# Intellectual Property Rights
# Patent & Trademark

**Conference for High Court Justices on Commercial Division and Commercial Appellate Division**
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**Anand Grover**
Senior Advocate
Former UN Special Rapporteur (2008-14)
on the Right to Health
Adjunct Professor Georgetown University
Director

LAWYERS COLLECTIVE

# WHAT IS A PATENT...

- **Monopoly** given to inventors for a period (now 20 years)

- Why: **To reward inventions** and to induce R&D investment
  - Does the patentee really **invest in R&D**?
  - **Public funded research institutes**
  - **Subsidies** and grants for research

- **A bargain** between private and public interest: For public disclosure of useful inventions patent granted:*Quid Pro quo*

- Creates monopoly→**hinders competition, raises costs, especially medicines: adversely affects the right to health**

- **Are Patents beneficial to society- NO [See Boldrin and Levine,** ***Against intellectual monopoly*** **]**

# What is a Patent?

- Types of patents: **product and process**
- Product patent: **absolute monopoly**
- Process patent: Can make the product by other methods; **Relative monopoly**
- Territorial right
- **No** international or **cross-border patent** (Unlike trademarks)
- Granted or refused **according to laws of a particular country**

# IP and Right to Health: Impact

- **1911** : Patents and Designs Act, 1911
  - Product and process patent protection
  - Term of patent: 16 years
- **1970** :Patents Act, (For pharmaceuticals and agrochemicals):
  - No product patent protection, only process patent
  - Maximum term of patent: 7 years

- **Consequence**:

- No monopoly on pharmaceutical products

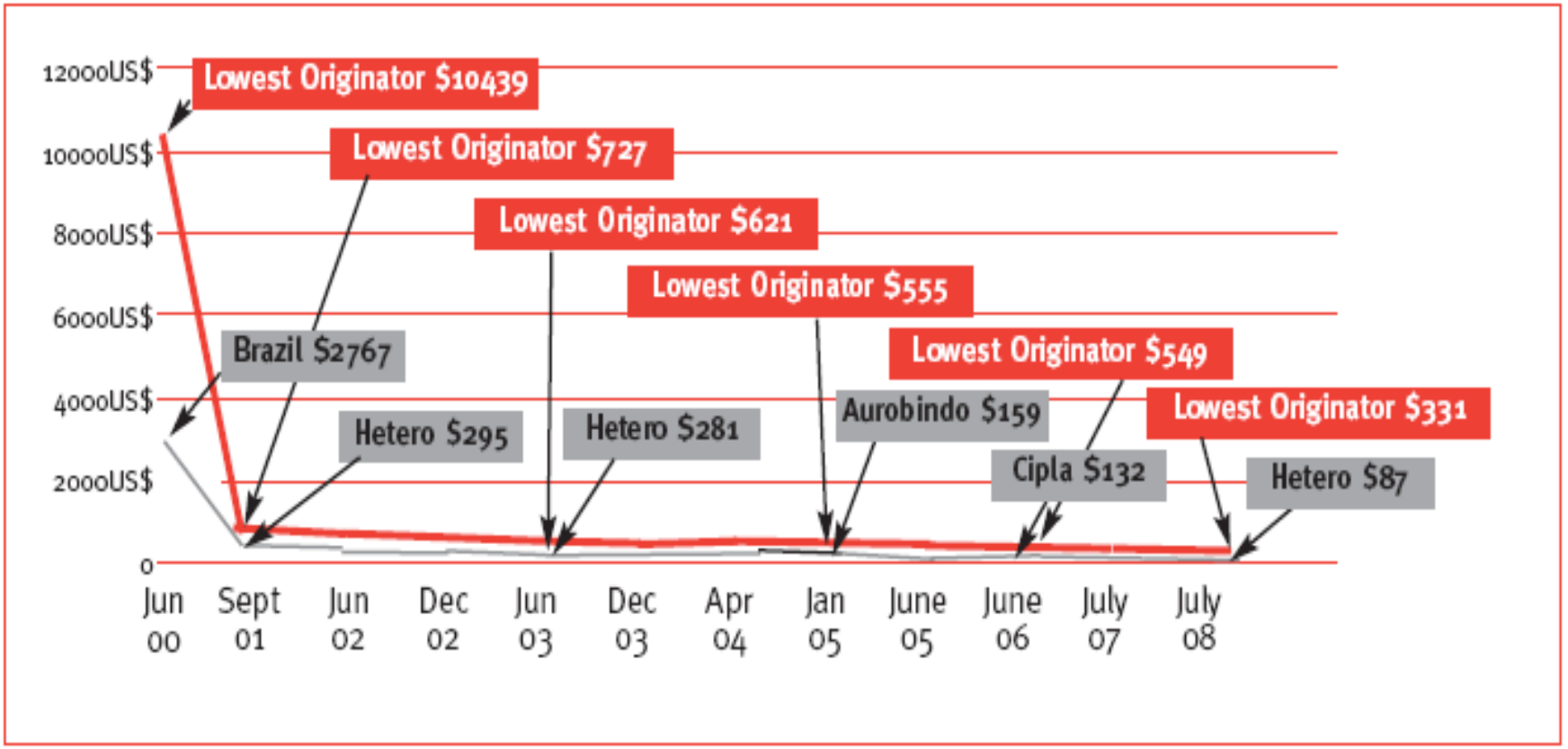
- Indian pharmaceutical companies used alternate, non-infringing processes to manufacture drugs

- More than one manufacturer of drug → competition → lower prices

- **Prices** of medicines in India are the **lowest in the world**.
- **50% percent of the health costs are on medicines: Effect on Right to Health**
- 1988 Indian became net exporter of drugs
- **1995 Indian companies met 95% of the quality affordable ARV generic drugs to developing countries**
- 2005 Indian drugs compete for off patent drugs in the US, EU, Japan

# Effect of Competition on Prices

Graph traces the fall in the prices of first line combination of stavudine(d4T)+ lamivudine (3TC), Nevirapine (NVP). Lowest world price per patient per year

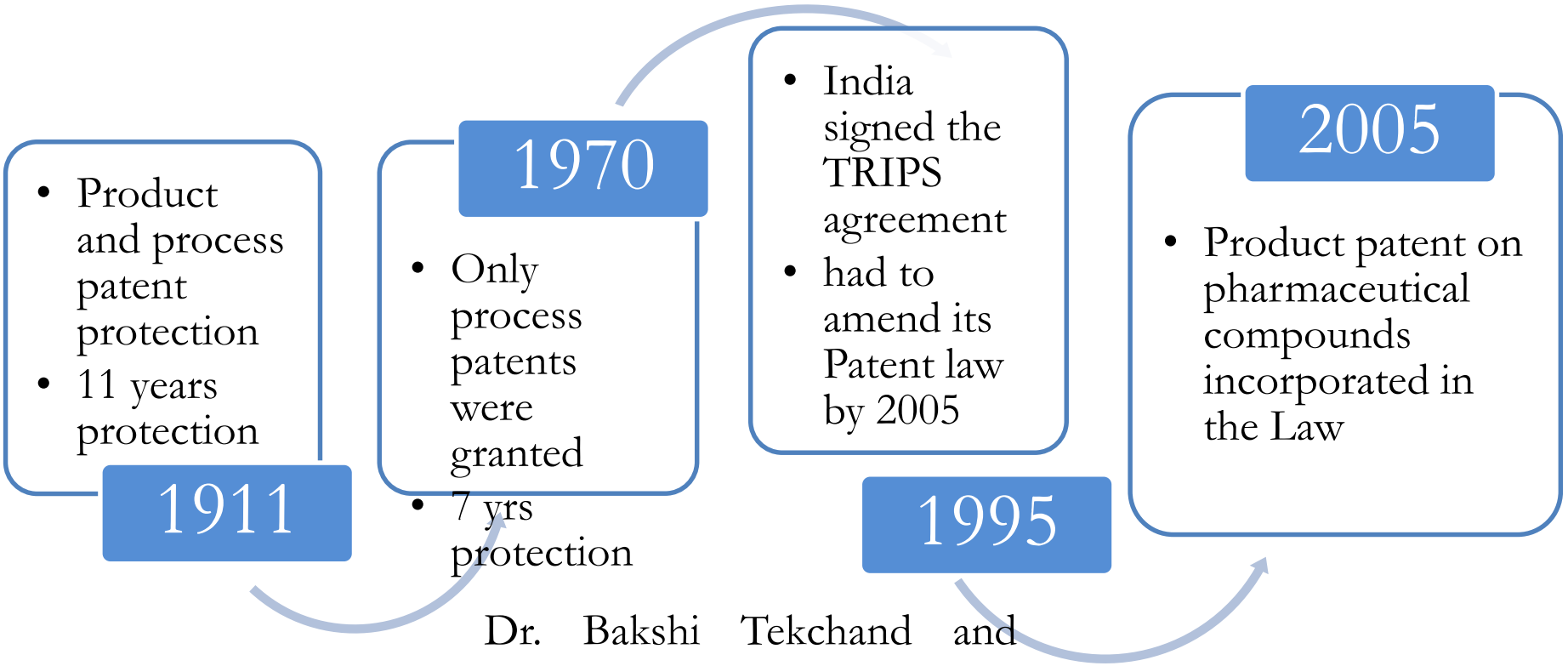



*Source: "Untangling Web of Price Reductions", 11 Edn, 2008, MédecinsSans Frontières*

# TRIPS REGIME

- 1980s onwards: Developed countries, at the behest of the US entertainment and pharmaceutical industries, sought uniform international standards of Intellectual Property (IP) protection to which developing and least-developed countries (LDCs) had to yield.
- Developing countries, including India, formed a group to oppose the inclusion of IP in GATTs
- The US used **Title 301 and Title 301 Special** to browbeat developing countries forging an alliance. That broke the alliance of the developing countries
- Intellectual property subsequently included in GATTs negotiations. India was one of the last to agree
- **1 JANUARY 1995: TRIPS Agreement came into force**
- Different periods for compliance for different countries: India 1st January 2005

# Indian patent regime




Dr. Bakshi Tekchand and Justice N. Rajagopala Ayyangar Report

# TRIPS AGREEMENT

- TRIPS Agreement- lays down mandatory minimum standards of IP protection with effect from 1 January 1, 1995
    - What is patentable?
        - » **new : not practiced or published**
        - » involves an **inventive step to POSITA**; and
        - » is capable of **industrial application** [Article 27]
    - Protection to both products and processes [Article 27]
    - Minimum 20 years [Article 33]

# Patent application- procedure

- Application filed before any of the patent offices (PCT or directly)
- Published on the website
- **Any person may file a pre-grant opposition S(25(1))**
- Examination and issue of First Examination Report (FER)
- Response and hearing in objections in the FER (along with hearing in pre-grant opposition if any)
- In case of rejection, no writ petition is maintainable by person intertested> file post grant opposition [***UCB Farchim v Cipla,*** 2010 SCC Online Delhi 530]

# Patent application- procedure

- If patent is rejected: cannot apply again, novelty lost
- If patent granted: **20 years exclusive right** to prevent others
- **Post-grant opposition (S. 25(2)): Grounds the same as Pre Grant**: By person interested upto 1 year from the date of publication of grant of patent, before the patent office
- **Revocation**: by any person interested before the IPAB
- **Counter-claim** in as suit as defence aginst infringement suit. Suit transferred to High Court

Can't pursue revocation and counter-claim simultaneously [*Aloys Wobben v Yogesh Mehra*, (2014) 15 SCC 360

# What is not an invention

- Certain subject matter excluded under **Section 3 of** the Indian Patent Act
- Frivolous
- Contrary to public order or morality
- Mere discovery or formulation of an abstract theory
- **Mere discovery of new form of a known substance**
- Mere admixture
- Method of agriculture or horticulture
- Medical procedure used in treatment of human beings and animals
- **Plants and animals in whole or any part thereof other than micro organisms but including seeds**
- Mathematical or business method or computer program *per se*

# Extending patent terms: Ever greening

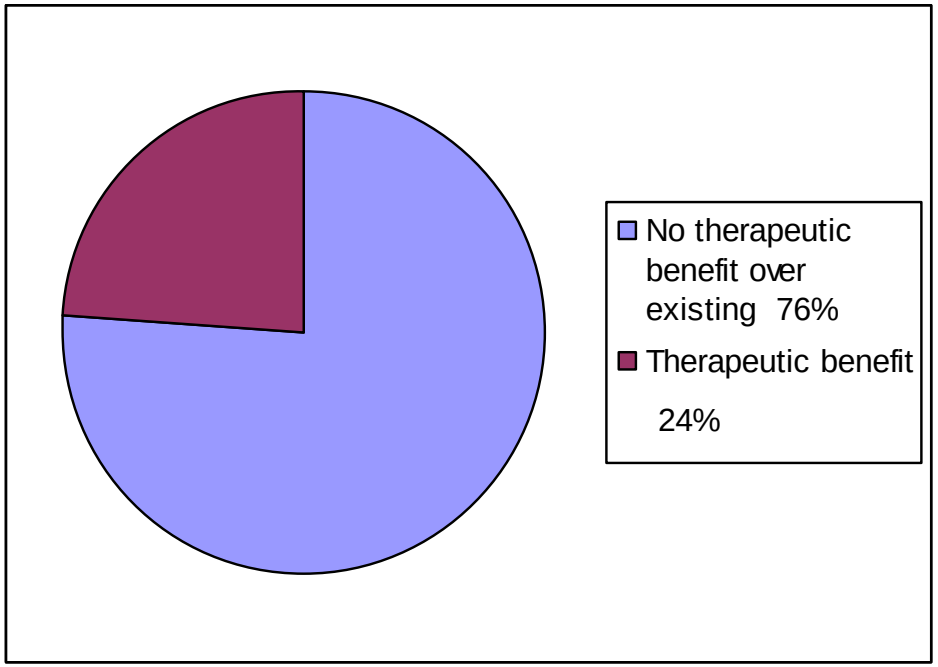
**New form**

| 1982 | 1991 | 1994 | 1995 |
|---|---|---|---|
| Ganciclovir patented | Esters of ganciclovir patented | Patent application filed in US for ester prodrug of ganciclovir (valganciclovir) and its salts | Pre-1995 molecule : patent application filed in India for valganciclovir and its salts |

**New formulations**

| 1996 | 1999 | 2000 | 2003 |
|---|---|---|---|
| Ritonavir patented | Lopinavir patented | Lopinavir +ritonavir soft-gel capsule patented | Lopinavir + ritonavir tablet patent application filed |

# Evergreening: reduces innovation




**New Drug approvals by USFDA from 1989-2000-** Only 15% of 1,035 new drugs approved were highly innovative priority NMEs. Of the remaining, **only 24% showed actual therapeutic benefits** over the existing drugs

**1995-2005:** An estimated 12,000 pharmaceutical applications filed in India, **very few of which have substantial therapeutic benefits** over the existing drugs

*Source: "Changing Patterns of Pharmaceutical Innovation", National Institute for Health Care, Management Research and Educational Foundation, May 2002*]

# Use of flexibilities: Ever greening

- **S 3(d)**, Patents Act, seeks to prevent pharmaceutical 'ever greening'
- ***S 3(d): No patents to new forms of a known substances unless the new form is significantly more efficacious than than the known substances***
- Sec. 3(d) challenged by ***Novartis AG*** as violating the Constitution and TRIPS in Madras High Court: Rejected and held that it is to safeguard the Right to Health, an obligation of the government
- Supreme Court of India in ***Novartis AG*** interpreted "efficacy" in S. 3(d) to mean **"therapeutic" efficacy**
- Supreme Court also held that the **physical properties** of hygroscopicity, free flow, **bio-availability** etc., by themselves do no result in enhanced efficacy
- To get over **S 3(d)**, the Patent applicant has to show the **enhanced efficacy in the application itself** (complete specification)

# New Drug Approvals - 1989-2000

- 1995-2005: estimated **12,000 pharmaceutical applications filed in India**.
- **Very few** have substantial **therapeutic benefits** over the existing drugs
- 2018: **78% of the patents granted are to new forms** of drugs (*How our safeguards against ever-greening have failed, and why the system must be reformed,* Dr. Feroz Ali *et al*, 2018)
- At the Patent Controllers level **S 3 (d) is not being followed**
- India continues to be on the US Special 301 Watch List

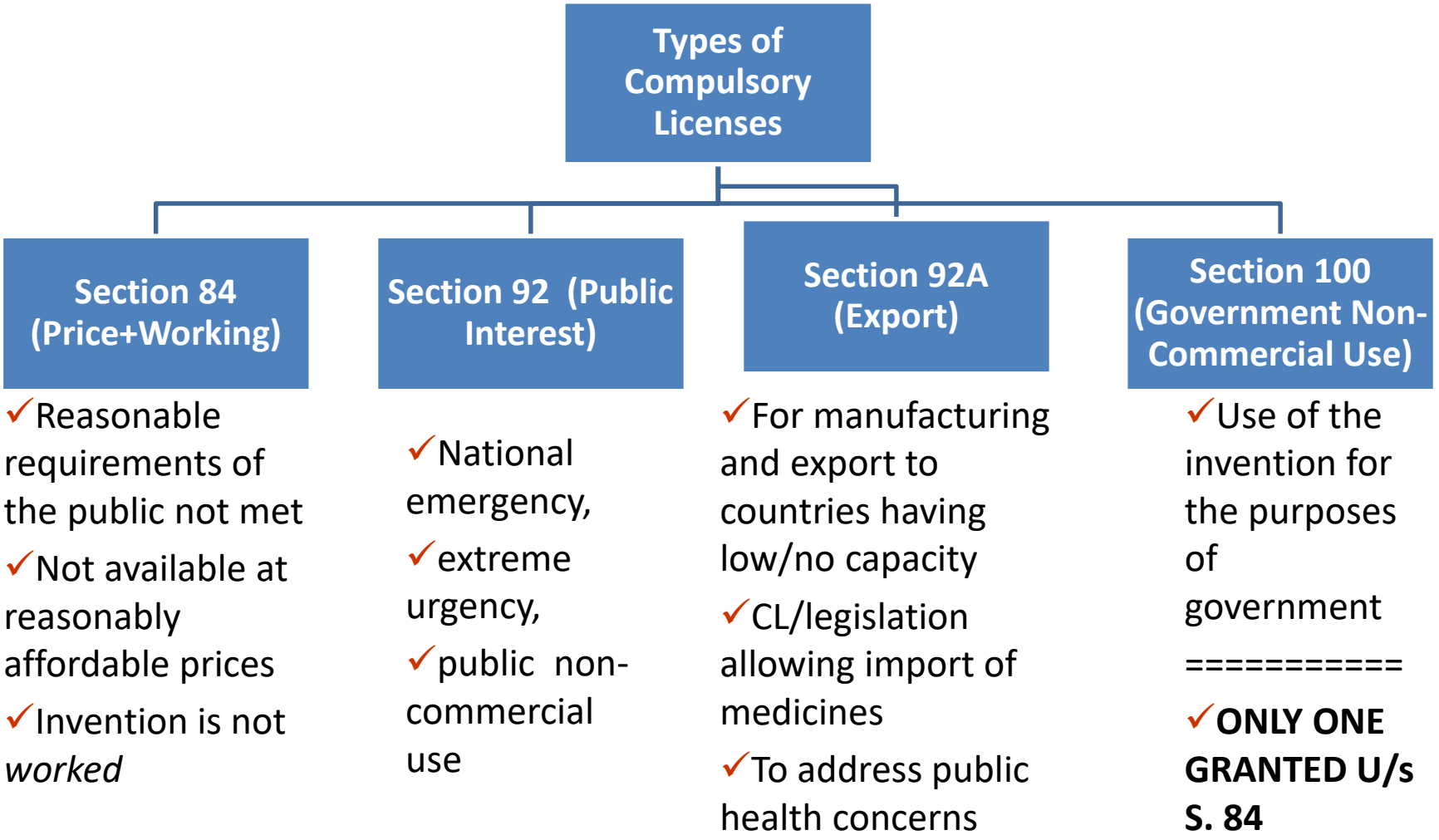
# Bio-technology S. 3 (j)

- Monsanto had **identified a gene (Cry2Ab) in the DNA in bacteria BT (Bacillus Thuringiensis)** found naturally in the soil.
- It synthesized the **Nucleic Acid Sequence (NAS)**, which did not exist in nature and was man made DNA construct.
- The **NAS is inserted into the cell** of the plant resulting in the production of **"a fusion protein"** resulting in the production of **delta endotoxin** which is toxic to bollworm and the Bt cotton plant **becomes resistant to them**.
- Monsanto had **license agreements with Nuzhiveedu** to commercially exploit its genetically modified Bt trait cotton seeds in India as well as use its trade marks.
- Disputes arose and Monsanto filed a **suit for infringement of patent**, **trade mark and passing off** in the Delhi High Court
- **Monsanto contended** that insertion of the **NAS was a bio-technological process** [as opposed to essentially a biological process **covered by Section 3(j)** of the Patents Act] and therefore patentable under the Patents Act.

# Bio-technology S. 3 (j)

- Nuzhiveedu claimed that the NAS is a chemical. **On its insertion into a plant cell, it becomes non-patentable under Section 3(j)** of the Patents Act and **IPRs in plants is protected under the Protection of Plant Varieties** and Farmers Rights Act, 2001, which has a specific provision to override the provisions of the Patents Act.
- **Nuzhiveedu had filed a counter claim** to revoke the patent
- The Single Judge held that counter claim would only be decided on evidence but that there was *prima facie* case of infringement and therefore granted an injunction
- The DB in appeal in deciding the counter claim held that the patent was invalid and dismissed the suit
- The Supreme Court held that **the DB should not have usurped** the jurisdiction of the Single Judge and **tried the counter claim in a summary manner**
- The suit involved complicated and mixed questions of law and facts on patentability and exclusion of patent, which **could be examined in the suit on basis of evidence**.
- The matter was **remanded to the Single Judge for trial on the counter claim** but the injunction granted by the Single Judge was directed to continue

# Compulsory Licenses under the Indian Patents Act , 1970



# Submission of Data to DCGI

- **Section 107A:** usually known as the Bolar exception
- *Bayer Corporation v Union of India & Ors.* (LPA No. 359/2017, Delhi High Court)
- Can any entity/person export a patented product for "development and submission of information"
- Test data is generated from animal studies, Phase I, II and III and post marketing studies
- Single judge has held that it can be done; **Pending before the Division Bench in appeal**
- Huge impact on Indian generic industry if not allowed
- Would make delay by 5 years access to cheaper generic drugs from in India in other countries

# Patent Linkage

- **Linking approval of drugs** subject to **expiry of patents**
- **Delays** entry of **generics** into the market
- Helps prolong the monopoly
- *Bayer v Cipla* (WP ( C ) No. 7833/2008)
  - Bayer filed a petition before the Delhi HC (DB) seeking the rejection of application of marketing approval for Nexavar (cancer drug) by Cipla
  - The writ petition was dismissed indicating that **drug-patent linkage is not permissible**

# Biologics

- **Trastuzumab, breast cancer drug** : Roche developed it
- Primary patent not filed in India
- **Secondary patent: filed** in the name of Genentech (member of Roche Group)
- Trastuzumab was **not manufactured** in India but imported and sold by Roche at **Rs. 1,35,200/- per vial of 440** mg- with discounts a vial could cost around Rs.1,00,000.
- In January, 2013, the Health Ministry made recommendations to the Department of Industrial Policy and Promotion (DIPP) for issuing CL for trastuzumab
- Roche announced 30% price cut to Rs. 75,000 per vial
- Later patent lapsed as Roche failed to renew
- 2016: **Trastuzumab added to National List of Essential Medicines (NLEM)**
- Price capped 440mg vial at Rs. 55,812.29

# Biologics

- **Generic biosimilars** entered the market with expiry of Trastuzumab patent (offered by Biocon Ltd. and Mylan Inc.)
- 2014: **Roche sued** Biocon Ltd. and Mylan and the Drugs Controller General of India (DCGI) claiming that Biocon and Mylan misrepresented their drugs as "biosimilar Trastuzumab" and that their biosimilar versions were not approved in accordance with the Guidelines on Similar Biologic. Roche had
- The Delhi High Court passed ***an ad-interim ex-parte order*** that ***Canmab and Hertraz could not claim any similarity with Roche's Herceptin, Herclon or Biceltis*** (Roche's brands); Trademark Passing off
- In an interim order (dated April 25, 2016), the Delhi High Court was of the opinion that approvals granted to ***Canmab and Hertraz were not in adherence of the Guidelines issued in 2012.***
- However, ***later, the Delhi HC allowed Biocon and Mylan for sale of Trastuzumab for three different types of cancer ( matter pending)***

# Trademarks and pharmaceuticals

- *Cadila Healthcare Ltd. v Cadila Pharmaceuticals Ltd.* (2001 5 SCC 73)
- Cadila Healthcare ***sold Falcigo since 1996***
- Cadila Pharmaceuticals *sold Falcitab since 1998*
- ***Both marks*** using the term ***"Falci"*** derived from the genus of of the mosquito, Falciparum causing cerebral malaria
- Appellant ***filed passing off suit at*** Vadodara District Court
- District court dismissed interim injunction application
  - that ***Falcigo and Falcitab differed in appearance, formulation and price***
  - ***no chance of deception*** as the drug was not meant to be sold to any individual.
- High Court also found ***little likelihood of confusion*** and rejected the appeal

# Trademarks and pharmaceuticals

- In SLP, ***SCt remanded*** the matter back for determination of similarity on evidence, on the following principles:-
- The ***nature of the marks***: whether the marks are word marks or label marks or composite marks, i.e***. both words and label works.***
- ***Phonetic or visual similarity***
- Nature of the goods in respect of ***which trade mark are used***
- ***Class of purchasers*** : their education/ intelligence /degree of care while purchasing the goods
- ***Mode of purchasing the goods*** (over the counter drugs)
- Weightage to be given to each based on facts of each case
- ***Look at the two marks as a whole***
- ***Stress is laid*** on common features instead of difference in essential features

# International Pressure

- Free Trade Agreements and Bilateral Investment Treaties such as RCEP
  - Lack of transparency in negotiations of FTAs/BITs
  - New chapters are added and the civil societies and stakeholders do not have access to it
  - Arbitration agreement in FTAs/BITs: bypasses national legal system and confers jurisdiction on private arbitral tribunals
  - Conflict of interest
  - Expands scope of patentability; limits scope of compulsory license and restricts parallel import
- Pressure to dilute provisions like S. 3(d)
  - India was earlier taken to the WTO panel twice on interim measures -USA and the European Communities
- Threat of trade sanctions being imposed : US 301
- Innovator Companies offering voluntary licenses: e.g. Sofosbuvir in India
  - Generic companies not only withdrew their opposition but also didn't request any compulsory license
  - Voluntary license agreement excludes high incident jurisdictions like Latin America and MENA