18MBO43E

Core: Elective paper -IV Biotechnology

UNIT - 3

Dr.V.C. Sarala Bai

Assistant Professor
PG and Research Department of Botany
Government Arts College (autonomous)
Coimbatore -18
Mobile No: 9944676865

Virus resistance in plants

PLANTS VIRUS RESISTANT TRANSGENIC



Modes of transmission of plant viruses:

- To transmit from one plant to another plant and from one plant cell to another, plant viruses must use strategies that are usually different from animal viruses
- Plant do not move so plant plants transmission usually involves vector
- > Through sap Eg:TMV,Potato virus
- > Nematodes Eg:Tobacco ring spot virus



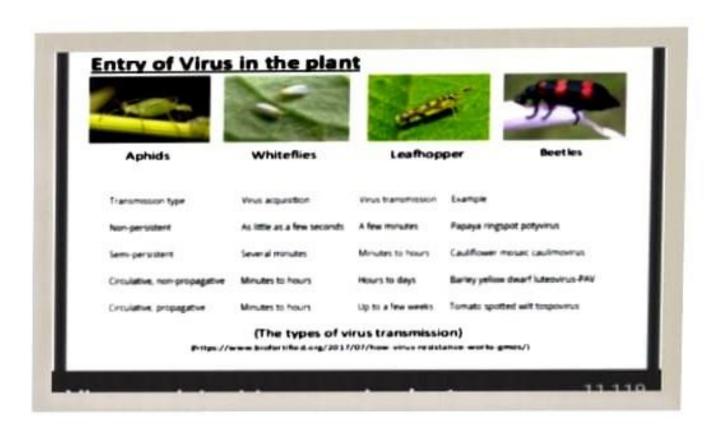
Mechanism of plant resistance to viruses:

The plant show two type of antiviral defense resistance are

- 1) R gene mediated
- 2) RNA silencing

R-gene mediated responses:

- Plant R genes confer resistance to many pathogen ,incluc
- Each R gene confers resistance to a specific pathogen.
- The first phenotype of defense in most R-gene mediated resistance responses is the hypersensitive response (HR) and the HR includes programmed cell death (PCD)
- The second phenotype of R-gene mediated resistance systemic acquired resistance (SAR)





Ribozymes:

- Ribozymes are small RNA molecules-catalytic cleavage of target RNA
- Block the replication of RNA
- > But not effective

Satellite sequences:

- Small RNA molecule that are unable to multiple in host cell without helper virus
- Cucumber mosaic virus cucumovirus(CMV)symptoms -reduced carrying satellite
- The satellite RNA always depends on the virus for its replication and

transmission and their nucleotide sequence seems to be unrelated to that of viral genome.

Satellite RNAs are specific of RNA associated with certain plant RNA virus.

Gene Silencing mediated resistance:

RNA Interference (RNAi)

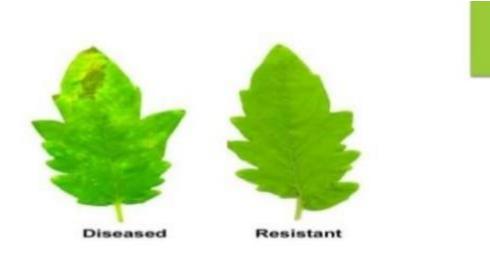
- Dicer like protein (DCL)
- Argonaute protein (AGO)
- RNA dependent RNA polymerases (RdRp)
- > HEN1 and HYN1

Plantibody Mediated Resistance:

- By the production of monoclonal antibodies in plants expressing a appropriate IgG fab2 fragment or single chain Fv antibody for possibility of providing protection against viral and other diseases.
- It may be very effective to use monoclonal antibody targeted against catalytic (non -structural) viral protein when the antigen concentrations are less and interfere virus replication

THANK YOU

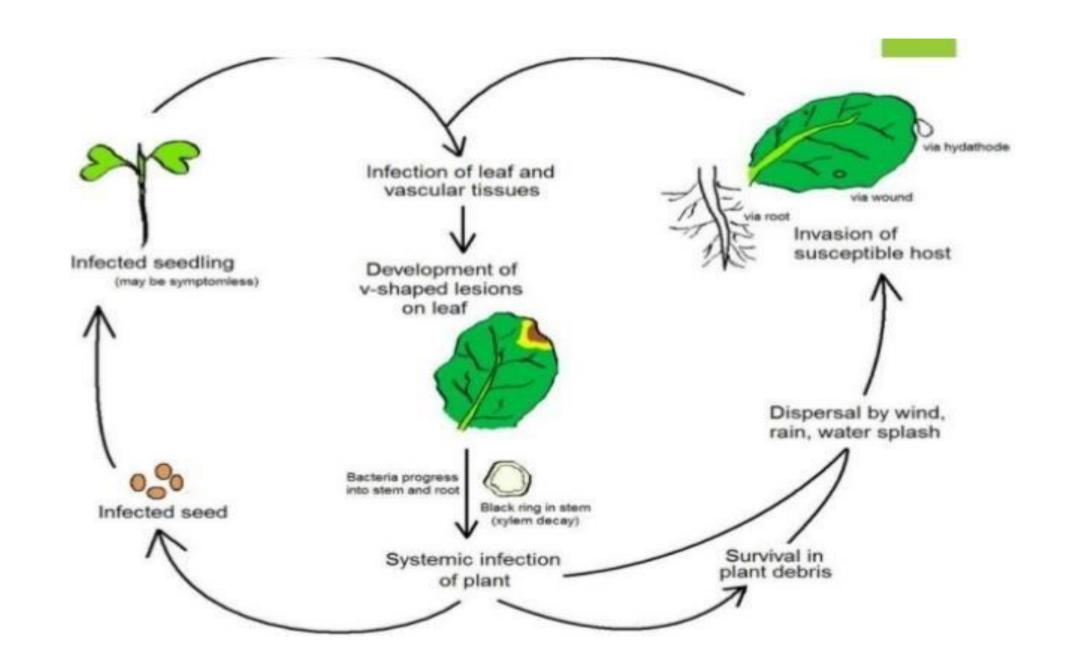
Pathogen resistance, salt and drough tolerance

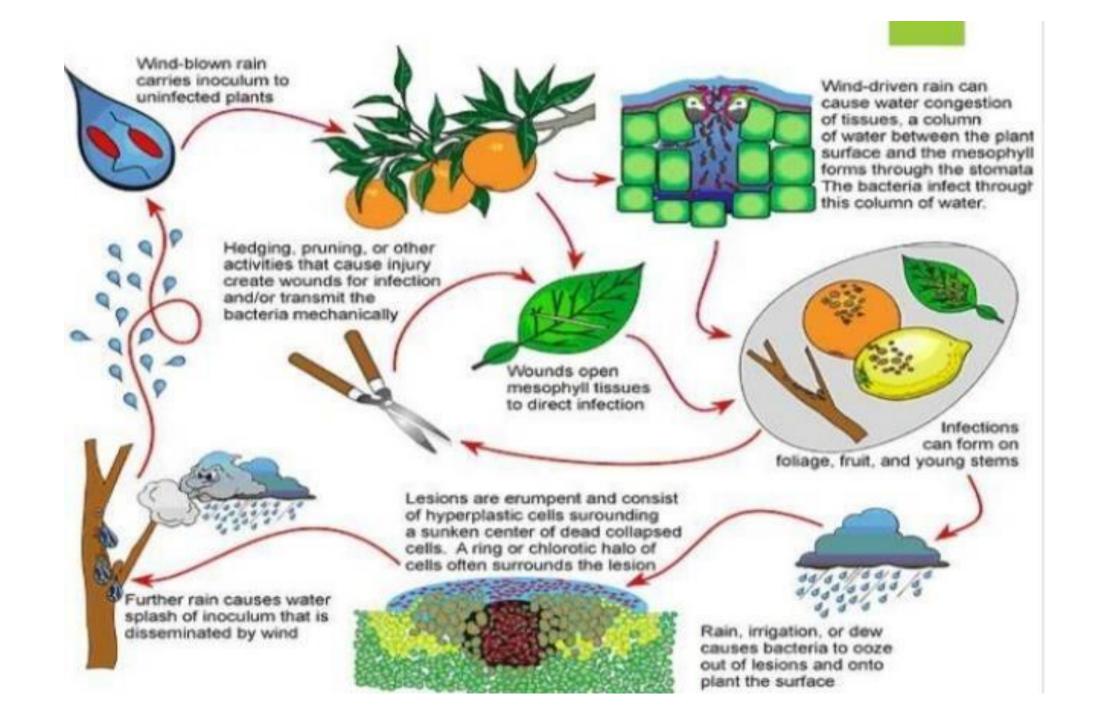


Plant disease resistance is a complicated arms race between the plant and pathogens. Bacteria, viruses and fungi evolve in lock-step with plants, creating new ways to overcome new disease resistance strategies. Resistance to disease has a foundation in the gene-for-gene model, a model that hypothesizes that plants and pathogens have a molecular relationship with each other that mediates pathogenicity.

How do Pathogens Find and Enter the Plant?

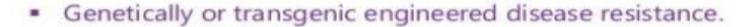
- For a microbe to cause disease, it needs to come into direct contact with its host plant, and often with a specific host plant tissue.
- Microbes are passively distributed from plant to plant by wind, splashing rains, or insect vectors.
- However, nonpathogenic microbes, once deposited, do not have the capacity to find wounds or natural openings on the plant surface, or to penetrate preformed surface barriers such as a waxy cuticle and thick cell walls.
- Pathogens, however, have evolved diverse mechanisms to find and enter plants to establish the disease.
- Once they reach the host plant, a pathogenic microbe may land on the part of the plant suitable for infection, called the infection court. In other cases, pathogens need to expend energy to move or grow toward the infection court





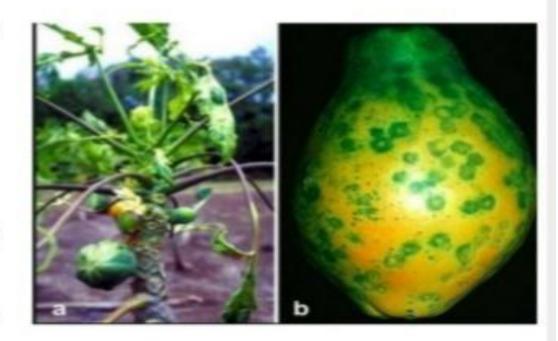
Special level resistance

- In a small number of cases, plant genes are effective against an entire pathogen species, even though that species that is pathogenic on other genotypes of that host species.
- Examples include barley MLO against powdery mildew ,wheat Lr34 against leaf rust and wheat Yr36 against wheat stripe rust. An array of mechanisms for this type of resistance may exist depending on the particular gene and plant-pathogen combination.
- Other reasons for effective plant immunity can include a lack of coadaptation (the pathogen and/or plant lack multiple mechanisms needed for colonization and growth within that host species), or a particularly effective suite of pre-formed defenses



- The term GM is often used as a synonym of transgenic to refer to plants modified using recombinant DNA technologies.
- Plants with transgenic/GM disease resistance against insect pests have been extremely successful as commercial products.
- especially in maize and cotton, and are planted annually on over 20 million hectares in over 20 countries worldwide.
- Transgenic plant disease resistance against microbial pathogens was first demonstrated in 1986.
- Combining coat protein genes from three different viruses, scientists developed hybrids with field-validated, multiviral resistance.

A similar strategy was deployed to combat papaya ringspot virus, which by 1994 threatened to destroy Hawaii's papaya industry. Field trials demonstrated excellent efficacy and high fruit quality. By 1998 the first transgenic virusresistant papaya was approved for sale. Disease resistance has been durable for over 15 years. Transgenic papaya accounts for ~85% of Hawaiian production. The fruit is approved for sale in the U.S., Canada and Japan.





- Resistance, like other traits, occurs in a qualitative or in a quantitative way. With the former the different genotypes in a population occur as discernible phenotypes; it is usually controlled by a major gene.
- Quantitative resistance (QR) is defined as a resistance that varies in a continuous way between the various phenotypes of the host population, from almost imperceptible (only a slight reduction in the growth of the pathogen) to quite strong (little growth of the pathogen).
- This resistance is often indicated with other terms such as partial, residual and field resistance or even (wrongly) with tolerance. QR occurs at various levels to nearly all important pathogens in most cultivars of our crops.

DURABLE RESISTANCE

- Resistance is considered durable when it remains effective for a considerable time, despite wide exposure.
- In this sense, it is a quantitative concept. The Rpg1 gene discussed above was durable, but did not last forever.

And in the evolutionary sense, no resistance will last forever.

- It is possible to discern three groups of resistances that are predominantly durable.
 - QR against specialists and based on some to several genes with additive effects seems durable.
 - Resistance to pathogens with a wide host range.

Non durable resistance

- In nature there is a constant race of arms between the attacking parasite and the defending host, and in the evolutionary sense, all resistance is transitory.
- But large differences exist in the ease by which parasites can overcome a resistance. In agriculture, too the durability of a resistance varies greatly.
- Resistance may already be neutralized in the last stages of the breeding program (at zero years) and may, still be effective after more than 130 years and wide exposure, as the case of the *Phylloxera* aphid resistance of grape.

Drough tolerance

Drought stress and tolerance mechanisms in crops:

What is drought:

Is a period or conduction of unusually dry weather with a geographic area where there is a lack of precipitation.

Drought stress account fro more production losses than all other factors combined.

Fraction of world arable land subject to drought (abiotic stress) 26%.

Drought is caverned by various factors, the most prominent are:

- Extreme of temp
- Photon irradiance
- Paucity of water

Effect drought stress on plants

✓ Effect on growth:

Reduction of turgor pressure, due to cell size will be smaller.

Effect on photosynthesis:

Photosynthesis decreases due to distruption of PS II (photo system II), stomatal closure and decrease in electron transport.

Decrease in nuclear acid and proteins

Different type of drought

Meteorological drought:

Due to prolonged period with less than average precipitation.

Agricultural drought:

Which affect crop production or ecology of range.

Hydrological drought:

When the water reserves available in sources such as lack and reservoirs fall be low statistical avreage.

Salt tolerance crops

Kainat Noor Elahi Roll no 15 MSc 4th semester GC Women University, Sialkot

Defination

Degree to which the plant can withstand high conc. of salts in water and soil, without adverse effect.

Types of salt tolerant crops

- Moderately tolerant
 - >5g/liter conc. of salt
 - >Oats, alfalfa, wheat, rice, maize, cucumber etc.
- Highly tolerant
 - >10g/liter salt conc.
 - Date-palm, barely, asparagus, sugar beat, cotton, spinach.

Carrot (Daucus carrota)

- A root vegetable usually orange in color
- Native to Europe and southwestern Asia.
- Tolerent to moderate salt concentration.
- According to international standard these carrots should be dead at a salinity level of 12dS/m. because level of salinity is high.



Cytoplasmic Male Sterility

INTRODUCTION

Male sterility in plants

Male sterility is characterisied by nonfunctional pollen grains, if and where produced, while female gametes function normally.

Features of Male sterility

- Prevents self pollination, permits cross pollination.
- Leads to heterozygosity
- Female gametes function normally
- Assayed through staining techniques
- ► Innature, occur due to spontaneous mutations
- Can be induced artificially

What is Male sterility?

An inability of a living organism to effect sexual reporduction.

What is Male sterility?

- 1. It is the failure of plants to produce functional anthers, pollen, or male gametes.
- 2. Occurs mainly in bisexual plants.
- 3. **J.k.koelreuter(1763)**observed anther abortion within species&species hybrids.
- 4. More prevalent than female sterility.



Why male sterility?

- 1. Reduced the cost of hybrid seed production.
- 2. Production of large scale of F1seeds.
- 3. It avoids enormous manual work of emasculation and pollination.
- 4. Speedup the hybridization programe.
- 5. Commercial exploitation of hybrid vigour.

History of Male Sterility

- Genic male sterility has been reported in cabbage (Rundfeldt 1960) cauliflower (Nieuwhof 1961)
- Male sterility system have been also developed through genetic engineerning (willams et al. 1997) and protoplast fusion(pelletier et al. 1995)
- ► Male sterility were artificially induced through mutagenesis(kaul 1988)

Manifestations of Male Sterility

- Absence or malformation of Male organs.
- ► Failure to develop normal microsporogenous tissue anther
- Abnormal microsporogenesis deformed or inviable pollen
- Abnormal pollen maturation
- ▶ Non dehiscent anthers but viable pollen, sporophytic control
- Barries other than incompatibility preventing pollen



phenotypic Expression of Male Sterility

- ► Absence of male sex organs.
- ▶ Lack of normal anther sac.
- Inability of the pollen to mature.
- Inability to develop normal pollen.

phenotypic

- ► Three types of sterility:
- 1. **Pollen sterility** " in which male sterile individuals differ from normal only in the absence or extreme scarcity of functional pollen grains (the most common and the only one that has played a major role in plant breeding)
- 2. **Structural or staminal male sterility"** in which male flowers or stamen are malformed and nonfunctional or completely absent
- 3. **Functional Male Sterility"** in which perfectly good and viable pollen is trapped in indehiscant anther and thus prevented from functioning

Genotypic

A) Genetic male sterility

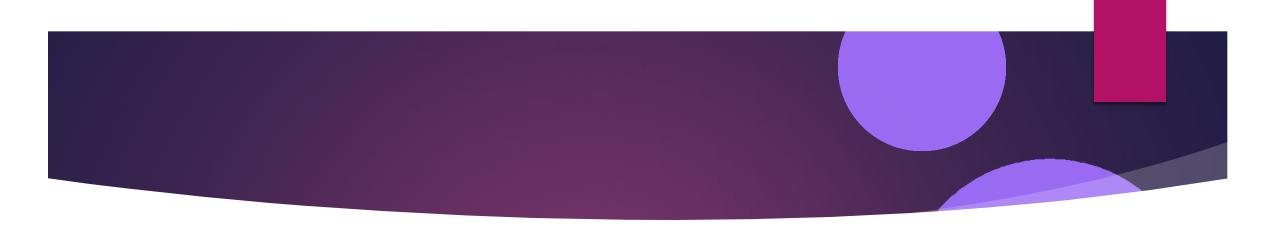
- GMS also called as nuclear male sterility.
- Ordinarily governed by single recessive gene Ms.
- Some dominant gene governing male sterility.E.g.in safflower.
- ► GMS occurs widely in plant and in given plant species several different Ms gene act monogenically to produced male sterility.

Types of Male Sterility

- Cytoplasmic male sterility(cms)-governed by cytoplasmic genes
- Genetic male sterility (Gms)-governed by nuclear genes
- Cytoplasmic-genetic male serility(CGMS)-governed by bothnuclear and cytoplasmic genes
- Transgenic male sterility- induced by the technique of genetic engineering
- ► Chemical induced male sterility induced by the use of Chemical



CLASSIFICATION



Kaul(1988) classified male sterility in three major groups

Phenotypic Male Sterility(Morphological):-not found inBrassicaceae

- 1. Structural or staminal male sterility
- 2. Pollen Male sterility
- 3. Functional Male sterility

GENOTYPIC MALE SERILITY

- Genetic male sterility(Gms)
- 1. Envinronmental sensitive (EGMS)
- Thermo sensitivitive genetic male sterility(TGMS)
- Photoperiod sensitive genetic male sterility (PGMS)
- Evinronmenta non-sensitive
- Cytoplasmic male sterility (cms)
- Cytoplasmic genetic male sterility (cgms)
- 3. Transgenic male sterility(Tms)
- Chemically induced male sterility (CHA)



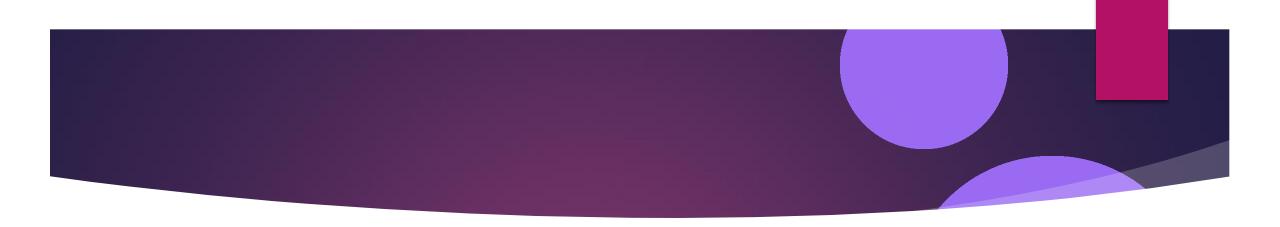
Cytoplasmic Male Sterility

Cytoplasmic male sterility is governed by cytoplasmic factors.in fertilization process, Zygote is formed by the fusion of egg cell and one male gametes. The zygote carries equal number of chromosomes from both(male&female) gametes, but cytoplasm of egg cell(female).so the cytoplasmic male sterility shows Maternal inheritance.

CYTOPLASMIC MALE STERILITY

- This type of male sterility is dermined by the cytoplasm.
- ► Since the cytoplasm of a zygote comes primarily from egg cell, the progeny of such male sterile plants would always be male sterile.
- Nuclear genotype of male stetile line would be almost identical to that of the recurrent pollimator strain.
- The male sterile line is maintained by crossing it with the pollinator strain used as the recurrent parent in the backcross programme since its nuclear genotype is identical with that of this male sterile line.
- Such a male feritile line is know as the maintainer line Or B line as it is used to maintaine the male sterile line is also known as the A line

- Cytoplasmic male sterility may be utilized for producing hybrid seed in certain ornamenta species or in species where a vegetative part is of economic value.
- ▶ But in those crop plants where seed is the economic part. It is of no use because the hybrid progeny wouldbe male sterile.
- Cytoplasmic male sterility is not influenced by envinronmenta fators such as low or high temperature in other words the sterility is stable.
- ► This type of male sterility found in onion, fodder jowar.cabbage.etc.



Application of cutoplasmic Male Sterility In plant Breeding

It is application in production of hybrids in ornamental crops and vegetatively propagated crops, overall, where grain or fruits is not the economic product.

Examples-Observed in sugarcane, potato, forage crops.

GOLDEN RICE



INTRODUCTION

- A genetically modified food crop
- Contain beta-carotene which is golden in colour
- Is intended to be used in combination with existing approaches to vitamin A Deficiency



- Developed in Europe and made its debut in Asia January 2001
- And also called as pro-vitamin A enhanced vitamin
- Has the potential to reach many people including those who do not have reliable access to or cannot afford other sources of



SOURCES OF VITAMIN A

MYFOODDATA

Top 10 Foods High in Vitamin A

900µg of Vitamin A (RAE) = 100% of the Daily Value (%DV)

1 Carrots



148% DV (1329μg) per cup cooked

55 calories

2 Tuna



143% DV (1287µg) in a 6oz fillet

313 calories

3 Butternut Squash



127% DV (1144μg) per cup cooked

82 calories

4 Sweet Potato



122% DV (1096μg) per cup baked

103 calories

5 Spinach



105% DV (943µg) per cup cooked

41 calories

6 Cantaloupe



33% DV (299 μ g) per cup

60 calories

7 Lettuce



23% DV (205μg) **per cup**

8 calories

8 Red Bell Peppers



22% DV (198µg) per cup cooked

38 calories

9 Pink Grapefruit



15% DV (133μg) **per cup**

97 calories

10 Broccoli



13% DV (120µg) per cup cooked

55 calories

EFFECTS OF MALNUTRITION

- Symptoms of vitamin A Deficiency(LAD) include; night blindness, increased susceptibility to inspection and cancer, anemia(Lack of red blood cells or hemoglobin) deterioration of the eye tissue and cardiovascular diesease
- Nearly 9 million children die from malnutrition each one year. A large proportion of those children die from common illnesses that could have been avoided through adequate nutrition.
- The reduce immune competence increases the morbidity and mortality rate of children

GOALS: MORE IS WHAT WE AIM FOR

Mutate rice plants to produce carotenoids, or organic pigments, specifically beta-carotene(pro vitamin A) in the endosperm, the edible part of the grain.

Make golden rice accessible locally, free of charge to farmers, who are able to grow, save, consume, replant and locally sell Golden Rice.

HOW DOES IT WORK?

- ▶ The addition of 2 genes in the rice genome will complete the biosynthetic pathway
- 1. Phytoene synthase(psy)- derived from daffodils(Narcissus Pseudoscience)
- ▶ (phytoene synthase is a transferase enzyme involved in the biosynthesis of carotenoids. It catalyse the conversion of geranylgeracy phyrophosphate to phytoene.)
- ► Lycopene cyclase(crt1)- from soil bacteria Erwinia uredovora
- Produces enzymes and catalysts for the biosynthesis of carotenoids (betacarotene) in the endosperm

BENEFITS

- Increase yields
- Disease/Pest resistance
- Climatic change resistance
- Enhanced nutrition
- Environmental benefits



DISADVANTAGES

- Environmental impact
- Excess vitamin and mineral intake/Toxicity
- Health risks
- Profiting- some GM rice developers develop GM rice with added benefits such as higher yields or disease resistance, but also prevent the seeds of the strain of rice from growing by making the transgenic crop sterile. This means the farmer has to buy new seeds from the developer every year, increasing the profits of the GM rice developer.



CONTROVERSIES

- Actual concentration of golden rice was even lower than originally stated.
- Bioavailability of the vitamin A is not possible as it's absorption is depended on other factors not addressed by golden rice.
- Risk to human health and even surrounding environment.



CONCLUSION

- No doubt good source if vitamin A.
- Market raised enormous expectations.
- Prime interest was to introduce Agriculture biotechnology.
- 1. Other internationally recognized programs have achieved considerable progress in alleviating vitamin A deficiency. These programs will continue to be essential in the future in solving programs locally.
- 2. In contrast, the long-term problems posed by Golden rice could turned out to be much greater than any benefits.





PLASTIC POTATO AND HIGH LYSINE CORN

MATERIAL

Num.	Material	Num.	Material
1	Potatoes	10	Measuring cylinder
2	Distilled water (dH20)	11	Aluminium Foil
3	12 ml glycerol	12	Tea strainer
4	0.1M NaOH	13	Oven
5	Tap water	14	Shredder
6	1-2 drops food colouring	15	Grinder stone
7	18 ml Hydrochloric Acid (0.1 M)	16	Hot plate
8	Beaker	17	Spatula
9	Universal indicator		

METHOD (PART A)

To produce potato starch

- Firstly, the potatoes were grated by using shredder
- The shredded potato was put into grinder stone with 100 ml water and then the potato was grinded until the juice squeezed out.
- >Then, the juice was poured into beaker through a tea strainer.
- >The process was repeated with more water.

METHOD (PART A) CONT ...

- After leaved the beaker for 10 minutes, the starch was settled out.
- The juice was decanted (poured) off. So, the starch was left in the beaker.
- After that, 100 ml water was added to rinse the starch.
- The process was repeated where the water was decanted off again.
- This process was leaved clean, wet starch.
- Lastly, the wet starch was dried by using oven to get a white powder.

METHOD (PART B)

To produce bioplastic

- ▶ 15 g of potato starch was measured and then poured into beaker.
- After that, 150 ml of water and 18 ml of 0.1M HCl was added.
- The mixture was stirred. Then, 12 ml of glycerol was added into the beaker.
- The mixture was stirred again until it mixes well.
- The heat on hot plate was turned on and the mixture was mixed thoroughly
- for 15 minutes until an opaque gel was formed.
- The mixture was stirred continuously until there are no lumps.

METHOD (PART B)cont...

- After that, the heat on hot plate was switched off.
- The mixture was tested by using universal indicator.
- If the solution was turned red, showing it was contained acid. So, 0.1 M NaOH was added and stirred.
- If the solution was turned green, showing that the solution was neutral.
- The solution was separated to two different beakers. One was dropped with green colouring whereas another one with orange colouring.
- Lastly, the mixture was poured into an aluminium foil and was spread it out. The mixture was allowed to dry.

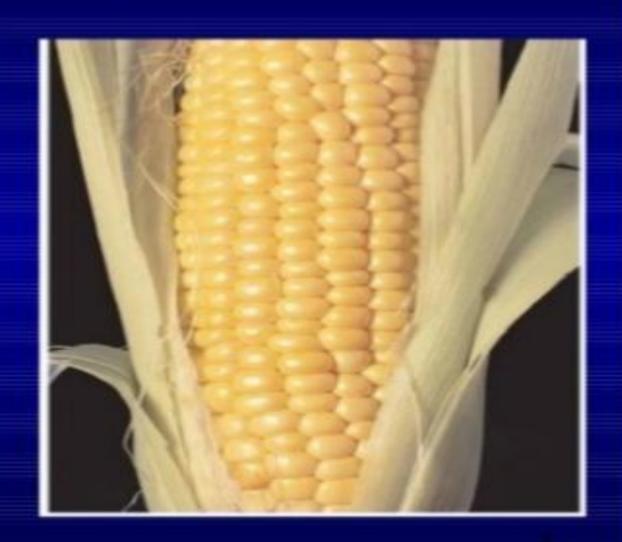
HIGH LYSINE CORN

Introduction

- Name of Crop: Maize
- Botanical Name: Zea mays L.
- Family: Poaceae
- Chromosome No.: 2n = 20
- Center of Origin: Central America (Mexico)
- Mode of pollination : Cross pollination
- Out crossing percentage: 95%
- •India is the sixth largest producer of maize in the world contributing 2% of the global production.
- •In India maize is the third most important crop after rice and wheat and accounts for 9% of the total food grain production in country.
- The important maize growing states are Karnataka, Andhra Pradesh,
 Bihar, Punjab and Himachal Pradesh

Maize in developing countries

- Primarily animal feed in
 - East and Southeast Asia
- Primarily human food in
 - Africa
 - Central America
 - South Asia
- 15-56% of total daily calories
 - For several hundred million people
 - Including weaning children
 - in 25 countries



Nutritional Limitations of Maize

Low lysine and tryptophan Need to improve nutrition

Low availability of niacin

- Essential amino acids
- Major seed protein (60%)
- Lysine level about 2%
- 4% recommended by FAO

- For humans and animals
- Quality Protein Maize:
 QPM

Quality Protein Maize

It is an improved variety of maize which contains higher amount of lysine and tryptophan with lower amount of leucine and isoleucine in the endosperm than those contained in normal maize.



Need Of Quality Protein Maize

- Y However, malnutrition still remains a widespread problem, and is particularly severe in developing countries with low per capita income.
- ✓ Animal protein, of course being of higher quality, is scarce and expensive, thereby unavailable to a vast sector of the population.
- Maize is a major cereal crop and plays very important role in human and animal nutrition in a number of developed and developing countries worldwide, derive their protein and calorie requirements from maize.
- With its high content of carbohydrates, fats, proteins, some of the important vitamins and minerals, maize acquired a well-deserved reputation as a "poor man's nutria-cereal".
- ✓ Normal maize varieties are deficient to two essential amino acids, lysine and tryptophan (Azevedo and Arruda, 2010; Mbuya et al., 2011).

Protein intake utilization

- *Common maize 37%
- •o2 maize protein -74%

Maize required for nitrogen equilibrium/ kg of body wt.

- Normal maize -24 g
- *QPM-8 g.

Other nutritional benefits

- Higher tryptophan and lower leucine content,
- *Higher calcium and carbohydrate and carotene
- *Higher niacin

Nutritional superiority of QPM: A compression

Lysine content

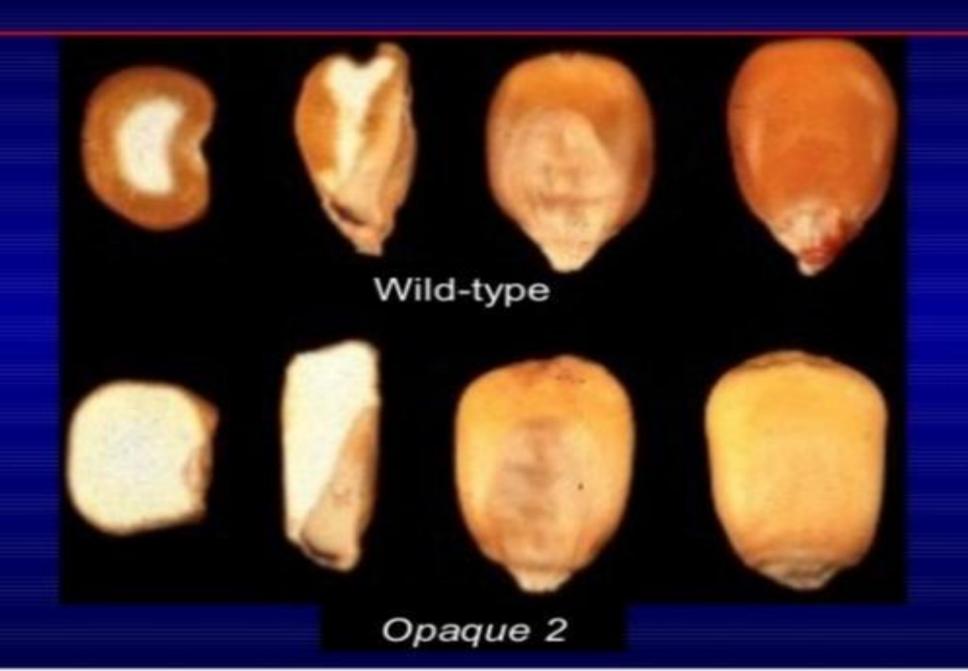
- *Normal -1.3 g per 100 g endosperm protein.
- " 02-3.3 to 4.0 g per 100 g of endosperm protein.

QPM protein contains

- •55% more tryptophan.
- *30% more lysine.
- *38% less leucine than that of normal maize.

Biological Value

- Normal maize protein is 45%.
- •o2 maize is 80%...



Opaque2 — a gene for improving quality of protein in maize

- A natural spontaneous maize mutant with soft and opaque grain was found in a maize fields in USA during the 1920s which was later named as opaque2 (o2) maize by Singleton.
- The mutant was passed onto Mertz at Purdue University, USA, who, in turn, reported that the o2 homozygous maize contained substantially higher lysine (+69%) in the grain endosperm compared to normal maize.
- The increase in lysine content doubled the biological value of the o2 maize protein and this increase in protein quality is due to increase in the ratio of non-zein to zein proteins.



INTELLECTUAL PROPERTY RIGHTS

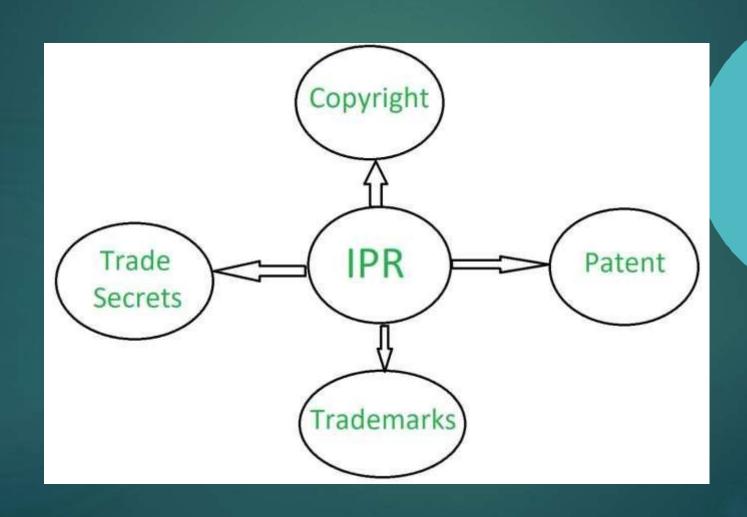
INTELLECTUAL PROPERTY

- ▶ INTELLECTUAL PROPERTY(IV) refers to the creations made by author.
- ▶ It includes:
- Inventions
- Library
- Artistic works
- Designs and Symbols
- Images

INTELLECTUAL PROPERTY RIGHTS (IPR)

- ▶ **Intellectual property rights** are the rights given to persons over the creations of their minds.
- It's the property created by the "Application of human mind"
- ▶ Its time limited.
- Its is a combination of science and technology.

4 major Types of INTELLECTUAL PROPERTY RIGHTS



TRADE SECRETS

- Trade secrets refer to specific, private information that is important to a business because it gives the business a competitive advantage in its marketplace. If a trade secret is acquired by another company, it could harm the original holder.
- When a person holds a trade secret protection, others cannot copy or steal the idea.
- Trade secrets are protected without official registration; however, an owner of a trade secret whose rights are breached-i.e. someone steals their trade secret-may ask a court to ask against that individual and prevent them from using the trade secret.

The 7 'Musts' of Trade Secrets





PATENTS

- A Patent is an exclusive right granted for an invention.
- A patent provides the owner the right to decide how the invention can be used by others.
- Definition of patent is given by U.S. Patent and Trademark Office(USPTO)
- When a property owner holds a patent, others are prevented, under law, from offering for sale, making, or using the product.
- It is the exclusive right of inventor to prevent others from possessing, using, selling, manufacturing and importing the patented invention or offering to do any of these with in a definite geographical area.
- Patents have territorial jurisdiction i.e., we have to register the patents in all countries where we have our interests.
- ▶ Term of Patent: 20 years from date of filing

FORM 1 THE PATENTS ACT 1970 (39 OF 1970)

The Patents Rules, 2003 APPLICATION FOR GRANT OF PATENT (See section 7,54 & 135 and rule 20 (1))

(a) Date

(a) Date

(a) Date

(b) Signature (s) Signature (c) Name(s) Inventor's name

(b) Signature (s) **N.A.** (c) Name(s) of the signatory

(b) Signature (s) N.A.

(i) Declaration by the applicant (s) in the convention country

Wile, the applicant(s) in the convention country declare that the applicant(s) herein is our assignee

(FOR OFFICE USE ONLY)

Application No.: Filing Date: Amount of Fee Paid: CBR No.:

Signature:

			ognature.			
1. APPLICANT						
Name		Nationality			Address	
Indian Institute of Bombay	Technology,	Indian		Powa	Indian Institute of Technology, Powai, Mumbai 400076, India	
2 INVENTOR (S)						_
Name		Nationality		Added		_
Inventor's name		Indian		Address Permanent Address		_
minenton a manne		Indian			Permanent Address	
		IIIWIGII		_		_
						_
3. TITLE OF THE I	NVENTION Title	to be added				_
4. ADDRESS FOR CORRESPONDENCE OF APPLICATION AUTHORIZED PATENT AGENT IN INDIA Dr. Prabuddha Ganguli, 103 B Senate, Lokha Township, Akurli Road, Kandivli East, Mumbai 400101, 5. PRIORITY PARTICULARS OF THE APPLICATION (S) Country Application Filing Date N			handwala 01, India (S) FILED IN	Fa×No.91-22-28844782 Mobile No.9820352815 E-mail:ramugang@vsnl.com		
,	Number					
NA.						
		TENT COOPERATI		Y (PCT) NAT	IONAL PHASE	
International application number			N.A.	N.A		
9. DECLARATION	IS :		_			
(i) Declaration by We, the above na applicant(s) herein (a) Date (b) Signature (s) S (c) Name(s) Inven	amed inventor(s) is our assignee. iignatur e	are the true & fire	st inventor(s	s) for this in	vention and declare that	th

APPLICATION FORM FOR PATENT IN INDIA



COPYRIGHTS

- Copyright is a legal term describing rights given to creators for their literary and artistic works.
- The works covered by Copyright include :
- Literary works such as novels, poems, plays, reference works, newspapers and articles.
- Computer programs and databases
- Films, musical compositions, dance & theatrical productions.
- Artistic works such as paintings, drawings, photographs and sculptures.
- Architecture, advertisements, maps, technical drawings and manuals.
- Copyright comes into existence as soon as the work is created and protects skill & labour employed by the creator in production of his work.



Copyright

Patent

Serves Authors

Protect Creative Works

Applies on Photograhy, Art, And Music

Serves time frame of 70-170 years Serves Inventors

Grant Exclusive Right to exploit an invention

Applies on Technologies And Medical Devices

Serves the timespan of 15-20 years

DIFFERENCE BETWEEN COPYRIGHT S AND PATENT

TRADEMARKS

- A trademark is a sign capable of distinguishing the goods or services of one enterprise from those of other enterprises. Trademarks are protected by intellectual property rights.
- ▶ The trademark owner can be an individual, business organization.
- It may include a device, brand, heading, label, ticket, name, signature, word, letter, numerals, shape of goods, packaging or combination of colors etc.,
- Trademark is a recognizable sign, design, or expression which identifies a project.
- It can either be individual or business organization.
- It is located on a package, a label on a product itself.
- Trademark symbol with "TM" and "SM" in superscript denotes unregistered trademark.
- Its used only for promotion of goods.
- Trademark symbol with letter "R" surrounded by circle denotes registered trademark.



TRADEMARK OF WELL KNOWN COMPANIES

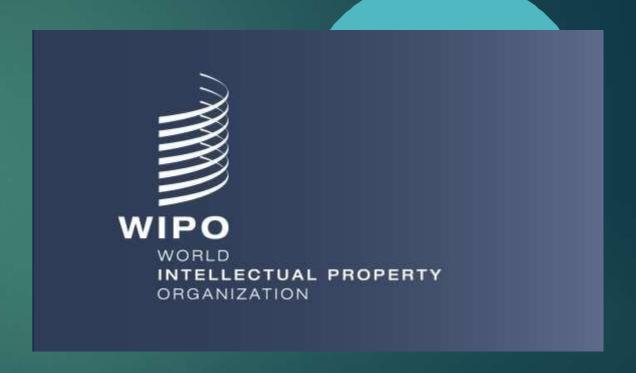


WIPO

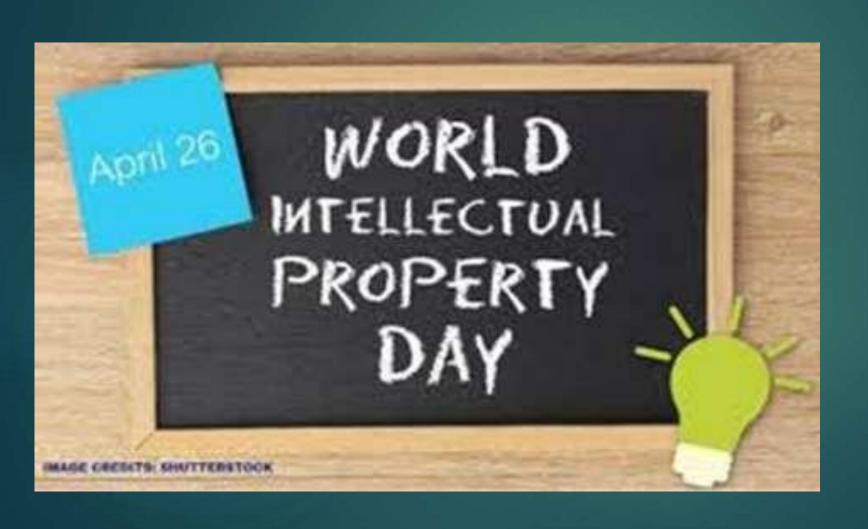
- World Intellectual Property Organization (WIPO)
- It was created in the year 1967 "to encourage creative activity, to promote the protection of intellectual property throughout the world.
- ▶ WIPO has 193 member states.
- ▶ The head quarters of WIPO is located in Geneva, Switzerland.

WIPO HEAD QUARTERS AND LOGO





WORLD INTELLECTUAL PROPERTY DAY



► Its celebrated on April 26th, everyyear

Bioethics

Ethics

involves the set of rules that society have agreed about living with other people for minimums, which are human rights.

Bioethics

 Bioethics is a branch of ethics, which is the interdisciplinary study of problems created by biological and medical progress (micro and macrosocial level), and its impact in society and value system, both for now and for the future.

The birth of bioethics

- Bioethics was preceded by medical ethics, which focused primarily on issues arising out of the physician-patient relationship.
- The ancient Hippocratic literature (which includes but is not limited to the Hippocratic Oath) enjoins doctors to use their knowledge and powers to benefit the sick, to heal and not to harm, to preserve life, and to keep in the strictest confidence information that ought not to be spread about (though precisely what must be kept confidential is not detailed).

- These basic values and principles remain an essential part of contemporary bioethics.
- After the Second World War it became clear that the old medical ethics was not sufficient to meet contemporary challenges.

Bioethics defined

- In the Introduction to the 1995 revised edition of the Encyclopedia of Bioethics, Warren Thomas Reich, defined bioethics as
- "the systematic study of the moral dimensions—including moral vision, decisions, conduct, and policies—of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting."

The Coining of the Term 'Bioethics

The word bioethics was coined in the early 1970s by biologists in order to encourage public and professional reflection on two topics of urgency:

- 1) The responsibility to maintain the generative ecology of the planet, upon which life and human life depends
- 2) The future implications of rapid advances in the life sciences with regard to potential modifications of a malleable human nature

Principles of Bioethics

- In bioethics they are four basic principles and they were proposed by Beaucham and Childress (1979):
- Autonomy
- Beneficence
- Non maleficence
- Justice

PRINCIPLE OF AUTONOMY

Actions are only autonomous when it exists:

- Intentionality
- Knowledge (it is essential)
- Not external control (there are not pressures)
- Authenticity (coherence with system of values and usual attitudes of the person)

PRINCIPLE OF BENEFICENCE

- It has to act in benefit of person, but it can cause collateral effects.
- It is important to know that you cannot do good against the other person's will.



PRINCIPLE OF NO MALEFICENCY

- You cannot harm unnecessary other people.
 Damage can be avoided not acting, with a passive attitude. However, good has done with active attitude.
- If someone asks you, you cannot do damage.

PRINCIPLE OF JUSTICE

 It involves to tract on the same way equal to equal and unequal to unequal. Vulnerable population have to receive an immediate benefit.



PATENIIING BIOLOGICAL MATERIALL

Criteria for Patentability

NOVELTY

NON-OBVIOUSNESS

INDUSTRIAL APPLICABILITY

Biological Patent

- A biological patent is a patent on an invention in the field of biology, that 'by law' allows the patent holder to exclude others from making, using, selling or importing the protected invention for a limited period of time.
- It may include biological technology and products, GMOs and even genetic material.
- The scope and reach of such patents vary among jurisdictions like Australia, Europe, India, China and USA etc...

Patenting of Life forms as per <u>TRIPS</u>

- Article 27.3 (b) explains that members which exclude from patentability are-:
- Plants and animals other than any kind of Micro-organisms.
- Essential biological process for the production of plants and animals.
- Naturally existing Life-forms.

On dissecting the same article, we figure out that:-

- Must allow patents for microbes and microbiological processes.
- Protection should be given for plant varieties.
- Patents should be provided for a genetically modified organism that is useful or purposeful.

....The first fightback

Living things became the legal subjects to patent in 1980, when the US supreme court held that a bacterium designed by its inventor ANAND MOHAN CHAKRABORTY, could breakdown crude oil components and so was the legitimate object of a patent.

 Indeed, as the Supreme court noted in that case, Congressional intent regarding the

US PATENT ACT was that... •

Anything under the sun that is made by man is patentable

 Since then, many living or modified organisms have been patented. For eg:- Oncomouse was the first patented mammal.

Quick-FACTS

- After the completion of Human Genome Project in 2003, nearly 25% of the genome (more than 4000 genes)- are already covered by atleast one US patent.
- These include genes for Alzheimer's disease, colon cancer, asthma and two in particular- BRCA1 and BRCA2 (associated with Breast cancer). Myriad genetics holds right to these two genes.
- Since 1980, genes considered to have been <u>"Isolated from their natural state and purified"</u> have been eligible for patent protection. The first few patents include the DNA altered for producing specific proteins like INSULIN.

Patent process in the United States of America

1

• Determine the type of Intellectual property you need

2

Determine if your invention is really patentable.

3

• Determine the kind of Patent (Utility, design or plant).

4

• Get ready to apply Prepare and submit your initial application.

5

Prepare and submit your initial application.

6

Work with an examiner.
 (Incomplete application will be notified of the deficiencies by an official letter from the USPTO)

7

Receive your approval

Ŕ

• Maintain your patent. Maintenance fees are required to maintain a patent in force beyond 4, 8 and 12 years after the issue date.

Patents granted in the US are by

First to invent rule

Other countries generally go for

First to file rule

☐ Bt Cotton

Monsanto company patented genuity 'Bollgard II cotton', designed to resist worm damage, reducing the need for farmers to spray an Insecticide.

* The same company holds many patents on agricultural products such as Cotton, Soybean, Canola and Corn.

Rise AGAINST patenting Life in USA

- Patentability of life forms is a contentious issue.
 While the usefulness of such inventions is proven, ethical questions abound.
- Many people call the idea of creating life in a labs "morally repugnant", as well as owning the products of that creation.
- Many fear a slippery slope: Today a mouse, a plant; tomorrow a human???

- Considering the Oncomouse, legitimate questions include whether intentionally creating life to experience pain, sickness and medical procedures is ethical?
- Regarding genetically modified agriculturally useful products, the wisdom of placing control and ownership over items essential to life-like staple crop products (seeds)- into the hands of few, is to a large extent a matter of concern.
- Complications arise when the GM crops crosspollinate with the non- modified ones, resulting in genes that are patented. In this scenario, patent Infringement is placed on the unwitting possessor of those progeny.

Patenting Scenario in INDIA

- India became a signatory of the Budapest treaty in 2001. It's purpose was the sufficiency of disclosure of biological material.
- International Depository Authority (IDA) was setup at MTCC centre at Chandigarh in 2002, for the deposit of various organisms and their requirements.
- The Indian Patent Act has been amended with effect from January 2005 to comply with the TRIPS agreement.
- Main provision of this act is to allow the grant of product patents in the field of Chemical, food, pharmaceutical and biotechnology.
- Grant of patents for microbiological inventions (that falls under product patent) is for a period of 20 years from the date of filing.

 The patentable Biotechnological inventions can be broadly categorized as-

Products in the form of chemicals, plant extracts, ferments, fermented material; processes/methods for using useful products and compositions/formulations of product such as VACCINES, PROTEINS and HORMONES.

- Unlike the developed countries, India does not provide patenting of micro-organisms that already exist in nature. WHY?*
- But Genetically modified versions of the same microorganisms that result in enhancement of its known efficacies are patentable.

The Landmark Case

- In 2002, Kolkata high court granted patent for the invention involving micro-organisms.
- This actually happened when Dimminaco A.G. filed a process patent of preparing infectious Bursitis vaccine.
- His application was initially turned down by the Patent Office.

Patentables in Indian BT Status

- Recombinant DNA, Plasmids
- Process of manufacturing Recombinant microorganisms.
- DNA sequence whose function is disclosed.
- Recombinant micro-organisms.

Non- Patentables in Indian BT Status

- Living entities of natural origin
- Any process of manufacture or production of living entities.
- Any method of treatment to human beings or animals.
- Biological materials such as organs, tissues, cells, viruses and process of preparing them.

- Any biological method or material causing serious prejudice to human, plant life, health or threats to environment.
- Transgenic plants and animals
- Process of cloning plants and animals.
- Essentially biological process of plants and animals.

Present needs in Indian BT status

Patent awareness programmes

Patent cell for biological materials

Increase the number of depositories

Biotech Inventions

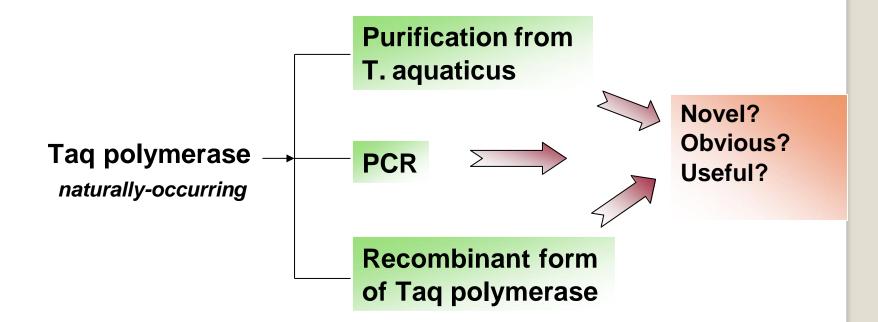
History and Facts

- Article 27 of TRIPS provides the basis for patentability
- US patent law grants patent to microorganisms when modified by human intervention (Diamond v Chakraborty, US Supr. Court, 1980)
- ☐ EPO has similar law with regard to patenting microorganisms
- □ Patentability Criteria Novelty, Inventive step (Non-Obvious in US), Industrial applicability (Utility in US)
- □ Patenting of transgenic animals Allowed in the US (ex: oncomouse); treated on a case by case basis elsewhere
- ☐ Dimminaco A.G. v Controller of Patents & Designs (Calcutta High Court, 2002)

Indian Patent Act

- Section 3 (Patent Amendment 2003) establishes Patentability Criteria for microbiological processes
- Microbiological process that can be established as 'inventions' are patentable
- □ Patentability Criteria Novelty, Inventive step, Industrial applicability
- Biological material deposited at MTCC and Gene Bank, IMTech, Chandigarh
 - all characteristics for identification of the microbial sample
 - access to material allowed after publication of the application
 - disclose the geographical source of the biological material
- Indian law does not allow patenting of animal, whole or part

What is patentable?



Biotech Patents - India

Indian Patent Applications Filed/Granted between 2000 to 2005 in allied areas

Year	Biotech	Chemical	Drug
2000-01	4/0	787/353	883/276
2001-02	2/0	778/483	879/320
2002-03	46/0	776/399	966/312
2003-04	23/0	2952/609	2525/419
2004-05	1214/71	3916/573	2316192

Source: Indian Patent Office, Annual Report 2004-2005

Biotech Patents - India

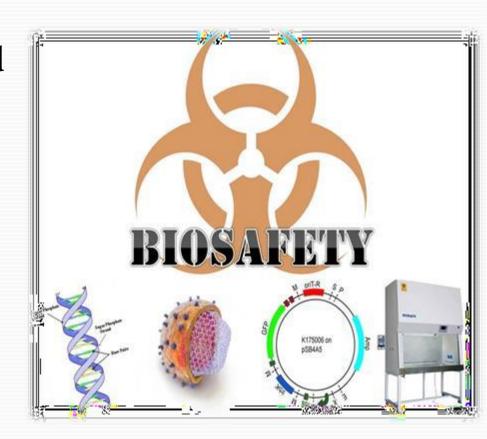
- First Product Patent Granted (post 2005 era)
 Pegasys (Roche) Pegylated IFNα 2a
- Increase in no. of Biotech Application Filings Homegrown company filings less in no.? Homegrown companies filed outside India pre-2005?
- Product vs Process ApplicationsProcess Product
- Patent ExaminersAbout 130-150Dwindling
- □ Patent Examining ProcessTraining in specific fields/art
- Oppositions

Thank You

BIOSAFETY



- "BIOSAFETY" means the need to protect human and animal health and environment from the possible adverse effects of the products of modern biotechnology.
- •Biosafety defines the containment conditions under which infectious agents can be safely manipulated.



CONTAINMENT

- The safety measures which prevent the escaping of GEOs From the laboratory are called containment.
- They help to destroy harmful GEOs within the laboratory itself. Hence there is no chance for the microbes to come out of the laboratory.
- In USA National Institute of Health set up the recombinant DNA advisory committee (RAC) in 1976.
- The RAC provides guidelines about safety measures to keep hazardous organism within limits.
- These guidelines discuss about physical and biological containment.

PHYSICAL CONTAINMENT

- The physical method being adopted inside the laboratories to prevent escaping of GEOs to the environment are called physical containment.
- It include,
- Air filtration
- Sterilization lights
- Waste disposal
- Protective handling

AIR FILTRATION

- The exhaust air from the laboratory is filtered through exhaust filters.
- It prevents the escaping of GEOs from the lab.

STERILIZATION LIGHTS

- Fluorescent tube lights which emit UV light, are fitted in the laboratory to sterilize the work areas and exposed surfaces of the lab.
- This technique destroys microbial containment inside the lab.

WASTE DISPOSAL

 All waste coming from the laboratory are sterilized by autoclaving or by incinerating them in an incinerator. • This will prevent the escaping of contaminated wastes from the lab.

PROTECTIVE HANDLING

- Persons working in the laboratory must follow certain techniques to avoid contamination and to prevent escaping of microbes.
- The person must wear protective clothing before entering the work area ,it should not be carried outside.
- Mouth pippeting should be avoided.

BIOLOGICAL CONTAINMENT

- The biological principles used in laboratories to prevent the escape of GEOs or microbes are called biological containment.
- Biological containment makes the organisms unable to survive in the outside environment.
- It prevents the spreading of vector DNAs to the organisms outside the laboratory by usual conjugation or transduction.
- Bacteria which cannot grow outside unless suitable nutrient have to be supplied are used for gene manipulations.

BIOSAFETY GUIDELINES

- Biosafety guidelines aiming at
- Regulation rDNA research with organisms that have least or no adverse effect.
- Minimizing the possibilities of occasional release of GEOs from the lab.
- Banning the release of GEOs if they are supposed to be causing potential risks in the encironment.
- Food storage, eating, drinking, and smoking are prohibited in lab.
- Mouth pipetting is prohibited
- Laboratory coats are obligatory and should be removed when exiting the lab.

- Working surfaces must be decontaminated using soap and alcohol after each working day.
- Waste products must be decontaminated by incineration or by autoclaving.
- Frequent hand wash is obligatory.
- Laboratory doors should be closed at all times.
- Working with fume producing chemicals must be under the laboratory hood.

Thank you