

# INDIAN PATENT LAW

## Biotech Medicines and IPRs in Developing Countries

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# INDIAN PATENT LAW

## SESSION PATHWAY

- Ayurveda – An ancient Indian Wisdom
- Invention V Discovery
- Non-Statutory Inventions

A cartoon illustration of a boy and a girl in a park. The boy, on the left, has brown hair and is wearing a blue and white striped shirt and brown shorts. He is holding a brown bag and a red and white striped hat. He is gesturing with his right hand towards the girl. The girl, on the right, has long black hair and is wearing a yellow and green dress. She has her hands clasped in front of her. In the background, there is a green lawn, a purple tree, a swing set, and a bright sun in the sky.

Hi!  
Can I be  
Your  
Friend?

No, Sorry.  
Friendster now  
has a **patent**  
on all my  
friendships.

*Puddle City*



# INDIAN PATENT LAW

## Ayurveda

- One of the 12-mega diverse countries of the world
- 7.8% the global recorded species
- Rich in traditional and indigenous knowledge
- Indian system of medicine is known as “Ayurveda”
- Ayurveda
  - āyus, - 'life'
  - Veda -'science'
- 6000 BC
- Sushruta Samhita and Charaka Samhita were influential works on traditional medicine during this era

# INDIAN PATENT LAW

## Art 27 of TRIPS

WORLD TRADE  
ORGANIZATION



- Patents shall be available for any inventions in all fields of technology
  - Products or processes
  - New, Inventive and capable of Industrial application

# INDIAN PATENT LAW

## INVENTION

### Section 2(i)(j) of IPA 1970

- A product or process including improvements that is
  - New
  - Inventive
  - Industrially applicable

**NI<sup>2</sup>**



# INDIAN PATENT LAW



## Discovery vs. Invention

- Substances freely occurring in nature -  
Discovery
- Human intervention leading to an invention  
can be patented
- Natural substance patentable if isolated  
from its surroundings and having a utility  
(European Directive 2001)



# INDIAN PATENT LAW

## INDIAN PATENTS ACT 1970

- Section 3(c) of IPA 1970
  - discovery of any living thing or non living substances occurring in nature

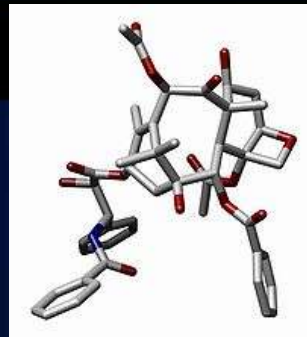
## Discovery V Invention

- Situation 1
  - a Lac is the scarlet resinous secretion of a number of species of Lac-producing insects (*Kerria lacca*)
  - Thousands of these tiny insects colonize branches of suitable host trees and secrete the resinous pigment
  - Coated branches of the host trees are cut and harvested as sticklac
  - It is used in violin
- Is Lac an invention or discovery?

## Discovery V Invention

- Situation 2

- Paclitaxel isolated from the bark of the Pacific Yew tree, *Taxus Brevifolia*
- Mitotic inhibitor used in cancer chemotherapy
- Is Paclitaxel an invention or discovery?



## Discovery Vs Invention

- Situation 3
  - Compound ‘Y’ synthesized in lab
  - Antiviral activity
  - Is compound ‘Y’ a Discovery or Invention

# INDIAN PATENT LAW

## Can a Garlic (*Allium Sativum*) be an “invention” under Sec 2(1)(j) of IPA 1970 ?

- GARLIC is traditionally known as having antibiotic & cholesterol lowering property
- Can this be protected in the form of an invention as an antibiotic?
- Can a bioactive fraction of GARLIC be protected?
- Can a composition of Garlic with other active ingredients be protected?





# INDIAN PATENT LAW

## Patenting Genes – A Discovery or Invention

- Genes per se
- How can one invent genes????
  - Philosophical Reasoning
    - Genes Exist in nature
    - Genes are discoveries
    - Genes are existing in nature and not Novel
    - Gene Isolation is now a well-established and not Inventive



# INDIAN PATENT LAW

## Patenting Genes – A Discovery or Invention

- Genes are composition of matter
- An isolated or purified DNA
- Isolation – removed from original environment
- Not a genomic DNA but cDNA (Human made construct)



# INDIAN PATENT LAW

## EXCLUSIONS

**Section 3(b) :**

Contrary to Public Order or Morality

**Section 3(c) :**

Discovery

**Section 3(d) :**

New Forms & New Use

**Section 3(e) :**

Admixtures

**Section 3(i) :**

Method of Treatment &  
Diagnostic Methods



# INDIAN PATENT LAW

## EXCLUSIONS

**Section 3(j) :**

Plants, Animals & Essentially  
Biological Process

**Section 3(p) :**

Traditional Knowledge

# INDIAN PATENT LAW

## Section 3(b) of IPA 1970



**Bt transformed cotton**

**untransformed cotton**



# INDIAN PATENT LAW

## Section 3(b) of IPA 1970

- An invention
  - contrary to public order or morality
  - serious prejudice to human, plant or environment

# INDIAN PATENT LAW

## Section 3(d) of IPA 1970

Mere discovery of new form of a known substance :

- ⇒ Salts
- ⇒ Esters
- ⇒ Ethers
- ⇒ Polymorphs
- ⇒ Metabolites
- ⇒ Pure form
- ⇒ Particle size
- ⇒ Isomers
- ⇒ Mixtures of isomers
- ⇒ Complexes
- ⇒ Combinations
- ⇒ Other derivatives of known substance

The above considered to be same substance unless they differ significantly in properties with regard to efficacy

# INDIAN PATENT LAW

## Section 3(d) of IPA 1970

### New use of a known substance:

- ➔ Mere discovery of new property or new use of a known substance
- ➔ Mere use of known process unless
  - ▶ results in a new product
  - ▶ employs at least a new reactant



# INDIAN PATENT LAW

## Section 3 (i) of IPA 1970

- ➔ Medicinal, surgical, curative, prophylactic, diagnostic, therapeutic treatment of animals and humans not patentable
- ➔ Treatment of plants patentable
- ➔ Diagnostic apparatus - patentable





# INDIAN PATENT LAW

## INDIAN PATENT MANUAL (Draft)

- A method of treatment
  - by surgery or
  - therapy or
  - of diagnosis
  - practised on the human or animal body shall not be taken to be capable of industrial application

## INDIAN PATENT MANUAL (Draft)

- Diagnosis is the identification of the nature of a medical illness, usually by investigating its history and symptoms and by applying tests
- *AGA Medical Corporation*  
(No.1283/DEL/2004),
  - A method for determining the stretched diameter of a septal defect within the heart of a patient
- Medical Treatment



# INDIAN PATENT LAW

## Section 3 (j) of IPA 1970

- Exclusions
  - Plants and animals or any part thereof
  - Essentially Biological Process for production and propagation of plants and animals
- Inclusion
  - Microorganisms per se



# INDIAN PATENT LAW

## Section 3 (j) of IPA 1970

- Essentially biological processes
  - Grey Area Between Essentially biological processes and other biological processes
  - There are processes which are biological, to the extent they contain some phases in which biological reproduction is employed, yet their most important steps consist of human direct interference

# INDIAN PATENT LAW

## Section 3 (j) of IPA 1970

- Rose cutting by propagation
  - Planted in a soil
  - Chemical addition
- Essentially Biological process



# INDIAN PATENT LAW

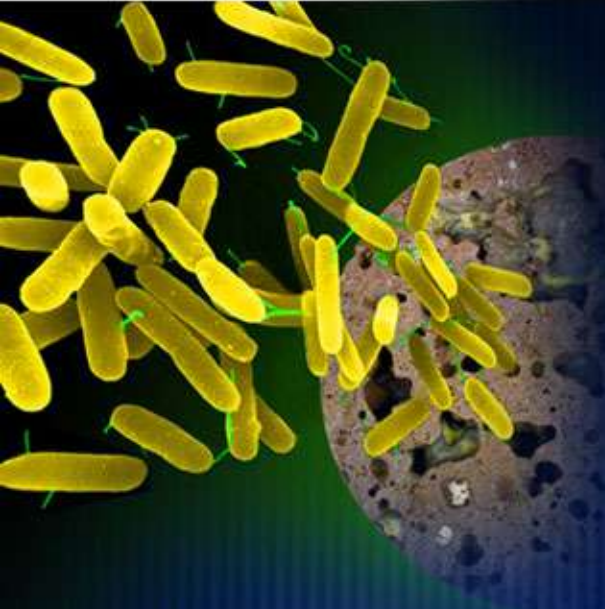
## Section 3 (j) of IPA 1970

- Tissue Culture using stem tips, anthers, petals, pollen and others plant tissues
- Growth medium
- Creating clones of each other
- Human interference
- Not Essentially Biological process



# INDIAN PATENT LAW

## Section 3 (j) of IPA 1970

- 
- ➔ Micro organisms - patentable
    - ▶ Isolated
    - ▶ Mutated
    - ▶ Adapted
    - ▶ Recombinant
  - ➔ Mandatory deposition of the micro organism in an IDA
  - ➔ Source and geographical origin to be disclosed



# INDIAN PATENT LAW

## Section 10 of IPA 1970

- Deposition of biological materials in IDA under Budapest Treaty
- Disclose the source and geographical origin of the biological material
- Deposition date shall be before the filing of Indian Application
- Reference number of deposition to be included in the description within 3-months from the date of filing the application
- On publication of application for patent, biological material will be available to public



# INDIAN PATENT LAW

## Section 3 (p) of IPA 1970

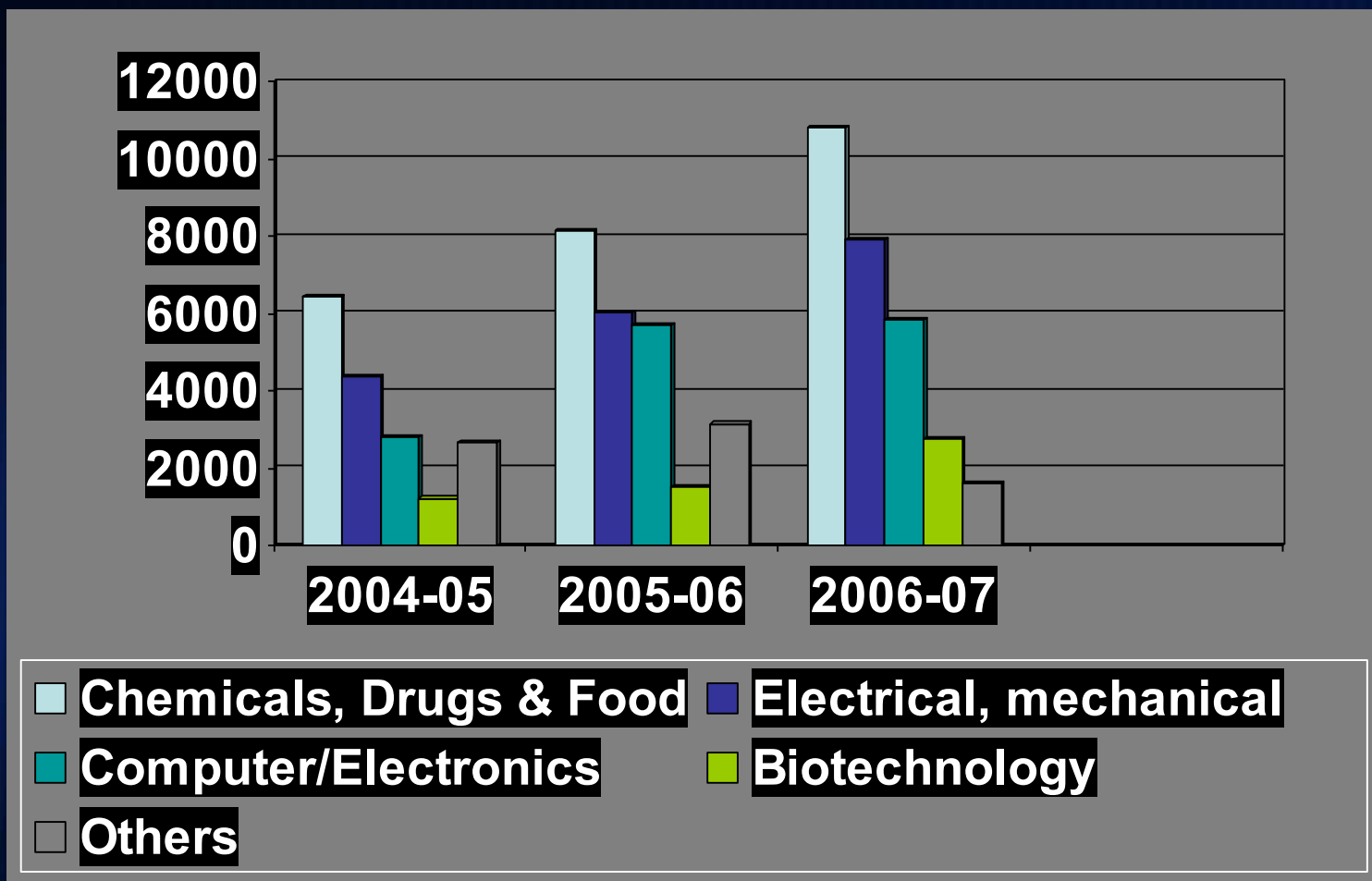
- An Invention
  - Traditional Knowledge
  - Aggregation of known properties



# INDIAN PATENT LAW



## Growth In Patent Applications filed - Area Wise





# INDIAN PATENT LAW

THANK YOU

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