Intellectual Property Rights (IPR)

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February 12, 2008
IIM – Ahmedabad, India

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- Trips and IPR – Some facts
- Benefits of Patent Protection
- What is a true R&D and what is not
- R&D Spend and Results
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Highlights of Patent Amendment Act 2005

- Passed by Parliament on 23rd March, 2005
- Product patent re-established after 34 years. Precludes salts, esters, etc. “unless they differ significantly in properties with regard to efficacy”.

Highlights of Patent Amendment Act 2005 contd..

- **Pre & Post Grant Opposition –**

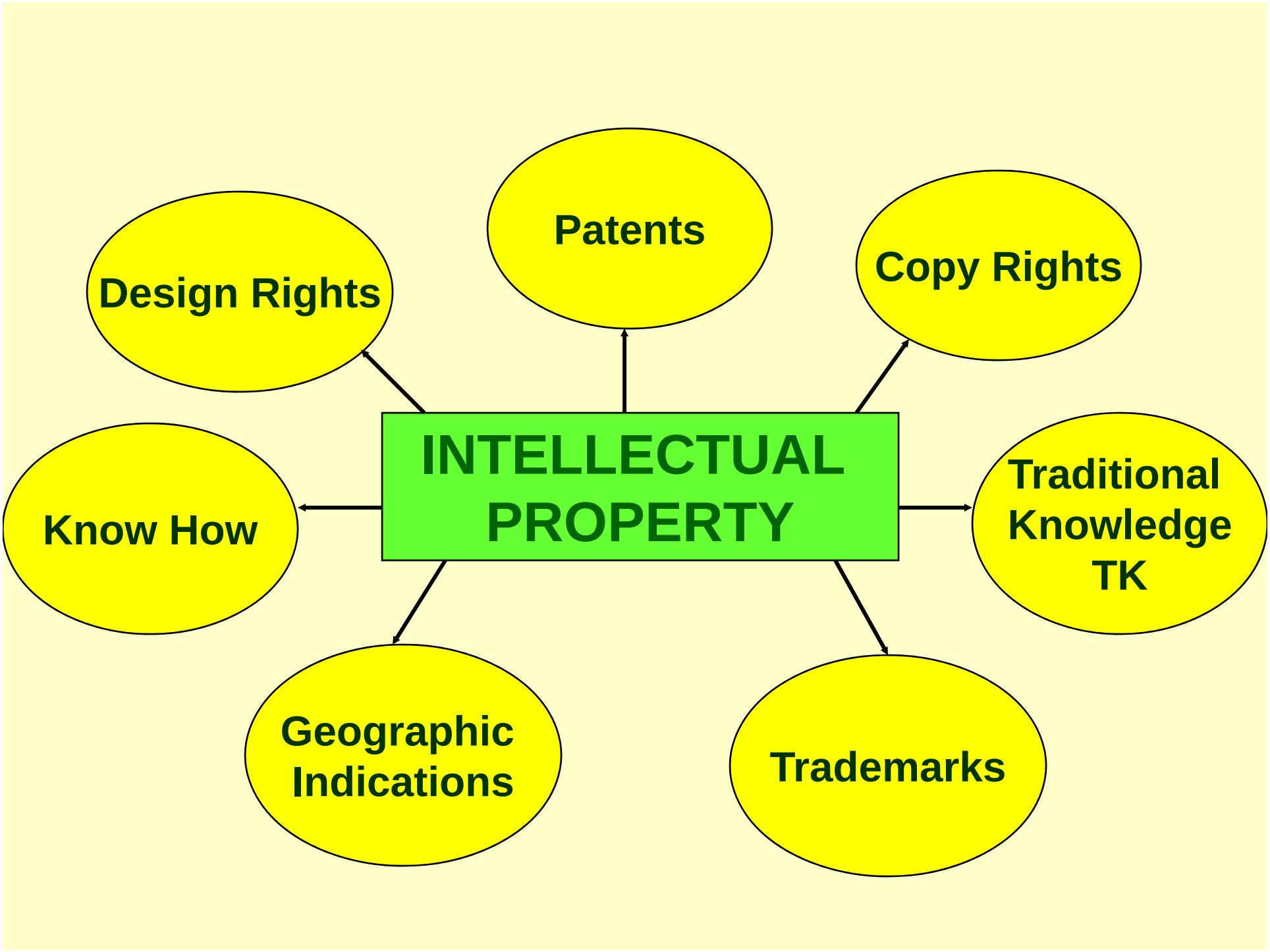
  Both applicable. No time limits for pre-grant opposition proceedings. Post grant proceedings limited to one year after patent grant.

  Some Grounds for Pre-grant Opposition are:

  - Lack of inventive step
  - Lack of novelty
  - Not constituting ‘invention’ as per provisions of the Act
  - Lack of information or incorrect information regarding Patent Corporation Treaty (PCT)
  - Non-disclosure / wrongful disclosure of source of geographical material
  - Traditional knowledge and folklore

What is IPR

- Creative people who disclose their work for benefit of mankind get ownership right over their creation.
- Protects their work from being copied or imitated without their consent.
- IPR can be used, sold, loaned, gifted, stolen.
- IPR encourages innovation.
- Contract between Government & Inventor.
- Government promises to protect invention from copying by others for specific time.
- Inventor commercializes invention for Society’s benefit.


INTELLECTUAL PROPERTY
Patents
Design Rights
Copy Rights
Know How
Traditional Knowledge TK
Geographic Indications
Trademarks

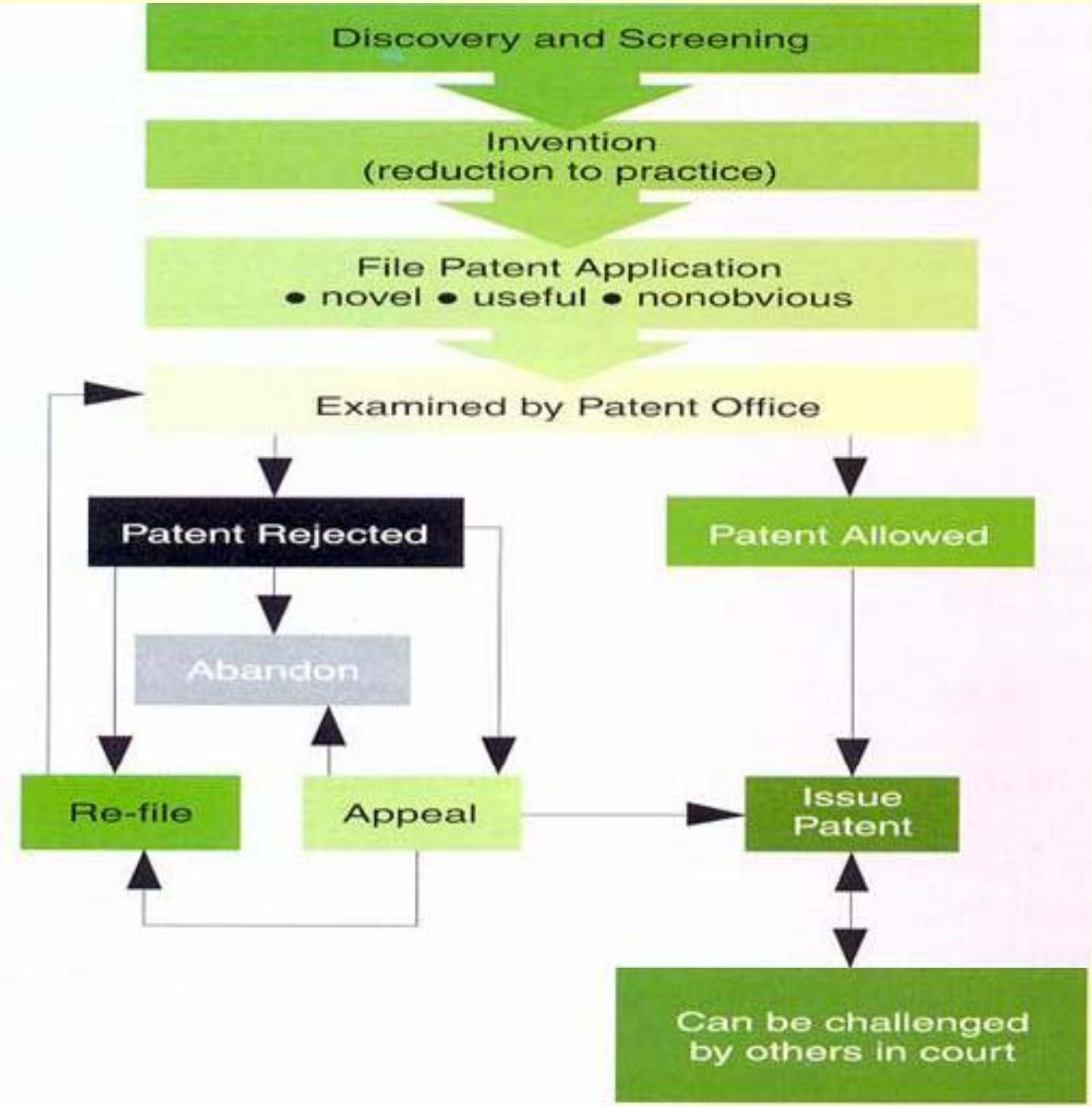
TRIPS

- Trade Related Aspects of Intellectual Property Rights came into force on January 1, 1995.
- Establishes minimum levels of protection Government must grant to IP of fellow WTO members.
- Strikes a balance between long term benefits and short term costs to Society.
- Provides for a Dispute Settlement Body (DSB) which is final authority on all IPR disputes.
- India’s laws cannot be different for Indian or foreign companies in India.

Patents

- Exclusive right granted for an invention which must be
  - novel
  - have an inventive step
  - must be useful
- Invention can be product or process.
- Process patent is a weak protection.
- Patent provides protection to the owner for a limited period like 20 years.
- Inventor gets exclusivity for 20 years in exchange for full disclosure of invention.

Key Steps involved in obtaining a Patent



Why are Patents Necessary?

In Pharmaceuticals

- Over 90% prescription medicines which are generic evolved out of patented medicines.
- Encourages researchers to take risk to develop new products and therapies.
- Strikes right balance between inventor's legitimate concerns about compensation and Society's need for more scientific developments.

How long & costly is Pharma R&D

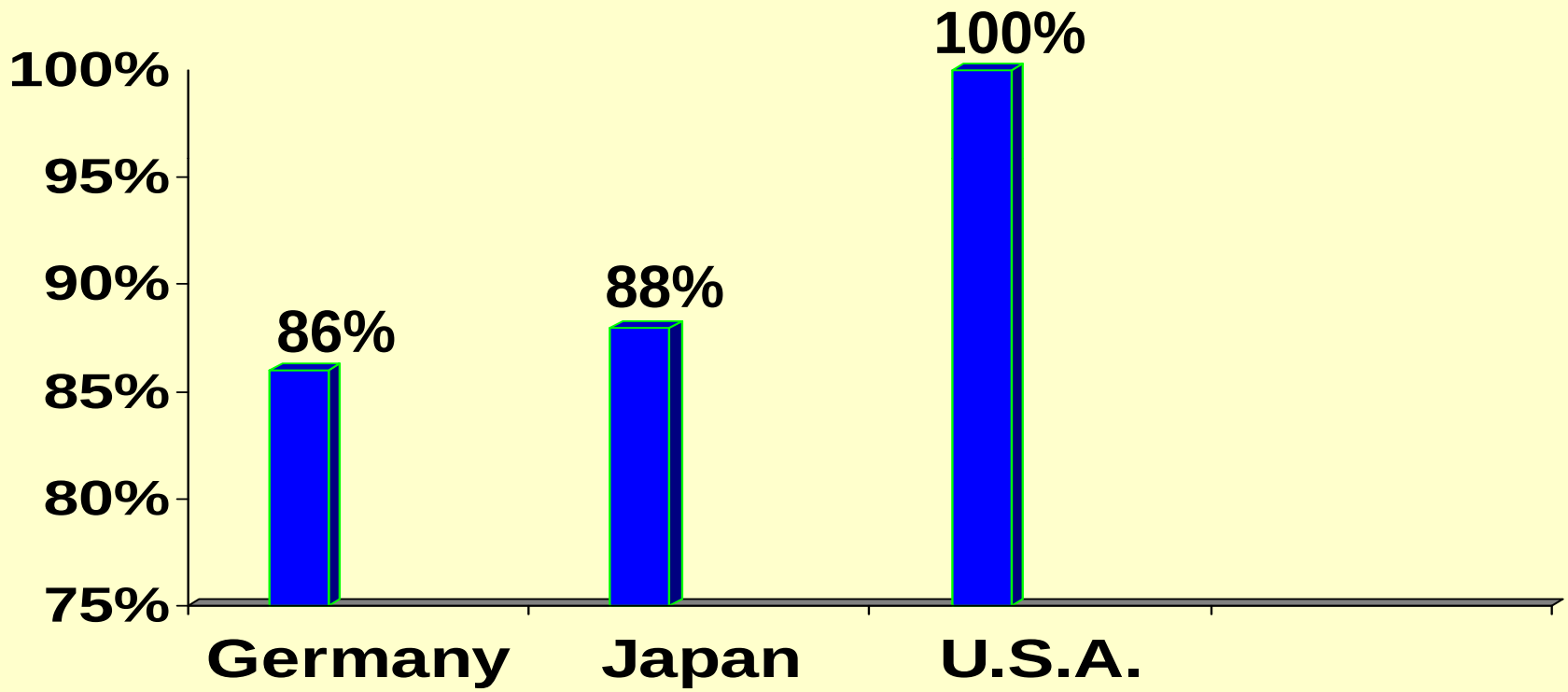
- Takes 8 to 12 years after patenting to launch product **– time consuming**
- Costs about U.S.$ 1 Bn. **– costly**
- Odds 1 in 5000 of new drug getting to market **– risky**
- **Reward** - discoverer deserves compensation for the product until patent expires

Relevance of IP Protection to Foreign Direct Investments (FDI)

- Areas considered before FDI:
  - labor costs
  - labor force quality
  - political risk
  - quality of knowledge workers
  - level of IPR
- Countries with strong IPR Laws receive innovations and knowledge before countries with weak protection.
- Work force benefits from superior training and country becomes more attractive to other high tech industries.

Intellectual Property Protection Strongly Influences Pharmaceutical Companies' Investment Decisions

Percentage of companies* reporting that intellectual property protection has a strong effect on their investment decision in R&D facilities



* Chemical and Drug Companies

Source: Mansfield, Edwin, Intellectual Property Protection, Direct Investment and Technology Transfer, International Finance Corporation, 1995

Will IP Protection Promote Research in Third World Diseases

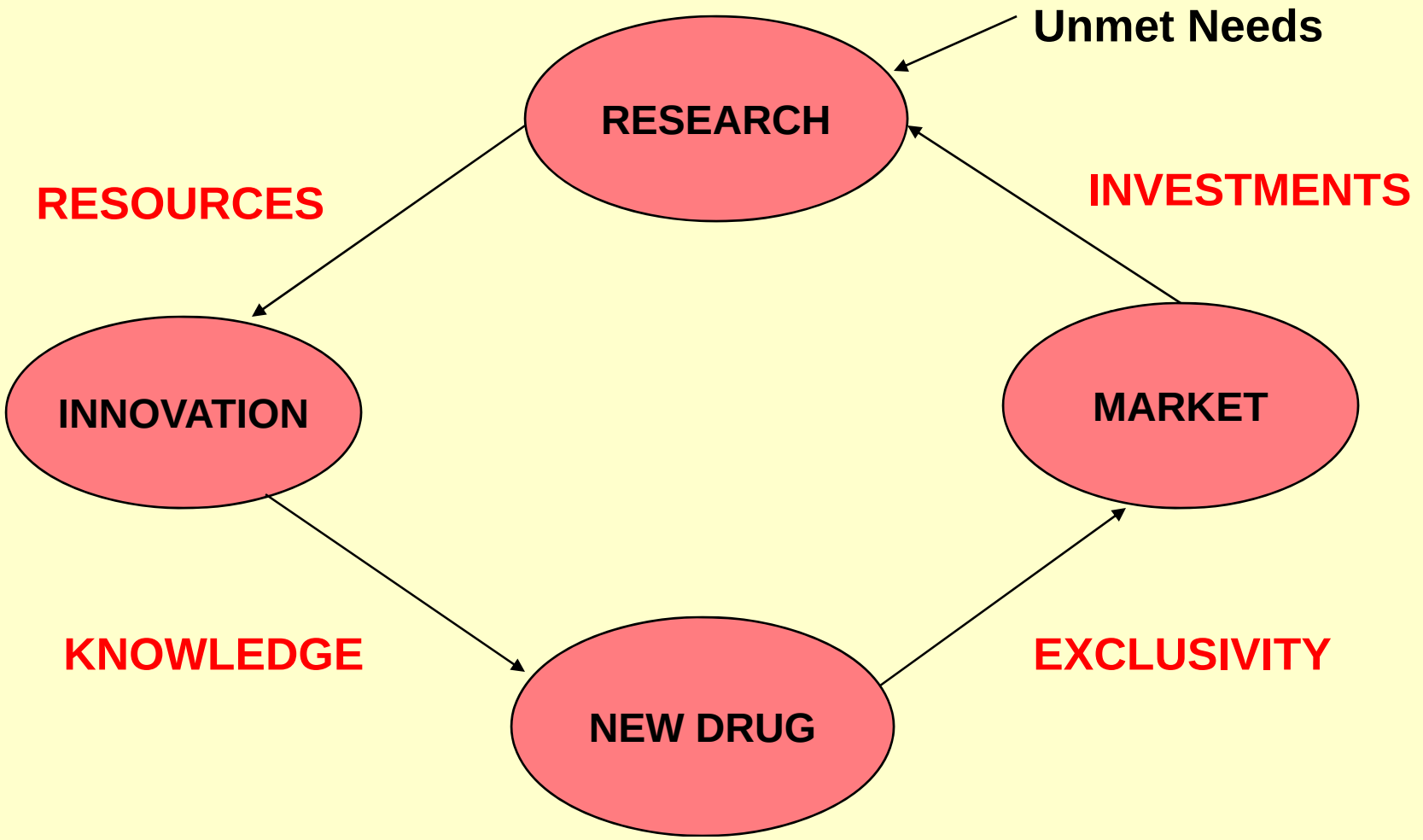
- AstraZeneca has a R&D centre in Bangalore dedicated to TB research.

- Novartis has a Research Institute for Tropical Diseases in Singapore

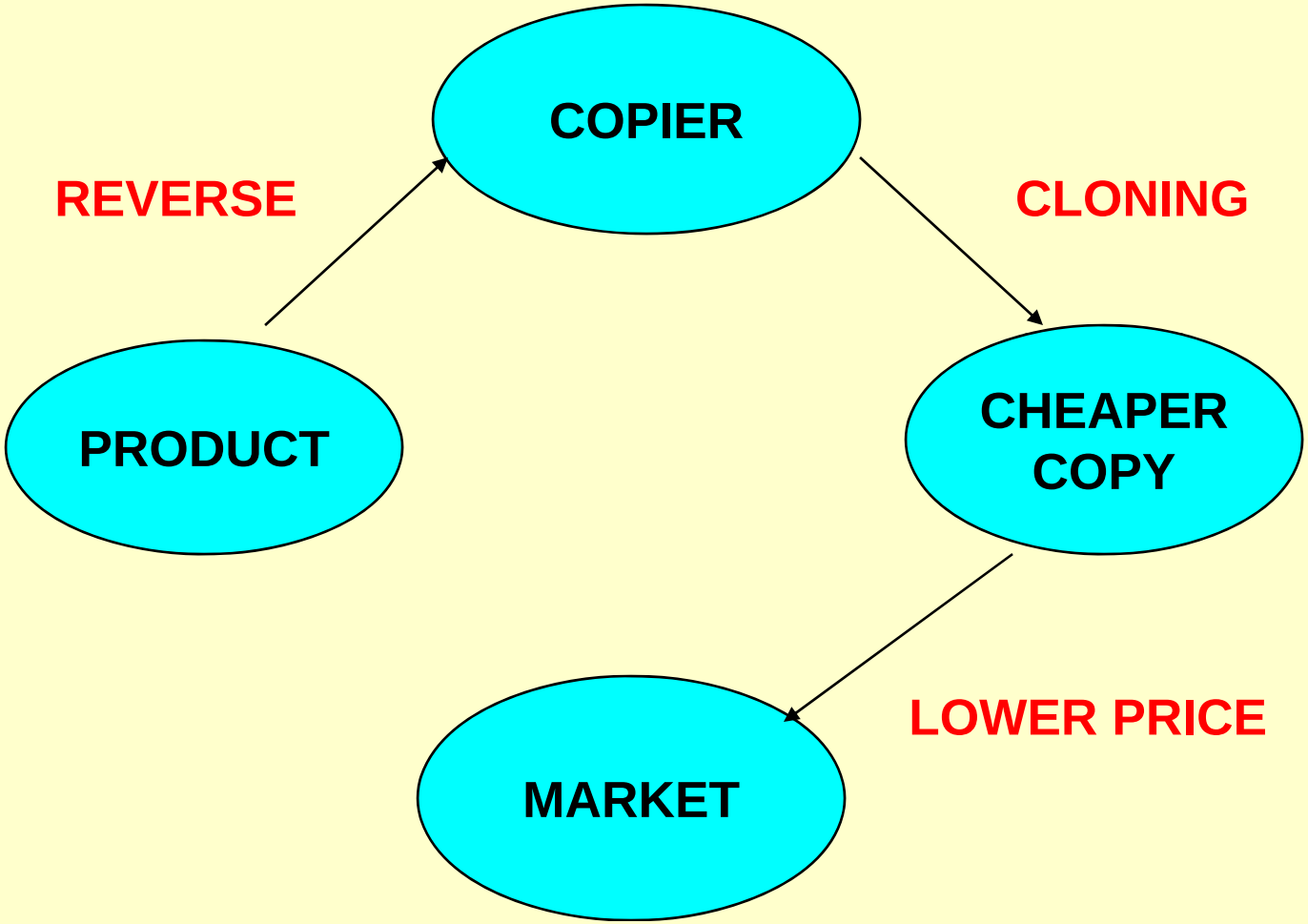
MNCs Focus on Developing Countries Diseases

Disease	Companies
TUBERCULOSIS	AstraZeneca, Bayer, GSK, Lupin, J&J, Novartis, Otsuka, Pfizer, Sanofi-Aventis, Crucell
MALARIA	BMS, GSK, Novartis, Pfizer, Ranbaxy, Sanofi-Aventis, Sigma Tau, Crucell
SLEEPING SICKNESS (African Trypansomiasis)	Bayer, Sanofi Aventis
SHISTOSOMIASIS	Pfizer
KALA AZAR (Leishmaniasis)	Zentaris, GSK
DENGUE	Novartis, GSK, Sanofi Aventis
RIVER BLINDESS (Onchoceriasis)	Wyeth

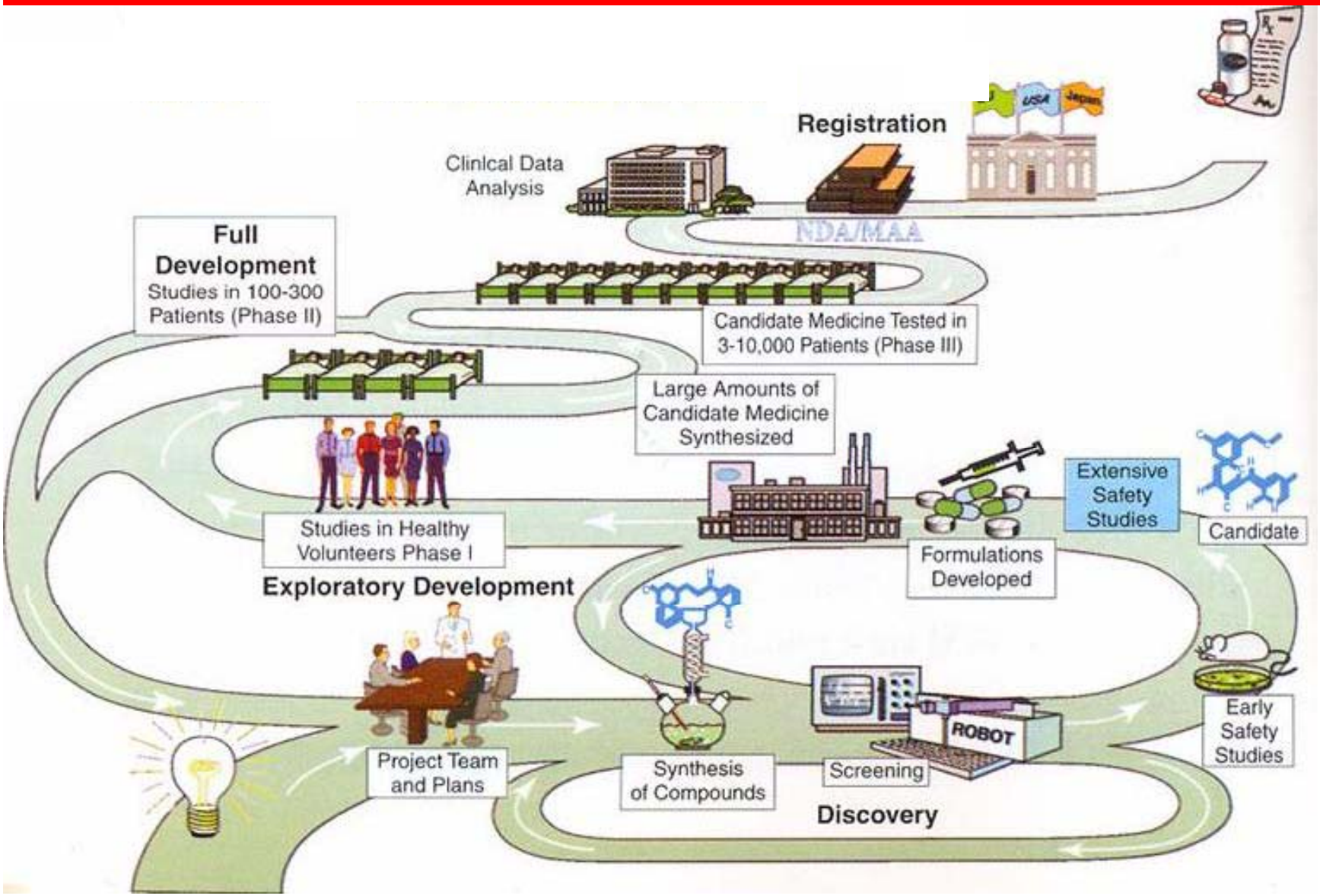
What is Medical Research



…… and what is not



The Long Road to a New Medicine



Will IPR “Kill” Local Generic Industry

- Without patents there are no new medicines and hence dries up pipeline for generic products.
- Generic industry relies on new medicine to copy after patent expiry
- IPR is essential for growth of generic industry

Will Prices of Essential Life-saving Medicines Increase due to Patents?

- Patent protection is prospective for discoveries made after 1st January, 1995.
- 97% of drugs on WHO Essential List are off patents.
- Most patented products have equivalent therapeutic generics.
- These exerts pressure on patented products price.

Are Patented Products Costly?

- Currently 97% of drugs are off-patent medicines.
- Most patients pay out of their pockets for medicines.
- Limited purchasing power - a check on high prices for patented products.
- Low priced generic therapeutic equivalents keep prices of patented products in control.
- Government also keeps a watchful eye on prices.

What happens when there are no Substitutes for Patented products

- Happens rarely 0.1 to 0.2% of cases.
- Government will ensure that these medicines reach the needy at affordable prices through proper distribution and subsidies.
- Manufacturers will also have special programs and prices for those who cannot afford, for eg. Glivec is given free to needy patients and Merck discovered a cure for river blindness and donated medicine free of charge to Africa and other afflicted countries.

Compulsory Licensing

- Patent holder should make his product available to all at a reasonable price.
- If inventor does not do this or engages in anti-competitive practices, his patent right can be taken away and other manufacturers can make and sell the same product.
- In times of national emergency or a health crisis, Government can get patent holder to license his product to other manufacturers to make it abundantly available for which patent holder gets compensated.

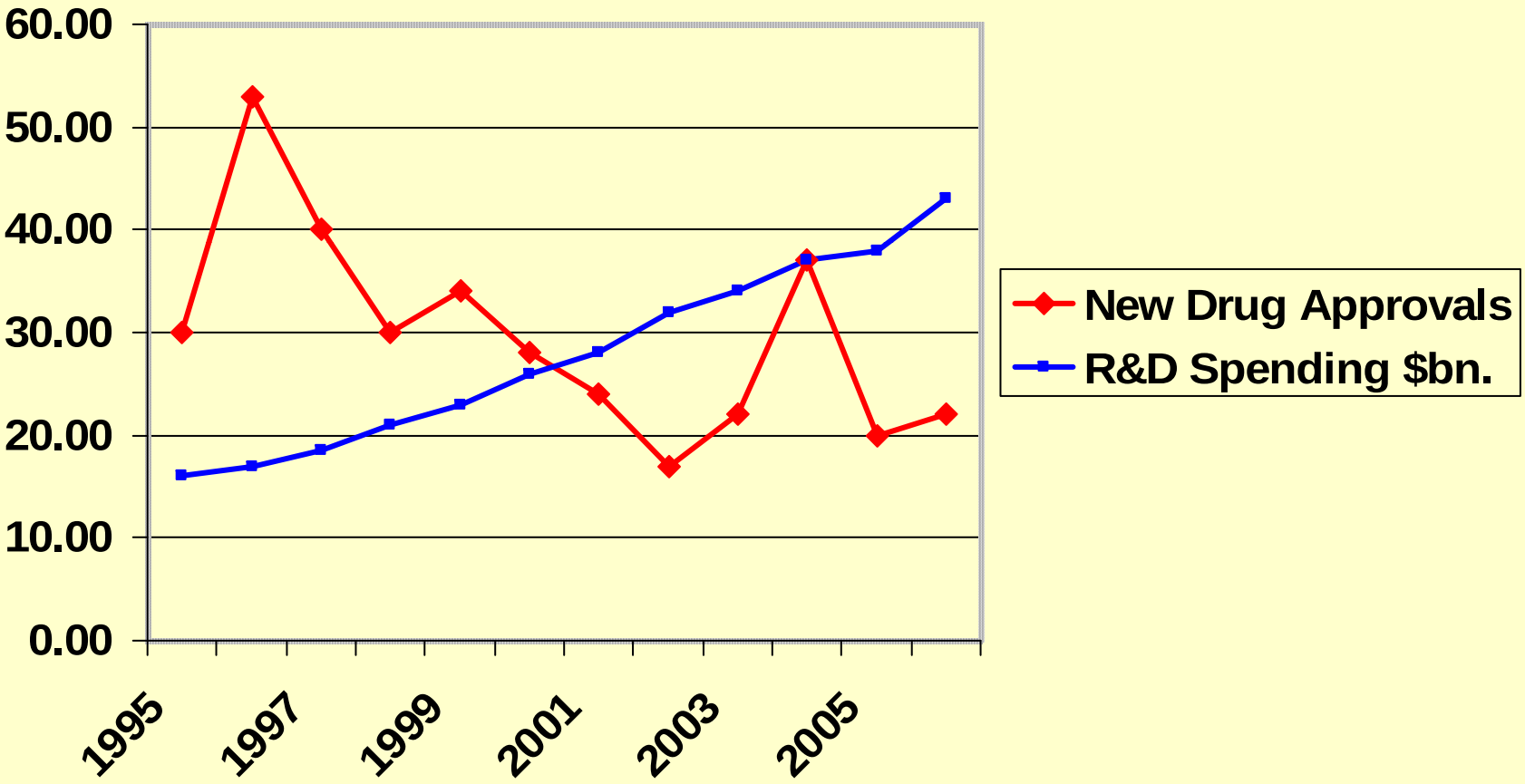
Can Compulsory Licensing be misused?

- It is stated in the Bill that –

  “Compulsory License shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for concerned product to address public health problems, provided Compulsory License has been granted by such country.”

  This provision can be misused for unfair commercial gain.

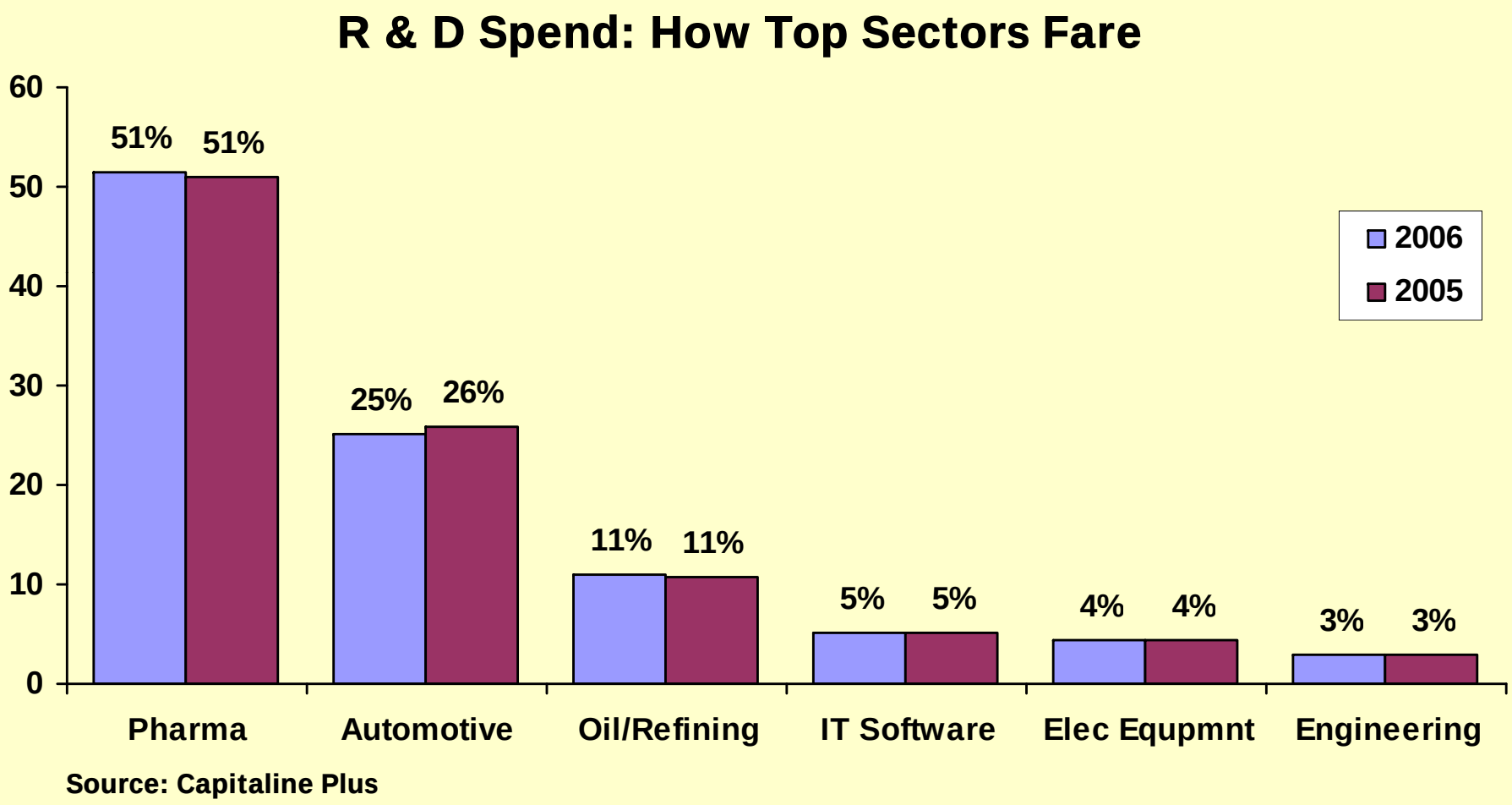
Increasing R&D Spend



*Pharmaceutical Research of American Companies only

Source: PriceWaterhouseCoopers (Economist June 30, 2007)

Indian Industry – R&D Spend

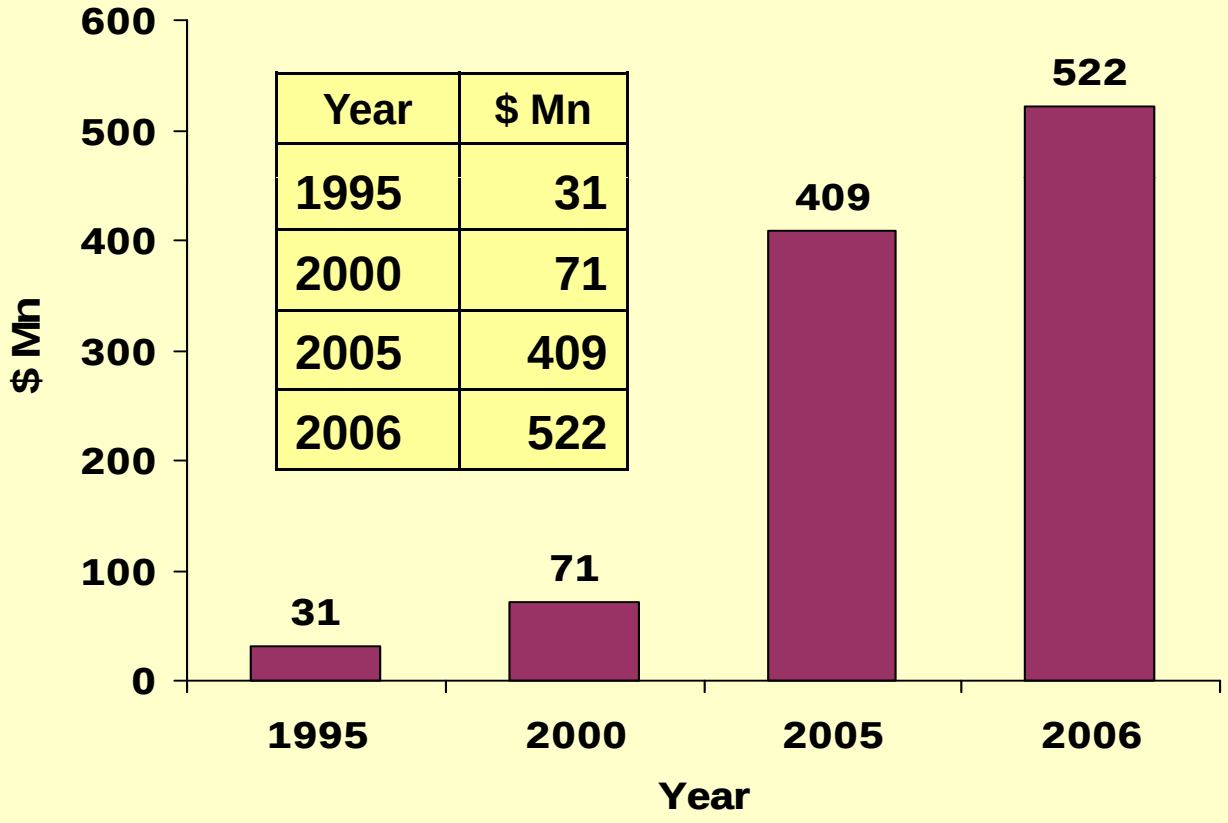


Source: Capitaline Plus

Pharma Spends More Than All Industries Put Together

Indian Industry

R & D Spend - Pharmaceuticals



Year	$ Mn
1995	31
2000	71
2005	409
2006	522

@ Constant $ (1 = INR 40)

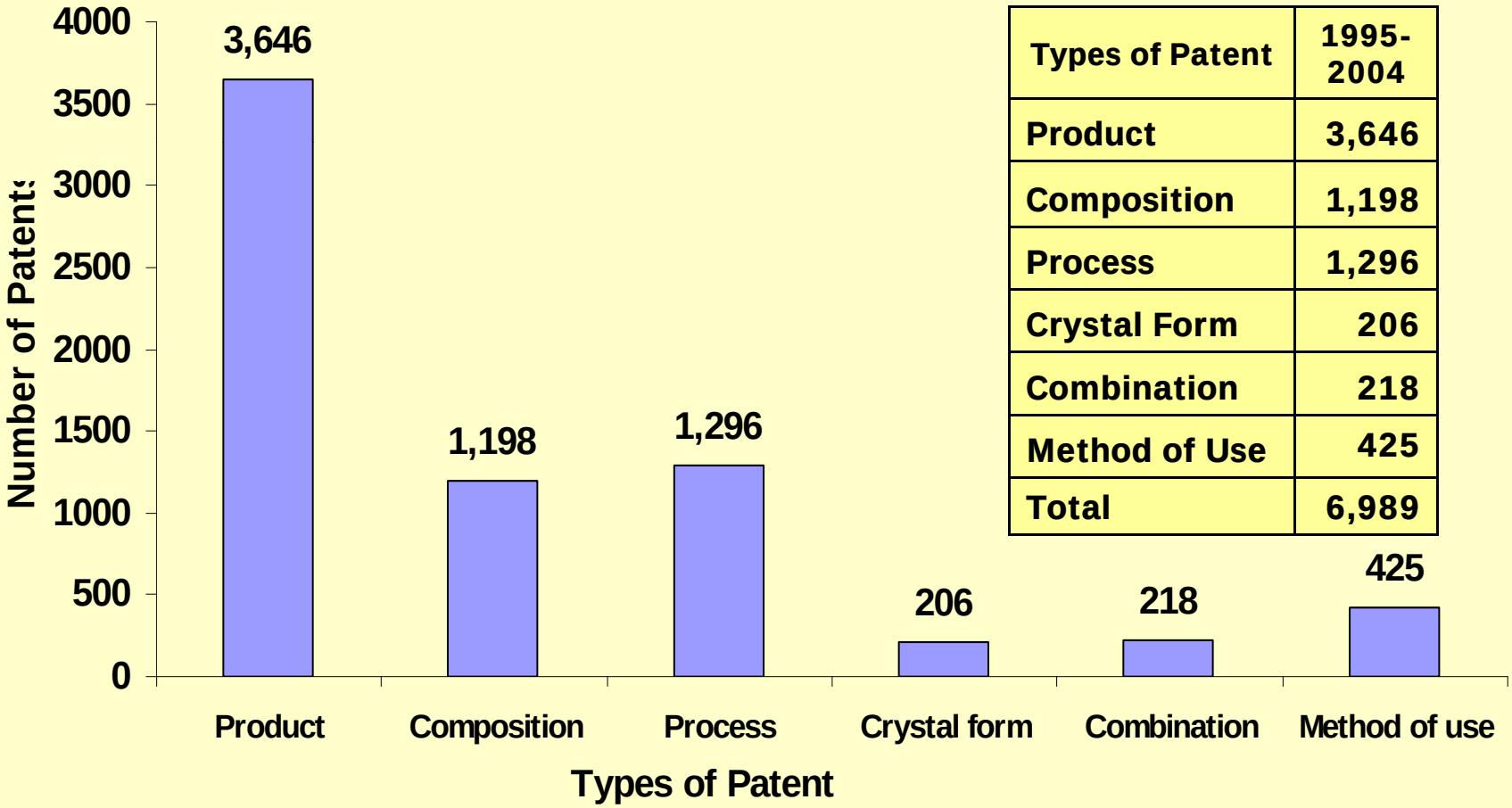
Source: IDMA

Almost 10% of 2006 Trade Sales

India: Patentability of Pharmaceuticals

Analysis of Mail Box Applications

Number of Pharmaceutical Patent Filings by MNCs: 1995-2004 (Source: IPO)



Types of Patent	1995-2004
Product	3,646
Composition	1,198
Process	1,296
Crystal Form	206
Combination	218
Method of Use	425
Total	6,989

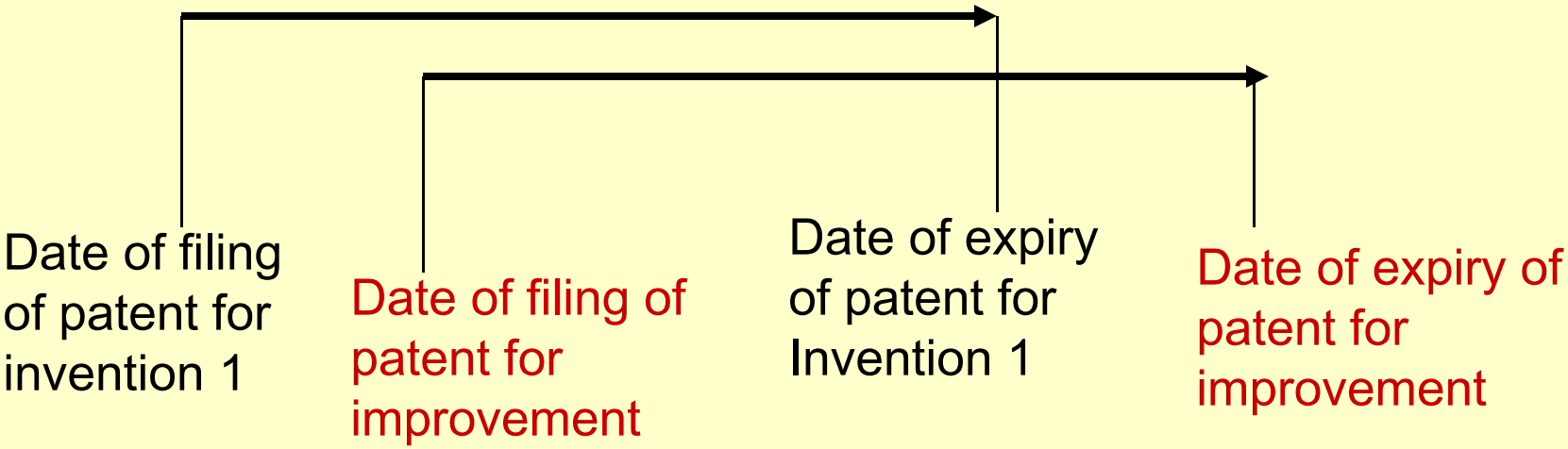
Indian Patent Law
Areas of Concern

- Narrowing the definition of Patentability
- Broadening the scope of Compulsory Licensing
- Pre & Post Grant Opposition
- Lack of Data Exclusivity/Protection
- I.P. Infrastructure

Patentability

- TRIPS allows NCEs, Polymorphs, Chiral Isomers, New Indications etc. (e.g. once a day Cipro – Ranbaxy).
- Section 3(d) of the Patent Act –
  "Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regards to efficacy."

Evergreening…a Misconception



Anyone is free to use the patent of invention 1 when the term for that is over. The innovator or anyone else who has patent for the improvement will have rights to his patent only. There is no extension of patent term as per the Indian Patent Act

Compulsory Licensing

- CL Provision broadened to include “Affordability”, “not worked in India”, etc.
- Should be restricted to true **NATIONAL EMERGENCY** situations (e.g. Epidemics, Pandemics, etc.)
- Only for **NON-COMMERCIAL USE**
- Interests of the Licensee can never be placed above those of Inventor
- Broad based Compulsory Licensing only helps the Copier and not the Patient

Post vs. Pre Grant Opposition

- Pre-grant Opposition has resulted in frivolous objections delaying the grant of patent. Practice of ‘serial” oppositions.

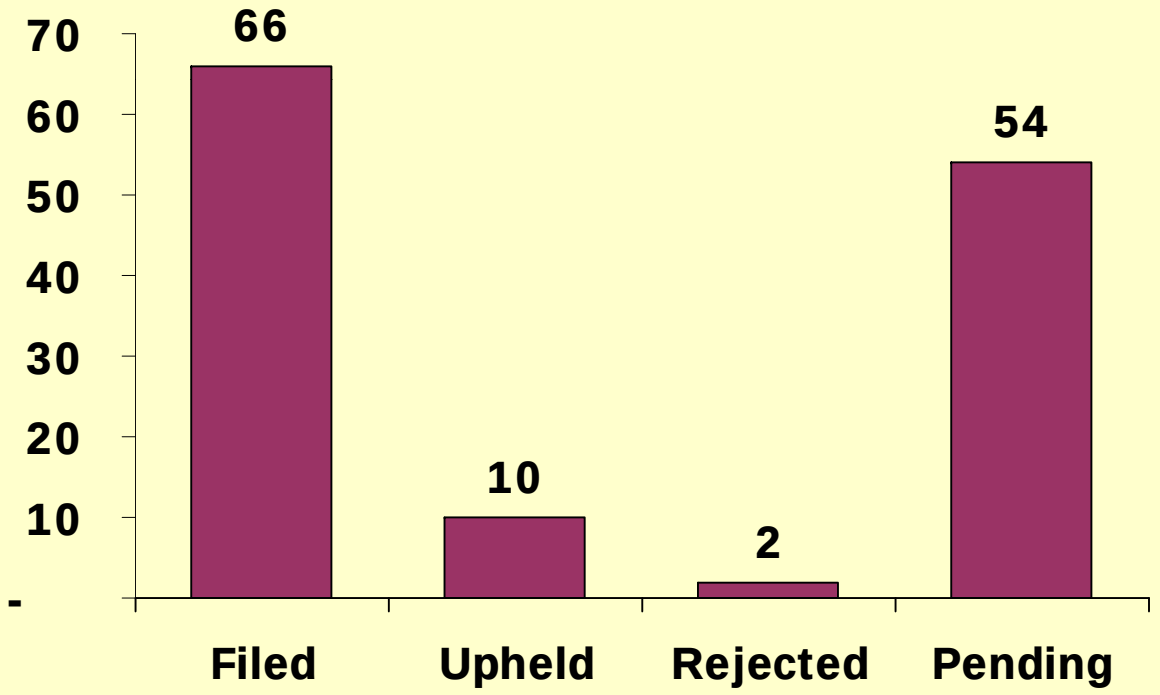
Patentability of Pharmaceuticals

Pre-Grant Opposition – Pharmaceutical Sector

Status Report March 2007

Pre-Grant Opposition	
Particulars	**No**
Filed	66
Upheld	10
Rejected	2
Pending	54

Source: IPO



Data Protection

TRIPS Article 39.3: Protection of undisclosed information through Data Protection.

Consumer Safety: DP ensures higher degree of overall safety and efficacy of Drugs launched in the market.

Incentive for Innovation: Gives enhanced protection and incentive to originator to discover drugs based on original research.

Period*:	U.S.A.	- 5 years
	E.U.	- 6 to 10 years
	China	- 6 years
	India	- Nil

(*From the time the product is approved for sale)

Financial Express - November 19, 2007

Cipla's i-pill hasn't gone through safety trials

Alok Sharma
New Delhi, Nov 18

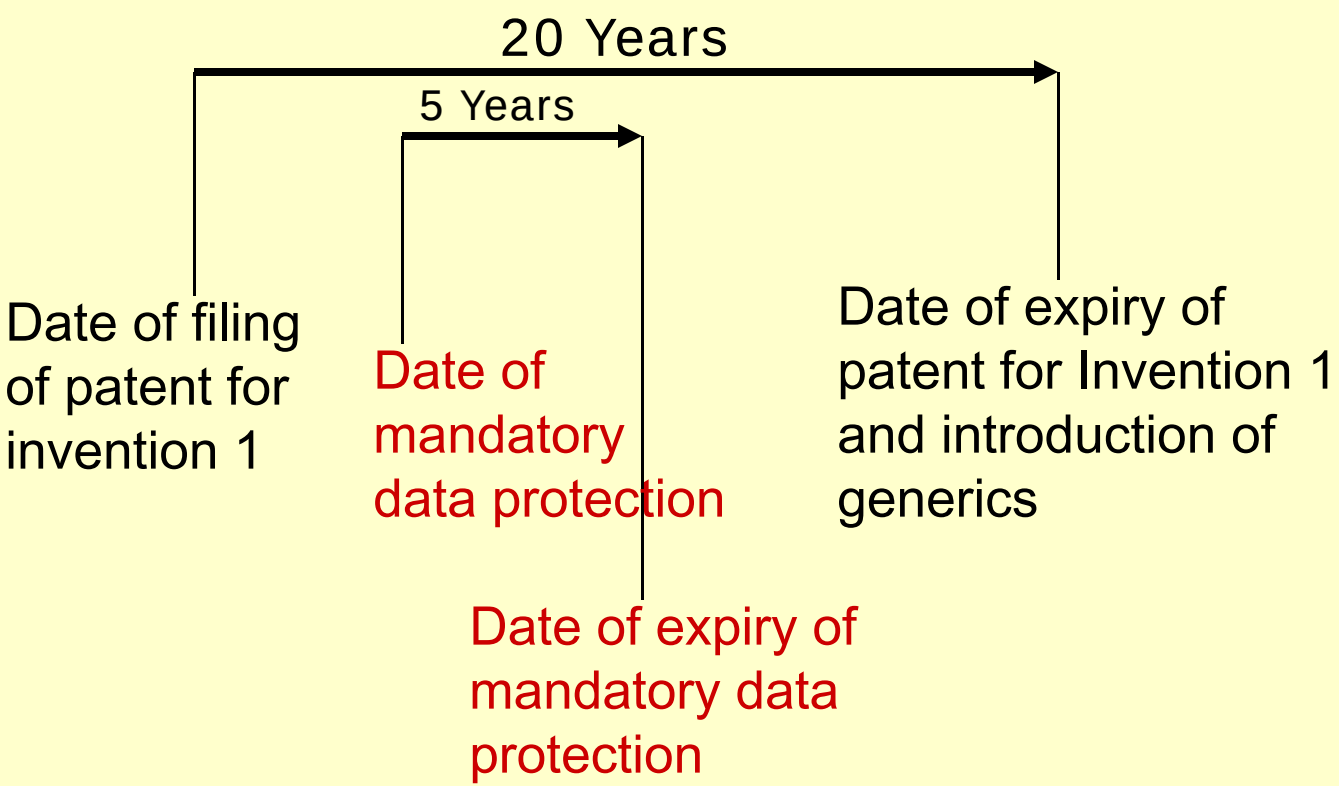
Top drug maker Cipla has said it hasn't carried out safety trials of its newly launched emergency contraceptive i-pill before marketing it in India.

When asked, Cipla's medical services director Jaideep Gogtay said the company had not undertaken safety trials in the country. "We had provided the safety data of a similar drug marketed in Europe."

Drug Controller General of India M Venkateswarlu said, "The company must have done clinical trials but I do not have the details." When informed that there were no safety trials on Indian women, he said, "The DCGI can approve a drug without safety data on local population if there are safety data available for similar drugs in other countries."

"Section 122 of the Drugs and Cosmetics Rules says, if the amount of active ingredient in a fixed-dose combination of cleared medicines is altered, it has to be deemed a new drug. So, safety trials need to be done before marketing," CM Gulati, editor, Monthly Index of Medical Specialities, told *FE*.

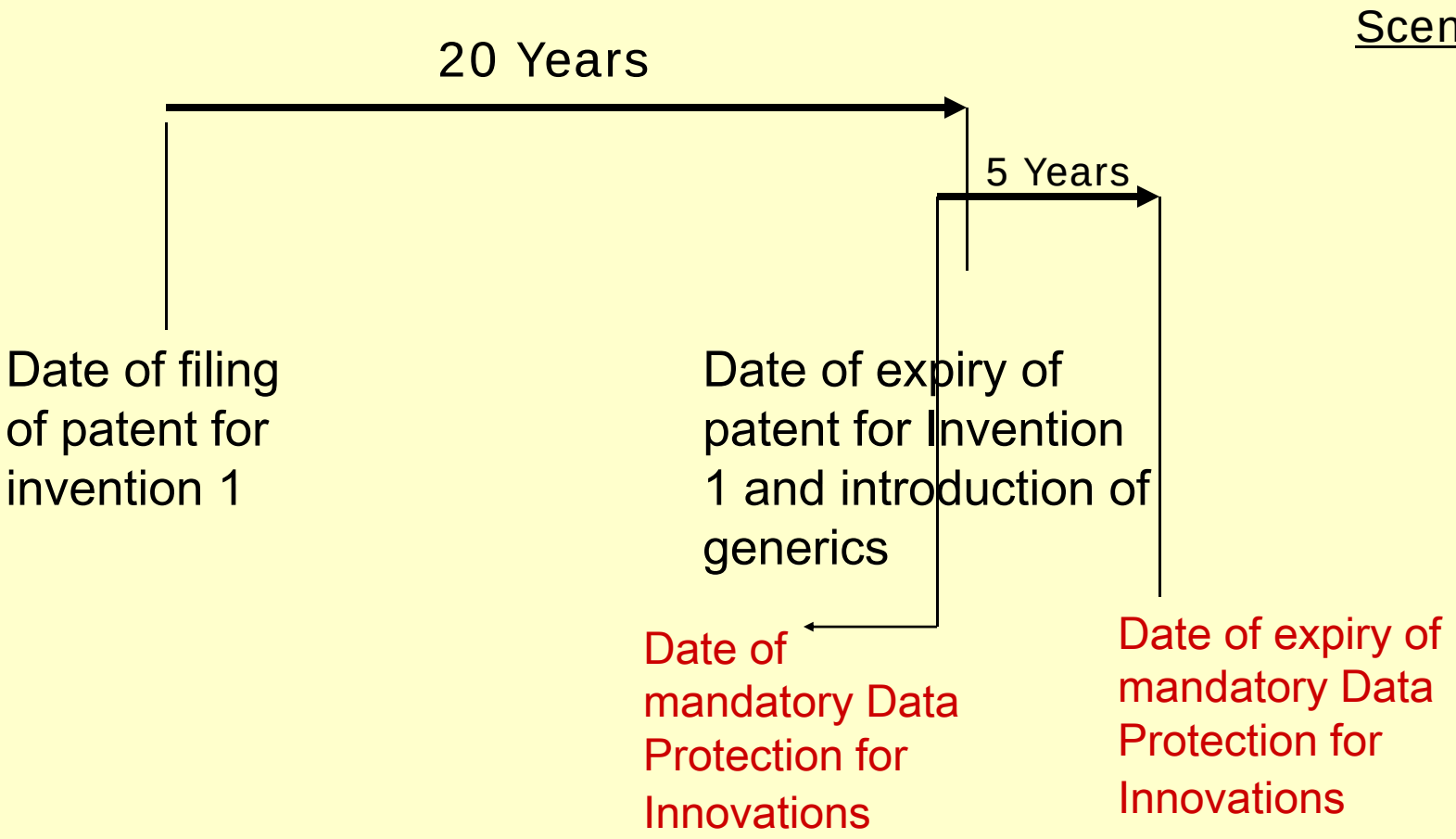
Mandatory Data Protection is 'Evergreening'…a Misconception



*Anyone is free to use the patent of invention 1 when the patent term expires. There is no extension of patent term with mandatory data protection of the innovator for a specified period

Mandatory Data Protection is 'Evergreening'…a Misconception

Scenario 2



*Anyone is free to use the patent of invention 1 when the patent term expires with one's own data. There is no extension of patent term with mandatory data protection of the innovator for a specified period

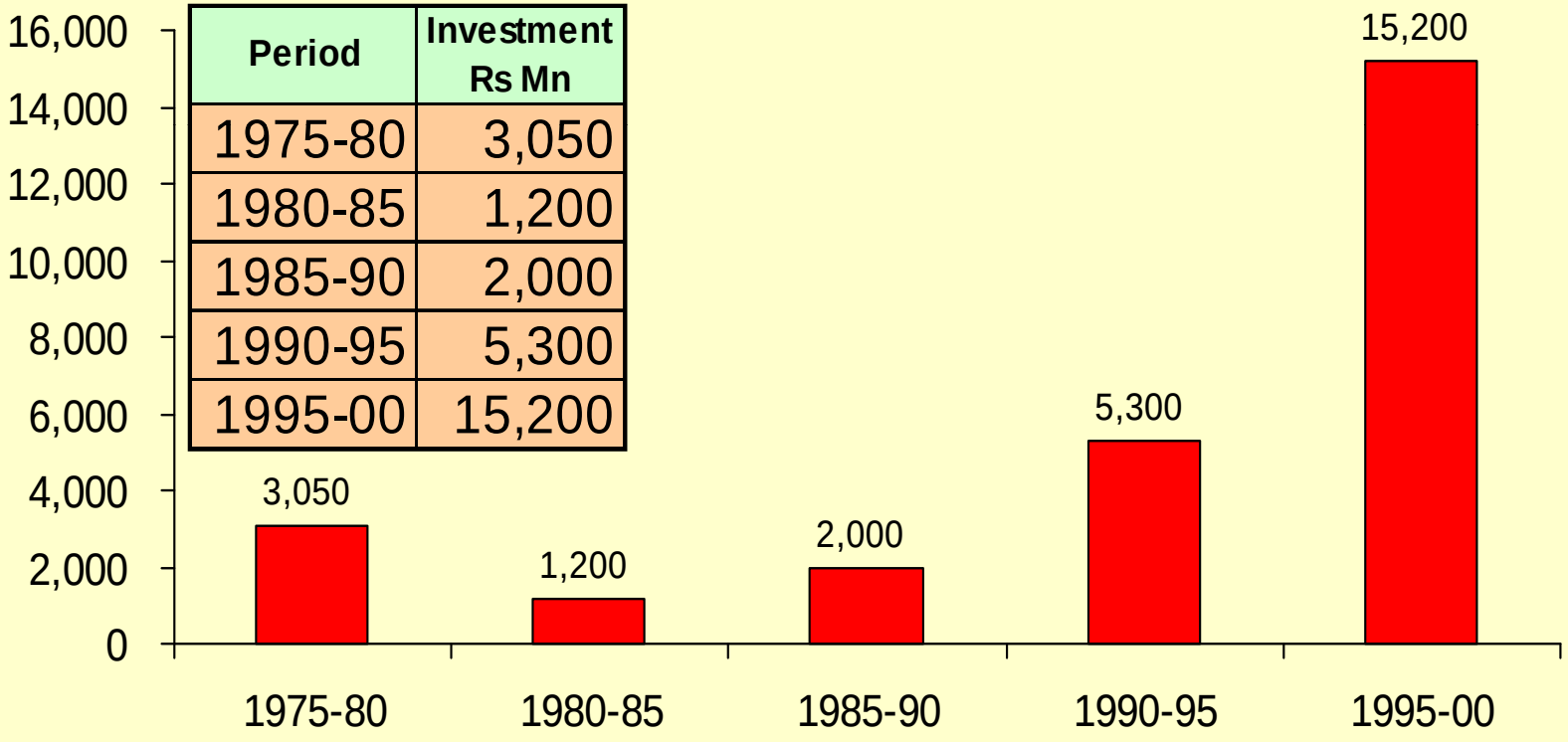
I.P. Infrastructure

- Massive Patent Literacy Programme – Formal Courses at school, graduate and post graduate levels.
- Patent Infrastructure – Examiners, Digitalisation, Information Processing
- Training of Judiciary – Quick and Effective Disposal
- Dedicated I.P. Courts

IPR and Investment

Protection of IPR a Must for Investment

Period	Investment Rs Mn
1975-80	3,050
1980-85	1,200
1985-90	2,000
1990-95	5,300
1995-00	15,200

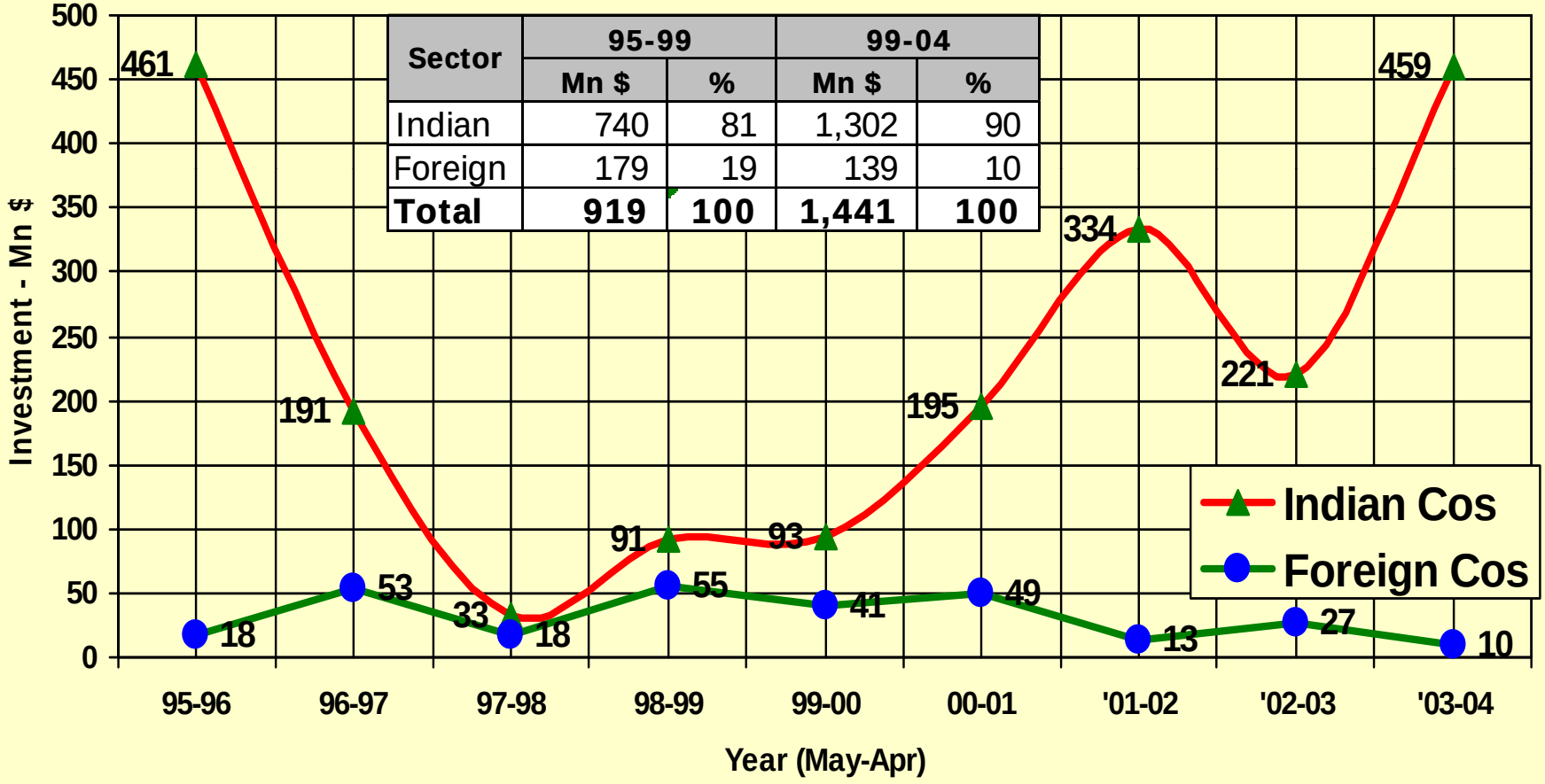


Reality: Maximum FDI Took Place Between 1995 & 2000

IPR and Investment

India Investment in Pharmaceuticals

Sector	95-99		99-04	
	Mn $	%	Mn $	%
Indian	740	81	1,302	90
Foreign	179	19	139	10
Total	**919**	**100**	**1,441**	**100**



Source: CMIE, Study Report: 1996-2004

(MIS) Managing Intellectual Property
KODAK VS POLAROID

CASE STUDY - 1

- Polaroid invents instant photography. Captures 15% of the market.
- Polaroid protects its invention with a wall of cleverly worded patents.
- Kodak tries to circumvent the patents and launches its own instant camera with much fanfare in 1976.
- Polaroid responds with a lawsuit claiming infringement of 12 of its patents.

(MIS) Managing Intellectual Property

KODAK VS POLAROID contd..

CASE STUDY - 1

RESULT

- Ensuing trial takes 9 years. Kodak loses.
- Total loss to Kodak
  1. U.S.$ 925 Mn. in damages to Polaroid
  2. U.S.$ 1.5. Bn. lost in closure of instant camera manufacturing plant
  3. 700 workers laid off
  4. U.S.$ 500 Mn. spent on buying back 16 million cameras already sold.
  5. Legal fees U.S.$ 100 Mn.
  6. Remainder R&D cost written off
  7. Customers sued Kodak who bought the camera – U.S.$ 150 Mn.

Total Cost – U.S.$ 3 Bn.

Kodak instant camera business destroyed.

IBM : Benchmark in I.P. Management

CASE STUDY - 2

- IBM 1998 R&D Budget – U.S.$ 5 Bn.
- Lou Gerstner, CEO of IBM decides to use I.P. as revenue generator.
- IBM Technology Group (ITG) was born. 2,500 Patents every year.

Strategy –

Instead of using patents as a defensive mechanism to protect its R&D work, use IP as aggressive commercial weapon to generate sales.

IBM : Benchmark in I.P. Management

contd..

CASE STUDY - 2

RESULT

ITG in the first 6 months of formation generated U.S.$ 8 Bn. by way of licensing revenues and component sales with a goal of U.S.$ 20 Bn. per year.

Revocation of Turmeric Patent

CASE STUDY - 3

1. U.S. Patent 5401540 granted to University of Mississippi by USPTO for Turmeric Wound Healing Properties - 1995.
2. CSIR requested for re-examination giving 32 references from Ancient Indian Literature (e.g. Ayurvedic Pharmacopoeia, The Wealth of India, Indian Home Remedies, etc.) – 1996.
3. CSIR proved that use of turmeric is not novel and it is prior knowledge.
4. Based on CSIR representation USPTO revokes Turmeric Patent – 1998.

Pharmaceutical I.P. Index to Benchmark India

Based on 5 Criteria

1. **Term of Exclusivity**
2. **Scope of Exclusivity**
3. **Strength of Exclusivity**
4. **Barriers to full I.P. Exploitation**
5. **Enforcement**

Ref. Meir Pugatch, University of Haifa – The Journal of World Investment & Trade

Pharmaceutical I.P. Index

Country	I.P. Index (2007)
U.S.A.	4.67
Singapore	4.40
U.K.	4.37
Chile	3.00
Israel	2.89
Brazil	2.00
China	2.62
India	1.80

Ref. Meir Pugatch, University of Haifa –The Journal of World Investment & Trade