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. I. SYBIYA VASANTHA PACKIAVATHY

SUBJECT NAME: BIODIVERSITY, BIOSAFETY AND IPR SUB.CODE: 19BTP105A

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	Molecular markers and their application in plant conservation	W1
8	1	National Biodiversity Authority	W1
9	1	Revision	W1
	Total No of Hours Planned for Unit I =09		
UNIT-II			
1	1	Introduction to Animal Rights.	J1
2	1	General issues related to environmental release of transgenic plants	W2
3	1	General issues related to environmental release of Transgenic animals	W3, J2
4	1	General issues related to environmental	W3, J2

		release of Transgenic microorganisms	
5	1	Ethical issues related to research in embryonic stem cell cloning	J3, J4
6	1	Human Genome Project	W4
7	1	Social Implications in HGP	W4
8	1	Discussion on ESE questions	
9	1	Unit test	
	Total Planned Hours for Unit II =9 hours		

UNIT III

1	1	Biological Safety cabinets	T1: 67-104
2	1	Primary containment for Biohazzards	T1: 67-104
3	1	Recommended Biosafety Levels	T1: 67-104
4	1	Cartagena protocol on biosafety	
5	1	Biosafety guidelines for Genetically Modified Micro organisms (GMM), GMP	T1:67-104
6	1	Risk assessment, guidelines for research activities	W5
7	1	Guidelines for environmental release of GMM, GMP and GLP	W5
8	1	GATT and World Trade Organizations	W5
9	1	Establishment and functions of GATT, WTO and WIPO, WTO Summits	W5
10	1	Roles of IBSC, RCGM and GEAC	W5
	Total No of Hours Planned for Unit III = 10		
UNIT-IV			
1	1	Types of IP, Patents , Trademarks	R1:19-78
2	1	Copyright and Related Rights	R1:19-78
3	1	Physiological and Intellectual Property	R1:19-78
4	1	Tangible and Intangible Property	R1:19-78
5	1	Agreement and Treaties, History of GATT	R1:19-78
6	1	TRIPS, Madrid Agreement	R1:19-78
7	1	Hague Agreement, WIPO Treaties	R1:19-78
8	1	Budapest Treaty, PCT	R1:19-78
9	1	Indian Patent Act 1970 and recent amendments	R1:19-78

10	1	International Patent Guideliness	R1:19-78
	Total No of Hours Planned for Unit IV = 10 hrs		

UNIT-V

1	1	Rules governing patents	J2, J5
2	1	Patent related cases	J2, J5
3	1	Licensing - Flavr Savr™ tomato as a model case	J2, J5
4	1	Biopiracy and case studies on patents- Basmati rice, Turmeric	W6, W7
5	1	Biopiracy and case studies on patents- Turmeric	W6, W7
6		Biopiracy and case studies on patents- Neem	W7
7	1	Biotechnological examples of patent , trademark	W9
		Biotechnological examples of Trade secret	W9
8	1	Biotechnological examples of copy right	W9
9	1	Traditional Knowledge	W9
	Total No of Hours Planned for Unit IV = 07		
Total Planned Hours	**48**		

TEXT BOOK

1. Laboratory Biosafety Manual (WHO)

REFERENCE BOOKS

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

WEBSITE

1. www.ugc.ac.in>oldpdf>chapter4
2. http://nepad-abne.net/environmental-biosafety/gmos-and-environment/
3. http://www.adelaide.edu.au
4. https://ncbi.nlm.nih.gov
5. www.uabc.ac/sites
6. www.sdpi.org>w37-Biopiracy
7. www.mondaq.com
8. www.acc.com/infopaks

JOURNALS

1. The ethics of Research involving animals ful report.pdf
2. http://www.planetnaturals.com/
3. Biosafety of Genetically Modified Organisms

Semester – I

19BTP105A BIODIVERSITY, BIOSAFETY AND IPR 4H-4C

Instruction Hours / week: L: 4 T: 0 P: 0 **Marks:** Internal: **40** External: **60** Total: **100**
End Semester Exam: 3 Hours

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 (CO's):

1. Knowing the biosafety, IPR and biodiversity aspects would help the student to 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. National Biodiversity Authority.

UNIT –II 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.

UNIT – III 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. Roles of IBSC, RCGM and GEAC.

UNIT –IV Intellectual Property Rights:
Types of IP: Patents, Trademarks, Copyright and Related Rights. Physical and Intellectual Property. Tangible and Intangible property. **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, International Patent guidelines.

UNIT – V 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.

Suggested Readings

1. Gaston, K.J. &Spicer, J.I. (2013) *Biodiversity: An Introduction* (2nd ed.). Wiley-Blackwell Publishers, New Jersey, United States.

2. National Biodiversity Authority of India. http://nbaindia.org/

3. Ministry of Environment, Forest and Climate Change, India. http://moef.gov.in/environment/biodiversity/

4. Biodiversity and Conservation. http://ncert.nic.in/ncerts/l/lebo115.pdf

5. U.S. Department Of Health And Human Services. (2016). Biosafety in Microbiological and Biomedical Laboratories. Lulu Publishers, North Carolina , United States.

6. Goel, D. & Parashar, S. (2013). *IPR, Biosafety and Bioethics* (1st ed.). Pearson Publishers, London, United Kingdom.

7. Transgenic Crops-Biosafety Concerns and Regulations in India. http://vikaspedia.in/agriculture/crop-production/advanced-technologies/transgenic-crops-biosafety-concerns-and-regulations-in-india

8. GEAC India. http://geacindia.gov.in/resource-documents/biosafety-regulations/guidelines-and-protocols/GuidelinesfortheERAofGEplants.pdf

9. Llewelyn, D. & Aplin, T. (2019). Intellectual Property: Patents, Copyrights, Trademarks & Allied Rights (9th ed.). Sweet & Maxwell Publishers, London, United Kingdom.

10. Office of the Controller General of Patents, Designs & Trade Marks, India. http://www.ipindia.nic.in/

11. Intellectual Propertry India. The Patents Act, 1970. http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_31_1_patent-act-1970-11march2015.pdf

12. World Intellectual Property Organization. http://www.wipo.int/portal/index.html.en

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

14. Legal and Public Aspects of Biotechnology. http://www.actahort.org/members/showpdf?booknrarnr=447_125.

15. IPR in UK. https://www.wilsongunn.com/guide-to-ip/

16. Balasubramaniam, S. (2017). India: Traditional Knowledge And Patent Issues: An Overview Of Turmeric, Basmati, Neem Cases. http://www.mondaq.com/india/x/586384/Patent/Traditional+Knowledge+And+Patent+Issues+An+Overview+Of+Turmeric+Basmati+Neem+Cases

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).

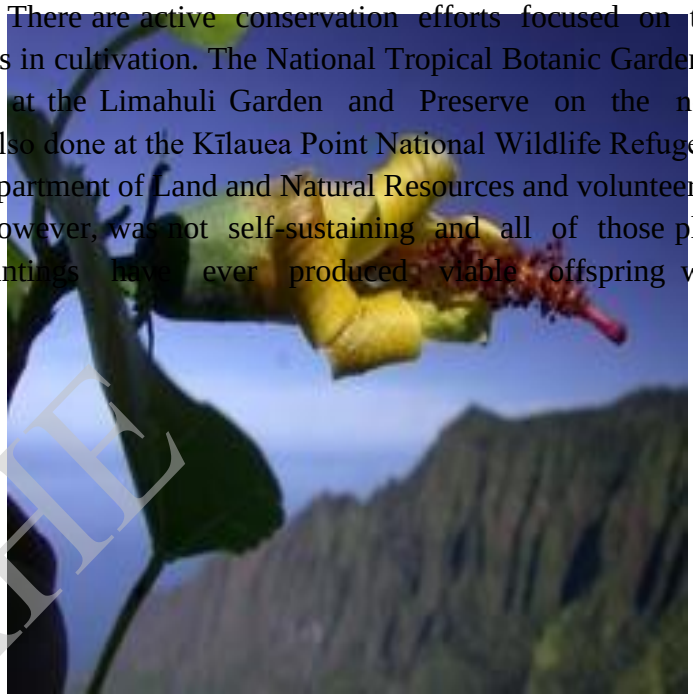
Along with 19 other Brazilian plants, the original assessment for Eryngium fluminense is written and published on The IUCN Red List in Portuguese, marking the start of non-English language assessments being included on The IUCN Red List.

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 km^2) 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 Kauʻi. 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).

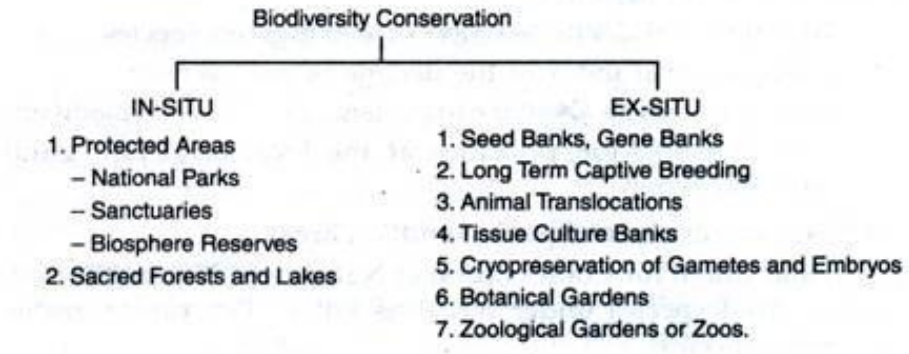
Conservation biodiversity - In situ and ex situ methods

Conservation is the protection, preservation, management, or restoration of wildlife and natural resources such as forests and water. Through the conservation of biodiversity and the survival of many species and habitats which are threatened due to human activities can be ensured. There is an urgent need, not only to manage and conserve the biotic wealth, but also restore the degraded ecosystems.

Types of Conservation:

Conservation can broadly be divided into two types:

1. In-situ conservation
2. Ex-situ conservation



In-situ Conservation:

In-situ conservation is on site conservation or the conservation of genetic resources in natural populations of plant or animal species, such as forest genetic resources in natural populations of tree species. It is the process of protecting an endangered plant or animal species in its natural habitat, either by protecting or cleaning up the habitat itself, or by defending the species from predators.It is applied to conservation of agricultural biodiversity in agro forestry by farmers, especially those using unconventional farming practices.

In-situ conservation is being done by declaring area as protected area.
1. National parks
2. Wildlife sanctuaries
3. Biosphere reserves

INDIA has over 600 protected areas, which includes over 90 national parks, over 500 animal sanctuaries and 15 biosphere reserves.

1. National Parks:

A national park is an area which is strictly reserved for the betterment of the wildlife and where activities like forestry, grazing on cultivation are not permitted. In these parks, even private ownership rights are not allowed.Their boundaries are well marked and circumscribed. They are usually small reserves spreading in an area of 100 Sq. km. to 500 sq. km. In national parks, the emphasis is on the preservation of a single plant or animal species.

2. Wildlife Sanctuaries:

A sanctuary is a protected area which is reserved for the conservation of only animals and human activities like harvesting of timber, collecting minor forest products and private ownership rights are allowed as long as they do not interfere with well-being of animals. Boundaries of sanctuaries are not well defined and controlled biotic interference is permitted, e.g., tourist activity.

3. Biosphere Reserves:

It is a special category of protected areas where human population also forms a part of the system. They are large protected area of usually more than 5000 sq.km. A biosphere reserves has 3 parts- core, buffer and transition zone.

1. **Core zone** is the inner zone; this is undisturbed and legally protected area.

2. **Buffer zone** lies between the core and transition zone. Some research and educational activities are permitted here.

3. **Transition zone** is the outermost part of biosphere reserves. Here cropping, forestry, recreation, fishery and other activities are allowed.

The main functions of biodiversity reserves are:

1. Conservation:

To ensure the conservation of ecosystem, species and genetic resources.

2. Development:

To promote economic development, while maintaining cultural, social and ecological identity.

3. Scientific Research:

To provide support for research related to monitoring and education, local, national and global issues. Biosphere reserves serve in some ways as 'living laboratories' for testing out and demonstrating integrated management of land, water and biodiversity.

Advantages of in-situ conservation:

1. The flora and fauna live in natural habitats without human interference.
2. The life cycles of the organisms and their evolution progresses in a natural way.
3. In-situ conservation provides the required green cover and its associated benefits to our environment.
4. It is less expensive and easy to manage.
5. The interests of the indigenous people are also protected

Ex-Situ Conservation:

Ex-situ conservation is the preservation of components of biological diversity outside their natural habitats. This involves conservation of genetic resources, as well as wild and cultivated or species, and draws on a diverse body of techniques and facilities. Such strategies include establishment of botanical gardens, zoos, conservation strands and gene, pollen seed, seedling, tissue culture and DNA banks.

1. Seed gene bank:

These are cold storages where seeds are kept under controlled temperature and humidity for storage and this is easiest way to store the germ plasma of plants at low temperature. Seeds preserved under controlled conditions (minus temperature) remain viable for long durations of time.

2. Gene bank:

Genetic variability also is preserved by gene bank under normal growing conditions. These are cold storages where germ plam are kept under controlled temperature and humidity for storage; this is an important way of preserving the genetic resources.

3. Cryopreservation:

This is the newest application of technology for preservation of biotic parts. This type of conservation is done at very low temperature (196°C) in liquid nitrogen. The metabolic activities of the organisms are suspended under low temperature, which are later used for research purposes.

4.. Tissue culture bank:
Cryopreservation of disease free meristems is very helpful. Long term culture of excised roots and shoots are maintained. Meristem culture is very popular in plant propagation as it's a virus and disease free method of multiplication.

5. Long term captive breeding:
The method involves capture, maintenance and captive breeding on long term basis of individuals of the endangered species which have lost their habitat permanently or certain highly unfavorable conditions are present in their habitat.

6. Botanical gardens:

A botanical garden is a place where flowers, fruits and vegetables are grown. The botanical gardens provide beauty and calm environment. Most of them have started keeping exotic plants for educational and research purposes.

7. Animal Translocation:

Release of animals in a new locality which come from anywhere else.

Translocation is carried in following cases:
1. When a species on which an animal is dependent becomes rare.
2. When a species is endemic or restricted to a particular area.
3. Due to habit destruction and unfavorable environment conditions.
4. Increase in population in an area.

8. Zoological Gardens:
In zoos wild animals are maintained in captivity and conservation of wild animals (rare, endangered species). The oldest zoo, the Schonbrumm zoo which exists today also, was established in VIENNA in 1759.In India, the 1st zoo came into existence at BARRACKPORE in 1800. In world there are about 800 zoos. Such zoos have about 3000 species of vertebrates. Some zoos have undertaken captive breeding programmes.

Advantages of ex-situ preservation:
1. It is useful for declining population of species.
2. Endangered animals on the verge of extinction are successfully breeded.
3. Threatened species are breeded in captivity and then released in the natural habitats.
4. Ex-situ centres offer the possibilities of observing wild animals, which is otherwise not possible.
5. It is extremely useful for conducting research and scientific work on different species

In- situ Conservation	Ex-situ Conservation
It means onsite conservation.	It means offsite conservation.
It is the conservation of wild species in their natural habitats in order to maintain and recover endangered species.	It is conservation of species in the man-made habitats that imitate the natural habitats of species.
It is more dynamic as it involves natural habitats of organisms.	It its less dynamic as it involves man-made habitats.
It provides protection to endangered species against predators.	It provides protection against all hostile factors.
It is suitable for animals that are found in abundance.	It is suitable for animals that are not found in abundance.
It is not suitable in the event of a rapid decline in the number of a species due to environmental, genetic or any other factor.	It is an ideal option in case of rapid decline in the number of a species due to environmental or any other reason.
Wildlife and livestock conservation involve in-situ conservation.	It can be used to conserve crops and their wild relatives.
Examples include national parks, wildlife sanctuaries, biospheres reserve etc.	Examples include zoo, aquarium and botanical garden.
It involves designation, management and monitoring of the target species in their natural habitat.	It involves sampling, storage and transfer of target species from their natural habitats to man-made habitats.
It helps maintain the ongoing process of evolution and adaptation within the natural environment of the species.	It separates the animals form the ongoing process of evolution and adaptations within their natural environment.

National Biodiversity Authority (NBA)

The National Biodiversity Authority (NBA) is a statutory autonomous body under the Ministry of Environment , Forests and climate change, Government of India established in 2003 to implement the provisions under the Biological Diversity Act, 2002, after India signed Convention on Biological Diversity (CBD) in 1992. Headquartered in Chennai, India. It acts as a facilitating, regulating and advisory body to the Government of India "on issues of conservation, sustainable use of biological resources and fair and equitable sharing of benefits arising out of the use of biological resources. Additionally, it advises State Governments in identifying the areas of biodiversity importance (biodiversity hotspots) as heritage sites.

In 2012, NBA organised the first ever National Biodiversity Congress (NBC), held at Thiruvananthapuram, Kerala. Since its establishment, NBA has supported creation of SBBs in 29 States and facilitated establishment of around 1,39,831 BMCs. The National Biodiversity Authority is mandated to regulate access to biological resources and / or associated knowledge for research, bio-survey and bio-utilization, commercial utilization, obtaining Intellectual Property Rights, transfer of results of research and transfer of accessed biological resources.

UNIT-II

SYLLABUS

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.

Genetic engineering (GE) and genetically modified organisms (GMOs) provide powerful tools for sustainable development in agriculture, healthcare and many other industries. GMOs are those which were genetically engineered in a laboratory by incorporating a small foreign DNA fragment carrying a gene of interest into the native DNA of the organism. The foreign gene is attached with the necessary regulatory elements to help its expression in the new genetic environment. This expression pattern may be different from its original expression to the extent that GMO may overproduce, under produce, differently produce or may not produce the protein it has been known to produce. Until recombinant-DNA is engineered in a laboratory and transferred into an organism, it is within the confines of the specialized laboratory with skilled scientists and people handling the GMO who are trained to deal with the positive and negative outputs as well the unperceived consequences which may comprise of the risks involved.

When it comes out of the laboratory confinement, the element of riskassociated with it passes into the hands of those who may not be aware about the unique features of the GMO or who may not have complete understanding of the technologies used. Hence, GMO requires to be handled within the confinements until it is established by tests and trials that its release into the environment would not be harmful. Even post-release monitoring plays a crucial role in

environmental risk assessment and management, and it is undertaken to gather information on long-term effects of the GMO on the environment.

GE has been successfully used to increase the level of particular protein, enzyme or series of enzymes in microbial cells, plants and animals. Some of the achievements of GE and GMO technologies include production of life-saving drugs in microorganisms, use of genetically modified (GM) crops and animals in agriculture, use of GM plants and animals as bioreactors for production of enzymes and chemicals for industrial uses, production of biodegradable plastics, development of biosensors, superbug etc. for tackling some of the environmental problems.

GE has been used for crop improvement to enhance resistance to insect pests, diseases, abiotic stresses and to improve nutritional quality of the produce. Increased crop yields and better food quality have reduced world hunger and malnutrition. In addition to these, it reduces the use of agrochemicals and environmental pollutions.

Instead of extensive mixing of genes as occurs in conventional breeding, GE enables targeted gene transfer from one organism to other. The genome of recipient individual remains intact, except for the introduced gene. Moreover, GE makes it possible to transfer a gene across natural barriers, thereby creates “universal gene pool” accessible to all the organisms.The use of genetically modified (GM) animals in basic research.

A systematic approach to the description of GM phenotypes is crucial for assessing and monitoring welfare implications, and for undertaking thorough cost-benefit assessments.

Humans have a variety of different relationships with animals. They bring pleasure to our lives as companions, and when we observe them in their natural environment, or in zoos and wildlife parks. In some cultures, certain animals are thought to have religious significance and are treated with special reverence. But we also use animals extensively for food, clothing, transport and sports such as racing or hunting.1 Animals are sometimes culled to maintain stable populations in natural ecosystems, or killed when they come into conflict with humans. For example rats, flies and mosquitoes are generally considered to be pests. These examples show clearly that the relationships between humans and animals differ in terms of the benefits they bring to humans, and their effects on the welfare of the animals.

Research involving animals is varied in both its nature and purpose, in the types of animals involved and in the effect that it has on them. At its least harmful, it takes the form of passive observations of wild animals in their natural habitats. Scientists also observe animal behaviour under laboratory conditions. Such studies may have a negative impact on the animals‟ welfare if they are kept in an environment that is incompatible with their species specific needs. Certain invasive laboratory techniques may affect the welfare of animals in relatively mild ways. For example, some pharmaceutical research requires the repeated taking of blood samples. More harmful research, such as testing the safety of novel medicines (toxicology), may cause substantial pain and suffering. Almost all laboratory animals are killed once experiments are complete; in some cases research is undertaken on anaesthetised animals that are killed before they recover consciousness. In the UK, any „procedures‟ involving vertebrates (and the common octopus) that may cause „pain, suffering, distress or lasting harm‟ must be licensed by the Home Office. The term „procedure‟ is a technical term that covers more than just the conditions entailed by an experiment (or series of experiments). Procedures also include specific conditions relating to the breeding, handling and housing of laboratory animals that may affect their welfare.

ETHICAL CONSIDERATIONS IN STEM CELL RESEARCH

General remarks

The entire field of biomedical research and technique is changing very fast. It is therefore necessary to try and find basic or fundamental principles that apply generally, and to avoid a situation where ad hoc rules are set up only to be quickly overtaken by further developments.

Stem cell research includes both theoretical (or basic) and applied (or practical) aspects. The main intended benefits are:

a) Theoretically, advancing understanding of tissue differentiation, development, repair and ageing.

b) Practically, the therapeutic use of undifferentiated tissue for organ/tissue replacement or repair.

The distinction between theoretical and applied research, in any field, is one of time scale. In the long run, theoretical advances find application. In the short term, research can address immediate problems. Others problems may arise unanticipated, however. If we knew the outcome of research in advance, we would not have to do it in the first place.

Therefore, the benefits of research, like its results, cannot be completely specified in advance. The costs, similarly, cannot always be foreseen. Such costs may include ethical and social costs.

Ethical and social issues arise to some extent whenever scientific research is carried out, because the outcome affects people. In particular, such issues arise in biomedical research because the interests of potential beneficiaries may compete with, and may have to be considered together with costs to society or to other individuals, such as donors.

There are relatively clear-cut guidelines on research ethics available elsewhere, e.g. US NIH guidelines on research on human embryonic stem cells.

Medical practitioners have obligations to individual patients, and therapeutic or preventive application of research findings has to be moderated on a case by case basis, such that there is a clear and identifiable benefit and no important general principle is contravened.

Then boundary between therapeutic, preventive, and non-therapeutic intervention is difficult to mark clearly. For example, the principle of intervention to improve on natural genetic endowment would seem to have been established by some uses of cosmetic plastic surgery (for example, breast enhancement). Similarly, recourse to abortion as a method of family planning is only loosely therapeutic, (on the argument that proceeding to term jeopardises the mother‟s mental state) and is primarily a quality of life issue.

Stem cell research raises a number of such issues, which seem to fall naturally into two groups:

c) Issues surrounding the origins of stem cells, in particular, the use of embryo stem cells. Even if it is assumed or determined that the source embryos would never have been enabled to develop as individuals, the use of such tissues does raise assumptions about the status of embryos which

have to be addressed. Similarly any claim that no further recourse to embryos is needed does not remove the obligation to address the issues, since the need may still recur. In any event moral principles have retrospective application, though the passage of time may blunt their urgency in particular cases.

d) Issues relating to the use of stem cell tissue. In general the issues are similar to those relating to organ donation and focus on the need for appropriate regulation. Stem cell research also prompts consideration of the potential non-therapeutic use of biomedical techniques, which might also include cloning, genetic modification, and artificial fertilization. These techniques allow the power to intervene actively in the physical creation, maintenance, alteration or repair of humans. In so doing they call into question many of the conventional assumptions about the propriety of interfering with the creation or modification of people. They may also be seen as threatening the conventional structure of families. It should be noted that these ethical issues do not hinge upon a distinction between what is natural and what is not. There is no necessary convergence between what is natural and what is best, though there may be (for example, in recommending mothers to breast feed). In its entirety, medical science is concerned with interventions, whether preventive, therapeutic, surgical, emergency, or aimed at improvin g quality of life and recommending healthy lifestyle choices. In this sense, it is never natural, though it is ultimately based on the scientific study of natural biological phenomena.

The origins of stem cells and the use of embryos

Stem cells may come from the sacrifice of embryos, or from adults in the form of umbilical cord or bone marrow tissue donations. There is some difference of opinion as to the merits and potential of stem cell lines from these respective sources, and the extent of likely future requirements for embryos. Balance of opinion appears to be that embryo stem cells have greater potence and potential for therapeutic use than adult cells. However, the ethical issues need to be considered anyway. As regards adult sources of stem cells the sourcing is not very controversial and is considered under the issue of regulation. Acceptability of the use of human embryo tissue for stem cell supply is more controversial. Such use raises ethical issues centred on the question of whether or not human embryos can be regarded as disposable for benevolent

purposes. An embryo used for the sake of its stem cell tissue is not able to develop to term, and a potential human being is denied existence. Regularising the use of embryos in this way in effect devalues their future human potential in favour of their immediate value as a source of tissue . This is not necessarily an unjustifiable priority, since no realistic possibility of development may ever have existed, but it certainly needs to be examined. The extent to which an embryo should be regarded as having a right to life is disputed and raises strong views, even though an embryo is by definition not a foetus.

Issues relating to the use of stem cell tissue

Normally the keeping or disposal of human organs or tissue is treated with respect or even reverence, because it is a part of some individual person, or even a complete person, and because it is normally evidence of death. The exception is when organs or tissues are donated. A stock of stem cell tissue has somewhat the character of a stock of blood in a blood bank. Taken together, developments in transplant technology and stem cell research might be held to undermine the idea that there is anything special about human tissue per se. Rather, it supports thee view that tissue is quite separate from the individuals whom it comprises. This argument is developed in 20-23 below. Over time, the constituent cells of the body, other than neurons, replace themselves. Even neurons, however, grow and alter their synaptic connections. These facts make it impossible to reduce an individual¨s identity to a collection of tissues, because these tissues change over time though the person they instantiate does not. People are therefore defined by the integrated action of their tissues. If the function of a tissue is maintained, its physical embodiment can change without prejudice to the integrity of the person as a whole. Some, in defining a person, would wish to argue an additional immaterial but essential constituent such as a soul or a mind. Others of a more materialist persuasion might feel that we have no need for recourse beyond the fully functioning brain to account for individuality. In either case, however, there would be wide agreement that integrated functioning is important for a coherent person to exist, i.e. that it is the nature of the system as a whole and not merely its parts that is important. This reflects a shift from structure to function as the defining mark of a person. If this is granted, it follows that tissue derived from stem cells can be used to repair or construct body organs, as can artificial materials, without any ethical complications arising from an unnecessary sense of residual ownership. For example, if animal tissues, say, or artificial

hearts, or synthetic blood, functioned equivalently to the corresponding E4 - 6 natural human article, they could be used in therapeutic ways without incurring any ethical dilemmas. Tissues are just tissues. Clearly some implications of this dissociation of tissues from people as individuals could offend taste or religious belief. For example, many people might find the idea of animal tissues or organ transplants distasteful, or in some cases prohibited by their religions, but taste and prohibitions are not ethical issues. Treatment is voluntary and no one need undergo a procedure they find unacceptable. Tissue donation and organ transplants have been generally recognised as acceptable. The exceptions tend to be belief systems generally hostile to medical or surgical interventions, preferring in principle other forms of therapeutic intervention, or none. No-one, however, is compelled to accept medical or surgical interventions, and debate tends to arise only over in the case of minors, where the beliefs of parents or guardians can conflict with the rights of minors as recognised in law. A further implication is that an individual does not retain ownership of tissue once donated, nor do they have any unique claim on the benefits of research. This does not preclude arrangements analogous to autologous blood donations in any situation in which stem cells could appropriately be maintained for the benefit of the donating individual. Examples of acceptable donations and their ethical justification include: w) Blood donation: immediate saving of life, minimal risk to donor. x) Bone marrow transplants: long term saving of life or delaying death. Slight operative risk to donor. y) Kidney donation: long term saving of life, sparing the expense and inconvenience of dialysis; some operative risk to donor and recipient, and long term loss of reserve function in donor, who has to rely on a single remaining kidney. z) Organs donated upon death of the donor: long term saving of life at no cost to the donor; some potential pain or distress to relatives in the process of securing permission where required (i.e. other than under prearranged donation schemes), or where relatives may object to donation for their own reasons irrespective of the donor‟s wishes. The ethi cal principles that apply in cases like this can be summarised as follows:

aa) Donor choice. People are free to donate tissue or organs. However, as there may be a risk to the donor, this choice should be one made freely. For this reason donations are not acceptable where there is a conflict of interest such that a donor might feel impelled to donate despite a health disadvantage. Examples arise when tissue or organs are sold, or donated for a consideration. Only autologous or unpaid anonymous donations avoid this problem.

bb) Donor information. It is necessary that donors be clear, and if necessary reassured, as to the scope and limitations of use of donated tissue, including their agreement to relinquish rights over the tissue and the research or treatments that use it, which have to be determined by research and clinical criteria. E4 - 7

cc) Donor competence. When the donor is incompetent, being dead, or not of sound mind, decisions have to be made by proxy. The default is that donation does not occur unless the law provides for an alternative default or other provisions have been made. The donation of stem cell tissue by consenting informed adult donors, whether for research or therapeutic purposes, does not seem to raise additional ethical issues per se, over and above those inherent in donation generally. The risks are low, or non-existent. In general, therefore, the issues of regulation appear very much capable of accommodation within the rules applicable to organs, and there need be no qualms about research with, or therapeutic use of, adult stem cell tissues. Non-therapeutic use of biomedical techniques Emerging biotechnologies, including stem cell research, offer the potential for proactive use of technology to actually design or improve humans, as opposed to

therapeutic uses that correct defects, repair injuries, or cure diseases. This implies a great increase in the control that can be exerted over people and society. How then is this control to itself be regulated? This is the concern that lies behind the catchphrase „playing God". It may be noted that the concern is over the design. For example, we at present grant parents more or less unlimited rights to produce accidental children by unassisted natural reproductive processes. To illustrate the problems raised by proactive genetic engineering consider the following hypothetical scenario. If we could in fact freely specify the genotype - as affecting characteristics, personality, ability, physical form and gender of our infants - what restrictions would we want to put upon that choice, and how administer them? If we take a time frame of, say, 20 years, it is by no means clear that this scenario is entirely hypothetical. However, it is instructive to try and imagine, given relatively unlimited power of design, the ways in which we might then see reasons to curb it.

dd) Possibility of choice raises the possibility of losing it and substituting totalitarian control.

ee) The interests of parents may conflict with each other, or their children, or state interests (e.g. gender choices under a one child policy).

ff) Ignorance of pleiotropic genetic effects or interactions might subvert good intentions.

gg) It undermines the notion of individual autonomy to (in effect) create designer children, because the designer (parent, doctor, etc.) carries the responsibility for the kind of person created.

hh) The intentions of parties may not necessarily be benevolent. ii) Insofar as an argument from what is natural has any force, it has force in arguing for a conservative approach to engineered change, because human nature, being a product of evolutionary pressures, is an integrated whole. Piecemeal „improvement" may prove undesirable in the long run in unforeseen ways.

jj) Those who reject an evolutionary approach for religious reasons would however see engineered change as ethically objectionable or even blasphemous because it usurped the role of the creator.

ELSI

According to the 1991-1992 Progress Report of the National Center for Human Genome Research, ELSI aims to develop programs addressed at understanding the project's ethical, legal, and social implications and to define major issues and develop policy to address them.

Knowledge gained through the genome project can be used by scientists in many ways: to unravel the pathogenesis of a disorder or understand the expression of a normal human trait, to develop clinical tests for disease or trait-specific forms of the gene, and to detect chemical-specific patterns of genetic changes.

But the effects of getting and using this knowledge create tough choices for nearly everyone. The progress report elaborates:

* Individuals and families must decide whether to participate in testing, with whom to share the results, and how to act on them.

* Health professionals must decide when to offer testing, how to ensure its quality, how to interpret the results, and to whom they disclose information.

* Employers, insurers, the courts, and other social institutions must decide the relative value of genetic information in the decisions they make.

* Governments must decide how to regulate production and use of genetic tests and the resulting information and how to make testing and counseling services accessible.

* Society must decide how to improve public understanding of science and its social implications and increase public participation in science policy making.

Concerns

The presymptomatic DNA-based diagnosis would seemingly eliminate much pain and suffering. It also, according to Jasny's Science editorial, "poses a challenge to a society that has not demonstrated a clear ability to evaluate risks and make reasoned choices."

Knowledge about whether someone has a genetic tendency toward a disease could invite social prejudices, a 1988 National Academy of Sciences report said. Health insurance companies could use genetic information to reject people who might be inherently risky investments, for example, or employers could reject prospective employees for similar reasons. In November, a committee of the Institute of Medicine of the National Academy of Sciences released a report outlining policy guidelines and legislative recommendations designed to "avoid involuntary and ineffective testing and to protect confidentiality."

The report, Assessing Genetic Risks: Implications for Health and Social Policy, identifies concerns such as quality control measures, including federal oversight for testing laboratories, and better genetics training for medical practitioners. It also recommends such measures as voluntary screening and genetic counseling for couples in high-risk populations and urges caution in using and interpreting presymptomatic or predictive tests. Also needed, according to the report, are increased public education about genetics and a national advisory committee to set genetic testing standards.

Thomas Murray summarizes these and other ethical concerns in "Ethical Issues in Human Genome Research," from The Ethical Dimensions of the Biological Sciences. "The most important movement in the ethics of workplace genetic testing," Murray writes, "has been away

from the original vision of a public health measure to screening as a way of reducing illness related costs with no effect on the overall incidence of disease."

Employee illness in the United States costs employers money. Growing health insurance costs are prompting employers to look for ways to reduce costs like health insurance, disability insurance, lost productivity, and training of replacement workers for skilled positions. Increased employer concerns about the costs of illness and the prospect of genetic tests that reveal predispositions to disease, Murray adds, "are fertile ground for the use of such tests to screen workers." Other factors may prompt insurers to use genetic tests. Once the tests become available, people can be tested privately to learn about their risks for disease. Those who are at risk are likely to buy insurance and in larger amounts. Competition among insurance companies will drive companies to genetic screening. A company that uses such tests would be able to give lower rates to those with no genetic predisposition to disease and higher rates to those at risk.

UNIT-III

SYLLABUS

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. Roles of IBSC, RCGM and GEAC.

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Biosafety

Biological Safety Cabinets

A biosafety cabinet (BSC)—also called a biological safety cabinet or microbiological safety cabinet—is an enclosed, ventilated laboratory workspace for safely working with materials contaminated with (or potentially contaminated with) pathogens requiring a defined biosafety level

Primary Containment for Biohazards

Biological Safety Cabinets (BSCs) are among the most effective and the most commonly used primary containment devices in laboratories working with infectious agents. The three general types available (Class I, II, III) have performance characteristics and applications which are described in this appendix. Properly maintained Class I and II BSCs, when used in conjunction with good microbiological techniques, provide an effective containment system for safe manipulation of moderate and high-risk microorganisms (Biosafety Level 2 and 3 agents). Both Class I and II BSCs

have inward face velocities (75-100 linear feet per minute) that provide comparable levels of containment to protect laboratory workers and the immediate environment from infectious aerosols generated within the cabinet. Class II BSCs also protect the research material itself through high-efficiency particulate air filtration (HEPA filtration) of the airflow down across the work surface (vertical laminar flow). Class III cabinets offer the maximum protection to laboratory personnel, the community, and the environment because all hazardous materials are contained in a totally enclosed, ventilated cabinet

Class I

The Class I Biological Safety ventilated cabinet usually operated with an open front and a minimum face velocity at the work opening of at least 75 linear feet per minute (lfpm). All of the air from the cabinet is exhausted through a HEPA filter either into the laboratory or to the outside. The Class I BSC is designed for general microbiological research with low and moderate-risk agents, and is useful for containment of mixers, blenders, and other equipment. These cabinets are not appropriate for handling research materials that are vulnerable to airborne contamination, since the inward flow of unfiltered air from the laboratory can carry microbial contaminants into the cabinet. The Class I BSC can also be used with an installed front closure panel without gloves, which will increase the inward flow velocity to approximately 150 lfpm. If such equipped cabinets are ducted to the outside exhaust, they may be used for toxic or radiolabelled materials used as an adjunct to microbiological research. Additionally, arm-length rubber gloves may be attached to the front panel with an inlet air pressure release for further protection. In this configuration, it is necessary to install a make-up air inlet fitted with a HEPA filter in the cabinet.

2. Class II

This Biosafety Cabinet is designed to provide personal, product and environmental protection when used properly.The Class II Biological Safety Cabinet is designed with inward airflow at a velocity to protect personnel (75-100 lfpm), HEPA-filtered downward vertical laminar airflow for product protection, and HEPA-filtered exhaust air for environmental protection. Design, construction, and performance standards for Class II BSCs, as well as a list of products that meet these standards, have

been developed by and are available from the National Sanitation Foundation International, Ann Arbor, Michigan. Utilization of this standard and list should be the first step in selection and procurement of a Class II BSC. As with any other piece of laboratory equipment, personnel must be trained in the proper use of the biological safety cabinets. Of particular note are activities that may disrupt the inward directional airflow.

- Sweeping sideways motion of hands in cabinet create eddies in airflow
- Repeated insertion and withdrawal of the workers' arms into and out of the work chamber
- Opening and closing doors to the laboratory or isolation cubicle
- Improper placement or operation of materials or equipment within the work chamber
- Brisk walking past the BSC while it is in use
- Improper placements of BSC in the lab room.

Class I and II cabinets should be located away from traffic patterns and doors. Airflow from fans, room air supply louvers and other air moving devices can disrupt the airflow pattern at the face of the cabinet. Strict adherence to recommended practices for the use of BSCs and their proper placement in the laboratory are as important in attaining the maximum containment capability of the equipment, as is the mechanical performance of the equipment itself.

Class III

The Class III Biological Safety Cabinet is a totally enclosed, ventilated cabinet of gas-tight construction and offers the highest degree of personnel and environmental protection from infectious aerosols, as well as protection of research materials from microbiological contaminants. Class III cabinets are most suitable for work with hazardous agents that require Biosafety Level 3 or 4 containment. All operations in the work area of the cabinet are performed through attached arm length rubber gloves or half-suits. The Class III cabinet is operated under negative pressure. Supply air is HEPA-filtered and the cabinet exhaust air is filtered through two HEPA filters in series, or HEPA filtration followed by incineration, before discharge outside of the facility.The Class III cabinet must be connected to a double-doored autoclave and/or chemical dunk tank used to sterilize or disinfect all materials exiting the cabinet, and to allow supplies to enter the cabinet. Several Class

III cabinets are therefore typically set up as an interconnected system.

Recommended Biosafety Levels

Biosafety Level	Practice Technique	Safety Equipment	Facilities
1	Standard Microbiological practices	None: Primary containment provided by adherence to standard laboratory practices during open bench work.	Basic
2	Level 1 practices plus: laboratory coats; decontamination of all infectious wastes; limited access; protective gloves and biohazard warning signs as indicated.	Partial containment equipment (e.g., Class I or II Biosafety Cabinets) used to conduct mechanical and manipulative procedures that have high aerosol potential that may increase the risk of exposure to personnel.	Basic
3	Level 2 practices plus: special laboratory clothing; controlled access.	Partial containment equipment used for all manipulations of infectious materials.	Containment
4	Level 3 practices plus: entrance through a change room where street clothing is removed and laboratory clothing is put on; shower on exit; all wastes are decontaminated on exit from the facility.	Maximum containment equipment (e.g., Class III Biosafety Cabinet or partial containment equipment in combination with full-body, air-supplied, positive-pressure personnel suit) used for all procedures and activities.	Maximum Containment

Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety is a legally binding protocol to the Convention on Biological Diversity (CBD). It was named in honor of Cartagena, Colombia, where negotiations were expected to conclude in February 1999. One year later, on January 29, 2000, the Protocol was finalized and adopted in Montreal, Canada by unanimous consent with 135 countries present.

It assists developing countries in building their capacity for managing modern biotechnology

- It creates an advanced informed agreement (AIA) procedure that requires exporters to seek consent from importing countries before the first shipment of LMOs meant to be introduced into the environment (e.g. seeds for planting, fish for release, and microorganisms for bioremediation)

- It establishes an internet-based "Biosafety Clearing-House" to help countries exchange scientific, technical, environmental and legal information about LMOs.
- It requires bulk shipments of LMO commodities, such as corn or soybeans that are intended to be used as food, feed or for processing, to be accompanied by documentation stating that such shipments "may contain" LMOs and are "not intended for intentional introduction into the environment".
- The Protocol includes a clause that makes clear the Parties' intent that the agreement does not alter the rights and obligations of governments under the World Trade Organization (WTO) or other existing international agreements.

I)Advanced Informed Agreement (AIA)

The Protocol's main mechanism is its Advanced Informed Agreement (AIA) requirement. It is a procedure that must be followed before the first intentional transboundary movement of an LMO into the environment of the importing country. The exporter must provide a notification to the importing country containing detailed information about the LMO, previous risk assessments of the LMO and its regulatory status in the exporting country. The importing country must acknowledge receiving the information within 90 days and whether the notifier should proceed under a domestic regulatory system or under the Protocol procedure. In either case, the importing country must decide whether to allow the import, with or without conditions or deny it within 270 days.

II) Biosafety Clearing-House (BCH)

The BCH is a website administered by the Secretariat to the Convention (http://bch.biodiv.org). It was established to:

- facilitate the exchange of scientific, technical, environmental and legal information on, and experience with LMOs; and
- assist Parties to implement the Protocol.

Examples of information contained in the BCH include: any existing laws, regulations, or guidelines for implementation of the Protocol, summaries of risk assessments or environmental reviews of LMOs, and final decisions regarding the importation or release of LMOs.

III) Risk Assessment

The Protocol requires that decisions on proposed imports be based on risk assessments.

- ✓ Risk assessments must be undertaken in a scientific manner based on recognized risk assessment techniques, taking into account advice and guidelines developed by relevant international organizations.
- ✓ Lack of scientific knowledge or scientific consensus must not necessarily be interpreted as indicating a particular level or risk, an absence or risk, or an acceptable risk.
- ✓ Risks associated with LMOs or products thereof should be considered in the context of risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.
- ✓ Risk assessment should be carried out on a case by case basis.

IV) Capacity Building

The Protocol promotes international cooperation to help developing countries acquire resources and capacity to use biotechnology safely and regulate it efficiently. It does this by encouraging member governments to assist with scientific and technical training to promote the transfer of technology, knowledge and financial resources. Governments are also expected to facilitate greater involvement of the private sector.

V) Public Awareness

Member governments must commit themselves to promoting public awareness, insuring public access to information, and public consultation. The Protocol recognizes that national measures are important to make its procedures effective. Nations must also take measures to prevent illegal shipments or accidental releases of LMOs.

Biological Risk Assesment

Biosafety guidelines

Biosafety Guidelines in Genetic Engineering and Biotechnology for Laboratory Work,Nov. 1993.
As a standard practice, genetically manipulated organisms from laboratory work must be field tested before planned commercial application or planned release into the environment. Such genetic manipulation field work is meant to address the following, underlying objectives:

1. To confirm the observations made during laboratory work, and the results from tests conducted at the laboratory level

2. To gather accurate information/data on the stability, transmission/heredity and expression of transgenes under field conditions

3. To assess the viability (e.g. survival, propagation, competitive ability) ofgenetically manipulated organisms under field conditions

4. To assess the adaptive or evolutionary potential of genetically manipulated organisms under changing environmental conditions

Biosafety guidelines for Genetically Modified Micro organisms (GMM)

Work with genetically modified plants must first take into consideration the nature or character of the biological system, as follows:

For experimental plants, considered to have a history of safe use in field work asfollows, let work proceed in accord with the basic standards appropriate to the particular plant.

A. Modified plants that result from conventional breeding practices (e.g. selective breeding, mutagenesis, protoplast fusion or embryo rescue

B. Genetically modified plants, having inherent characteristics typical of modified plants from conventional breeding practices.

C. Plants, with genetic inserts that are known to be harmless and inoffensive to the environment.

For experimental plants which do not meet the conditions mentioned above, let work proceed under the appropriate containment level and criteria,:

A. There is no cross-hybridization.

B. There are arrangements to contain the dispersal of plants and plant materials.

C. Introduced gene expression is stable, and does not fluctuate with changing environmental conditions

Biosafety guidelines for Genetically Modified Plants (GMM)

Microorganisms from a strain that has been involved in previous, documented field work.

Microorganisms which perform the same functions as strains that have been involved in previous, documented field work.

Microorganisms which are confined to sites and surroundings that resemble previous field conditions

Environmental Release of Genetically modified organisms

What Are GMOs?

GMOs (genetically modified organism) are the result of a laboratory process where genes from the DNA of one species are extracted and artificially forced into the genes of an unrelated plant or animal. The foreign genes may come from bacteria, viruses, insects, animals or even humans. Because this involves the transfer of genes, GMOs are also known as "transgenic" organisms

According to World Health Organization, the main ecological concerns related to GMOs are:

- The capability of the GMO to escape and potentially introduce the engineered genes into wild populations
- The susceptibility of non-target organisms (e.g. insects which are not pests)to the gene product
- The stability of the gene
- The reduction in the spectrum of other plants leading to loss of biodiversity
- The increased use of chemicals in agriculture
- The report prepared by the Law Centre of IUCN, the World Conservation Union (2004), enlists numerous environmental risks likely to occur by the use of GMOs in the field.

These risks are as follows;

Genetic Contamination/Interbreeding

Introduced GMOs may interbreed with the wild-type or sexually compatible relatives. The novel trait may disappear in wild types unless it confers a selective advantage to the recipient. However, tolerance abilities of wild types may also develop, thus altering the native species' ecological relationship and behaviour.

Competition with Natural Species

Faster growth of GMOs can enable them to have a competitive advantage over the native organisms. This may allow them to become invasive, to spread into new habitats, and cause ecological and economic damage.

Increased Selection Pressure on Target and Non target Organisms

Pressure may increase on target and nontarget species to adapt to the introduced changes as if to a geological change or a natural selection pressure causing them to evolve distinct resistant populations.

Ecosystem Impacts

The effects of changes in a single species may extend well beyond to the ecosystem. Single impacts are always joined by the risk of ecosystem damage and destruction.

Impossibility of Follow-up

Once the GMOs have been introduced into the environment and some problems arise, it is impossible to eliminate them. Many of these risks are identical to those incurred with regards to the introduction of naturally or conventionally bred species. But still this does not suggest that GMOs are safe or beneficial, nor that they should be less scrutinized.

Horizontal Transfer of Recombinant Genes to Other Microorganisms

One risk of particular concern relating to GMOs is the risk of horizontal gene transfer (HGT). HGT is the acquisition of foreign genes (via transformation, transduction, and conjugation) by organisms in a variety of environmental situations. It occurs especially in response to changing environments and provides organisms, especially prokaryotes, with access to genes other than those that can be inherited.

At present the main ecological concerns related to Genetically Engineered Organism are related to GMO crops and plants.

These are:

1. Firstly, toxicity is a huge issue surrounding chemical pesticides and herbicides, used commonly with GMOs, in addition to the toxicity inherent to these plants. GMOs may be toxic to non-target organisms, bees and butterflies being the most talked-about examples currently. Bees are hugely important in the pollination of many food crops, but are unfortunately extremely endangered by modern agricultural techniques, such as GM crops. Monarch butterflies are specifically at risk from GMO maize plants. In addition to bees and butterflies, birds are also at risk from pesticides, and work as biological control agents and pollinators, again, like bees.

2. The longterm effects of GMOs are not certain. Pests that are targeted by these agricultural methods can adapt to pesticides and herbicides, in addition to the DNA changes in GM plants to make them ¨resistant.¨ This means that they will not always be effective, but their toxic legacies will remain.

3. Cumulative effects of products such as GMOs are important to take into consideration. Evidence also suggests that small genetic changes in plants may produce even larger ecological shifts, meaning that there is potential for GMO 織 s to become persistent and weedy in agricultural conditions, since they are modified to be resistant to some modern agricultural techniques. This can also mean being invasive in natural settings, where GMOs, of course, do not occur naturally. It is not impossible for new, human modified, plants to become invasive species in delicate, natural ecosystems.

4. Biodiversity is put at risk by GMOs. When GM crops are planted, generally in a monocrop fashion, many heritage seeds are no longer used. The nature of GMOs means fewer weed flowers and, therefore, less nectar for pollinators. Toxins released into the soil through the plants´ routes mean fewer soil bacteria, which are integral to healthy soil for plants to grow without the use of chemical fertilizers. Toxic residues are left in the soil of GM crops. Nutrients are not returned to the soil in mono crops and from GMO foods, meaning that soil is becoming dry and void of all nutrients, generally integral to the growing process. A cycle of dependence on GMO seeds and chemical fertilizers, pesticides, and herbicides is then created in order to grow a single crop. In addition to soil issues, the irrigation used to grow GM foods naturally carries all of these problems into water sources and into the air. This exposes different bacteria, insects, and animals to the same problems.

Environmental issues and GM forest trees

Research on the genetic modification of forest trees is undertaken almost exclusively with a view to application in plantation forestry. One of the first reported trials with GM forest trees was initiated in 1988 using poplars. Since then, there have been more than 100 reported trials in at least 16 countries, involving at least 24 tree species - mostly timberproducing species for use in intensively managed plantations. There is no reported commercial-scale production of GM forest trees.

Traits for which genetic modification can realistically be contemplated in the near future include insect and virus resistance, herbicide tolerance and modified lignin content. Investments in GM technologies should be weighed against the possibilities of exploiting the large amounts of generally untapped genetic variation that are available within forest tree species in nature.Biosafety aspects of GM trees need careful consideration because of the long generation time of trees, their important roles in ecosystem functioning and the potential for long-distance dispersal of pollen and seed.

Environmental law and provisions related to GMOs

The Rules for Manufacture, Use, Import, Export, and Storage of Hazardous Micro-organisms, Genetically Engineered Organisms or Cells, 1989 promulgated under the Environment (Protection) Act, 1986 was entered into force on 13 September 1993

The Rules purport to protect the environment, nature and health in relation with the application of gene technologies and micro-organisms. They regulate 'genetically engineered organisms , micro-organisms, cells and any substance, and products and foodstuffs etc. of which such cells, organisms or tissues form part (rule 2(2)). The Rules extends to the following activities

(a) sale, offer for sale, storage for the purpose of sale, offers and any kind of handling over with or without a consideration;

(b) exportation and importation of genetically engineered cells or organisms

(c) production, manufacturing, processing, storage, import, drawing off, packaging and replacing of the genetically engineered products;

(d) production, manufacture etc. of drugs and pharmaceuticals and food stuffs, distilleries and tanneries etc. which make use of genetically engineered micro-organisms in one way or other [rule 2(4)].

The two main agencies responsible for implementation of the rules are the Ministry of Environment and Forests (MoEF) and the Department of Biotechnology (DBT), Government of India. The rules have also defined competent authorities and the composition of such authorities for handling of various aspects of the rules.

There are six competent authorities as per the rules:

1. Recombinant DNA Advisory Committee (RDAC): The Recombinant DNA Advisory Committee (RDAC) constituted by DBT takes note of developments in biotechnology at national and international level and prepares suitable recommendations.

2. Review Committee on Genetic Manipulation (RCGM)

3. Genetic Engineering Approval Committee (GEAC)

4. Institutional Biosafety Committees (IBSC)

5. State Biosafety Coordination Committees (SBCC): The State Biotechnology Coordination Committees (SBCCs) set up in each state where research and application of GMOs are contemplated, coordinate the activities related to GMOs in the state with the central ministry. SBCCs have monitoring functions and therefore have got powers to inspect, investigate and to take punitive

action in case of violations.

6. District Level Committees (DLC): District Level Committees (DLCs) are constituted at district level to monitor the safety regulations in installations engaged in the use of GMOs in research and application.

Out of these, the three agencies that are involved in approval of new transgenic crops are:

a) IBSC set-up at each institution for monitoring institute level research in genetically modified organisms. This committee is to assist the occupier or any person including the research institution in handling micro-organisms or genetically engineered organisms in preparing an upto date site emergency plan according to the manuals/ guidelines of RCGM and make available copies of the District Level Committee/ State Biotechnology Coordination Committee and Genetic Engineering Approval Committee.

b) RCGM functioning in the DBT to monitor ongoing research activities in GMOs and small scale field trials. It functions are to monitor safety related aspects in respect of research or projects, bring about guidelines specifying procedures for regulatory process, review on-going process and to lay down procedures restricting or prohibiting sale or production or import etc.

c) GEAC functioning in the MoEF to authorize large-scale trials and environmental release of GMOs. The Committee works under the Department of Environment Forest and Wildlife and has power to take punitive action under Environment (Protection) Act.

The approvals and prohibitions under Rules 1989 are summarized below

1. No person shall import, export, transport, manufacture, process, use or sell any GMOs, substances or cells except with the approval of the GEAC.

2. Use of pathogenic organisms or GMOs or cells for research purpose shall be allowed under the Notifi cation, 1989 of the EPA, 1986.

3. Any person operating or using GMOs for scale up or pilot operations shall have to obtain permission from GEAC.

4. For purpose of education, experiments on GMOs IBSC can look after, as per the guidelines of the Government of India.

5. Deliberate or unintentional release of GMOs not allowed.

6. Production in which GMOs are generated or used shall not be commenced except with the approval of GEAC

7. GEAC supervises the implementation of rules and guidelines.

8. GEAC carries out supervision through SBCC, DLC or any authorized person.

9. If orders are not complied, SBCC/DLC may take suitable measures at the expenses of the person who is responsible.

10. In case of immediate interventions to prevent any damage, SBCC and DLC can take suitable measures and the expenses incurred will be recovered from the person responsible.

11. All approvals shall be for a period of 4 years at fi rst instance renewable for 2 years at a time.

12. GEAC shall have powers to revoke approvals in case of:

Any new information on harmful effects of GMOs.

GMOs cause such damage to the environment as could not be envisaged when approval was given.

Non-compliance of any conditions stipulated by GEAC

Conclusion

Genetic Engineering is the technique by which heritable materials which do not usually occur or will not occur naturally in the organism or cell concerned generated outside the organism of the cell is inserted into said cell or organism. It also means the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally as well as a modification of an organism or in a cell by delegation and removal of parts of the heritable material. Thus, A genetically modified organism (GMO) also called Genetically Engineered Organisms, are organisms in which the genome, that is the DNA which determines its characteristics, has been modified by human intervention.

The ecological concerns of GMOs stem from our inability to control them (or their environment) once “released” into nature and no longer subjected to the strict controls possible in a laboratory setting Growing concerns include: their toxicity level, The susceptibility of non-target organisms, effect of reduction in biodiversity. Since, the creation and release of GMOs has a huge impact on the environment and thus it falls in the domain of environmental law.

Various efforts have been made in form of international and regional treaties and domestic legislations to deal with the adverse effects of GMOs. Indian environmental jurisprudence has also

deal with this issue and has introduced number of provisions to deal with the concerns related to genetically engineered organism.

GATT

The General Agreement on Tariffs and Trade was a free trade agreement between 23 countries that eliminated tariffs and increased international trade. It was the first worldwide multilateral free trade agreement. It was in effect from January 1, 1948 until January 1, 1995. It ended when it was replaced by the more robust World Trade Organization.

Purpose

The purpose of GATT was to eliminate harmful trade protectionism. That had sent global trade down 65 percent during the Great Depression. GATT restored economic health to the world after the devastation of the depression and World War II.

Three Provisions

GATT had three main provisions. The most important requirement was that each member must confer most favored nation status to every other member. All members must be treated equally when it comes to tariffs. It excluded the special tariffs among members of the British Commonwealth and customs unions. It permitted tariffs if their removal would cause serious injury to domestic producers.

Second, GATT prohibited restriction on the number of imports and exports. The exceptions were:

- When a government had a surplus of agricultural products.
- If a country needed to protect its balance of payments because its foreign exchange reserves were low.
- Emerging market countries that needed to protect fledgling industries.

In addition, countries could restrict trade for reasons of national security. These included protecting patents, copyrights, and public morals.

The third provision was added in 1965. That was because more developing countries joined GATT, and it wished to promote them. Developed countries agreed to eliminate tariffs on imports of developing countries to boost their economies. It was also in the stronger countries' best interests in the long run. It would increase the number of middle-class consumers throughout the world.

WTO

The Uruguay round of GATT (1986-93) gave birth to World Trade Organization. The members of GATT singed on an agreement of Uruguay round in April 1994 in Morocco for establishing a new organization named WTO. It was officially constituted on January 1, 1995 which took the place of GATT as an effective formal, organization. GATT was an informal organization which regulated world trade since 1948.

Contrary to the temporary nature of GATT, WTO is a permanent organization which has been established on the basis of an international treaty approved by participating countries. It achieved the international status like IMF and IBRD, but it is not an agency of the United Nations Organization (UNO).

Structure

The WTO has nearly 153 members accounting for over 97% of world trade. Around 30 others are negotiating membership. Decisions are made by the entire membership. This is typically by consensus.

The WTO's top level decision-making body is the Ministerial Conferences which meets at least once in every two years. 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 Disputes Settlement Body.

Secretariat:

The WTO secretariat, based in Geneva, has around 600 staff and is headed by a Director-General. Its annual budget is roughly 160 million Swiss Francs. It does not have branch offices outside Geneva. Since decisions are taken by the members themselves, the secretariat does not have the decision making the role that other international bureaucracies are given.

The secretariat s main duties 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 important objectives of WTO are:

1. To improve the standard of living of people in the member countries.
2. To ensure full employment and broad increase in effective demand.
3. To enlarge production and trade of goods.
4. To increase the trade of services.
5. To ensure optimum utilization of world resources.
6. To protect the environment.
7. To accept the concept of sustainable development

The main functions of WTO are;

1. To implement rules and provisions related to trade policy review mechanism.
2. To provide a platform to member countries to decide future strategies related to trade and tariff.
3. To provide facilities for implementation, administration and operation of multilateral and bilateral agreements of the world trade.
4. To administer the rules and processes related to dispute settlement.
5. To ensure the optimum use of world resources.
6. To assist international organizations such as, IMF and IBRD for establishing coherence in Universal Economic Policy determination

World Intellectual Property Organization

The World Intellectual Property Organization (WIPO) is the United Nations specialized agency. It seeks to develop a balanced and accessible International Intellectual Property system, which rewards creativity, stimulates innovations, and contributes to economic development while safeguarding public interests.

Intellectual Property (IP) refers to creations of the mind: literary and artistic works, inventions, symbols, names, images, and designs used in commerce.

The WIPO is the oldest organization in the field of IP protection. Actually, it was created at the diplomatic conference in 1893. The two offices applying the administrative functions of the Paris

Convention for the Protection of Industrial Property and Bern Convention for the Protection of Literary and Artistic Works united in a single entity — the United International Bureau for the Protection of Intellectual Property.

The member states wanted to make this International Bureau a fully fledged intergovernmental organization. That is why in 1967 in Stockholm the WIPO was created through the signing of the Convention. The WIPO is headquartered in Geneva (Switzerland).

In 1974 the WIPO became a UN specialized agency. Under the agreement, the WIPO should stimulate creativity and promote IP protection all over the world through the cooperation between countries.

Currently, the WIPO includes 184 member-states. It is made up of more than 90 per cent of all countries. The WIPO Director General is Harry Francis.

The WIPO main functions are:

1. Assisting campaigns development to improve IP protection all over the world and to harmonize national legislations in this field;
2. Signing international agreements on IP protection;
3. Applying the administrative functions of the Paris and Berne Unions;
4. Rendering technical and legal assistance in the field of IP;
5. Collecting and disseminating the information, conducting researches and publishing their results;
6. Ensuring the work of the services facilitating the international IP protection;
7. Applying any other appropriate action

Function of various Regulatory Authorities of India

Review Committee for Genetic Modification RCGM:

The function of this committee is to frame the regulations for the institutions involved in rDNA research activities and

i. to review the on-going researches involving hazardous microorganisms

ii. to visit the experimental site and ensure that the trial is being carried out as per the guidelines,

iii. to advice the custom authority on import of microorganism and G.M. products.

Principal Investigator (PI): The principal investigator of the company is primarily responsible for ensuring compliance with biosafety standards. The PI functions as a project manager as well as a researcher, communicating with the IBSC and bearing responsibility for training and supervising personnel. His functions include:

1. to make an initial determination of the required levels of physical and biological containment in accordance with the DBT guidelines.
2. to submit the initial research protocol and any subsequent changes (such as changes in the source of DNA or host vector system) to the IBSC for review and approval.
3. . to ensure that no work is initiated until the research project has been approved by the IBSC and has met all requirements of DBT guidelines.
4. remain in communication with the IBSC throughout the conduct of the project.
5. to ensure the safe conduct of the rDNA experiments in his laboratory
6. to make available the protocols that describe the potential biohazards and the precautions to be taken to all laboratory staff.
7. to instruct laboratory staff about the practices and techniques required to ensure safety, and the procedures for dealing with accidents including the reasons and provisions for any precautionary medical practices advised or requested (e.g. vaccinations or serum collection).
8. to supervise the performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
9. to undertake corrective measures promptly for any work errors and conditions that may result in the release of recombinant DNA materials.

Institutional Biosafety Committee (IBSC): IBSC is the nodal point of interaction within a commercial organization/applicant company involved in rDNA research for the implementation of

rDNA guidelines. IBSC has to furnish half yearly reports on the ongoing projects in the organization to RCGM regarding the observance of the safety guidelines including accidents, risks and deviations, if any. IBSC functions include:

1. To bring out manuals of guidelines specifying producers for regulatory process on GMOs in research, use and applications including industry with a view to ensure environmental safety
2. To review all ongoing r-DNA projects involving high risk category and controlled field experiments.
3. To lay down producers for restriction or prohibition, production, sale, import & use of GMOs both for research and applications.
4. To permit experiments with category III risks and above with appropriate containment.
5. To authorize imports of GMOs/ transgenes for research purposes. vi. to authorize field experiments in 20 acres in multi-locations in one crop season with up to one acre at one site.
6. To generate relevant data on transgenic materials in appropriate systems.
7. To undertake visits of sites of experimental facilities periodically, where projects with biohazard potentials are being pursued and also at a time prior to the commencement of the activity to ensure that adequate safety measures are taken as per the guidelines.
8. To adopting emergency plans.

State Biotechnology Coordination Committee (SBCC): The function of this committee is mainly to

i. to inspect, investigate and has the power to take punitive action in case of violations of statutory provisions through the State Pollution Control Board or the Directorate of Health etc.

ii. to review periodically the safety and control measures in various institutions handling GMOs.

iii. to act as nodal agency at State level to assess the damage, if any, due to release of GMOs and to take on site control measures. The Committee coordinates the activities related to GMOs

in the State with the Central Ministries. This committee also nominates State Government representatives in the activities requiring field inspection of activities concerning GMOs.

Genetic Engineering Approval Committee (GEAC): The main function of this committee is to approve or deny various activities. In the cases of large-scale field trials, deregulation and commercialization, a permission of GEAC constituted under the MoEF is required in addition to the DBT approval process. Precisely, approval of the GEAC is required from the environmental angle on:

1. Import, export, transport, manufacture, process, selling of any microorganisms or genetically engineered substances or cells including food stuffs and additives that contain products derived by gene therapy.

2. Discharge of genetically engineered/classified organisms/cells from Laboratory, hospitals and related areas into environment.

3. Large-scale use of genetically engineered organisms/classified microorganisms in industrial production and applications. Production can only be commenced after obtaining such approval. iv. Deliberate release of genetically engineered organisms.

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.

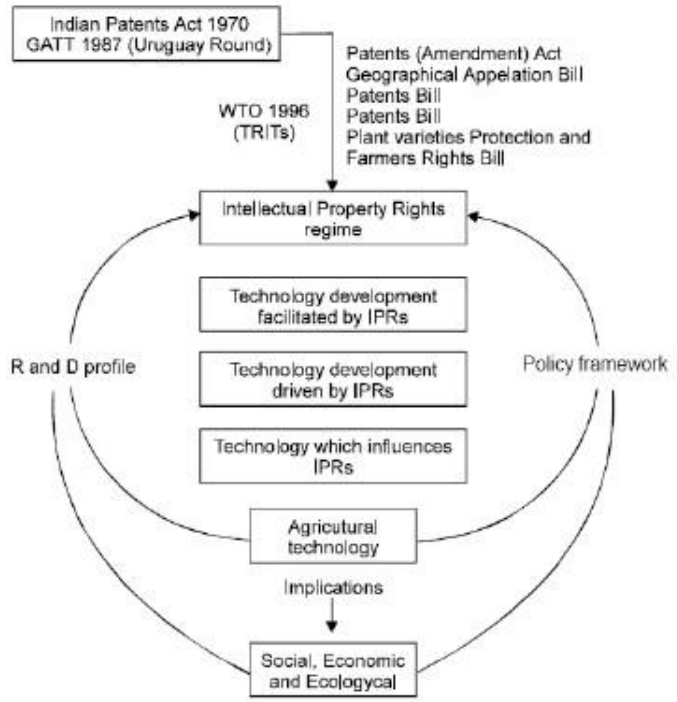
Ultimately, only the courts can decide whether something is original, but there is much case law indicating, for example, that names and titles do not have sufficient substantiality to be original and that, where an existing work is widely known, it will be difficult to convince a court that there has 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-V

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

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.

The term environment literally means……..	The surroundings	The structures	The system	The climate	The surroundings
The Primary consumer are also called as	herbivores	carnivores	omnivores	detrivores	herbivores
Valuable, practical services that help to preserve ecosystem performed by nature are called_____	ecosystem service	biological control	the green house effect	biosphere balancing	ecosystem service
The surrounding physical and biological factor with which organisms closely interact and remain adapted is known as	nature	ecology	forest	environment	environment
The organic matter produced by the Photosynthetic activity of green plants is called as _____	light energy	cellular process	energy flow	primary productivity	primary productivity
The species rich ecosystem	Marine ecosystem	Terrestrial ecosystem	Special Ecosystem	Extra terrestrial ecosystem	Marine ecosystem
The most fundamental level of biodiversity	Genetic diversity	Species diversity	Population	Diversity	Genetic diversity
The lowest species diversity in the tropical areas……..	Eastern Atlantic	Eastern Pacific	Western Atlantic	Indo-Pacific Region	Eastern Atlantic
Physically India is divided into…….	Four region	Seven region	Five region	Two region	Four region
Some species play ecological roles that are of great importance than predicted…….	primary species	Keystone species	Climax species	Decomposers	Keystone species
People love, live, a phenomenon called…….	Spirituality	Meditation	Peace	Biophilia	Biophilia
Three important issues of biodiversity…….	Commodity, Amenity, and Morality	Genus, species and population	Community, diversity amd ecosystem	Flora, Fauna and Humans	Commodity, Amenity, and Morality
Total identifies species on theearth……	1.5 million	5-30 million	3 million	10 million	1.5 million
Two biodiversityhotspots in India……	Gangetic and Western Himalayas	Western Ghats and Eastern Himalayas	Peninsular and Vindhyas	J&K and Rajasthan	Western Ghats and Eastern Himalayas
Total biodiversity hotspots in the world……..	25	2	15	50	25
Levels of biodiversity include all but one……	Genetics	Species	Population	Ecosystem	Population
The type of diversity including all the different kinds of living things found in a certain habitat is called as……	Species diversity	Genetic diversity	Ecosystem diversity	Population diversity	Species diversity
A taxon with restricted geographical distribution is termed as?	Rare	Vulnerable	Extinct	Endemic	Endemic
Conservation of biodiversity outside the natural habitat is called as……..	Ex-situ	In-situ	Conservation	In-vivo	Ex-situ
Which of the following does not come under the threatened categories?	Endangered	Vulnerable	Least concern	Rare	Least concern
Biosphere reserve has following zone except one…….	Core zone	Command zone	Buffer zone	Spherical zone	Spherical zone
In which of the following boundaries are not circumscribed……	Biosphere reserve	Sanctuary	National parks	Colony parks	Sanctuary
The knowledge of which of the following factor does not help in the wildlife Management…….	Habitat of wildlife	Behaviour of wildlife	Food habit of wildlife	Name of wildlife	Name of wildlife
In _____ type of wildlife management the wildlife is protected from hunting mainly during breeding season and is enforced by law and if violated is punishable and termed as	Closed season	Open wildlife season	Custodial management	Limited entry zone	Closed season
The tigers are found in which of the following biosphere reserve:	Thar desert biosphere reserve	Neelgiri biosphere reserve	Namdhapa biosphere reserve	Sunderbans biosphere reserve	Sunderbans biosphere reserve
How many biosphere reserves are present in India ?	41	34	14	17	14
Biodiversity of which organism is more in Eastern Ghat in comparison to Western Ghat ?	Reptilia	Amphibian	Aves	Mammals	Amphibian
Which one of the following is not used for *ex situ* plant conservation?	Field gene banks	Seed banks	Shifting cultivation	Botanical Gardens	Shifting cultivation
Which one is odd for species diversity ?	alpha diversity	gamma diversity	beta diversity	lamnda diversity	lamnda diversity
Which micro organism is responsible for synthesis of antibiotics ?	Bacteria	Virus	Fungus	Algae	Fungus
Species diversity is responsible for which phenomena ?	process of Evolution	speciation	For alternative types (allele) of gene	For stability and normal function of Ecosystem	For stability and normal function of Ecosystem

How many botanical gardens are registered in IABG ?	1500	80,000	800	900	800
Which of the following represent maximum number of species among global biodiversity?	Algae	Lichens	Fungi	Mosses and Ferns	Fungi
Prolonged liberal irrigation of agricultural fields is likely to create the problem of……	Aridity	Metal toxicity	Salinity	Acidity	Salinity
The greatest problem of water conservation is to reduce the amount of……	Precipitation	Runoff water	Groundwater	Evaporation	Runoff water
Maximum nutritional diversity is found in the group……	Monera	Plantae	Fungi	Animalia	Monera
Which regions are included in Biodiversity Hot-spot ?	Sanctuary	National park	Garden	Only Hotspot	Sanctuary
Which one is odd for India ?	7th rank in agriculture species	origin place of 166 species of crop plants	Primary centre for domestication of ginger, turmeric, citrus, cardamom	It contains 12 mega biodiversity region	7th rank in agriculture species
Which one is endangered member of flora	Drosera indica	One horned rhino	flying squirrel	Crane	Drosera indica
For which animal sunderbans is declared as a National Park ?	Lion	Rhino	Tiger	Wild ass	Tiger
Which one is odd for Amzon rain forest ?	Africa	Russia	Mauritius	Java	Java
Among the recently extinct animal, Guagga is of which country ?	Mammals-472	Reptile-427	Birds-1300	piceis-3000	Mammals-472
Which organisation is active for conservation of biodiversity at world level ?	WWF	WCU	a and b both	EE	a and b both
The most widely used group of disinfectants and antiseptics are	Phenols	Alcohol	Halogens	Heavy metals	Alcohols
Which animal is remnant gene pool in the world ?	Flamingo	Painted Frog	Wild ass	Spring tailed Lizard	Wild ass
Find odd one out :	Nanda devi	Great Nicobar	Mannar	Thar	Thar
Which is the example of ex-situ conservation ?	National park	Sanctuary	Biosphere reserve	Zoo	Zoo
Which is true for wild life conservation ?	Hunting of prey	ex-situ conservation	In-situ conservation	ex-situ conservation and In-situ conservation	ex-situ conservation and In-situ conservation
At which place animals and plants are most protected ?	Botanical gardens	National Park	Zoos	Sanctuary	National Park
Which is not applicable institute conservation ?	National Park	Sanctuary	Botanical Garden	Biosphere reserve	Botanical Garden
What is called the area which is remain around the core zone of biosphere region ?	Buffer	Transition zone	Developed zone	Peripherial zone	Buffer
Which is the Hot spot of India ?	Gangatic plain	Western Ghat	Eastern Ghat	Arravali mountain	Western Ghat
Which is the most appropriate method for conservation of wild life ?	Vaccination	Hybridization	conservation in natural habitat	Killing of predator	conservation in natural habitat
Where Mangroves forest found ?	Dry region	Coastal region	Open area	tropical region	Coastal region
Where is the genes of rare plants species to stored ?	Gene bank	Gene Library	Herberium	Open area	Gene bank
For which animal Project Gir is famous ?	Elephant	Hangul	Tiger	Lion	Lion
MAB means ….....	Man and biosphere programme	Mammal and biological programme	Mammal and biosphere programme	Men and biological programme	Man and biosphere programme
Who publish Red-list ?	WWF	IUCN	MAB	IBWL	IUCN
In India different types of mangoes species are example of …..	species diversity	Genetic diversity	Induced mutation	Breeding	Genetic diversity
Which number is correct for Indentfied popular species ?	1.1 to 1.1 million	0.5 to 1.0 million	2.5 to 3.0 million	1.7 to 1.8 million	1.7 to 1.8 million
IUCN means ….....	International union for conservation of nature and natural resources	Indian union for conservation of nature and natural resources	International union for conservation of nature and nutrients resources	Indian Union chemical nomenclature	International union for conservation of nature and natural resources
In India, which example has maximum varieties ?	Wheat	Rice	Mango	Tea	Mango

In India, Western ghat is known as Hot-spot because of …..	Evergreen forest	High endemism	more height	Topical climate	High endemism
What is important of gene diversity ?	Maintenance of species	speciation	Research of genetic code	Maintenance and research of spices	speciation
Which is the modern concept of conservation ?	Biosphere reserve	sanctuary	National park	Protected forest	Biosphere reserve

UNIT II

The worldwide increase of development and use of new technology to increase the yield of food crops is termed the	Industrial Revolution	Agricultural Revolution	Green Revolution	Medical Revolution	Green Revolution
The greatest single disadvantage of planting a single crop would be	Monoculture	Soil erosion	Attraction of pests	Depletion of soil nutrients	Depletion of soil nutrients
Plants which are able to synthesize their own food substances are called	Autotrophs	Heterotrophs	Saprophytes	Anaerobes	Autotrophs
A condition when fields remain unplanted for several years in order to regain moisture and nutrients.	Rotation	Terracing	Fallowing	Desertification	Fallowing
The range of animal and plant species and the genetic variability of these species are referred to as	Biosphere	Biodiversity	Survival of the fittest	Biomagnification	Biodiversity
The continent with the most serious food shortages is	Europe	Africa	Australia	South America	Africa
E.coli is a	Gram negative bactrium	Gram positive bactrium	Not bacterium	Virus	Gram negative bactrium
If a host other than E.coli is to be used, what property of DNA to be inserted is disadvantageous?	Circular DNA	Linear DNA	Replicating DNA	Non Relicating DNA	Replicating DNA
If plasmids direct their own transfer from one bacterium cell to another, then they are called as:	Self-transmissible	Auto - transmissible	Autonomously replicating	Auto transfer	Self-transmissible
If a plasmid can't be transferred from one cell to another, then it is called as	Non-transmissible	Non-mobilizable	Untransferrable	Immobilized	Non-mobilizable
Choose the incorrect statement for shuttle vectors.	These are vector hybrids constructed from E.coli and other plasmids	They are having a varied use	They can replicate and selected in both the species	They are the plasmids which are having naturally broad host range	They are the plasmids which are having naturally broad host
Which of the bacteria are used as hosts?	Gram positive only	Gram negative only	Both are preferred equally	Both can be used but gram positive is preferred	Both can be used but gram positive is preferred
Basically, there are how many methods for introduction of DNA into the bacterial cells?	1	2	3	4	3
Competence is determined by the excretion of	Cellular high molecular weight proteins	Cellular low molecular weight proteins	Extracellular low molecular weight proteins	Extracellular high molecular weight proteins	Extracellular low molecular weight proteins
What are protoplasts?	Protoplasts are the cells from which cell membrane has been removed	Protoplasts are the cells from which cell wall has been removed	Protoplasts are the cells from which vacuole has been removed	Protoplasts are the cells from which golgi bodies are removed	Protoplasts are the cells from which cell wall has been removed
The plasmid that is transferred by conjugation is known as	Cargo	Conjugal	Helper	Vector	Cargo
UV radiation is an effective microbial control agent because	it oxidizes cellular constituents	it damages DNA	It damages cell membrane	All the above	it damages DNA
The transfer of plasmid from one bacterial cell to another when cargo and conjugal plasmids are used, it is usually is carried out by	Diparental mating	Uniparental mating	Triparental mating	Multiparental mating	Triparental mating
Technique of inserting deoxyribonucleic acid (DNA) into plants is known as	Bio injection	Bio fission	Bio genetic	Bio diffusion	Bio fission
Transformation method of plants and animals in which plants and animals are given shocks is known as	Microinjection	Genome breeding	Electroporation	Genome engineering	Electroporation
Which of the following microorganism belongs to 'Risk group I'?	Bacillus subtilis	Hepatitis A	Mycobacterium tuberculosis	Ebola virus	Bacillus subtilis
Element which allows easy visualization of genetic modification products is known as	Green fluorescent protein	Blue fluorescent protein	White fluorescent protein	Red fluorescent protein	Green fluorescent protein
Traditional breeding methods are	Selective	Cell fusion	Mutation breeding	All of the above	All of the above
Which toxic is used to protect plants from insects?	Blue green bacteria	Bacterium Bacillus thuringinsis	Acidobacteria	Proteobacteria	Bacterium Bacillus thuringinsis
Bt Stands for	Genetically Modified Crops	Bacterium bacillus Theogin	Bacterium Bacillus thuringiensis	Bacteria Bacili thuringien	Bacterium Bacillus thuringiensis
Bt reduce use of	Fertizers	pesticides	seeds	Manure	pesticides

What is GM crops?	Genetically Modified Crops	Genetically poor crops	Gene pool	Nomadic crops	Genetically Modified Crops
Asia uses what percentage of water for agricultural purpose?	85%	88%	81%	83%	85%
Anti-viral proteins that are produced by virus infected cells are called	Interferon	Thymosin	Beta-endorphin	Urokinese	Interferon
A vector is used to	Transfer gene	Copy a gene	Produce a gene	Remove a gene	Transfer gene
In 1977 an E.coli was created to synthesize	Animal growth hormone	Plant growth hormone	Human growth hormone	Human reproductive hormone	Human growth hormone
Which one of the following is an example of sterilizing gas that kills microbes	Ethylene oxide	Betapropiolactone	Vapourized hydrogen peroxide	All the above	All the above
The disease crown gall is caused by which bacteria?	Agrobacterium tumefaciens	Agrobacterium rhizogenes	Both of the above given bacterium cause the disease crown gall	Any bacteria belonging to genera Rhizobium	Agrobacterium tumefaciens
Agrobacterium tumefaciens form _____ plasmids	Root inducing	Tumour inducing	Shoot inducing	Leaf inducing	Tumour inducing
Agrobacterium rhizogenes form _____ plasmids.	Root inducing	Tumour inducing	Shoot inducing	Leaf inducing	Root inducing
The region which is transferred from bacterium to the nucleus of the plant cell is called as	T-DNA	A-DNA	B-DNA	Z-DNA	T-DNA
Transfer of T-DNA depends on a set of genes called as	Vir	Chv	Tum	Chromosome	Chv
What is the function of onc genes in T-DNA?	Tumour suppressing potential	Tumour inducing potential	Tumour suppressing potential	Act as replicative genes	Tumour inducing potential
Which of the plant growth regulators are produced by T-DNA?	Salicyclic acid	Cytokinin	Cytokinin nad Auxin	Jasmonic acid	Cytokinin nad Auxin
If a small intermediate vector system is used along with a selectable marker, then it is called as:	Fusion plasmids	Hybrid plasmids	Co-integrative plasmids	Complex plasmids	Co-integrative plasmids
If transfer of DNA from Agrobacterium to plants is done via incubation of explanted material and the vector containing DNA of interest and then selection is done via selectable	Transformation	Co-cultivation	Co-transformation	Floral dipping	Co-cultivation
If gene of interest is inserted into protoplasts but the transformation is not stable, then it is called as _____ expression systems.	Permanent	Temporary	Transient	Unstable	Transient
35S promoter is obtained from	Tobacco mosaic virus	Cauliflower mosaic virus	Agrobacterium	Arabdopsis	Cauliflower mosaic virus
What is the function of glyphosate?	It is a fungicide	It is an herbicide	It is an enzyme used in place of glucose as a carbon source	It is used for adding phosphate groups	It is an herbicide
Baciullus thuringiensis is used for production of toxins which can be used as	Insecticides	Pesticides	Germicides	Fungicides	Insecticides
Which of the following compounds control ripening in tomatoes?	Auxin	Cytokinin	Ethylene	Jasmonic acid	Ethylene
A recombinant DNA molecule is produced by	Joining of two DNA fragments	Joining of three DNA fragments	Joining of many DNA fragments	Joining of two or more DNA fragments originating from different organisms	Joining of two or more DNA fragments originating from
The gene formed by the joining of DNA segments from two different sources are called as	Recombinant gene	Joined gene	Both A and B	Chimeric gene	Chimeric gene
Which of the following enzyme is used to cut DNA molecule in rDNA technology	Ligase	Phosphatase	Ribonuclease	Restriction enzymes	Restriction enzymes
Restriction enzymes are also called as	Biological scissors	Molecular scalpels	Molecular knives	All of the above	Biological scissors
The most important discovery that lead to the development of rDNA technology was	Double helix model of Watson and Crick	Discovery of restriction enzymes	Discovery of ligaese enzymes c	Discovery of plasmid	Biological scissors
Energy source of the cell	ATP	ADP	NADP	NADH	ATP
Who created the first rDNA molecules	Nathan, Arber and Smith	Watson, Crick and Wilkins	Boyer and Cohen	Palul Berg	Palul Berg
The DNA molecule to which the gene of insert is integrated for cloning is called	Carrier	Transformer	Vector	Transporter	Vector
The DNA segment to be cloned is called	Gene segment	DNA fragment	DNA insert	All of these	DNA insert
Which of the following statements are true regarding rDNA technology	rDNA technology is used to obtain larger number of copies of specific DNA fragments	rDNA technology is used to obtain large quantity of the protein	rDNA technology is used to integrate genes into chromosomes	all of the above	rDNA technology is used to integrate genes into chromosomes
For cloning to occur, plasmid of bacteria must be cut by	Restriction enzymes	Polymerase enzymes	Helicase enzyme	Gyrase enzyme	Restriction enzymes

ELSI was established as part of the Human Genome Project to	study the ethical, legal, and social implications of mapping the human genome	educate society about the opportunities and challenges of the new genetics	create new technologies that will accelerate the sequencing process	to develop computational tools for capturing, storing, analyzing, displaying, and	study the ethical, legal, and social implications of mapping the human
The Human Genome Project was created to map out what?	the DNA of apes	diseases	plant matter	The DNA of apes	Humans
How many chromosomes do humans have?	46	48	54	56	46
Genes are made up of:	DNA	RNA	Protein	Enzymes	DNA
The human genome is:	All of our DNA	All of our genes	Responsible for all our physical characteristics	all of our genes	all of our DNA
Who was the first scientist to conceive the idea of cellular differentiation	Theodor Schwann	Robert Hooke	Alexander Maksimov	John Enders	Theodor Schwann
Approximately how many embryonic stem cell lines are federally approved	20	100	65	93	93
What is the scientific challenge in developing a new therapy based upon embryonic stem cell replacement	Tissue rejection and tumor formation	Hard to harvest	Slow to proliferate	easy to reduce	Tissue rejection and tumor formation
Who is credited with discovering and developing iPS technology?	Shinyi Yamanaka	John Gearhart	John Enders	Charles Darwin	Shinyi Yamanaka
What does pluripotency mean?	Self-renewal property of the cell	The ability to transform into any type of cell	The ability to form tumors	inability to develop stem cells	The ability to transform into any type of cell
What is the gold standard "stem cell"?	Fertilized human egg	Stem cells obtained from the inner mass of embryos	Stem cells obtained from umbilical cord blood	Stem cells from bone marrow	Fertilized human egg
The types of stem cells in mammals are	2	3	4	5	2
Stem cells are present in	A. unicellular organisms	A. multicellular organisms	A. non-living things	all of the above	A. viruses
in a developing embryo, the stem cells can differentiate into	ectoderm	endoderm	mesoderm	all of the above	all of the above
he process in which one stem cell develops into two differentiated daughter cells, another stem cell undergoes mitosis and produces two identical stem cells is called	A. stochastic differentiation	A. asymmetric replication	A. potency	A. self-renewal	A. stochastic differentiation
Multipotent stem cells can be derived from which of the following adult tissues:	Adipose tissue (fat)	Bone marrow	Umbilical cord blood	all of the above	all of the above
Which of the following are concerns about adult stem cells?	Difficult to isolate	Difficult to maintain in culture		Proliferate more slowly than hESC	all the above
Scientists who are funded by federal grants limit research on human embryonic stem cells to:	7days	14days	21days	40days	*14days*
Pre-implantation genetic diagnosis (PGD) raises which of the following ethical issues?	Termination of an embryo with a gene for a disorder is seen by some as a form of eugenics	Gender selection	Creation of "designer" babies by selecting embryos having certain	Selection of an embryo to create a child whose tissue will be used to cure an ill	Selection of an embryo to create a child whose tissue will be used to
the major ethical concern with Somatic Cell Nuclear Transfer (SCNT) is that:	There is very little ethnic diversity in the eggs that are donated	People are seeking blastocysts from foreign sources	The blastocyst has to be destroyed to derive the stem cells	The SCNT stem cells might harbor genetic disorders	The blastocyst has to be destroyed to derive the stem cells
Approximately what proportion of the public approves of stem cell research in 2011?	30%	60%	80%	100%	60%
To date, stem cell medicine has yielded proven therapies for which of the following illnesses:	Alzheimer's disease	Breast cancer	Macular degeneration	None of the above	None of the above
Transformation method of plants and animals in which plants and animals are given shocks is known as	microinjection	genome breeding	electroporation	genome engineering	electroporation
Technique of inserting Deoxyribonucleic Acid (DNA) into plants is known as	bio injection	bio-fission	bio diffusion	bio genetic	bio-fission
Technique of inserting DNA (Deoxyribonucleic Acid) into animal cells is known as	microinjection	macro injection	fusion injectin	genome injection	microinjection
Element which allows easy visualization of genetic modification products is known as	green fluorescent protein	blue fluorescent protein	A. white fluorescent protein	A. red fluorescent protein	green fluorescent protein
Traditional breeding methods are	selectiuve breeding	cell fusion	budding	all of the above	all of the above
What does GMO mean?	genetically modified organisms	grow more organic	od more over	get Monsanto Quatta-here	genetically modified organisms
Cry genes or Bt genes are obtained from	cotton pest	tobacco plant	Bacillus thuringenesis	E.coli	Bacillus thuringenesis

Transgenic plants are developed by	intyroducing foreign genes	introducing gene mutations	deleting certain chromosome parts	stopping spindle formation	introducing gene mutations
animal cell cultures are used widely for the production of	insulin	somatostatin	mabs	thrroxine	mab
the first avccine developed from animal cell culture was	He[patitis B vaccine	Influenza vaccine	small pox vaccine	polio vaccine	polio vaccine
The human Genome project officially began in	1988	1990	1992	1995	1990
the cell line used for the productin of polio vaccine was	priamte kdiney cell line	CHO cell line	Dog kdiney cell line	mouse fibroblast cell line	priamte kdiney cell line
the technique used in ABT for the rapid multiplication and productio of animals with a desirable genotype	protoplast fusion and embryo transfer	hybrid selectiona and embryo transfer	in vitro fertilization and embryo transfer	None of the above	in vitro fertilization and embryo transfer
the production of complete animals from somatic cells of an animal is called	gene cloning	animal cloning	cell cloning	all of the above	animal cloning
the first successfully cloned animal was	monkey	gibbon	sheeep	rabbit	sheeep
transgenic animals used for gene farming or molecualr farming called	biopests	bioreactors	biofarmers	none of these	bioreactors
omouse is prefererred mammals for studies on gene transfer due to	short estrous cycle and gestation period	short generation time	convernient in vitro fertilization	all of the above	all of the above
whhich of the following mice are used for immunization in the hybridoma technology	swiss mice	balb mice	out bred mice	indigenous mice	balb mice
WHO	World Health Organization	Word Health Organization	well hospitalised organization	Wear House Organization	World Health Organization
……..has been used to selectively control certain insect pests	*Bacillus thuringiensis*	E.coli	Pseudomonas putida	Spirulina	*Bacillus thuringiensis*
Golden rice is a genetically modified crop plant where the incorporated genes are meant for biosynthesis of	Vitamin A	Vitamin B	Vitamin C	Beta-carotene	Beta-carotene
Which organism among the following was not used in the genetic engineering programme leading to the development of Golden Rice?	Escherichia coli	Vitamin B	Agrobacterium tumefaciens	Erwinia uredovora	Escherichia coli
------- is the product of RNAi technique in genetic engineering.	Cry proteins of Bt cotton	Cry proteins of Bt cotton	Beta carotene enriched Golden rice	Nematode resistance in tobacco	Beta carotene enriched Golden rice
Interference RNA was discovered by	Cohen & Boyer	Fire & Mello	Yonath & Ramakrishnan	Holley & Khorana	Fire & Mello
This is not a product of recombinant DNA technology	Golden rice	Tracy	Bt cotton	Dolly	Dolly
This is not a GMO	Bt cotton	Golden Rice	Pomato	Tracy	Pomato
In the famous rDNA experiment to produce humulin, the substance was produced attached with another protein called -	beta-galactosidas	tetracycline	ampicillin	beta-galactoside	beta-galactosidas
One of the advantages of developing transgenic mice is it is very useful in	Keeping mice population under control	Producing new varieties of mice	Developing a show piece example	Gene targeting	Gene targeting
When these parts of a plant are used as explants in a tissue culture experiments the newly generated plants could be virus-free.	Pollen grains	meristems	parts of the embryo	flower buds	meristems
the main GM crop for animals is ….	corn	soy bean	pomato	tomato	corn
CSR stands for	Customer Satisfaction Ratios	Corporate Sales Returns	Customer Sales Ratios	Corporate Social responsibility	Corporate Social responsibility
complete draft of humnan genome was announdced in	2003	1990	1998	2015	2003
NIH stands for	National Institutes of Health	National Human Genome Research Institute	National Institutes of Hospitality	None	National Institutes of Health
HGP started in the year	1992	1998	1990	1953	1990

UNIT III

Who publishes the Laboratory Biosafety Guidelines?	Public Health Agency of Canada	CFIA	PHAC	Canadian Food Inspection Agency	Public Health Agency of Canada

Which of the following are tools used in risk analysis?	toxicology	Epidemiology	Clinical trials	All of the above	All of the above
The exhaust air would be autoclaved in	Class I BSC	Class II BSC	Class III BSC	Class IV BSC	Class I BSC
The exhaust air would be filtered in	Class I BSC	Class II BSC	Class III BSC	Class IV BSC	Class I BSC
WTO head office located in	Geneva	Delhi	London	Moscow	Geneva
World Intellectual Property Organization was established in	14-Mar-59	14-Aug-65	14-Oct-60	14-Jul-67	14-Jul-67
World Intellectual Property Organization is specialized agency of	United Nations	United Nations Security Council	United nations Economic Council	United Nations Social Council	United Nations
WIPO copyright treaty established in the year	1996	1990	1998	1993	1996
International organization with objective to encourage creative activity and to promote intellectual property throughout world is	WIPO	UPU	IBRD	UNDP	WIPO
World Intellectual Property Organization was established in	14-Mar-59	14 July, 1967	14-Aug-65	14-Oct-60	14-Jul-67
World Intellectual Property Organization is specialized agency of	United Nations	United Nations Security Council	United nations Economic Council	United Nations Social Council	United Nations
First World Intellectual Property Organization on Changing Face of Innovation was published in	2005	2007	2011	2009	2011
Headquarter of World Intellectual Property Organization is located in	Rome, Italy	Bern, Switzerland	Berlin, Germany	Geneva, Switzerland	Geneva, Switzerland
The present Copyright Act in India came to force in	1957	1987	1894	1953	1957
In which of the article the TRIPS agreement deals with Copyright and related matters ?	Article 9-14	Article 20-24	Article 2-8	Article 14-20	Article 9-14
The WIPO was established in the year	1987	1925	1970	1956	1970
The copyright board shall be deemed to be a	Supreme Court	Civil Court	High Court	Criminal Court	Civil Court
Expansion of WIPO is	World infringement property Organization	World inter patent Organization	World intel patent Organization	World invesment property Organ ization	World infringement property Organization
What is GM crops?	Genetically Modified Crops	Genetically poor crops	Gene pool	Nomadic crops	Genetically Modified Crops
Anti-viral proteins that are produced by virus infected cells are called	Interferon	Thymosin	Beta-endorphin	Urokinese	Interferon
A process that reduces microbes to a level deemed safe by public health standard is	Antisepsis	Disinfection	Sanitation	Sterilization	Antisepsis

UNIT IV

Intellectual Property Rights (IPR) protect the use of information and ideas that are of	Ethical value	Moral value	Social value	Commercial value	Commercial value
The term 'Intellectual Property Rights' covers	Copyrights	Know-how	Trade dress	All of the above	All of the above
The following can not be exploited by assigning or by licensing the rights to others	Patents	Designs	Trademark	All of the above	Trademark
The following can be patented	Machine	Process	Composition of matter	All of the above	All of the above
Trade mark	is represented graphically	is capable of distinguishing the goods or services of one person from those of others	may includes shapes of goods or combination of colours	All of the above	All of the above
Which of following would not gain copyright protection?	A DVD	An unrecorded speech	Written lyrics of a song	books	An unrecorded speech
What is the duration of copyright protection for a novel?	A novel will not gain copyright protection.	The day the author dies	The end of the calendar year in which the author died.	70 years from the end of the calendar year in which the author died.	70 years from the end of the calendar year in which the author died.
Which one of the following actions is not a breach of copyright?	To import copied CDs	To make a copy of a CD and sell it.	To borrow a CD from a friend and copy it to your laptop for your own	To purchase a CD and copy it to your laptop for your own private use.	To purchase a CD and copy it to your laptop for your own private

Which of the following is not one of the three essential elements for a patent to be granted for an invention?	Be a product.	Be new to the public.	Involve an inventive step.	Be capable of industrial application.	Be a product.
Which one of the following statements is true?	A patent must be registered in order to gain protection.	Copyright must be registered in order to gain protection.	The owner of a patent cannot sell it but can prevent others using his	The definition of an invention is set out in the Patents Act 1977.	A patent must be registered in order to gain protection.
The law governing registered trade marks can be found in which Act?	The Intellectual Property Act 1994.	Copyright, Designs and Patents Act 1988.	The Registered Trade Marks Act 1994.	The Trade Marks Act 1994.	The Trade Marks Act 1994.
Which one of the following could not be registered as a trade mark?	The mark is an image.	The mark is made up of letters and numbers.	The mark is made up of a symbol with no words or letters.	The mark represents the natural or technical shape of the goods.	The mark represents the natural or technical shape of the goods.
EBT contaminate the	Methionine	Alanine	Lipin	Tryptophan	Tryptophan
Unless a contract provides otherwise, who is the first owner of a design right created on or after 1 October 2014?	The person who commissioned the design.	The manufacturer of the design.	The government.	The designer.	The designer.
The tort of passing off is governed by which statute?	The Passing-off Act 1977.	The Tort Act 1977.	The Unfair Contract Terms Act 1977.	There is no statute that governs the law of passing-off.	There is no statute that governs the law of passing-off.
International organization with objective to encourage creative activity and to promote intellectual property throughout world is	WIPO	UPU	IBRD	UNDP	WIPO
World Intellectual Property Organization was established in	14-Mar-59	14 July, 1967	14-Aug-65	14-Oct-60	14-Jul-67
World Intellectual Property Organization is specialized agency of	United Nations	United Nations Security Council	United nations Economic Council	United Nations Social Council	United Nations
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Headquarter of World Intellectual Property Organization is located in	Rome, Italy	Bern, Switzerland	Berlin, Germany	Geneva, Switzerland	Geneva, Switzerland
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The WIPO was established in the year	1987	1925	1970	1956	1970
The copyright board shall be deemed to be a	Supreme Court	Civil Court	High Court	Criminal Court	Civil Court
The term of the copyright in anonymous and pseudonymous is	60 years	15 years	25 years	45 years	60 years
The present Copyright Act in India came to force in	1947	1957	1967	1977	1957
Which one of the following is not coming under copyright?	Books	Computer Program	Brand	Cinem a	Brand
The Name Kanchipuram Silks comes under the division	Copyright	Geographic al indication	Trade mark	Patent	Geographic al indication
Expansion of WIPO is	World infringement property Organization	World inter patent Organization	World intel patent Organization	World invesment property Organ ization	World infringement property Organization
Which one of the following is included in Geographical indication of Goods ?	Handicrafts	Foodstuff	Manufactured product	All of the above	All of the above
The Validity of a Patent is	10 years	20 years	30 years	40 years	20 years
World Intellectual Property Organization was established in	14-Mar-59	14-Aug-65	14-Oct-60	14-Jul-67	14-Jul-67
World Intellectual Property Organization is specialized agency of	United Nations	United Nations Security Council	United nations Economic Council	United Nations Social Council	United Nations
WIPO copyright treaty established in the year	1996	1990	1998	1993	1996
Indian patent right established in	1965	1975	1970	1985	1970
Indian patent right is a background of which country ?	USA	England	UAE	Germany	England
The Statutory life of Patent is 20 years from the	date of completion	date of establishment	date of filling of the ap plication	date of acceptance	date of filling of the ap plication
The Country which deals with DNA Sequence in plant species for patent is	India	Japan	Spain	USA	USA
Musical, Literary artistic works , photographs , computer software comes under	Patent	Designs	Copyright	layouts	Copyright

Recent Patent act was amended in the year	2013	2009	2005	2007	2005
TRIPS means	Trade required intellectual product	Trade related intellectual property	Trade related inter probes	Trace related intellectual property	Trade related intellectual property
Patent can be revoked in India	Yes	No	Yes in some cases	none of the above	Yes in some cases
Computer program is considered as	Literary work	artistic work	station work	none of the a bove	Literary work
Plan of a building can be protected by	Trade mark	Law	Copy right	Patent	Copy right
Genetically engineered mice have been granted patent by	Belgium and Finland	India and US	German and It aly	Russia and Africa	Belgium and Finland
Patent ,design and trademark was govern by	Ministry of Law	Ministry of Law and social justice	Ministry of Commerce and industri es	Ministry of Labour	Ministry of Commerce and industri es
A USA patent was taken for	Basmati rice	Lerma Roja	CO-668	Sharbati Sonara	Basmati rice
Patents are classified into how many types ?	4	3	8	9	8
The design act of 1911 was replaced by design act	2000	2002	2005	2009	2000
Trademark act passed in the year	1998	1999	1987	1989	1999
WTO head office located in	Geneva	Delhi	London	Moscow	Geneva
Symbol of Maharaja of Air India is	Copyright	Patent	Trademark	All of the a bove	Trademark
Berne Convention held in the year	1887	1889	1886	1890	1886
If you file provisional specification, the complete specification is required to be filed within	8 months	10 months	12 months	18 months	12 months
Plant varities patent comes under the ministry of	Agriculture	law	Justice	Researc h and Development	Agriculture
Utility Model protection is available in which country	USA	China	German	All the a bove	All the a bove
set standards used to regulate own or community activity in relation to biological world is	Biopotency	Biowar	Bioethics	Biopiracy	Bioethics
National application office in India for patent receiving in	Chennai	Gujarat	New Delhi	Mumbai	New Delhi
Commercial use domain names will normally use the following suffix in their website address.	.net	.org	.com	.edu	.com
Utility model protects	Creation	Invention	Design	All the a bove	Invention

UNIT-V

Who is referred to as the father of the Green Revolution?	John Chapman	Norman Borlaug	George Washington Carver	Gregor Mendel	Norman Borlaug
The principal crop behind the Green Revolution was	corn	potato	rice	wheat	wheat
The loss of over 20,000 native varieties of rice in India is an example of	somaclonal variants	germplasm	genetic erosion	lodging	genetic erosion
Transgenic plants	are to produce human antibodies	contain genes in their cells	contain foreign genes in their cells.	All of the above	contain foreign genes in their cells.
What are protatoes?	genetically modified potatoes	have a gene from grain amaranth	They show high levels of essential amino acids, lysine, and methionine	All of the above	genetically modified potatoes
Genetically modified (GM) crops can be produced by	recombinant DNA technology	somatic hybridisation	cross breeding	micropropagation	recombinant DNA technology
Which of the following is known as ‘Flavr Savr’?	Toxic insecticidal protein.	Specific variety of pesticide	Breed of chicken	Transgenic tomato	Transgenic tomato

Maximum number of existing transgenic animals is of	fish	mice	cow	pig	mice
Golden rice is	a type of rice grown along the Yellow river in China	a transgenic rice having gene for p-carotene	normal variety of rice with golden coloured grains	wild and long sized rice having golden tint	a transgenic rice having gene for p-carotene
A USA patent was taken for	Basmati rice	lerma roja	Co-668	sharabati sonara	Basmati rice
A patent gives the owner the right to	publish the results of others	make her invention	keep others from making her invention	commercialize her invention	keep others from making her invention
---------- include the rights arising from conserving, improving and making	Copyright	Agricultural act	Plant breeder's act	Farmer's right	Copyright
IPR are usually limited to _____	Non-rival goods	Rival goods	Imported goods	Food products	Non-rival goods
Modern usage of the term IPR began in _____	1987	1977	1967	1955	1967
In 1994 which act was amended _____	Tread mark	trade secrete	patent	copy right	copy right
In 1957 which agreement was approved for copy right act	TRIPS	PPVFR	IPR	PCT	TRIPS
The maximum limit of 17 years for monoply was given by	Paris	UK	USA	India	USA
The meaning for patere	property	To lay open	Protection	To open	To lay open
Haeckel proposed the theory of _____	Colonical	gem theory	Theory of koch	Theory of Pasteur	Colonical
There is a 20 claims present in _____	original patent application	New developed patent application	patent application	IPR application	original patent application
In 1988 the first patent was given to	Living organism	hybride plant	plant	Fungi	Living organism
In 1883 which convention for production of industrial property was signed	Paris	US	UK	USSR	Paris
Three years of patent was issued by	TRIPS	PPVFR	IPR	USPTO	USPTO
According to PPVFR Act How many rights have been given to farmers	6	7	10	9	9
_____is classified into two categories	PBR	IPR	FDA	USR	IPR
Trademark uses symbols in _____	Intellectual committee	Intellectual property	Indian committee	Indian property	Intellectual property
Geographical indications protects the quality,reputation of products originated from _____	Histarical area	Seasonal area	developmental area	Geographical area	Geographical area
Trade secrets protects _____ of industries	Trade information	confidential information	Machinery information	Tribunal information	confidential information
Copyrights prevents copying and _____	Reproduction	Construction	Development	Tradition	Reproduction
IPR develops and protects ____resources.	Physical	chemical	biological	academic	biological
For breeder’s right, _____ Act is in practice.	PPR	PPVFR	PPVR	PPFR	PPVFR
In which year patent Act was published in India	1945	1990	1999	2000	1999
In which year patent bill was introduced to upper part of india parliament	1970	1980	1960	1990	1970
When copyright Act got TRIPS agreement	1950	1960	1957	1980	1957
When did geographical indication good bill got published	1920	1960	1999	2004	1999
Which year Act was replaced in 1999	1920	1999	1990	1911	1911
Stem cell research investigation about--- therapies to treat disease	cell bared therapies	cell therapies	Plant enzymes	Plant cell research	cell bared therapies
Trade secrecy applicable rather than patents in ----------	Fermentation	drugs	chemicals	invitro fertilization	Fermentation

Which can be protected using patents	micropropagation	tissue	organ culture techniques	method for reducing pathogenecity	method for reducing pathogenecity
. _____ is an important example for gene piracy.	. GM *Pseudomonas*	*Pentacliplandra brazzeana*	*Clostridium*	*Bacillus*	*Pentacliplandra brazzeana*
In India, _____ is an important example biopiracy	Dalbergia	Neem	Ginger	Onion	Neem
---------- Serve as a source of transplanted organs for humans.	Transgenic pigs	Transgenic rabbits	Transgenic goats	Transgenic sheep	Transgenic pigs
Trade secrete comprise the information about ----------	Specific technical procedures	symbol	particular product	document.	Specific technical procedures
Recombinant DNA technology,were known by several phasses such as	playing god	manipulation of life	man made evolution	all the above	all the above
The original guide line providede by NIH was modified in need by……committee	NIH-RAC	GEO's	FDA	none of the above	NIH-RAC
3.earlier, most prominently used strain/host organism in RD	*klebsiella.spp*	*E.coli k-12*	*E.coli*	*Pseudomonas aeruginosa*	*E.coli k-12*
……is responsible for the regulating the introduction of foods,drugs,pharmaceutical and medical devices into the market place	FDA	WHO	NIH	none of the above	FDA
…..is an enzyme approved by FDA in making cheese	chymosin	tryptophan	streptomycin	Penicillin	chymosin
milk clotting activity for cheese making is derived from the fourth stomach of calves and consist of mixture of substances called…..	K-casein	rennet	chymosin	proteolytic enzyme	rennet
for cheaper industrial supply of chymosin,genes were cloned and the product was harvested from….	*E.coli k-12*	*Pseudomonas aeruginosa*	*klebsiella.spp*	B.thuringiensis	*E.coli k-12*
a consistent feature among the occurrence of eosinophilia myalgia syndrome(EMS),due to the consumption of large doses of aminoacid……in food supplement	Tryptophan	leucine	isoleucine	lysine	tryptophan
recombinant bovine somatotropin (BST) which also known as ……	bovine growth hormone	bovine releasing hormone	bovine serum	none of the above	bovine growth hormone
milk production in dairy cows was increased by……% after the injection of recombinant form of BST	20-25%	30-35%	.40-45%	20-45%	20-25%
The patenting of multicellular organisms constitute to raise	Ethical and social concern	Ethical concern	social concern	trede concern	Ethical and social concern
Indian patent Act allow to patent	products	process	preparation		process
In USA the maximum limit of monoply is for	10years	5 years	17 years	2 years	17 years
The word Patent derived from	Latin word patere	paten	pantor	patentor	Latin word patere
PCT is	Patent Cooperation Treaty	Patent Control Term	Public Cooperation Team	Private Cooperation Team	Patent Cooperation Treaty
PCT is an agreement for cooperation on patenting	National	Local	International	State	International
What is the mode of revocation of patent	State government	Central government	Union territories	UN	Central government
Who got the patent for Psuedomonas	Robert Koch	Louis Pastuer	Dr. Chakrabarty	Edward Jenner	Dr. Chakrabarty