal, but by virtue of its existence it provides services that keep the ecosystem healthy. Indirect values would include ethical or moral value, existence value, ecological value, aesthetic value, cultural or spiritual value, option value and scientific or educational value.

Social values

Social value of biodiversity lies in the more and more use of resources by affluent cieties. Local use or sale of products if biodiversity is not included in it. Yet, ecosystem people' value biodiversity as a part of their livelihood as well as through cultural and religious sentiments. Now a day's Government is spending a lot of money on lush green vegetation and Coral Reef Island for the purpose of tourism. Apart from traditional agricultural systems, in recent years, farmers have begun to receive economic incentives to grow each crop for national or international markets rather than to supply local needs. This has resulted in local food shortages, unemployment, landlessness and increased tendency to drought and floods.

Ethical and Moral value

Every species has its moral right to exist on earth. Every human culture, religion and society has its own ethical values. There are several cultural, moral and ethical values, which are associated with the conservation of biodiversity. We have in our country a large number of sacred grooves or deolis preserved by tribal people in several States. These sacred groves around ancient sacred sites and temples act as gene banks for wild plants.

Economical value

We depend heavily on biological products for our survival. Biodiversity has economic value because it is a source of important products.

Some of these products are :

- Food supplies: Agriculture, the very basis of human survival, depends on plants and animals.
- Source of medicines: A large number of medicines are obtained from plants and animals. Cinchonas, Belladonna are important medicinal plants. Snake venom is used in making medicines.
- Source of raw materials for industries.
- It supports the economy of a country. Industries and agriculture generate revenue or income. They also generate employment. In fact the economy of many countries is heavily dependent on biodiversity.

Aesthetic value

Nature contributes immensely to the beauty of the world. Can you imagine a world without trees, grass, flowers, birds or animals? Thus, biodiversity has immense aesthetic value for us.

Ecological value

Every species plays a unique role in the ecosystem. Through this role its maintains the ecological balance. Thus, the ecosystems don't get disrupted. So, even if we do not use a plant or animal for making products in our industries, by virtue of its very existence in the wild it provides us with many important services. These services maintain ecological balance and the ecosystem.

Waste Management:

Nature has a unique way of managing wastes. The waste of one organism becomes food for another organism. So, wastes don't accumulate. For example, forests absorb greenhouse gases like carbon dioxide during photosynthesis. This helps to reduce global warming. Forests also contribute to precipitation due to transpiration. Many other plants and animals help to keep forests healthy. So, the entire biodiversity contributes towards maintaining climate stability.

Scientific value or Educational value

Biodiversity is of great scientific value. Many species of plants and animals are the subjects of our research. We use many species for research and in turn get a lot of knowledge from their study. Through research on plants, insects and animals we find better ways of making medicines, hybrid plants, engineering designs and many other things that are of immense value to human beings. For example, the design of Velcro is developed from cockle-burrs which cling fast to clothing as we walk in the woods.

Cultural and Spiritual value

Many cultures of human beings are closely related to many species of plants and animals. For example, Hindus Identify owls as the transport of Goddess Lakshmi. Many religions identify themselves with such plants and animals which renders to them a cultural or spiritual value.

Option value

There are many plants and animals which have not yet been discovered or even if they have been discovered we do not know if they can be of any use to us. This untapped potential is referred to as option value. For example, there might be a plant or animal which we can use in the future to find a cure for corner. If we destroy biodiversity then we lose this chance of finding a cure for cancer. Thus biodiversity has great potential of being useful to us in the future.

Types of Natural vegetation in India

Natural Vegetation

Natural vegetation are gifts of nature. They grow naturally. They follow the climatic variables. Due to a variety of climates, a wide range of natural vegetation grows in India. Types of natural vegetation vary according to climate, soil and altitude. A study of the distribution of the forests in India reveals that there is a marked relation between the rainfall zones and their belts of natural vegetation.

Types of Natural Vegetation

The following are the principal types of natural vegetation in India: (1) Tropical Evergreen Rain Forests, (2) Deciduous or Monsoon Type of Forests, (3) Dry Deciduous Forests and Scrubs, (4) Semi Desert and Desert Vegetation, (5) Tidal or Mangrove Forests and (6) Mountain Forests.

1.Tropical Evergreen Rain Forests:

These forests grow in areas where rainfall is more than 200 cm. They are mainly found on the slopes of the Western Ghats and the north-eastern regions of Arunachal Pradesh, Meghalaya, Assam, Nagaland, the Tarai ar-eas of the Himalayas and the Andaman groups of Islands. The trees in these forests never shed their leaves all at a time in any part of the year.

Under humid tropical condition, sub-soil water never dries up completely. So that during the dry-season, trees in these forests do not shed their leaves due to lack of sub-soil water supply. The trees in these belts have dense growth. Important varieties of trees are sisthu, chaplash, rosewood, mahogany, bamboos, garjan and sandal wood.

2. Deciduous or Monsoon type of Forests:

These forests are found in areas where the rainfall is between 100 cm and 200 cm. These forests grow on the lower slope of the Himalayas, Assam, West Bengal, Bihar, Jharkhand, Orissa, Madhya Pradesh, Chhattishgarh, Maharashtra, Karnataka and the adjoining regions. The trees of these forests shed their leaves during dry-winter and dry-summer. The main trees are teak, sal, sandal wood, deodar, bluegum, ebony, sisam, jack-fruit, mahua, palash, arjun, khair and bamboo. Teak and sal are valuable trees. These forests supply valuable timber.

3. Dry Deciduous Forests and Shrubs:

These forests grow in areas where the rainfall is between 50 cm and 100 cm. These are found in areas of central Deccan plateau, south-east of Rajasthan, Punjab, Haryana and parts of Uttar Pradesh and Madhya Pradesh. Dwarf deciduous trees and long-grasses grow in these regions. Most of these areas are used for agriculture.

4. Semi-deserts and Deserts vegetation:

These types of vegetation grow in areas where rainfall is less than 50 cm mostly thorny bushes, acacia, babul and sand binding grasses (graminoids) are found in this vegetation zone. The Indian wild date, known as "Khejur" is common in these deserts. These plants grow far apart from each other. They have long roots and thick fleshy stems in which they store water to survive during the long drought. These vegetation are found in Rajasthan and parts of Gujarat, Punjab and Karnataka. The leaves of short trees, shrubs, herbs and grass that are found in Thar desert have got high nutritional values.

5. Tidal or Mangrove Forests:

These forests grow along the coast and on the edges of the deltas, e.g. the deltas of the Ganga, Mahanadi, Godavari, Krishna and Kaveri. Tides plays an important role in formation of mud and silt along these coastal mangrove forests. They are called 'Tidal Forests' because their

dense growth depends upon tidal water which submerges the deltaic lands during high tides. They are also known as Littoral Forests. In West Bengal these forests are known as 'Sundarbans.'

The 'sundri' is most significant tree in these forests. The other notable trees of these forests are hogla, garan, gewa, golpata, pasur, etc. These forests supply timber and fire wood. Palm and coconut trees adorn the coastal strip.

6. Mountain Forests:

Mountain forests vary considerably according to altitude with varying rainfall and temperature along the slopes of mountain:

On the foothills of the Himalayas up to a height of 1500 meters, evergreen trees, such as, sal, teak, bamboo and cane grow abundantly.

On higher slope between 1,500 meters to 3,500 meters, temperate conifer trees, such as, pine, fir, oak, maple, deodar, laurel, spruce and ceder grow.

At the higher altitude of the Himalayas, rhododendrons and junipers are found. Beyond these vegetation-belts, alpine grasslands appear up to snowfield.

BIODIVERSITY HOTSPOTS IN INDIA

Himalaya: Includes the entire Indian Himalayan region (and that falling in Pakistan, Tibet, Nepal, Bhutan, China and Myanmar)

Indo-Burma: Includes entire North-eastern India, except Assam and Andaman group of Islands (and Myanmar, Thailand, Vietnam, Laos, Cambodia and southern China)

Sundalands: Includes Nicobar group of Islands (and Indonesia, Malaysia, Singapore, Brunei, Philippines)

Western Ghats and Sri Lanka: Includes entire Western Ghats (and Sri Lanka)

Biodiversity is the collection of flora and fauna of a place. Biodiversity Hotspot is a region which is a prime location for the existence of rich biodiversity but also faces the threat of destruction. It is a place which needs our immediate and constant attention to survive and thrive in the future as well.

This idea of identifying hotspots was put forth by Norman Myers in 1988. By now, a total of 35 biodiversity hotspots have been identified out of which most of them lie in tropical forests. Almost 2.3% of the land surface of Earth is represented by these hotspots. These also comprise of around 50% of the world's most common plant species and 42% of terrestrial vertebrates prevalent. Sadly, these biodiversity hotspots have been losing 86% of their habitats some of which are still on the verge of extinction due to serious threats posed by climate change and human intervention.

To be called a hotspot, a region has to be able to fulfil at least two criteria including-

1. It should comprise of at least 1500 species of vascular plants i.e. more than 0.5% of the world's total plants.

2. It should have lost greater than or equal to 70% of its original habitat.

India has always been on the list of the richest countries in the world for its biodiversity which can easily be seen in the demography of its land. Though biodiversity and demographic diversity are two completely different topics, the human population has been dependant on biodiversity since forever in numerous ways. Also, as a result of exponential growth in human population, their survival pressure too has increased tremendously on the biodiversity.

Rich biodiversity of India

India is a country rich in biological diversity. It is situated in the Indomalaya ecozone and comprises of 2 out of the 35 biodiversity hotspots in the world. The third one, that is, Indo Burma lies partially in North-East India.

In India, there are approximate-

-350 mammals which make up 7.6% of world species

-1224 birds which make up 2.6% of the world species

-197 amphibians which make up 4.4% of the world species

-408 reptiles which make up 6.2% of the world species

-2546 fishes which make up 11.7% of the world species

-15000 flowering plants which make up 6% of the world species

Some of these biodiversity hotspots are present in India which includes-

1. The Western Ghats and Sri Lanka

These hills are present along the western edge of peninsular India. Since they are situated near the ocean, they are likely to receive a good amount of rainfall. Most of the deciduous, as well as rainforests, are present in this region. Around 77% of the amphibians and 62% of the reptiles found here cannot be spotted elsewhere in the world. Sri Lanka in South India is a country which is rich in species too. It is connected to India through a land bridge which has a width of nearly 140 km.

There are more than 6000 vascular plants here which belong to more than 2500 genus. 3000 plants out of these are endemic. Most of the spices found in the world such as black pepper and cardamom all are believed to have originated in the Western Ghats. Most of the species are however present in the Agasthyamalai Hills situated in extreme South. The region is also home to around 450 species of birds, 140 mammals, 260 reptiles and 175 amphibians. Such diversity is quite beautiful as well as rare but now lies on the verge of extinction. The vegetation in this region was originally spread over 190,000 square kilometres but has reduced to 43,000 square kilometres today. Only 1.5% of the original forest is still prevalent in Sri Lanka.

2. The Eastern Himalayas

This region comprises of Bhutan, Northeast India, and Southern, Central and Eastern Nepal. These Himalayan Mountains are the highest in the world and abode to some of the highest peaks of the world including Mount Everest and K2. Some of the major rivers in the world originate from the Himalayas. The Himalayas comprise of more than 100 mountains beyond 7200 meters.

There are almost 163 endangered species in this region including one-horned rhinoceros, wild Asian water buffalo and as many as 45 mammals, 50 birds, 12 amphibians, 17 reptiles, 3 invertebrate and 36 plant species. One such endangered species found here is the relict dragonfly whose only other species is found in Japan. Himalayan Newt is also present in this region. Coming to the fauna, there are 10,000 species of plants in the Himalayas a third of which are endemic and cannot be located anywhere else in the world. Some of the threatened ones include Cheer pheasant, Western Tragopan, Himalayan quail, Himalayan vulture, White-bellied heron and the like. Mammals too can be spotted here with over 300 species such as Asiatic wild dogs, sloth bears, snow leopard, black bear, blue sheep and wild water buffalo. Namadapha flying

squirrel is, however, a mammal which is almost on the verge of extinction and therefore needs immediate attention.

3. Indo-Burma

This region consists of numerous countries including North-Eastern India (to the south of the Brahmaputra River), Myanmar, and China's Yunnan provinces southern part, Lao People's Democratic Republic, Vietnam, Cambodia, and Thailand. It is spread over a distance of 2 million square kilometres.

Although this region is quite rich in its biodiversity, it has been worsening over the past few decades. Six species of mammals have been discovered in this region recently including large-antlered muntjac, Annamite Muntjac, gray-shanked douc, leaf deer, saola and Annamite striped rabbit. Other species such as monkeys, langurs, and gibbons too can be found here with a population as less as a hundred. Freshwater turtle species found in the region are however endemic. 1300 species of birds too can be spotted here including the white-eared night-heron, Gray-crowned crocias, and orange necked Patridge most of which are endangered. Almost 13,500 plant species can be spotted in the region half of which are endemic and cannot be found in any other place in the world.

4. Sundaland

This region lies in South-East Asia and includes Thailand, Singapore, Indonesia, Brunei, and Malaysia. The Nicobar Islands represent India. These islands were declared as the world biosphere reserve in 2013 by United Nations. These islands have a rich terrestrial as well as marine ecosystem including mangroves, seagrass beds, and coral reefs. Species such as dolphins, whales, turtles, crocodiles, fishes, prawns, lobsters and sea shells comprise the marine biodiversity. In case the marine resources are over-used, it can pose a serious threat to the biodiversity.

Major reasons for loss of biodiversity in hotspots

These include:

1. Destruction of habitats

2. Pollution and environmental degradation

3. Poachings

4. Climate Change

It is high time to step up and start taking measures to protect our natural biodiversity beforetime actually runs out.

Red Listed plants

Spring Wild Oat (Avena fatua) is the primary genetic relative of the Oat (Avena sativa) crop plant normally seen growing in agriculture. Crop wild relatives such as this are vital to human health and nutrition as they are potential gene donors and can be used to improve crop yield, health and resilience. Spring Wild Oat has an extremely widespread distribution across Europe, temperate Asia, India, Nepal and Pakistan in tropical Asia and North Africa and grows in a wide range of habitats including within field crops, on waste ground, along disturbed river banks, highways, railroad tracks, etc. There are no major threats affecting the species, therefore it is assessed as Least Concern (LC).

Along with 19 other Brazilian plants, the original assessment for Eryngium fluminense is written and published on The IUCN Red List in Portuguese, marking the start of non-English language assessments being included on The IUCN Red List.

This species is found in National Park and Three Peaks State Park (Brazil). Recent collections have shown that despite this species being frequently encountered around the Caledonia Peak (e.g., at Three Peaks), it has a restricted area of occupancy (16 km²) and is restricted to just four locations. With potential threats from forest fires, invasive species, and impacts from tourism and recreation, urban and commercial expansion, and increased frequency and/or intensity of fires, Eryngium fluminense entered The IUCN Red List as Vulnerable (VU) in 2016.

Found only in wet forest on the island of (Polyscias waimeae) enters the Red List as Endangered. In common with many other Hawaiian plants, major threats to this plant include predation and habitat degradation by non--native animals, particularly pigs, goats, deer and rats. Non-native, invasive plant taxa are also a major threat, as they displace the taxon and significantly alter the native habitat upon which it depends. In addition, the species is considered extremely vulnerable to climate change.

There are only 46 individuals of the Haha plant Cyanea remyi remaining, and it is therefore assessed as Critically Endangered. This shrub is found in Hawaiian lowland wet forest on the island of Kau'i. As with other Hawaiian plant species, competition with introduced invasive plant species is a major threat, as is habitat degradation and direct damage by invasive animals. Seed dispersal cycles have also been greatly reduced due to the drastic decline of endemic avian fauna. In addition, the taxon is also threatened by floods and landslides since it grows in areas subject to such stochastic events.

Alula (Brighamia insignis) has moved from Critically Endangered to Critically Endangered (Possibly Extinct in the Wild), and is one of 38 Red Listed Hawaiian plant species with less than five wild individuals remaining. The Alula has been so impacted by invasive species and landslides, that only one plant remained in the wild in 2014 and it has not been seen since. Historically it occurred on the islands of Kaua'i and Ni'ihau, but it has not been reported from Ni'ihau since 1947. There are active conservation efforts focused on the species, which has surviving individuals in cultivation. The National Tropical Botanic Garden has outplanted over a hundred individuals at the Limahuli Garden and Preserve on the north shore of Kaua'i. Outplantings were also done at the Kīlauea Point National Wildlife Refuge on the northeast coast of Kaua'i by the Department of Land and Natural Resources and volunteers in 1995. The Kīlauea Point outplanting, however, was not self-sustaining and all of those planted have since died. None of the outplantings have ever produced viable offspring without intense human intervention.

Hibiscadelphus woodii is one of 38 Hawaiian plant species now assessed as **Extinct**. It was only known from four individuals when it was first seen in 1991. It was last recorded in the wild in 1999 and the last remaining individual was observed to have died by August 2011. Its extinction was due to a variety of threats but especially the impacts of non-native plants and animals and probably human vandalism of the last remaining plant. Although cuttings and seeds were collected, propagation was not successful and so there are no specimens in cultivation. All known species in this genus are either Extinct or Critically Endangered.

In 2003 the Gumwood (Commidendrum robustum) was estimated to have a population of 1,000 individuals, this reassessment finds that less 700 now exist. The population decline is due to a combination of habitat degradation, poor regeneration and competition from invasive species. In addition, the population is also now considered to be severely fragmented triggering the species to be uplisted from Endangered (EN) to Critically Endangered (CR).

UNIT-IV

SYLLABUS

Patent application: Rules governing patents. Patent related cases. Licensing – Flavr Savr™ tomato as a model case. Biopiracy and case studies on patents (Basmati rice, Turmeric, and Neem). Biotechnological examples of patent, trademark, trade secret, copy right. Traditional Knowledge.

Licensing – Flavr Savr™ tomato as a model case

The FLAVR SAVR tomato was the first genetically engineered crop product to be commercialized. The research and marketing efforts that produced the FLAVR SAVR tomato resulted in scientific success, a temporary sales success, and then commercial demise. The FLAVR SAVR story reveals how difficult it can be to bring genetically engineered products to market, how objections with little or no scientific merit can influence the outcome, and how important public opinion is in determining commercial success.

Circumstantial evidence available in the 1980s suggested that the tomato fruit enzyme polygalacturonase (PG), because of its ability to dissolve cell-wall pectin, was key to fruit softening. Researchers at Calgene, Inc., in Davis, proposed to suppress PG accumulation in ripening tomatoes by introducing a reverse-orientation copy of the gene, an "antisense" copy designed to prevent or drastically reduce the formation of PG.

Their expectation was that ripe fruit would remain firm longer, perhaps even allowing it to be transported to market after vine-ripening. Transporting vine-ripened fruit would avoid the practice of picking green fruits and artificially ripening them by ethylene treatment, which gives a ripe tomato color but not the full array of vine-ripened tomato flavors.

By 1987, Calgene researchers identified and cloned a tomato fruit PG gene, developed methods for tomato transformation and regeneration, and produced tomato plants with inserted PG antisense DNA constructions. Some of the resulting tomato lines generated as little as 1% of the PG found in conventional tomatoes. Based on the results from eight contained field trials, in October 1992 the U.S. Department of Agriculture determined that the PG-antisense tomato lines were not a "plant-pest" risk and no longer required permits for field testing or transport.

In May 1994, the U.S. Food and Drug Administration, responding to a Calgene petition, approved the introduction of kanamycin-resistance gene constructions needed to create the PG-antisense tomato lines.

Kanamycin-resistant organisms in human and animal guts and in soil were determined to be so common and abundant that they would overcome any potential influence of the corresponding genes in engineered crop plants. Allergic reactions to the kanamycin-resistance protein were also determined to be highly unlikely.

Data submitted by Calgene, including animal feeding studies, showed the PG-antisense tomato to be indistinguishable in almost every way from traditional tomatoes. The exceptions were that fruit cell-wall pectin degraded more slowly, and tomato paste had a higher viscosity.

Paralleling Calgene's efforts to develop the PG-antisense tomato lines, the company began to gain experience in the conventional fresh-market tomato business and to meet with community leaders, media representatives and consumers in Davis and Chicago, the two sites selected for initial introduction of the FLAVR SAVR tomato. On May 21, 1994, the genetically engineered FLAVR SAVR tomato was introduced. Demand for this product was high and remained high, but the product was never profitable because of high production and distribution costs.

In 1996, Zeneca, under license, introduced in the United Kingdom paste from PG-antisense tomatoes grown and processed in California, in collaboration with the grocery chains Sainsbury's and Safeway. More than 1.8 million cans, clearly labeled as derived from genetically engineered tomatoes, were sold from 1996 through early 1999. Reduced processing costs allowed a 20% lower price. The paste from genetically engineered tomatoes initially out-sold conventional tomato paste at many locations, but sales of this product declined dramatically in fall 1998.

Subsequently, Safeway and Sainsbury's declared that their house brands would not have genetically engineered ingredients, to satisfy the stated concerns of some customers rather than for any reason of food safety.

A report of a select committee of the U.K. House of Commons (1999), suggests that the decline in sales of the Zeneca tomato paste can be traced to an August 1998 British broadcast featuring Dr. Arpad Pusztai and subsequent media attention to the broadcast. He announced his conclusion that feeding rats genetically modified potatoes resulted in biological effects that "could" be attributed to the process of genetic engineering, rather than to the product of the introduced gene. Subsequently, independent analysis of the data, commissioned by Dr. Pusztai, and his testimony to the select committee (U.K. House of Commons 1999), both indicate that the conclusions stated in the broadcast are incorrect. However, the Zeneca product has not returned to grocery store shelves, with a corresponding loss to California agriculture.

Biopiracy and case studies on patents (Basmati rice)

An American company RiceTec Inc, was granted a patent by the US patent office to call the aromatic rice grown outside India 'Basmati'. RiceTec Inc, had been trying to enter the international Basmati market with brands like 'Kasmati' and 'Texmati' described as Basmati-type rice with minimal success. However, with the Basmati patent rights, RiceTec will now be able to not only call its aromatic rice Basmati within the US, but also label it Basmati for its exports. This has grave repercussions for India and Pakistan because not only will India lose out on the 45,000 tonne US import market, which forms 10 percent of the total Basmati exports, but also its position in crucial markets like the European Union, the United Kingdom, Middle East and West Asia. In addition, the patent on Basmati is believed to be a violation of the fundamental fact that the long grain aromatic rice grown only in Punjab, Haryana, and Uttar Pradesh is called Basmati. According to sources from the Indian Newspaper, Economic Times, "Patenting Basmati in the US is like snatching away our history and culture."

Basmati rice means the "queen of fragrance or the perfumed one." This type of rice has been grown in the foothills of the Himalayas for thousands of years. Its perfumy, nut-like flavor and

aroma can be attributed to the fact that the grain is aged to decrease its moisture content. Basmati, a long-grained rice with a fine texture is the costliest rice in the world and has been favored by emperors and praised by poets for hundreds of years. According to the Agricultural and Processed Food Products Export Development Authority (APEDA), India is the second largest producer of rice after China, and grows over a tenth of the world's wheat. In 1993, Basmati rice attracted the highest premium because it is a very-long grained rice, with an aroma of its own which enhances the flavors its mixed with.

The Rice Patent

RiceTec Inc, was issued the Patent number 5663484 on Basmati rice lines and grains on September 2, 1997.

In abstract, "the invention relates to novel rice lines and to plants and grains of these lines. The invention also relates to a novel means for determining the cooking and starch properties of rice grains and its use in identifying desirable rice lines. Specifically, one aspect of the invention relates to novel rice lines whose plants are semi-dwarf in stature, substantially photoperiod insensitive and high yielding, and produce rice grains having characteristics similar or superior to those of good quality Basmati rice. Another aspect of the invention relates to novel rice lines produced from novel rice lines. The invention provides a method for breeding these novel lines. A third aspect...relates to the finding that the starch index (SI) of a rice grain can predict the grain's cooking and starch properties, to a method based thereon for identifying grains that can be cooked to the firmness of traditional Basmati rice preparations, and to the use of this method in selecting desirable segregants in rice breeding programs."

Rice is an important aspect of life in the Southeast and other parts of Asia. For centuries, it has been the cornerstone of their food and culture. During this period, farming communities throughout the region developed, nurtured, and conserved over a hundred thousand distinct varieties of rice to suit different tastes and needs. It is for this reason that patenting of Basmati by RiceTec Inc. is perceived as not only intellectual property and cultural theft, but it also directly threatens farm communities in Southeast Asia. According to Dr Vandana Shiva, director of a Delhi-based research foundation which monitors issues involving patents and biopiracy, the main aim for obtaining the patent by RiceTec Inc. is to fool the consumers in believing there is no

difference between spurious Basmati and real Basmati. Moreover, she claims the "theft involved in the Basmati patent is, therefore, threefold: a theft of collective intellectual and biodiversity heritage on Indian farmers, a theft from Indian traders and exporters whose markets are being stolen by RiceTec Inc., and finally a deception of consumers since RiceTec is using a stolen name Basmati for rice which are derived from Indian rice but not grown in India, and hence are not the same quality.

In fact, Basmati rice has been one of the fastest growing export items from India in recent years. In the year to March 1997, India exported more than half a million tonnes of Basmati to the Gulf, Saudi Arabia, Europe and the United States, a small part of its total rice exports, but high in value. More substantively, Indian farmers export $250 million in Basmati every year and U.S. is a target market. RiceTec Inc. had attempted to sell its long-grain rice in Europe under such brand names as 'Texmati' and 'Kasmati' but not as Basmati. However, if the patent is not revoked, RiceTec Inc., can now sell its rice under the brand name Basmati which will definitely cut into India's and Pakistan's global market share, especially as the rice grown in the US could be sold cheaper than the Indian and Pakistani varieties.

UNIT-IV

SYLLABUS

Intellectual Property Rights: Types of IP: Patents, Trademarks, Copyright and Related Rights. Agreements and Treaties : History of GATT and TRIPS Agreement; Madrid Agreement; Hague Agreement; WIPO Treaties; Budapest Treaty; PCT; Indian Patent Act 1970 and recent amendments.

Intellectual Property Rights

Intellectual property, often known as IP, allows people to own their creativity and innovation in the same way that they can own physical property. The owner of IP can control and be rewarded for its use, and this encourages further innovation and creativity to the benefit of us all.

In some cases, IP gives rise to protection for ideas but in other areas, there will have to be more elaboration of an idea before protection can arise. It will often not be possible to protect IP and gain IP rights (or IPRs) unless, they have been applied for and granted, but some IP protection such as copyright arises automatically, without any registration, as soon as there is a record in some form of what has been created.

The four main types of IP are:

• Patents for inventions—new and improved products and processes that are capable of industrial application

• Trade marks for brand identity—of goods and services allowing distinctions to be made between different traders

• Designs for product appearance—of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture or materials of the product itself or its ornamentation

• Copyright for material—literary and artistic material, music, films, sound recordings and broadcasts, including software and multimedia. However, IP is much broader than this extending to trade secrets, plant varieties, geographical indications, performers rights and so on. To understand exactly what can be protected by IP, you will need to check the four main areas of copyright, designs, patents and trade marks as well as other IP. Often, more than one type of IP may apply to the same creation.

Patent

A patent gives an inventor the right for a limited period to stop others from making, using or selling an invention without the permission of the inventor. It is a deal between an inventor and the state in which the inventor is allowed a short-term monopoly in return for allowing the invention to be made public.

Patents are about functional and technical aspects of products and processes. Most patents are for incremental improvements in known technology—evolution rather than revolution. The technology does not have to be complex.

• Specific conditions must be fulfilled to get a patent. Major ones are that the invention must be new. The invention must not form part of the "state of the art". The state of the art is everything that has been made available to the public before the date of applying for the patent. This includes published documents and articles, but can also include use, display, spoken description, or any other way in which information is made available to the public.

• Involve an inventive step, as well as being new, the invention must not be obvious from the state of the art. Obviousness is from the viewpoint of a person skilled in the area of technology that the invention is in.

• Be industrially applicable. This condition requires that the invention can be made or used in any kind of industry.

A patented invention is recorded in a patent document. A patent document must have

• description of the invention, possibly with drawings, with enough details for a person skilled in the area of technology to perform the invention.

• claims to define the scope of the protection. The description is taken into account while interpreting the claims.

The original patent document of a patent application is published by a patent office. The application then adds to the state of the art for later applications and anyone can comment on the application. Often the patent document needs altering or amending to meet the conditions above before a patent can be granted. The final version of the granted patent document is then republished. If more information about the state of the art is discovered after grant, the patent document can be amended and republished again. Patent rights are territorial; a UK patent does not give rights outside of the UK. Patent rights last for up to 20 years in the UK. Some patents, such as those for medicinal products, may be eligible for a further 5 years protection with a Supplementary Protection Certificate.

A patent can be of value to an inventor—as well as protecting his business, patents can be bought, sold, mortgaged, or licenced to others. They also benefit people other than the inventor since large amounts of information can be learnt from other peoples patents — they can stop you from reinventing things or you can monitor what your competitors are doing. Patents also spur you or others on to develop your idea further, and once the term of the patent expires it can be freely performed by anyone which benefits the public and the economy.

TRADEMARK

A trademark is any sign which can distinguish the goods and services of one trader from those of another. A sign includes words, logos, colours, slogans, three-dimensional shapes and sometimes sounds and gestures. A trademark is therefore a "badge" of trade origin. It is used as a marketing tool so that customers can recognize the product of a particular trader. To be registrable in the UK it must also be capable of being represented graphically, that is, in words and/ or pictures.

DESIGN

A design refers to the appearance of the whole or a part of a product resulting from the features of, in particular, the lines, contours, colours, shape, texture or materials of the product or its ornamentation.

In the United Kingdom, designs are protected by three legal rights:

(a) Registered designs rights

• gives the owner a monopoly on their product design

• brings the right to take legal action against others who might be infringing the design and to claim damages

• may deter a potential infringement.

• also brings the exclusive right to make, offer, put on the market import, export, use or stock any product to which the design has been applied or is incorporated or to let others use the design under the terms agreed with the registered owner, in the UK and the Isle of Man.

Design registration gives the owner a monopoly on their product design, *i.e.*, the right for a limited period to stop others from making, using or selling a product to which the design has been applied, or in which it has been incorporated without their permission and is additional to any design right or copyright protection that may exist automatically in the design.

(*b*) Unregistered design right.

Is not a monopoly right but a right to prevent deliberate copying, and lasts until 10 years after first marketing articles made to the design, subject to an overall limit of 15 years from creation of the design. Unlike design registration, you do not have to apply to register design right. A design right is a property that, like any other business commodity, may be bought, sold or licensed.

(*c*) Artistic copyright.

Work can only be original if it is the result of independent creative effort. It will not be original if it has been copied from something that already exists. If it is similar to something that already exists but there has been no copying from the existing work either directly or indirectly, then it may be original.

The term "original" also involves a test of substantiality—literary, dramatic, musical and artistic works will not be original if there has not been sufficient skill and labour expended in their creation. But, sometimes significant investment of resources without significant intellectual input can still count as sufficient skill and labour.

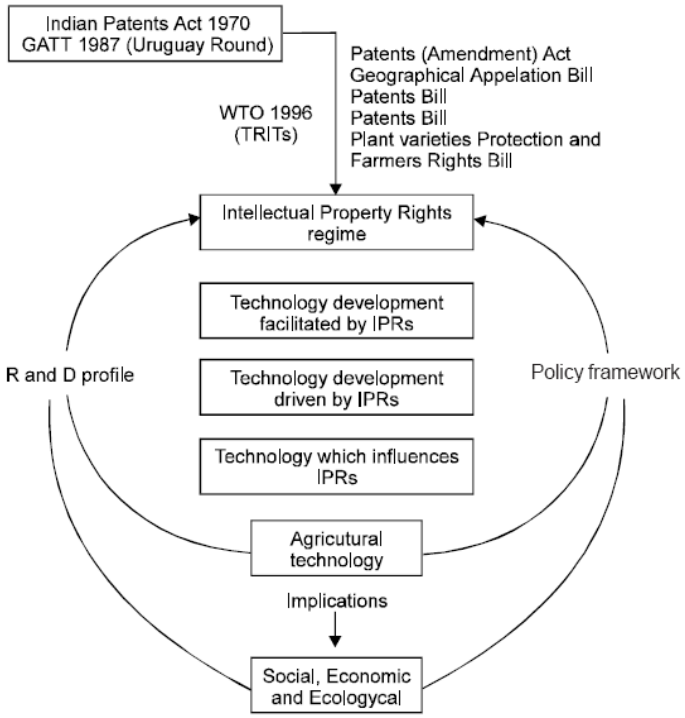
Ultimately, only the courts can decide whether something is original, but there is much case law indicating, for example, that names and titles do not have sufficient substantiality to be original and that, where an existing work is widely known, it will be difficult to convince a court that there has been no copying if your work is very similar or identical. Sound recordings, films and published editions do not have to be original but they will not be new copyright works if they have been copied from existing sound recordings, films and published editions. Broadcasts do not have to be original, but there will be no copyright, if, or to the extent that, they infringe copyright in another broadcast.

IMPLICATIONS OF IPRs AND AGRICULTURAL TECHNOLOGY

The dynamics and interplay of IPRs and technological innovations have multiple impacts. These can be categorized into social, economic and ecological. Due to peculiarities of Indian agriculture, the magnitude of these impacts will be manifold. The IPR regime not only influences research portfolio but also the contours of technology development. Primarily, the underlying motive of protection is to share profits with innovators. Therefore, the economic implications are not only predominant but also most obvious. The other two implications of access to newer technologies are on social and ecological dimensions. These three impacts are not mutually exclusive and often overlap.

Social Implications

Social impact of new technologies is manifested in terms of its influence on equity. Other important issue pertains to "scale effect". These issues can be explained by the illustration of Green Revolution. This seed-fertiliser technology was predominantly applicable in the areas with assured irrigation. These technologies contributed to the widening of the regional disparity. Viewed from a macro-perspective, however, the revolution was a great success that helped realize cherished goal of self-sufficiency in food grains. Therefore, the magnitude and nature of social implications vary according to the category of the technology (Table). Knowledge-based technologies and technologies concerning conservation of natural resources have positive impact on the society. Because of their nature (public good), the net social welfare increases manifold. Certain technologies like HYVs and hybrids require intensive input use and therefore have a mixed impact on the society. The predominant positive impact (+ + –) clouds the negative effects. Yield enhancement by conventional breeding is an ideal example. By the same yardstick, if conventional breeding aims at preventing yield loss (pest- and disease-resistant varieties) it becomes cost-reducing and has no negative impact (+). There are technologies where the negative component impact is marked (– +). Current levels of technologies (and its costs) in farm machinery and power precludes their accessibility to small and marginal farmers. There is a distinct possibility that in the near future farm machinery is tailor-made to suit small holdings?



Economic Implications

Most technologies, excluding agricultural biotechnology and crop protection chemicals have a net positive impact on the economy. There are also implicit benefits like savings from potential losses due to pests and diseases. Newer techniques invariably shift production functions thereby improving income of individuals and that of the nation. Research in the public domain will concentrate in cost-reducing technologies that are helpful to the weaker sections. Conservation of genetic resources have huge positive externalities (both intra and inter generational). Considering the market structure of crop varieties and crop protection chemicals and the nature of potential technologies, the scope for market malpractice such as monopoly and cartelisation is real. Generally embodied technologies are likely to have relatively more apparent impacts. Active presence of the public sector is vital for the provision of disembodied technologies.

Ecological implications

Increased use of agrochemicals will accelerate environmental degradation (– – –).Though biotechnological innovations minimise the use of agrochemicals to some extent (+ –), they are feared for their contribution to gene pollution (– ? ?). Development of such resistant varieties by conventional breeding has no negative impacts (++). Any technology encouraging the use of improved varieties is likely to contribute to narrowing of genetic base (–).

Increasingly, the use of antibiotics, hormones, unconventional feeds and genetic engineering in livestock and fisheries have raised questions about health hazards and animal biodiversity (– –). Destruction of soil structure and groundwater depletion are serious ecological risks associated with the excessive use of technologies associated with farm machinery and power. Technological advancements in the conservation of soil, water and genetic resources have profound positive impacts on the ecology (+++). Being locally evolved and practice based, knowledge based technologies optimise resource use thereby imparting positive externalities to the environment.

WORLD TRADE ORGANISATION (WTO)

In brief, the World Trade Organisation (WTO) is the only international organisation dealing with the global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and freely as possible.

Location: Geneva, Switzerland

Established: 1 January 1995

Created by: Uruguay Round negotiations (1986-94)

Membership: 146 countries (as of April 2003)

Budget: 155 million Swiss francs for 2003

Secretariat staff: 560

Head: Director-General, Supachai Panitchpakdi

Functions:

• Administering WTO trade agreements

• Forum for trade negotiations

• Handling trade disputes

• Monitoring national trade policies

• Technical assistance and training for developing countries

• Cooperation with other international organizations

The result is assurance. Consumers and producers know that they can enjoy secure supplies and greater choice of the finished products, components, raw materials and services that they use. Producers and exporters know that foreign markets will remain open to them. The result is also a more prosperous, peaceful and accountable economic world. Decisions in the WTO are typically taken by consensus among all member countries and they are ratified by members' parliaments. Trade friction is channeled into the WTO's dispute settlement process where the focus is on interpreting agreements and commitments, and how to ensure that countries' trade policies confirm with them. That way, the risk of disputes spilling over into political or military conflict is reduced. By lowering trade barriers, the WTO's system also breaks down other barriers between peoples and nations.

At the heart of the system—known as the multilateral trading system—are the WTO's agreements, negotiated and signed by a large majority of the world's trading nations, and gratified in their parliaments. These agreements are the legal ground-rules for international commerce. Essentially, they are contracts, guaranteeing member countries important trade rights.

They also bind governments to keep their trade policies within agreed limits to everybody's benefit. The agreements are negotiated and signed by governments. But their purpose is to help producers of goods and services, exporters, and importers conduct their business. **The goal** is to improve the welfare of the people of the member countries.

A Closer Look at These Principles

1. *Trade without Discrimination*

(*a*) Most-favoured-nation (MFN): Treating other people equally. Under the WTO agreements, countries cannot normally discriminate between their trading partners. Grant someone a special favour (such as a lower customs duty rate for one of their products) and you have to do the same for all other WTO members. This principle is known as Most-Favoured-Nation (MFN) treatment. It is so important that it is the first article of the General Agreement on Tariffs and Trade (GATT), which governs trade in goods. MFN is also a priority in the General Agreement on Trade in Services (GATS) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), although in each agreement the principle is handled slightly differently. Together, these three agreement cover all the three main areas of trade handled by the WTO. Some exceptions are allowed. For example, countries can set up a free-trade agreement that applies only to goods traded within the group—discriminating against goods from outside. Or they can give developing countries special access to their markets. Or a country can raise barriers against products that are considered to be traded unfairly from specific countries. And in services, countries are allowed, in limited circumstances, to discriminate. But the agreements permit these exceptions only under strict conditions. In general, MFN means that every time a country lowers a trade barrier or opens up a market, it has to do so for the same goods or services from all its trading partners—whether rich or poor, weak or strong.

(*b*) National treatment: Treating foreigners and locals equally. Imported and locallyproduced goods should be treated equally—at least after the foreign goods have entered the market. The same should apply to foreign and domestic services, and to foreign and local trademarks,

copyrights and patents. This principle of "national treatment" (giving others the same treatment as one's own nationals) is also found in all the three main WTO agreements (Article 3 of GATT, Article 17 of GATS and Article of 3 TRIPS), although once again the principle is handled slightly differently in each of these.

National treatment only applies once a product, service or item of intellectual property has entered the market. Therefore, charging customs duty on an import is not a violation of national treatment even if locally-produced products are not charged an equivalent tax.

2. *Free Trade: Gradually, Through Negotiation*

Lowering trade barriers is one of the most obvious means of encouraging trade. The barriers concerned include customs duties (or tariffs) and measures such as import bans or quotas that restrict quantities selectively. From time to time other issues such as red tape and exchange rate policies have also been discussed.

Since GATT's creation in 1947-48 there have been eight rounds of trade negotiations. A ninth round, under the Doha Development Agenda, is now underway. At first, these are focused on lowering tariffs (customs duties) on imported goods. As a result of the negotiations, by the mid-1990s industrial countries' tariff rates on industrial goods had fallen steadily to less than 4%.

But by the 1980s, the negotiations had expanded to cover non-tariff barriers on goods, and to the new areas such as services and intellectual property. Opening markets can be beneficial, but it also requires adjustment. The WTO agreements allow countries to introduce changes gradually, through "progressive liberalization". Developing countries are usually given longer time period to fulfil their obligations.

3. *Predictability: Through Binding and Transparency*

Sometimes, promising not to raise a trade barrier can be as important as lowering one, because the promise gives business a clearer view of their future opportunities. With stability and predictability, investment is encouraged, jobs are created and consumers can fully enjoy the benefits of competition—choice and lower prices. The multilateral trading system is an attempt to governments to make the business environment stable and predictable.

In the WTO, when countries agree to open their markets for goods or services, they "bind" their commitments. For goods, these bindings amount to ceilings on customs tariff rates. Sometimes countries tax imports at rates that are lower than the bound rates. Frequently, this is the case in developing countries. In developed countries, the rates actually charged and the bound rates tend to be the same.

A country can change its bindings, but only after negotiating with its trading partners, which could mean compensating them for loss of trade. One of the achievements of the Uruguay Round of multilateral trade talks was to increase the amount of trade under binding commitments. In agriculture, 100% of products now have bound tariffs. The result of all this: a substantially higher degree of market security for traders and investors. The system tries to improve predictability and stability in other ways as well. One way is to discourage the use of quotas and other measures used to set limits on quantities of imports administering quotas can lead to more red-tape and accusations of unfair play. Another is to make countries' trade rules as clear and public (transparent) as possible. Many WTO agreements require governments to disclose their policies and practices publicly within the country or by notifying the WTO. The regular surveillance of national trade policies through the Trade Policy Review Mechanism provides a further means of encouraging transparency both domestically and at the multilateral level.

4. *Promoting Fair Competition*

The WTO is sometimes described as a "free trade" institution, but that is not entirely accurate. The system does allow tariffs and, in limited circumstances, other forms of protection. More accurately, it is a system of rules dedicated to open, fair and undistorted competition. The rules on non-discrimination—MFN and national treatment – are designed to secure fair conditions of trade. So too are those on dumping (exporting at below cost to gain market share) and subsidies. The issues are complex, and the rules try to establish what is fair or unfair, and how governments can respond, in particular by charging additional import duties calculated to compensate for damage caused by unfair trade.

Many of the other WTO agreements aim to support fair competition: in agriculture, intellectual property, services, for example. The agreement on government procurement (a "plurilateral" agreement because it is signed by only a few WTO members) extends competition rules to purchases by thousands of government entities in many countries, and so on.

5. *Encouraging Development and Economic Reform*

The WTO system contributes to development. On the other hand, developing countries need flexibility in the time they take to implement the system's agreements. And the agreements themselves inherit the earlier provisions of GATT that allow for special assistance and trade concessions for developing countries. Over three quarters of WTO members are developing countries and countries in transition to market economies. During the seven and a half years of the Uruguay Round, over 60 of these countries implemented trade liberalization programmes autonomously. At the same time, developing countries and transition economies were much more active and influential in the Uruguay Round negotiations than in any previous round, and they are even more, so in the current Doha Development Agenda. At the end of the Uruguay Round, developing countries were prepared to take on most of the obligations that are required of developed countries. But the agreements did give them transition periods to adjust to the more unfamiliar and, perhaps, difficult WTO provisions— particularly so for the poorest, "least-

developed" countries. A ministerial decision adopted at the end of the round says better-off countries should accelerate implementing market access commitments on goods exported by the least-developed countries, and it seeks increased technical assistance for them. More recently, developed countries have started to allow duty-free and quota-free imports for almost all products from least-developed countries. On all of this, the WTO and its members are still going through a learning process. The current Doha Development Agenda includes developing countries' concern about the difficulties they face in implementing the Uruguay Round agreements.

DEVELOPING COUNTRIES DEVELOPMENT AND TRADE

Over three quarters of WTO members are developing or least-developed countries. All WTO agreements contain special provision for them, including longer time periods to implement agreement and commitments, measures to increase their trading opportunities, provisions requiring all WTO members to safeguard their trade interests, and support to help them build the infrastructure for WTO work, handle disputes, and implement technical standards. The 2001 Ministerial Conference in Doha set out tasks, including negotiations, for a wide range of issues concerning developing countries. Some people call the new negotiations the Doha Development Round.

Before that part in 1997, a high-level meeting on trade initiatives and technical assistance for least-developed countries resulted in an "integrated framework" involving six intergovernmental agencies, to help least-developed countries increase their ability to trade, and some additional preferential market access agreements.

A WTO committee on trade and development, assisted by a sub-committee on least-developed countries, looks at developing countries' special needs. Its responsibility includes

implementation of the agreements, technical cooperation, and the increased participation of developing countries in the global trading system.

TECHNICAL ASSISTANCE AND TRAINING

The WTO organizes around 100 technical cooperation missions to developing countries annually. It holds on average three-trade policy courses each year in Geneva for government officials. Regional seminars are held regularly in all regions of the world with a special emphasis on African countries. Training courses are also organized in Geneva for officials from countries in transition from central planning to market economies. The WTO set up reference centres in over 100 trade ministries and regional organizations in capitals of developing and least-developed countries, providing computers and internet-access to enable ministry officials to keep abreast of events in the WTO in Geneva through online access to the WTO's immense database of official documents and other material.

• Assisting developing countries in trade policy issues, through technical assistance and training programmes.

• Cooperating with other international organizations.

THE ORGANIZATION FUNCTIONS

The WTO's overriding objective is to help trade flow smoothly, freely, fairly and predictably. It does this by:

• administering trade agreements;

• acting as a forum for trade negotiations;

• settling trade disputes;

• reviewing national trade policies.

STRUCTURE

The WTO has nearly 150 members, accounting for over 97% of world trade. Around 30 others are negotiating membership. Decisions are made by the entire membership. This is typically byconsensus. A majority vote is also possible but it has never been used in the WTO, and was extremely rare under the WTO's predecessor, GATT. The WTO's agreements have been ratified in all members' parliaments.

The WTO's top level decision-making body is the **Ministerial Conference** which meets at least once every two years. The Fifth WTO Ministerial Conference was held in Cancun, Mexico from 10 to 14 September, 2003.

Below this is the **General Council** (normally ambassadors and heads of delegation in Geneva, but sometimes officials sent from members' capitals) which meets several times a year in the Geneva headquarters. The General Council also meets as the Trade Policy Review Body and the Dispute Settlement Body.

At the next level, the **Goods Council, Services Council and Intellectual Property (TRIPS) Council** report to the General Council. Numerous **specialized committees, working groups and working parties** deal with the individual agreements and other areas such as environment, development, membership applications and regional trade agreements.

SECRETARIAT

The WTO Secretariat, based in Geneva has around 560 staff and is headed by a director general. It does not have branch offices outside Geneva. Since decisions are taken by the members

themselves, the Secretariat does not have the decision-making role those other international bureaucracies are given. The secretariat's main duties are to supply technical support for the various councils and committees and the ministerial conferences, to provide technical assistance for developing countries, to analyze world trade, and to explain WTO affairs to the public and media. The Secretariat also provides some forms of legal assistance in the dispute settlement process and advises governments wishing to become members of the WTO. The annual budget is roughly 155 million Swiss francs. relied on such licenses in order to limit exclusive rights and prevent or remedy abusive practices in several areas. The study reveals there is a broad range of grounds under which compulsory licenses may be granted in both developed and developing countries. The grounds and conditions on which compulsory licenses have been regulated and granted in developed countries illustrate the flexibility and potential of the compulsory licensing system to address a multiplicity of public interests and concerns. The evidence also indicates that arguments— often voiced by the developed countries' business community and governments— against compulsory licenses as a deviation from acceptable standards for intellectual property rights, are not reflected in the policies actually applied in such countries.

Three Main Conclusions Particularly Relevant for Developing Countries may be Drawn from the Previous Analysis.

• Compulsory licenses should be considered as an essential element in patent laws and other intellectual property regimes. Developing countries should disregard any attempts by developed countries to limit under bilateral or other agreements the scope of and grounds for compulsory licensing.

• The grounds and conditions for compulsory licenses should be carefully determined by national laws. The extent to which such licenses would be available and effective depend on the provisions of national legislation and on its adequate administration by informed national authorities.

• Developing countries should preserve the maximum possible freedom under international rules to design their compulsory licensing systems, according to their own interests and needs,

including in such areas as the protection of health and the environment, and the promotion of transfer of technology and local industrialization. Should the issue of compulsory licenses be included in the agenda of possible future negotiations in WTO, developing countries should seek to clarify the scope for the granting of such licenses in certain cases (*e.g.*, of non-exploitation), as well as to remove some of the restrictive conditions imposed by the said TRIPs Agreement.

UNIT-IV

SYLLABUS

Patent application: Rules governing patents. Patent related cases. Licensing – Flavr Savr™ tomato as a model case. Biopiracy and case studies on patents (Basmati rice, Turmeric, and Neem). Biotechnological examples of patent, trademark, trade secret, copy right. Traditional Knowledge.

Licensing – Flavr Savr™ tomato as a model case

The FLAVR SAVR tomato was the first genetically engineered crop product to be commercialized. The research and marketing efforts that produced the FLAVR SAVR tomato resulted in scientific success, a temporary sales success, and then commercial demise. The FLAVR SAVR story reveals how difficult it can be to bring genetically engineered products to market, how objections with little or no scientific merit can influence the outcome, and how important public opinion is in determining commercial success.

Circumstantial evidence available in the 1980s suggested that the tomato fruit enzyme polygalacturonase (PG), because of its ability to dissolve cell-wall pectin, was key to fruit softening. Researchers at Calgene, Inc., in Davis, proposed to suppress PG accumulation in ripening tomatoes by introducing a reverse-orientation copy of the gene, an "antisense" copy designed to prevent or drastically reduce the formation of PG.

Their expectation was that ripe fruit would remain firm longer, perhaps even allowing it to be transported to market after vine-ripening. Transporting vine-ripened fruit would avoid the practice of picking green fruits and artificially ripening them by ethylene treatment, which gives a ripe tomato color but not the full array of vine-ripened tomato flavors.

By 1987, Calgene researchers identified and cloned a tomato fruit PG gene, developed methods for tomato transformation and regeneration, and produced tomato plants with inserted PG antisense DNA constructions. Some of the resulting tomato lines generated as little as 1% of the PG found in conventional tomatoes. Based on the results from eight contained field trials, in October 1992 the U.S. Department of Agriculture determined that the PG-antisense tomato lines were not a "plant-pest" risk and no longer required permits for field testing or transport.

In May 1994, the U.S. Food and Drug Administration, responding to a Calgene petition, approved the introduction of kanamycin-resistance gene constructions needed to create the PG-antisense tomato lines.

Kanamycin-resistant organisms in human and animal guts and in soil were determined to be so common and abundant that they would overcome any potential influence of the corresponding genes in engineered crop plants. Allergic reactions to the kanamycin-resistance protein were also determined to be highly unlikely.

Data submitted by Calgene, including animal feeding studies, showed the PG-antisense tomato to be indistinguishable in almost every way from traditional tomatoes. The exceptions were that fruit cell-wall pectin degraded more slowly, and tomato paste had a higher viscosity.

Paralleling Calgene's efforts to develop the PG-antisense tomato lines, the company began to gain experience in the conventional fresh-market tomato business and to meet with community leaders, media representatives and consumers in Davis and Chicago, the two sites selected for initial introduction of the FLAVR SAVR tomato. On May 21, 1994, the genetically engineered FLAVR SAVR tomato was introduced. Demand for this product was high and remained high, but the product was never profitable because of high production and distribution costs.

In 1996, Zeneca, under license, introduced in the United Kingdom paste from PG-antisense tomatoes grown and processed in California, in collaboration with the grocery chains Sainsbury's and Safeway. More than 1.8 million cans, clearly labeled as derived from genetically engineered tomatoes, were sold from 1996 through early 1999. Reduced processing costs allowed a 20% lower price. The paste from genetically engineered tomatoes initially out-sold conventional tomato paste at many locations, but sales of this product declined dramatically in fall 1998.

Subsequently, Safeway and Sainsbury's declared that their house brands would not have genetically engineered ingredients, to satisfy the stated concerns of some customers rather than for any reason of food safety.

A report of a select committee of the U.K. House of Commons (1999), suggests that the decline in sales of the Zeneca tomato paste can be traced to an August 1998 British broadcast featuring Dr. Arpad Pusztai and subsequent media attention to the broadcast. He announced his conclusion that feeding rats genetically modified potatoes resulted in biological effects that "could" be attributed to the process of genetic engineering, rather than to the product of the introduced gene. Subsequently, independent analysis of the data, commissioned by Dr. Pusztai, and his testimony to the select committee (U.K. House of Commons 1999), both indicate that the conclusions stated in the broadcast are incorrect. However, the Zeneca product has not returned to grocery store shelves, with a corresponding loss to California agriculture.

Biopiracy and case studies on patents (Basmati rice)

An American company RiceTec Inc, was granted a patent by the US patent office to call the aromatic rice grown outside India 'Basmati'. RiceTec Inc, had been trying to enter the international Basmati market with brands like 'Kasmati' and 'Texmati' described as Basmati-type rice with minimal success. However, with the Basmati patent rights, RiceTec will now be able to not only call its aromatic rice Basmati within the US, but also label it Basmati for its exports. This has grave repercussions for India and Pakistan because not only will India lose out on the 45,000 tonne US import market, which forms 10 percent of the total Basmati exports, but also its position in crucial markets like the European Union, the United Kingdom, Middle East and West Asia. In addition, the patent on Basmati is believed to be a violation of the fundamental fact that the long grain aromatic rice grown only in Punjab, Haryana, and Uttar Pradesh is called Basmati. According to sources from the Indian Newspaper, Economic Times, "Patenting Basmati in the US is like snatching away our history and culture."

Basmati rice means the "queen of fragrance or the perfumed one." This type of rice has been grown in the foothills of the Himalayas for thousands of years. Its perfumy, nut-like flavor and

aroma can be attributed to the fact that the grain is aged to decrease its moisture content. Basmati, a long-grained rice with a fine texture is the costliest rice in the world and has been favored by emperors and praised by poets for hundreds of years. According to the Agricultural and Processed Food Products Export Development Authority (APEDA), India is the second largest producer of rice after China, and grows over a tenth of the world's wheat. In 1993, Basmati rice attracted the highest premium because it is a very-long grained rice, with an aroma of its own which enhances the flavors its mixed with.

The Rice Patent

RiceTec Inc, was issued the Patent number 5663484 on Basmati rice lines and grains on September 2, 1997.

In abstract, "the invention relates to novel rice lines and to plants and grains of these lines. The invention also relates to a novel means for determining the cooking and starch properties of rice grains and its use in identifying desirable rice lines. Specifically, one aspect of the invention relates to novel rice lines whose plants are semi-dwarf in stature, substantially photoperiod insensitive and high yielding, and produce rice grains having characteristics similar or superior to those of good quality Basmati rice. Another aspect of the invention relates to novel rice lines produced from novel rice lines. The invention provides a method for breeding these novel lines. A third aspect...relates to the finding that the starch index (SI) of a rice grain can predict the grain's cooking and starch properties, to a method based thereon for identifying grains that can be cooked to the firmness of traditional Basmati rice preparations, and to the use of this method in selecting desirable segregants in rice breeding programs."

Rice is an important aspect of life in the Southeast and other parts of Asia. For centuries, it has been the cornerstone of their food and culture. During this period, farming communities throughout the region developed, nurtured, and conserved over a hundred thousand distinct varieties of rice to suit different tastes and needs. It is for this reason that patenting of Basmati by RiceTec Inc. is perceived as not only intellectual property and cultural theft, but it also directly threatens farm communities in Southeast Asia. According to Dr Vandana Shiva, director of a Delhi-based research foundation which monitors issues involving patents and biopiracy, the main aim for obtaining the patent by RiceTec Inc. is to fool the consumers in believing there is no

difference between spurious Basmati and real Basmati. Moreover, she claims the "theft involved in the Basmati patent is, therefore, threefold: a theft of collective intellectual and biodiversity heritage on Indian farmers, a theft from Indian traders and exporters whose markets are being stolen by RiceTec Inc., and finally a deception of consumers since RiceTec is using a stolen name Basmati for rice which are derived from Indian rice but not grown in India, and hence are not the same quality.

In fact, Basmati rice has been one of the fastest growing export items from India in recent years. In the year to March 1997, India exported more than half a million tonnes of Basmati to the Gulf, Saudi Arabia, Europe and the United States, a small part of its total rice exports, but high in value. More substantively, Indian farmers export $250 million in Basmati every year and U.S. is a target market. RiceTec Inc. had attempted to sell its long-grain rice in Europe under such brand names as 'Texmati' and 'Kasmati' but not as Basmati. However, if the patent is not revoked, RiceTec Inc., can now sell its rice under the brand name Basmati which will definitely cut into India's and Pakistan's global market share, especially as the rice grown in the US could be sold cheaper than the Indian and Pakistani varieties.

EXAMPLES OF PATENTS IN BIOTECHNOLOGY

In recent years, society has witnessed the explosive growth of biotechnology research. Much of this research has had a profound effect on our perception of the fundamental fabric of life itself. However, because of the complex nature of these discoveries, commercialization is often a long and expensive process. As a result of the need to achieve a proprietary position over this technology and the investment entailed in its commercialization, the field has seen phenomenal growth in the number of biotechnology patent applications which have been filed. Intellectual property is a term used to describe property that is not tangible, but which instead originates through the creative effort of the inventor. Such property can be further characterized as a trademark, a copyright, a trade secret, or a patent. These divergent areas have in common a highly abstract concept of property.

(a) Trademarks include words, names, slogans, logos, and symbols which are used to indicate the source of a product or service. A trademark owner has the right to stop the commercialization of competitive goods having trademarks which are confusingly similar to those of the trademark owner.

(b) A copyright is the right to the exclusive publication, reproduction, adaptation, display, and performance of an original work which is fixed in a tangible medium of expression. A copyright protects the expression of an idea, but not the idea itself.

(c) A trade secret can be patentable and, unlike patents, is potentially indefinite in duration. However, the value of a trade secret is lost once it is disclosed. Also, the holder of a trade secret has no cause of action against those who independently discover the trade secret. From a societal standpoint, probably the greatest disadvantage of a trade secret is that, by its very nature, the trade secret may die with the owner. For example, the methods of treating wood employed by the famous violin maker, Stradivarius, have been lost forever. It was partly in response to the drawbacks of trade secret protection, as embodied by the Guild System of Medieval Europe, that the patent system was established.

The public policy behind the patent system is to encourage inventors to share their discoveries with the general public and thereby advance the general status of technology. The advancement is accomplished by encouraging innovation through giving the inventor the right of exclusive commercial use, and by encouraging competitors to design around the invention. Thus, the knowledge of the inventor is preserved for the benefit of society and future generations. In the U.S., patent can be further categorized as design, plant, and utility patents. A design patent can be obtained for a new, original, and ornamental design; the invention covered by the design patent must not be for a characteristic which is primarily functional. For example, a design patent application might be filed for a pitcher which has a particularly attractive handle. If it were found that the handle of the pitcher were primarily functional (for example, it provided a better grip), then a design patent would not be appropriate.

Under the Plant Patent Act (PPA), patent protection is available for new varieties of asexually-reproduced plants. Protection under the PPA is very narrow; only one claim is permitted, and it covers only the whole plant. Thus, under the PPA, it is not possible to claim seeds, fruit, cells, or any other part of a plant which may be of commercial value. Also, because the PPA covers only plants which are asexually reproduced, such as roses and other ornamental plants, many agriculturally important plants cannot be protected under the PPA. The most important type of patent, from a scientific and commercial standpoint, is the utility patent. From the standpoint of the inventor, the purpose in trying to obtain a utility patent is to secure the exclusive right to make, use and sell the patented invention. Those exclusive rights exist for the term of the patent.

Patent terms were recently changed: (1) for applications filed after June 8, 1995, the term of any patent that issues will be 20 years from the first effective United States filing date of the application; (2) for applications on file on or before June 8, 1995, and for patents in force on June 8, 1995, the term of the patent is the longer of 20 years from the date of filing or 17 years from issuance of the patent.

The first thing which should be considered in determining whether a utility application should be filed is whether the subject matter of the invention is proper under the patent laws. One can address this issue by first considering what types of subject matter are not patentable.

Non-patent subject matter includes:

1. Printed matter, where the invention resides solely within the printed matter and does not involve any mechanical features;

2. Naturally occurring articles, where there has been no human intervention;

3. Methods of doing business, such as book-keeping and accounting techniques; and

4. Scientific principles, such as theories and formulas.

Utility patent protection is available for:

(i) processes (i.e., methods);

(ii) machines;

(iii) articles of manufacture; and

(iv) compositions of matter.

Examples of process-type inventions that may be patented include chemical processes, such as the manufacture of chemicals, and methods of treating or diagnosing disease. Also included in the category are methods of using previously-known drugs. The terms “machines” and “articles of manufacture” should be fairly self-explanatory.

A. In biotechnology, some of the most valuable types of patents fall into the composition of matter category. The term “composition of matter” includes mixtures of chemicals, pure chemical compounds, polymers (such as plastics), and purified products not pure in nature.

Examples of this latter category are antibiotics, enzymes, and lymphokines. More specifically, patents can be obtained for:

(i) DNA

(ii) proteins

(iii) antibodies (e.g., monoclonal antibodies)

(iv) pure cultures of microorganisms and viruses

(v) transgenic plants and animals.

Assuming an invention is patentable in terms of subject matter, there then remain three statutory requirements which the invention must meet: the invention must be useful, novel, and non-obvious.

"Useful" means the invention must be of some (even if small) benefit. Thus, the statute precludes obtaining a patent on an invention which is merely a curiosity, or which is illegal or immoral. For example, a machine useful solely for producing counterfeit money is unpatentable. The requirement that the invention be useful does not mean it must rise to the level of being commercially useful. Many inexperienced applicants believe they must delay filing a patent application until they have developed the invention to the point where it is a commercial product.

For example, where a new anti-cancer drug has been discovered, inventors sometime believe, wrongly, that human data meeting the requirements of the FDA must be obtained in order to file a patent application, whereas it is usually sufficient to have in vitro data showing inhibition of a cancer cell line. In fact, delaying filing a patent application in order to generate elaborate experimental results carries with it the very real risk that another inventor will file ahead of you.

Another statutory requirement of the patent law is that the invention be novel. The events which can prevent an invention from being considered novel are events which occur before the date of invention, and more than 12 months before the filing date of the patent application.

Thus, a patent cannot be obtained if, before the date of invention, the invention was: publicly known or used by others in this country, or patented or described in a printed publication anywhere in the world. Further, a patent cannot be obtained if, more than 12 months before the

filing of the patent application, the invention was patented or described in a printed publication anywhere in the world, or in public use or on sale in this country. It is important to keep in mind that the 12-month publication grace period is unique to U.S. law; most foreign countries have a different rule, known as absolute novelty. (Absolute novelty means patent protection is lost by sale or publication of the invention prior to the filing of the patent application).

Non-obviousness of an invention, like novelty, involves a comparison of the invention with the prior art. But, unlike novelty, which only considers prior art which is the same as the invention, obviousness considers the prior art with respect to what the next obvious step would have been. In evaluating obviousness, it is necessary to evaluate the so-called subjective and objective indicia of obviousness. The subjective factors relating to obviousness have been defined by the U.S. Supreme Court: the scope and content of the prior art; the differences between the invention and the prior art; and the level of ordinary skill in the art.

The objective obviousness factors, developed by the courts over several decades, are: commercial success; long-felt need; failure of others; unexpected results; skepticism by others; and teaching away in the literature.

A patent application also must teach one of the ordinary skill in the field how to make and use the invention. This is known as the enablement requirement. If the patent application is so inexact as to require substantial experimentation for success, the invention may be unpatentable. The patent statute also requires that the inventor disclose the best mode for making and using the invention. Thus, where an inventor has developed two different processes for synthesizing a compound, but one of the processes is less expensive or simpler, then the patent application must teach that preferred process.

B. In biotechnology, the enablement and best mode requirements have resulted in what has become known as the deposit requirement. When life forms are an essential part of a patent application, special problems arise with respect to satisfying the enablement requirement. Sometimes these types of inventions cannot be reproduced by following a written description. For example, new antibiotics made by microorganisms not generally available to the public raise the issue of whether merely describing the microorganisms, and where and how they were found, satisfies the enablement requirement. It was on this basis that the Patent Office established the policy of requiring inventors to place these rare organisms in depositories accessible to the public.

Investorship: Another issue which must be addressed when filing a patent application is that of inventorship. In the U.S., unlike many foreign countries, the patent application must be filed in the name of the true inventor or inventors. Joint inventorship requires that each inventor contribute to the conception of the invention. Conception is the mental formulation of an idea complete enough so as to enable one of ordinary skill in the field to reduce the concept to practice without undue experimentation. Contribution to the actual reduction to practice is irrelevant for purposes of determining inventorship.

Although it is not necessary for joint inventors to physically work together, there must be some degree of collaboration among them. Further, an individual who merely follows the instructions of another is not a joint inventor. For example, a lab technician who carries out experiments under someone else's instructions and records the results is not an inventor. Finally, an individual does not become a joint inventor by suggesting a desirable end or result without suggesting the means of accomplishing the result.

I. Biotechnology has increased the availability of many natural biological products useful in treating various diseases. These products, such as human growth hormone (hGH), often exist in such minute quantities that isolation from natural sources is impractical or extremely expensive. Sometimes, such as in the case of insulin, the product can be isolated from alternative natural sources (e.g., pig), but may be less effective or accompanied by undesired side effects.

II. Biotechnology has also been used in disease detection. For example, HIV diagnostic tests have been developed using recombinant DNA technology.

III. Biotechnology research is extremely risky and expensive and often involves time-consuming, resource-intensive characterization of the genes that encode the desired biological product. Sometimes, the product itself has to be characterized to determine which gene is the "right" one. Organizations who do biotechnology research are very interested in protecting their investment by obtaining patents to prevent others from freely practicing the "fruits" of this research. What "fruits" of biotechnology research can be patented? This list is almost endless. For example, patents can be (and have been) obtained on the isolated gene, modifications of the gene, purified and modified biological products encoded by the gene, methods for making the gene and its encoded products, as well as methods for using the gene and its encoded products.

The ability to obtain patents on these "fruits" has been aided by the perception of biotechnology as an "unpredictable" art. One of the requirements for getting patent coverage is that the invention not be obvious to one of ordinary skill in the art. The perception of biotechnology as an unpredictable art tends to negate obviousness, as reflected in many court cases that have upheld the validity of biotechnology patents.

IV. As owners of biotechnology patents have unfortunately found out, the perception of biotechnology as unpredictable is a two-edged sword. To be valid, the patent must also contain a written description of the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art" to make and use the invention ("enablement requirement"). The predictability as to what will (and will not) work greatly determines how much of the patented invention is enabled. The enablement requirement has proven to be a significant barrier to enforcing broad biotechnology patents. Many broad biotechnology patents claim the invention in terms of its functional characteristics, rather than its chemical structure, to obtain broader coverage. For example, some biotechnology patents claim the gene in terms of its ability to encode a class of proteins that are functionally analogous to a particular biological protein. Other broad biotechnology patents claim the biological protein (e.g., hormone) in terms of its activity. These broad "functionalized" biotechnology patent claims have not faired well in court. The courts have applied a fairly stringent enablement standard to such broad claims because of the perceived unpredictability of biotechnology. This stringent standard has been difficult to satisfy, especially since the litigated patents usually have had only one or a few working examples of the gene or product.

The difficulty in satisfying the enablement requirement in the biotechnology area has led alternatively to claims limited to genes or encoded products that are specifically exemplified in the patent. However, as the litigated patents show, a competitor may slightly alter the gene or encoded product, and thus avoid infringing such narrow patent claims.

So how does one get broad biotechnology patent claims that will satisfy the enablement requirement? Here are some suggestions:

(a) Exemplify as much as possible in the patent disclosure the scope of the biotechnology being claimed. This includes how to make and how to use the claimed biotechnology. It is also important to understand as much as possible the operative limits of the claimed biotechnology and to put that knowledge into the patent disclosure. Be careful in relying on "illustrative" or

"prophetic" examples without actually testing a representative selection of such examples to see if they do work. The litigated patents have shown the danger of relying on such examples when they later turn out not to work. Also, make sure each term, competent and step recited in the patent claim is defined in sufficient detail. As one 1996 court case painfully demonstrates, reliance on general teachings in the art can be extremely risky in the biotechnology area.

(b) Augment the initial patent disclosure by filing continuation or provisional patent applications to include new working examples or learnings. To preserve patent rights in "first to file" countries such as Europe, it is not unusual for a biotechnology patent to be filed with broad claims, but with only a few or possibly only one working example disclosed. Rather than rely on what later may be held to be inadequate enablement, consider filing continuation or provisional patent applications to include new working examples or learnings. Provisionals are especially valuable for doing multiple filings (at relatively low cost) to augment the initial patent disclosure. For example, five U.S. provisional applications can be filed for less than the cost of one traditional U.S. patent application.

(c) Where possible, pursue broad claims to methods for making the gene or biological product. Do not overlook the value getting patent coverage on the method of or making the gene or biological product. Under appropriate circumstances, importation of the gene, and more importantly the biological product, into the U.S. can be prevented if the gene or biological product is made by a patented method. Indeed, one court case that prevented importation of hGH made by a patented method involving recombinant DNA suggests broad method claims for making genes or biological products may be less likely to run afoul of the enablement requirement. The perceived unpredictability of biotechnology has certainly made it more difficult to get enforceable broad claims on the "fruits" of biotechnology research. However, as the courts have made clear, broad patent coverage on these "fruits" is not precluded. The challenge is to craft patent disclosures that satisfy the more stringent enablement standard applied by the courts to the biotechnology area.

SPECIAL APPLICATION OF PATENTS IN BIOTECHNOLOGY

Patenting in drugs, filings by Indians/Indian companies

Indian scientists and technologists have been quick in responding to the post TRIPS challenge by filing substantially more patent applications. The filing by Indians has gone up by 155% over the

applications published in 1996 as compared to an increase of 25% in the filing by foreigners/foreign companies. However, the former is now about 33% of the latter as against 16% observed in the earlier analysis, a significant improvement to be noted. Further, now there are seven companies/institutions which have filed 5 or more applications as against two observed in the preceding analysis, showing a growth of about 250%. It has been noted that almost 30% of the applications relate to herbal and ayurvedic medicines; such applications have even been filed by companies like Lupin and JB Chemicals. However, this is only the beginning of a triumphant journey, a successful end will be determined by how many of these are finally accepted and how many of these are picked up for commercialization. A good beginning portends good results.

Of the Indian applications filed, 114 applications were filed by Indian companies and the rest 52 by individuals. CSIR with 19 patent applications, ranks first among Indian companies and enjoys an overall 8th position jointly with Merck Patent. The CSIR applications relate to inventions for processes producing the following: oxindole as intermediate for producing the tenidap, an anti-inflammatory agent, analgesic analogous to enkephalin, vaginal contraceptive, 17-ketosteroids, dihydroasperoside and dihudrosiredloside, artmesnin, antibiotic from fermented froths, ciprofloxacin, organotin useful as cytotoxic agents, L-alanyl-l lysyl derivatives useful as antiasthmatic/antiallergic, pyridines as potent cardiovascular agents, codeinone, chloropropane and 2-piperidone useful as potential hypotensive agents, pyridine and 3-picoline, lipopolysaccharide (LPS), 7 methoxy deoxyvasicinone, 4-arylamino/alkylamino-4-demethylpodophyllotoxins as potential anticancer agents: and epichloromydrin. Three of the Lupin's applications concern anti-tubercular composition. Other applications include process for purification of atenolol (2-4-hydroxy-3-1) phenyl acetamide, process for extraction of hydroxycitric acid from fruit and garcinia species, process for the manufacture of ceftazidime, process for isomerization of N-7 isomer to N-9 isomer, process for the manufacture of 3-hydroxy- 3-cephem derivatives, process for manufacture of cephalosporin antibiotics such as cefazolin, a regiospecific process for synthesis of acyclic nucleosides and ayurvedic formulation from Amla and Ritha. Neam Herbal Remedies has focused on pre-cooked ayurvedic medicinal food and all the applications fall in this area. The applications from Dr. Reddy's Foundation relate to new heterocyclic compounds having antidiabetic, hypolipidaemic, antihypertensive properties, their preparation and pharmaceutical compositions containing them; benximidazole derivatives as antiulcer agents; novel heterocyclic compounds for treating diabetics and related problems; 4-hydroxy-10-deacetylbaccatin III derivatives; azolidinediones useful for the treatment of diabetes dyslipidemia and hypertension; podophyllotoxin analogues and their derivatives as anti-cancer and anti-viral agents. Applications filed by Hindustan Lever are not included under the Indian companies as all of these are convention applications. All the seven applications filed by the Indian citizens, P.B. Mathur et al, are ayurvedic medicines for reducing cholesterol and treating chronic diseases such as cough, acidity and gastritis, piles, sinusitis, and cold. Two of the Sun Pharmaceuticals' applications relate to antihypertensive fixed-dose

combination products while the other two are on topical antibacterial anaesthetic combinations. The remaining two applications are entitled ‘a process for the recovery of tramadol as cis-hydrochloride in asymptotically quantitative amount from mixtures of diastereomers of tramadol’ and ‘an improved process for the preparation of 1-(2,3-epoxypropyl)- 5-nitroimidazole’.

A few other Indian companies and institutions who have filed more than one application with the no. of applications filed given in brackets are Panacea Biotech (4), Ranbaxy Laboratories (4), Raptakos Brett & Co. (4), Tablets (India) Ltd. (4), National Institute of Immunology (3), Osmania University (3), Dabur Research Foundation (2), Hindustan Antibiotics (2), IIT (2), Sonic Biochem Extraction Pvt. Ltd. (2), Sree Chitra Tirunal Institute for Medical Science and Technology (2), and Themis Chemicals (2).

PATENTING OF LIVING ORGANISMS

Patenting Life? — An Introduction to the Issues

Once upon a time, we knew that animals were products of nature. We used them and “owned” them, but it was different from owning a pair of shoes. Animals could get up and walk away; shoes couldn’t. And unlike patent leather, you couldn’t patent a cow. Patents are about inventions, and since when had human beings invented an animal? Since 1984, if you believe Harvard University and the US Patent Office. For that waswhen Harvard applied for a patent on a genetically modified mouse, which was granted 4 years later, causing a big bang of controversy which soon reached the shores of Europe and whose ripples are still very much in evidence. For this was the first time it was officially decreed that an animal could indeed be classed as an invention. Moreover, it was a mouse specifically engineered to have an increased probability of suffering malignant tumours — for use as a “model” for studying human cancers and carcinogens.

Controversy in Europe

The combination of these two factors has raised human hackles far and wide. It generates surprisingly heated arguments wherever the issue is debated. The question of patenting “animate matter” has given long term headaches to the European Patent Office in Munich, and in March 1995, it led to the first ever rejection by the European Parliament of a European Commission Directive. A new draft EC Directive on patenting is currently being discussed in the early committee stages of the European Parliament, and is again the subject of deep seated controversy

between industry proponents and many diverse groups which include church groups, NGO's, environmental and animal welfare organisations, and also many doctors, farmers and ethicists.

Biotechnological Inventions — Products of Nature or Products of Industry?

You cannot patent a mere discovery. It must have a non-obvious "inventive step", and some specified practical application. Patent law was framed in an industrial context, and typically applied to objects, chemicals, designs and processes. Agriculture was seen as lying outside this realm. You could patent a mouse trap, but not a mouse. But, with the rise of biotechnology, a shift has occurred, partly in technical sense, and partly in our perceptions. Once it became possible to alter the genetic make up of living things, researchers could genuinely claim an "inventive step" in the organism itself. And since such research is expensive and easily copied, organisations wanted to patenting genetically modified organisms to protect their valuable investment. The key case concerned a micro-organism, perhaps only a small step from patenting biochemical products. It went right up to the US Supreme Court, who in 1980 ruled that "anything under the sun that is made by man" was patentable subject matter, which turned it into the giant leap which has set the trend ever since. But it was not until its implications began to extend from micro-organisms to warm and furry animals that the fundamental question dawned on people generally: were they right? Oncomice, transgenic sheep, or whatever: should we be patenting our fellow creatures at all? Isn't this violating something rather basic in our attitudes to nature, implying they are nothing more than machines for our use? We say we "own" animals, but what does this really mean? They have their own lives and freedom which we are surely to respect – simply as parts of nature alongside us, and, from a Christian perspective, as God's creatures each of inherent worth. For many, the heart of the problem is that to patent an animal includes it in the same category as mere mechanical objects. Is that symbolic association sending ourselves and our society entirely the wrong kind of signal? Patent expert Stephen Crespi suggests that living things are now regarded as "products of manufacture" and agriculture to be a kind of industry.

The Guidelines for Labelling of Genetically-Modified Foods

Pre-packed food must state in the list of ingredients for any soya or maize, which has been genetically-modified e.g., "produced from genetically-modified soya" or "produced from genetically modified maize" or, those words may display in footnote to the list of ingredients related by means of an asterisk (*) to the ingredient concerned e.g., soya * flour. *genetically-modified.

Some approaches proposed by the European Commission that leads to the following labelling:

1. Voluntary labelling (e.g., “this does not contain GMO…)” for certified non-GMO produce.

2. Mandatory labelling (e.g., “this contains GMO…”) for produce known to be of GMO origin or “this may contain…” in cases where material of GMO origin cannot be excluded but where no evidence of such material is available).

In order to make an educated decision on the matter, one needs to see the both sides of the issue.

Disadvantages

(a) Difficult to trace every use of GM technology. Unless you follow the farmer step by step, it is difficult to assess what has been modified, especially when the ingredients come from various farms.

(b) On what level should labeling be done? i.e., do you label beef as being GM if the grass the cow ate was sprayed with GM pesticides?

(c) Not economical for farmers to segregate their GM crops from conventional ones.

(d) Would cause trade barriers between countries. i.e., if Canada wanted to export foodstuffs to a country that had strict mandatory labeling on all GM foods, the receiving country may not accept the products if they have not been labeled appropriately.

Advantages

(a) Consumer knowledge of potential health concerns. i.e., allergens.

(b) Increased customer awareness. i.e., give them the choice of what to buy and eat such as for religious reasons or vegetarianism, etc.

(c) Economical for retailers to make two-tiered system of products : conventional and nonconventional. Can charge higher prices for conventional foods if there is a demand for it.

Social and Political Issues

Food is of particular interest when considering biotechnology. Because we take it into our bodies, we have a fundamental right to know what it is, how it was processed and that it is safe.

About 60 percent of our processed foods are genetically engineered. Therefore, it is important to concern about the pros and the cons sides of labeling genetically-modified foods.

Pros

European Union states that labeling must be applied to novel foods and their ingredients produced by means of genetic engineering when there is no substantial equivalence between a novel food and its original counterpart; when materials present in the novel food are not present in an equivalent non-modified product and may have consequences for the health of certain groups of people; when the novel food contains biotechnologically-derived material that may present ethical problems; and when living Genetically-Modified Organisms (GMOs) are present in the novel food (Nature biotechnology 16(10), 889, 1998 Oct).

In an Environics poll conducted in August 1999, 80 percent of respondents said they wanted labeling which told them what foods were Genetically Modified. Government and industry have responded with a voluntary labeling plan. That has some consumers dissatisfied. "I don't want to take the risk I would like to have them labeled, so that I can decide what I'm going to buy and not going to buy", "You hear about plants being altered with animal genetic material and vice versa. I don't know how that works but I'm really apprehensive about it". Therefore, consumer have the right to choose whether they want to buy GM food or not (Marketplace "Labeling Genetically Modified Foods" Dec. 7, 1999).

Lawsuit also argues that the Food and Drug Administration (FDA) should be treating genetic modifications as new food additives, which need to be tested for safety and approved before being sold. Moreover, the lawsuit claims that the agency should be treating all genetic modifications as additives (Nature "Lawsuit demands labels for modified foods", June 4, 1998). Consumers International (CI) says that labeling is not just an issue of health and safety, they are labeled to enable consumer choice. CI says that surveys from many countries indicate widespread public support for comprehensive labeling of GM foods, 92% of respondents to survey by the UK Consumers' Association wanted GM food to be labeled, regardless of the presence of a GM ingredient in the final produce (Nature "GM foods debate needs a recipe for restoring trust", 22 April, 1999).

Genetically-Modified Foods are inherently allergenic and/or harmful. By labeling, consumers have knowledge about the potential allergens and other health risks of the GM food. (UCT "The

Genetically-Modified Foods debate in South Africa" 22 May, 1999). The Government is determined that all food which contain Genetically-Modified material should be clearly labeled. Food will also require labeling if there are any health or ethical concerns or if it contains a labeling of ingredients derived from GM soya and maize. Committee on the Ethics of Genetic Modification and Food Use recommended that a GM food should be labeled if it contains a gene derived from a human, or from an animal which is the subject of religious dietary restrictions; or if is plant or microbial material containing a gene derived from an animal. These recommendations are now a legal requirement, having been implemented under the Novel Foods Regulation 1997.

Cons

Labeling requires the availability of a technique that can guarantee the detection of transgenic DNA and protein, however, the detection of transgenic DNA or protein is not an easy task, and currently there is no officially validated protocol available for use. Currently, a few private companies and public laboratories are offering a PCR-based method for the detection of traces of specific transgenic genes in soya and maize. It would also be necessary to establish threshold levels above which labeling should be mandatory.