OPPI – NASSCOM Seminar – Indian Patent Act 2005 - An Impetus to Pharmaceutical Science in India

TAPAN RAY

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Goa, India

CONTENT

- Economic Indicators of India
- Pharmaceutical Industry & Healthcare Scenario – An Overview
- Ideal IPR Policy for India
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  - Data Protection
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  - Pre-Grant Opposition
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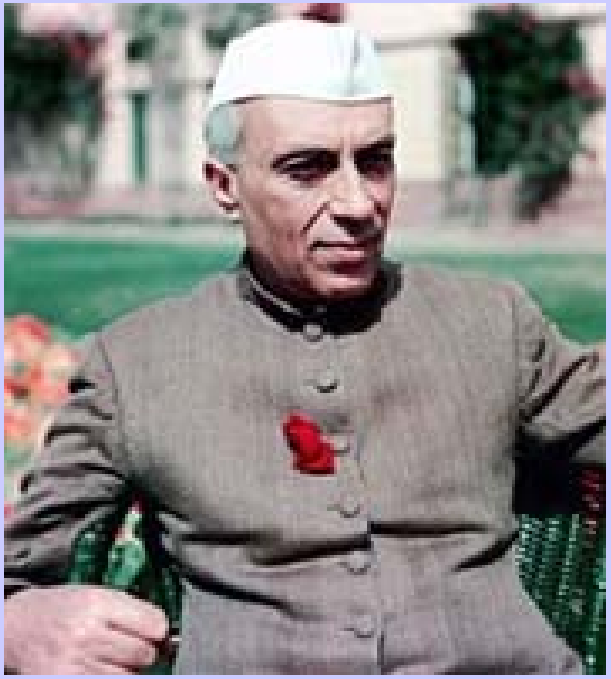
SELECTIVE ECONOMIC INDICATORS

	1990-91	2006-07
Real GDP	USD 48 billion	USD 840.1 billion
GDP Growth	5.3%	9.4%
Forex Reserves	USD 1 billion	USD 220 billion
FDI	USD 0.36 billion	USD 15.7 billion
Inflation	10.3%	< 5%


AUGUST 13, 2007
SPECIAL REPORT: 60 YEARS OF INDEPENDENCE
TIME
India Charges Ahead
It faces challenges the size of an elephant, but the world's largest democracy is living up to the dreams of 1947

JAWAHARLAL NEHRU SAID ON THE EVE OF INDEPENDENCE



“A new star rises ……. A new hope comes into being”

PHARMA IS POISED

- Government to provide enabling environment for growth
- Improve access to medicines
- Invest in health infrastructure
- Encourage R&D

INDIAN PHARMACEUTICAL INDUSTRY: 2006-2007

- U.S.$ 8 Bn. Domestic Sales
- U.S.$ 5 Bn. Exports
- Highest number of U.S. FDA approved plants outside U.S.
- Ranks 4th in Volume & 14th in Value
- McKinsey projects U.S.$ 20 Bn. by 2015

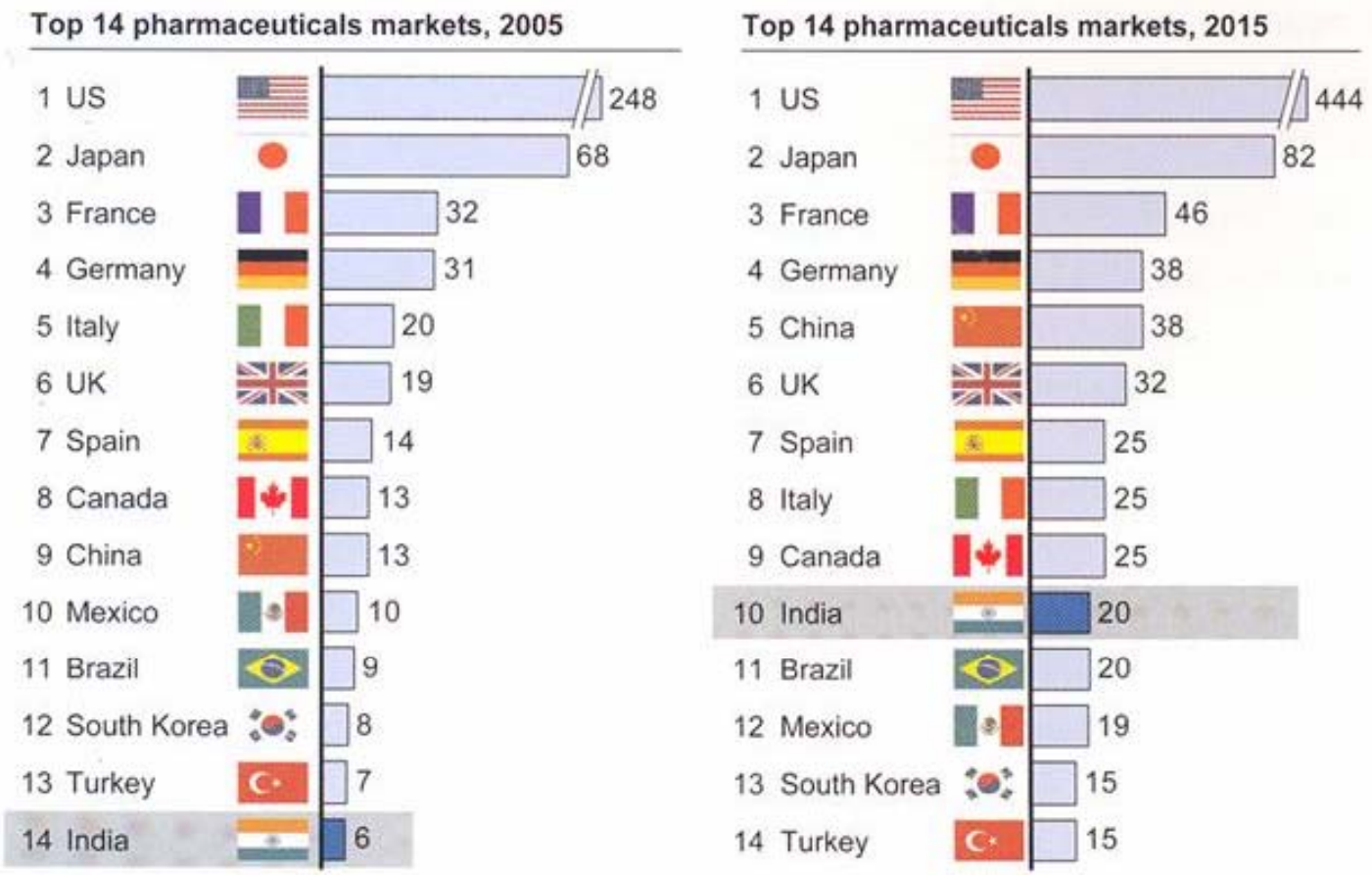
MCKINSEY PROJECTION 2015*

- Domestic Sales to reach U.S.$ 20 Bn.
- Incremental growth between 2005 – 2015, 14 Bn. U.S.$
- Key Drivers for Growth:
  - Robust Economy
  - Increasing Affordability
  - Deeper Penetration of Health Insurance
  - Increase in Organised Retail Chains
  - Shifting Disease Patterns
  - Increase in Healthcare Spend
    (from present 7% to 13% of average household income)
  - The New IPR Regime

* “Indian Pharma 2015”, McKinsey & Co. – August 22, 2007

INDIA IS PROJECTED TO BE THE 10th LARGEST MARKET BY 2015

US$ billion



Source: IMS World Review; analyst projections; McKinsey India Pharmaceutical Demand Model

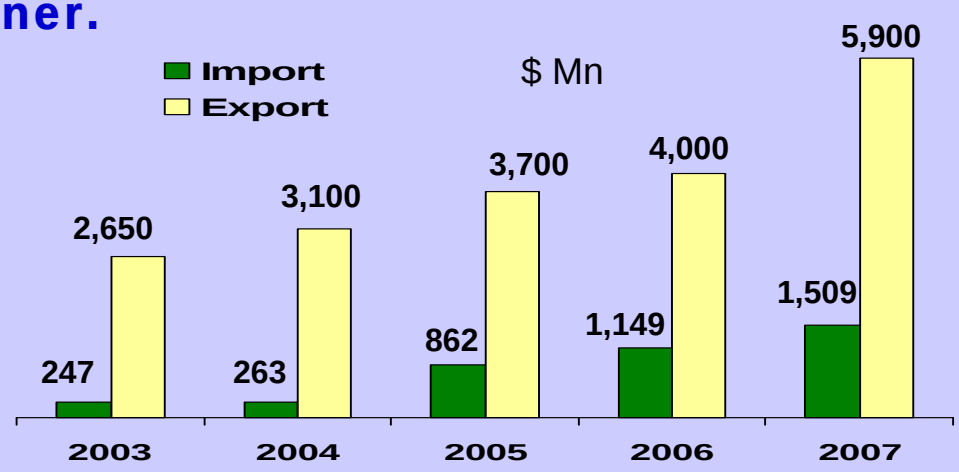
TOTAL EXPENDITURE ON HEALTH AS A % OF GDP

Country	Public Sector	Private Sector	Total
India	**1.2**	**3.6**	**4.8**
Sri Lanka	1.6	1.9	3.5
China	2.0	3.6	5.6
Japan	6.4	1.5	7.9
Switzerland	6.7	4.8	11.5
USA	6.8	8.4	15.2
UK	6.9	1.1	8.0
France	7.7	2.4	10.1

Source: World Health Report, 2006, WHO

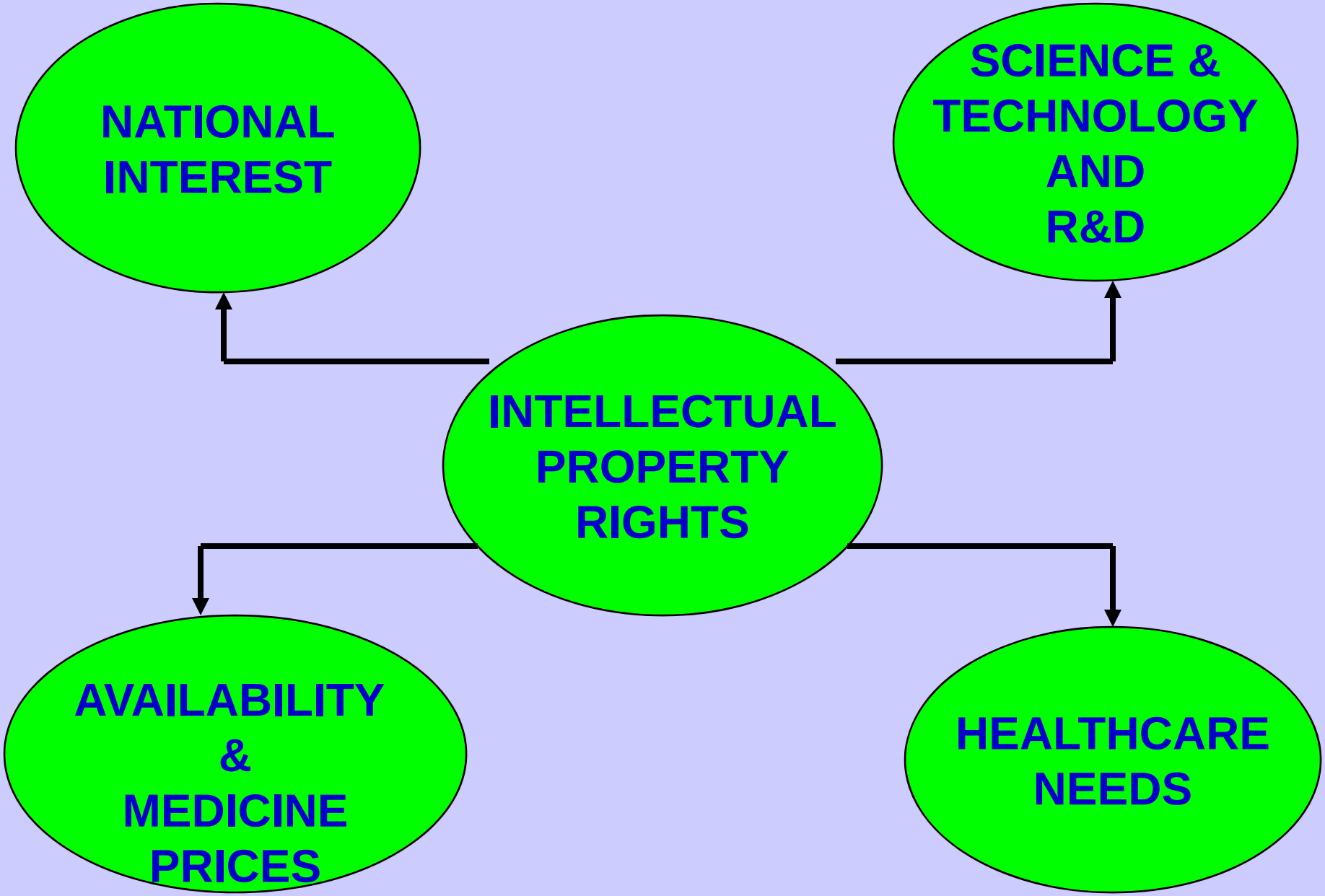
INDIAN PHARMA INDUSTRY … A TRULY SHINING EXAMPLE OF GLOBAL SUCCESS

- **Amongst the top 15 countries in consumption value: fourth largest country in the world production volume.**
- **Though India's pharmaceutical market is just 1% of the global pharmaceutical industry in value, it accounts for 8.5% of global pharmaceutical production in the generics space, Indian firms account for 22% of global production.**
- **Net foreign exchange earner.**

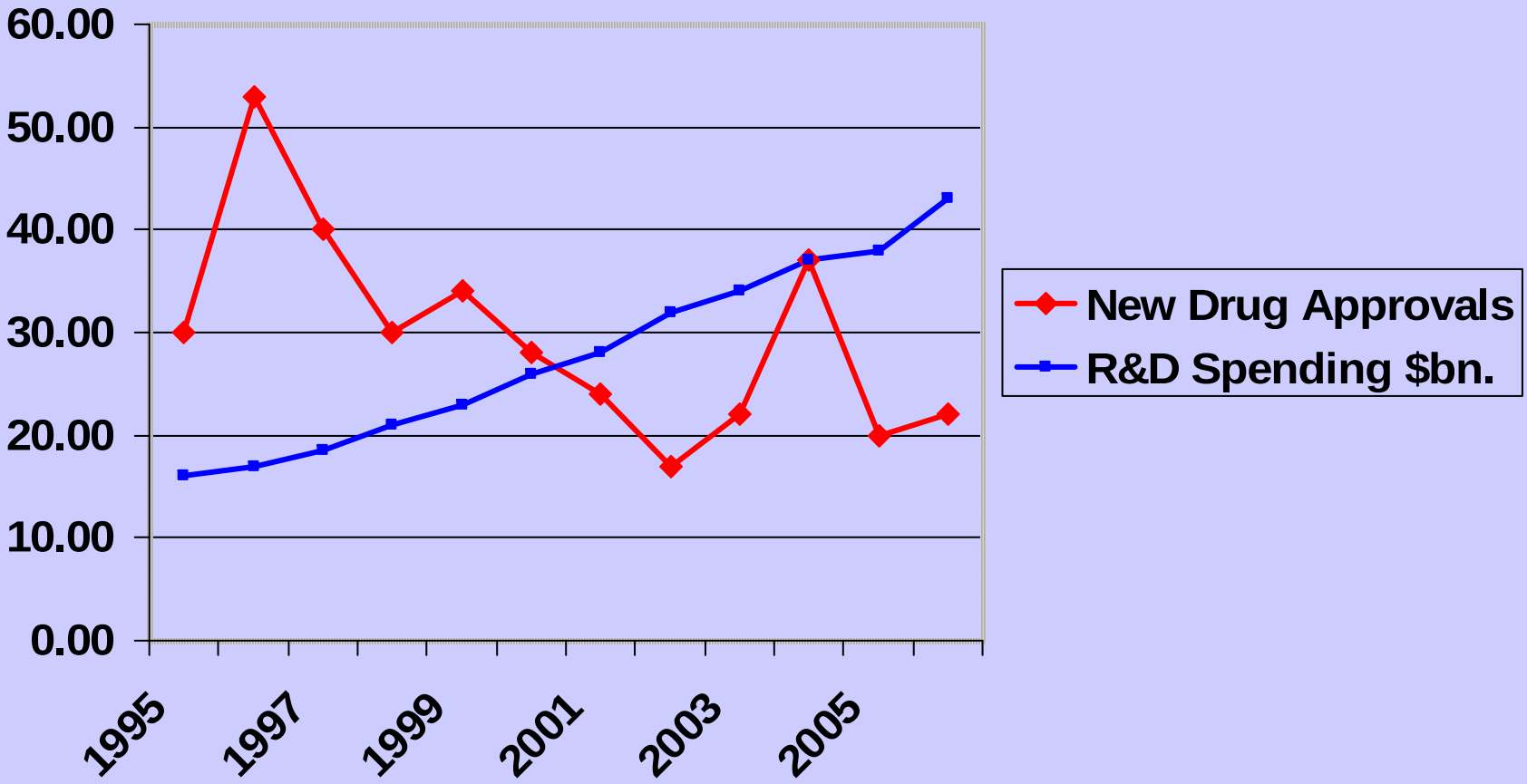


Source: The Financial Express, February 26, 2007;
U.S. International Trade Commission May 2007

IDEAL IPR POLICY FOR INDIA



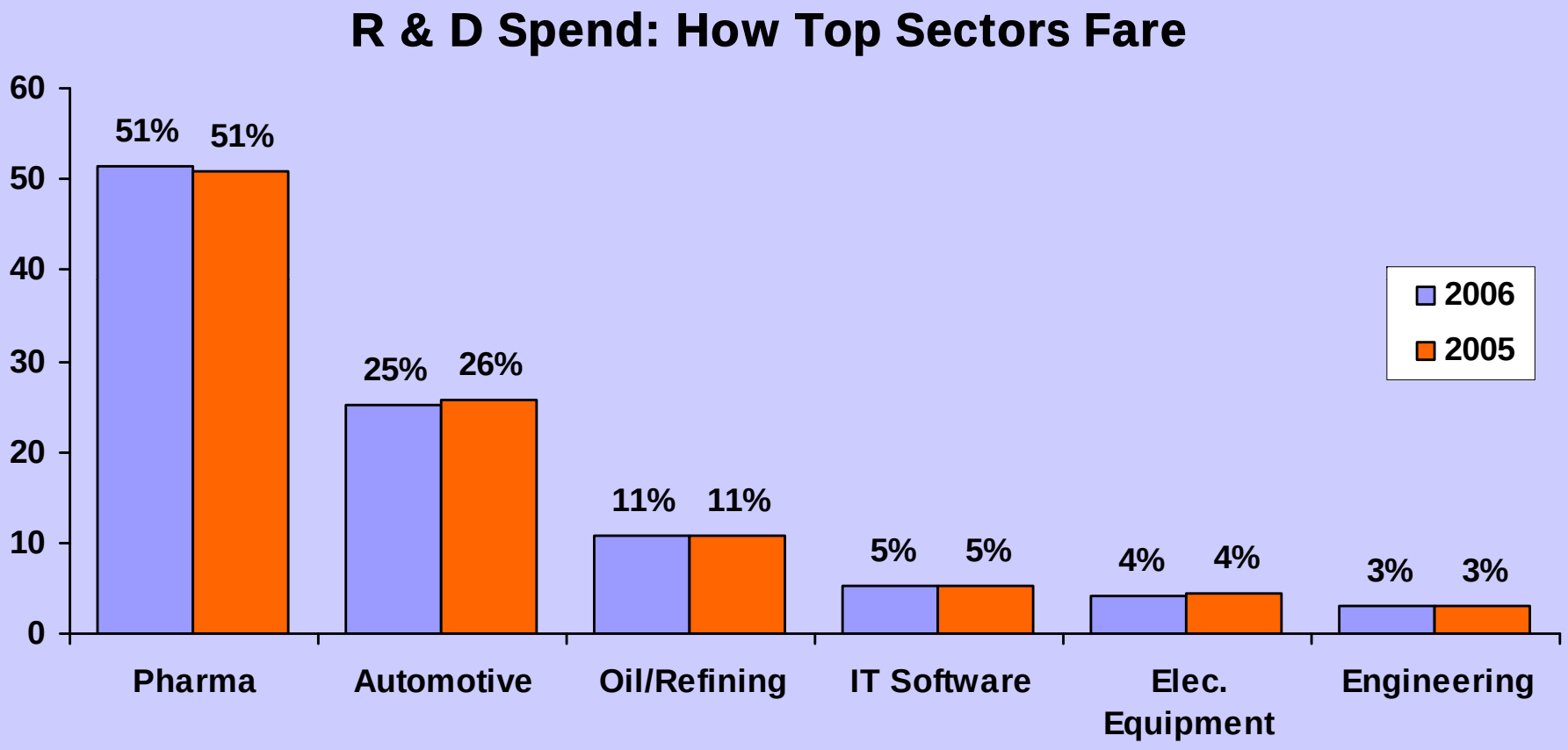
INCREASING R&D SPEND



*Pharmaceutical Research of American Companies only

Source: PriceWaterhouseCoopers (Economist June 30, 2007)

INDIAN INDUSTRY – R&D SPEND

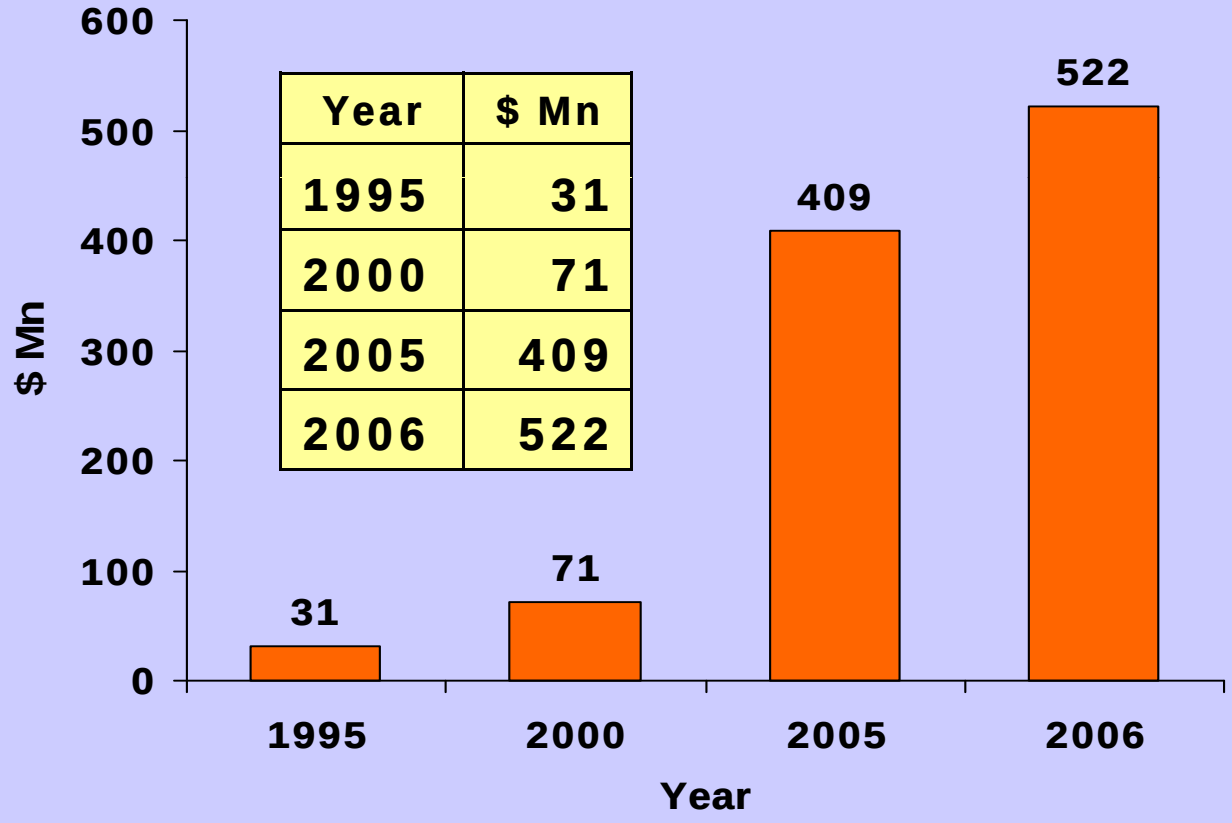


Source: Capitaline Plus

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)

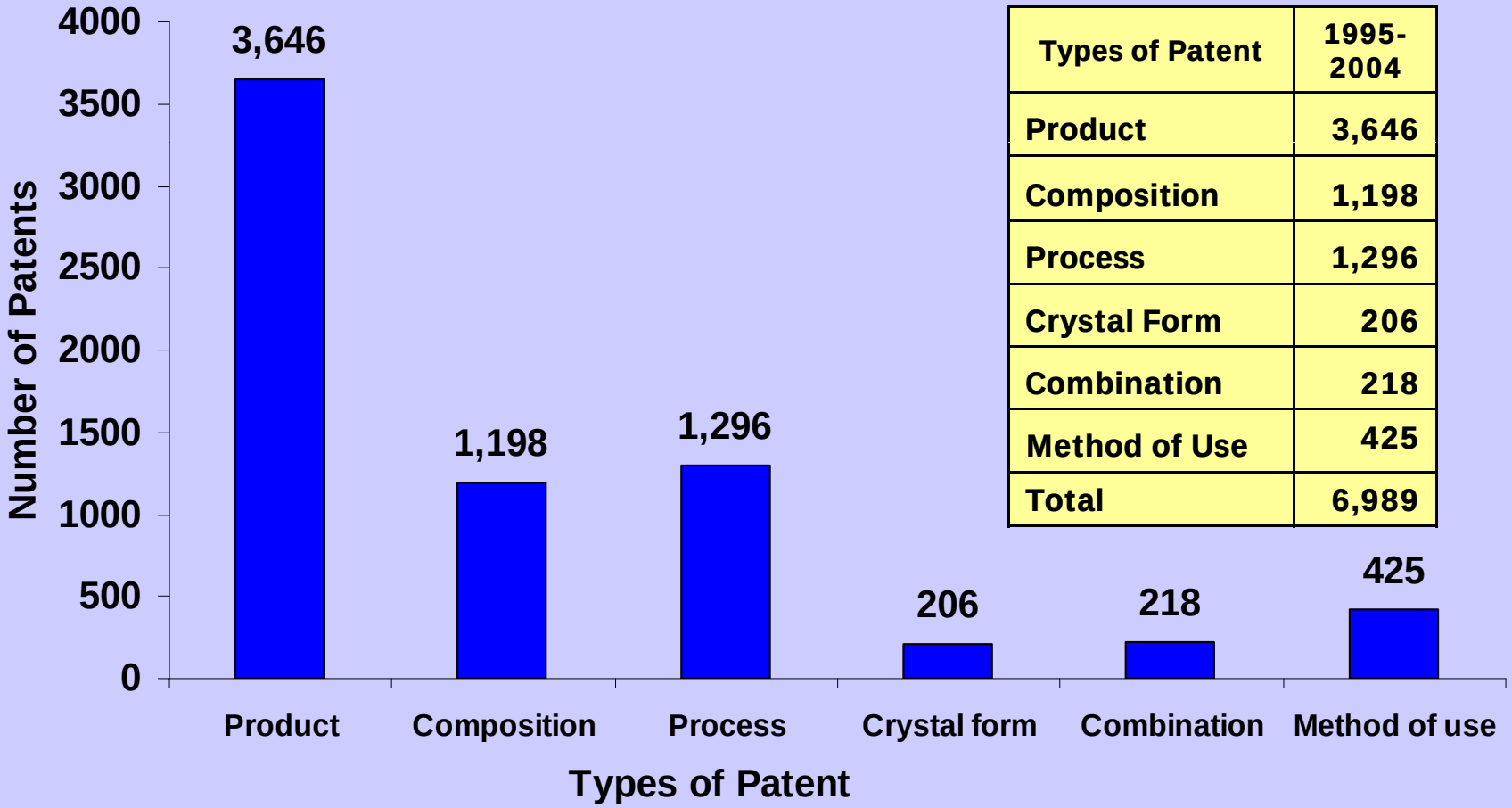
Source: IDMA

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

- **Definition of Patentability**
- **Data Protection**
- **Scope of Compulsory Licensing**
- **Pre-Grant Opposition**
- **I.P. Infrastructure**

INCREMENTAL INNOVATION

- ITS RELEVANCE AND VALUE

INCREMENTAL INNOVATIONS

“Incremental innovations are sequential developments that build on the original patented product and could be of tremendous value in a country like India. Therefore such incremental innovations ought to be encouraged by the Indian patent regime.”

IMPORTANCE OF INCREMENTAL INNOVATION

- Incremental innovation generally results in better health outcomes
  - by increasing efficacy
  - reducing side-effects and/or making administration easier
  - resulting in improved compliance and
  - greater effectiveness

Source: International Chamber of Commerce

1. PATENTABILITY

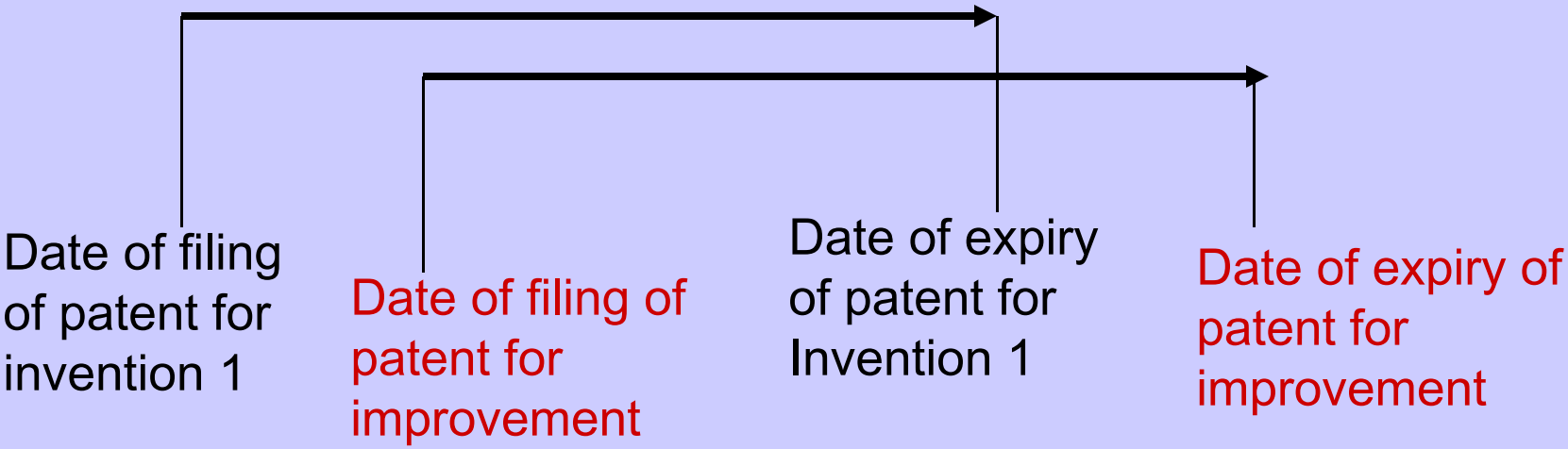
- TRIPS Allows NCEs, Polymorphs, Chiral Isomers, New Indications etc.
- Section 3(d) of the Patent Act –
  "Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be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

EXCEPTIONS TO PATENTABILITY

RECOMMENDATION:

- **Explanation to Section 3(d): "Salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance, unless they differ significantly in properties with regard to efficacy Utility / Benefits / Usefulness.**
- **Amend 3(d) to remove additional hurdles for patentability for Pharma inventions and second use patents.**
- **In the meanwhile, provide guidelines for interpretation and scope of the term "Efficacy" in the manual.**

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

MANDATORY REGULATORY 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)

- **Ms. Satwant Reddy Committee report released May 2007 (Calibrated Approach)**

MANDATORY REGULATORY DATA PROTECTION

TRIPS Article 39.3

- "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products, which utilise *new chemical entities*, the submission of undisclosed information or other data, the origination of which involves a *considerable effort*, shall *protect such data against unfair commercial use*. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the *data is protected against unfair commercial use."*."

REGULATORY DATA PROTECTION

RECOMMENDATIONS:

- **Recognise RDP as an IP and as an outstanding obligation (w.e.f. Jan 1, 2000) within the meaning of TRIPS Article 39.3**
- **Recognise that the provision includes two obligations – protection against disclosure and protection against unfair commercial use.**
- **Amend Rules 122 A & B, Rule 122 E and Schedule Y (Appendix I and IA) of the Drugs and Cosmetics Rules, 1945 to disallow marketing approval based on similarity and new drug approvals to subsequent applicants.**
- **Retain definition of a 'new drug' under Rule 122 E of the Drugs and Cosmetics Rules, 1945 for purposes of RDP.**

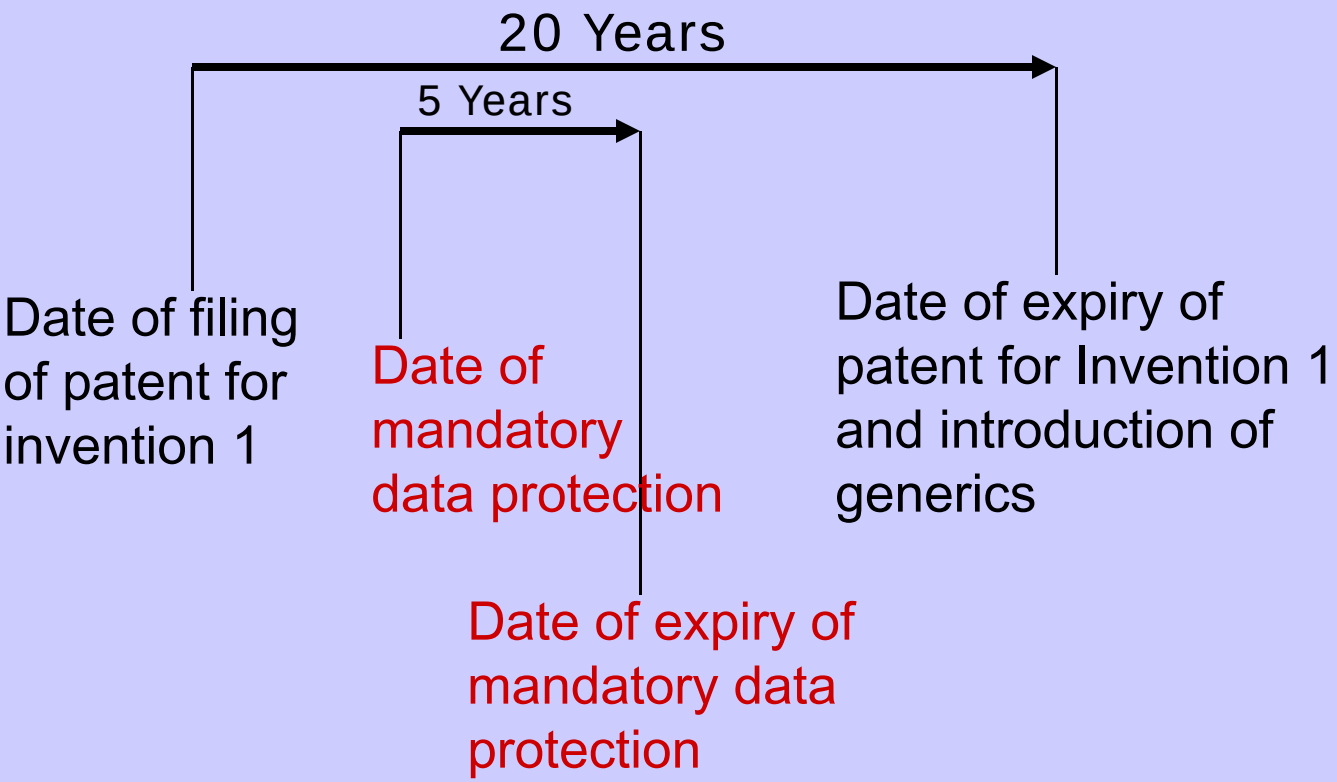
REGULATORY DATA PROTECTION

RECOMMENDATIONS:

- **Ensure a minimum five-year exclusivity period for new drug products (beginning from the date of market approval of the innovative product in the in India.**
- **Strengthen the regulatory system to ensure safety, quality and efficacy of medicines - crucial for life and health of the human beings – bioequivalence does not mean clinical equivalence**
- **RDP will incentivise research in biologics and new personalised and predictive medicines that accommodate genetic profiling, pharmacogenetics, novel diagnostics and gene therapy**

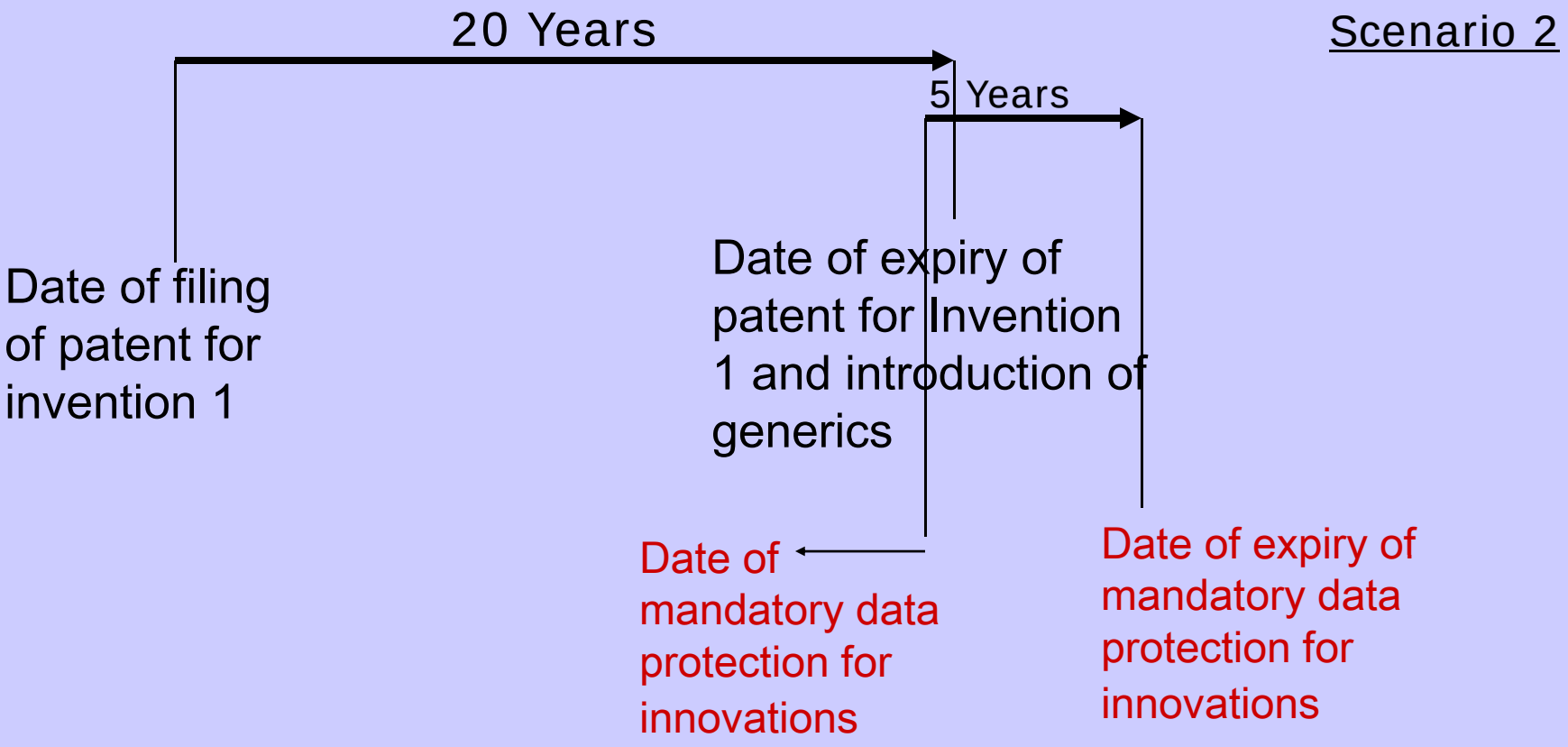
MANDATORY DATA PROTECTION IS 'EVERGREENING'…A MISCONCEPTION

<u>Scenario 1</u>



*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



*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

COMPULSORY LICENSES

- **As the entire concept is based on “Working of Patents in India, the term “Working of patents needs to be defined explicitly.**

- **Article 27 (1) of the TRIPS agreement provides for importation also .**

COMPULSORY LICENSES - RECOMMENDATIONS

- Restrict issuance of CL to National Emergency, Extreme Urgency, and public non-commercial use, and cases where there is an anti competitive finding

- Amend provisions (Sec. 84 [7]) that provide grounds for triggering CL by competitors for Commercial benefits

- Provide safeguards enshrined in the Aug 30 Decision (Motta-Menon text) for exports under Section 92A of the Patents Act, corresponding to Para 6 of the *Declaration on the TRIPS Agreement and Public Health* at Doha

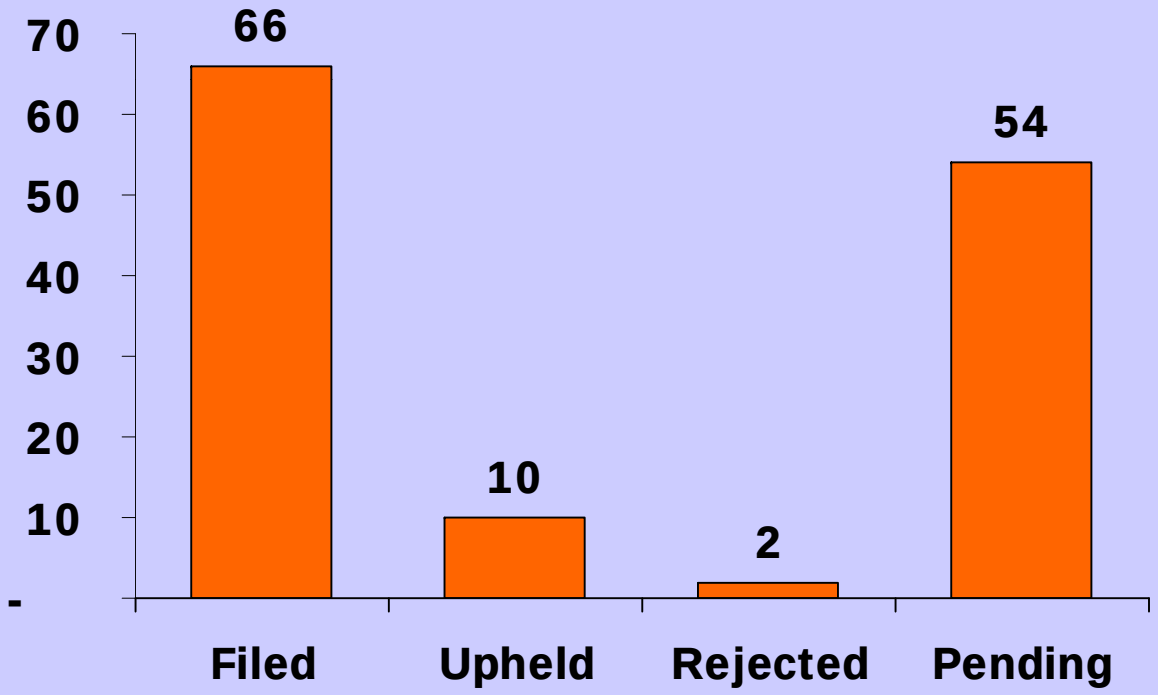
PATENTABILITY OF PHARMACEUTICALS

Pre-Grant Opposition – Pharmaceutical Sector

Status Report March 2007

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

Source: IPO



PRE-GRANT OPPOSITION BY REPRESENTATION

Objectives:

1. To ensure genuine pre-grant opposition
2. To eliminate opposition in seriatim

The need:

1. Ensure that Innovation is not put to undue disadvantage for delay in Pre-grant proceedings
2. Need to introduce statutory time limits for setting up hearings by the Controller and disposing off pre-grant matters for ‘Accountability’

PRE-GRANT OPPOSITION BY REPRESENTATION

RECOMMENDATIONS:

1. **Pre-grant opposition must be filed within 6 months of publication**
2. **Pre-grant opposition must be disposed within 12 months of commencement of pre-grant proceedings.**
3. **If not concluded within 12 months, provide equivalent Patent Term Restoration**

I.P INFRASTRUCTURE

I.P INFRASTRUCTURE

- Increase in number of applications each year
- GOI proposes to have the Indian Patent Office recognized as International Search Authority (ISA) and International Preliminary Examining Authority (IPEA)
- To enable the above – requirement for technology upgradation and human resource development and capacity building

I.P INFRASTRUCTURE

- Total number of Examiners (all branches): 135 – significant attrition
- Out of the above around 100 are available for Examining Applications at any given time
- Each examiner is required to Examine 10 new cases per month. Even if 100 Examiners examine their quota of 10 applications a month, total number of cases examined in an year would be 12,000
- However, number of applications filed in 2006-07 alone are 28, 882
- Backlog for examination at present : 22, 000 applications

I.P INFRASTRUCTURE

- Examiners and Controllers are required to determine patent application in multiple disciplines, which may effect the quality of prosecution - a Controller with mechanical engineering background is examining a biotech patent

- Unlike USPTO and JPO, India has four patent offices as per regional jurisdiction, more or less working independently

- Lack of synergies between the four offices: (1) Filing is independent; (2) Prosecution is independent and (3) Grant is independent and only aspect of synchronization is in issuing Patent Numbers after grant

I.P INFRASTRUCTURE -RECOMMENDATIONS

- Patent examiners need better training
- More Patent examiners required – China has 3000 Examiners and we have 135
- Examiners should be experts in specific technology areas – biotechnology, chemistry and pharmaceuticals
- Patent Examiners and Controllers should be better paid and a system of bonuses and other incentives created both for talent retention and encouraging better performance
- Detailed guidelines in the form of a Manual (MPPP) necessary to encourage transparency and clarity

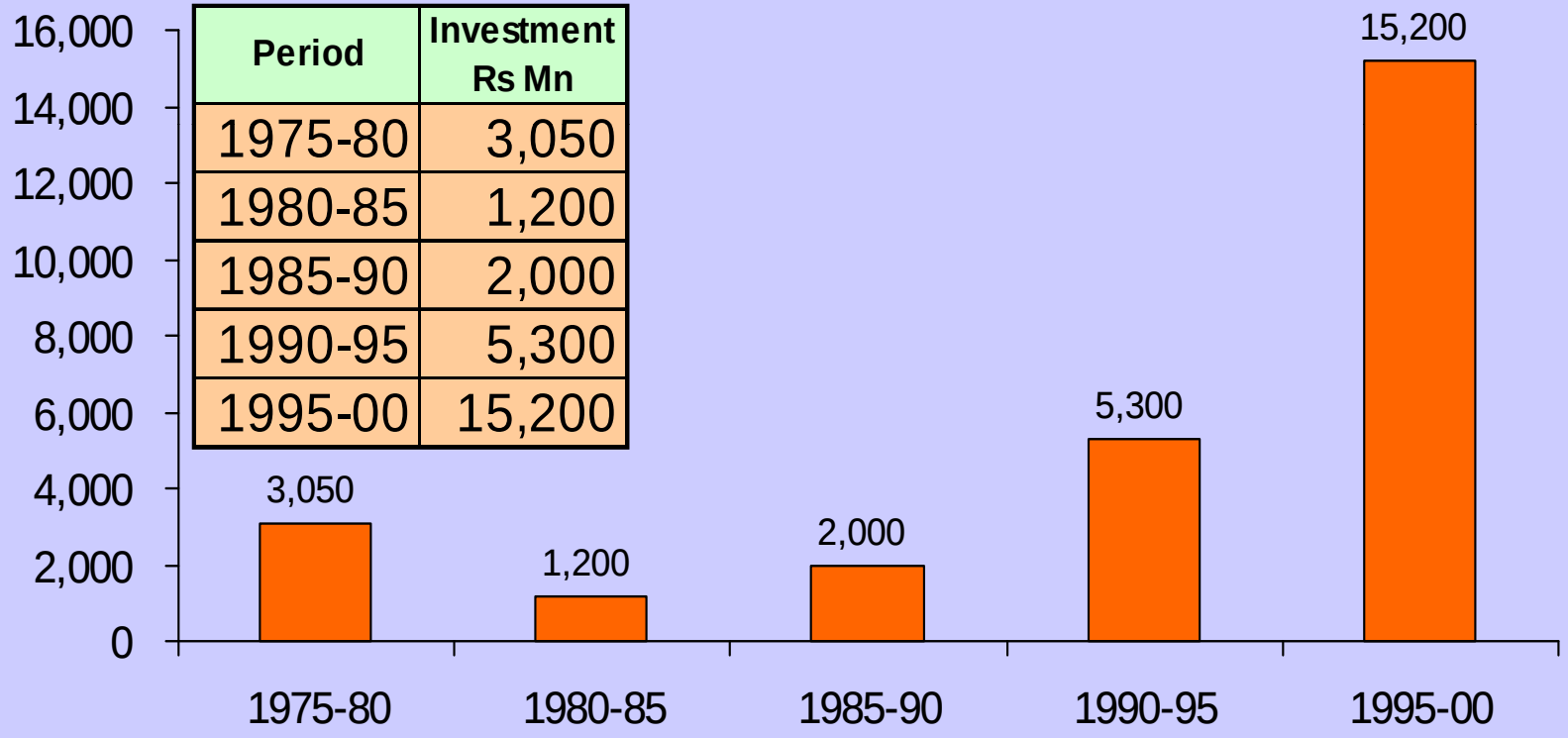
PUBLIC-PRIVATE PARTNERSHIP: I.P. INFRASTRUCTURE

- **Industry ready to partner with Government in:**
  - **Training**
  - **Capacity Building**
  - **Sharing Best Practices**

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

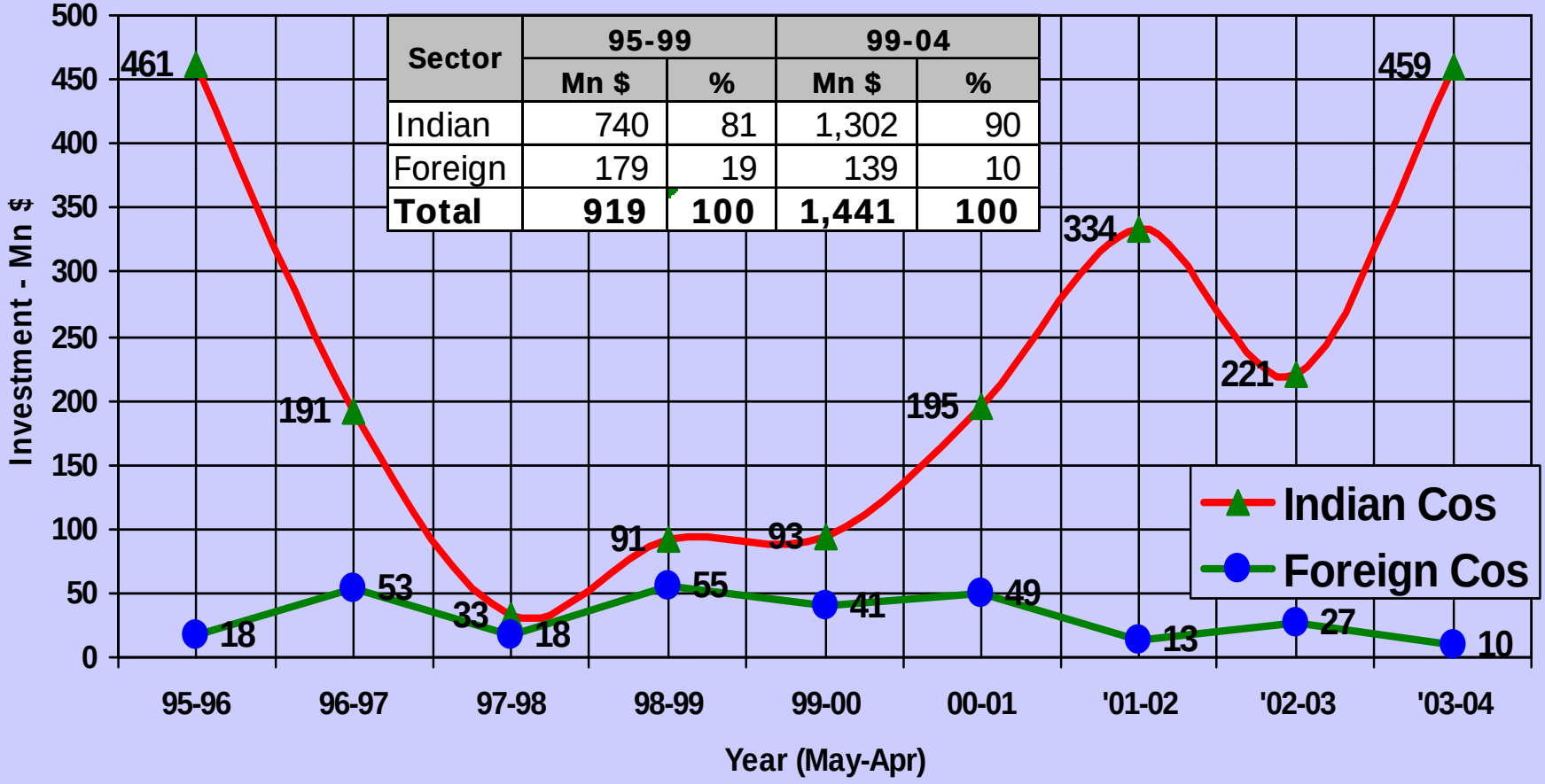


Reality: Maximum FDI Took Place Between 1995 & 2000

IPR AND INVESTMENT

India Investment in Pharmaceuticals

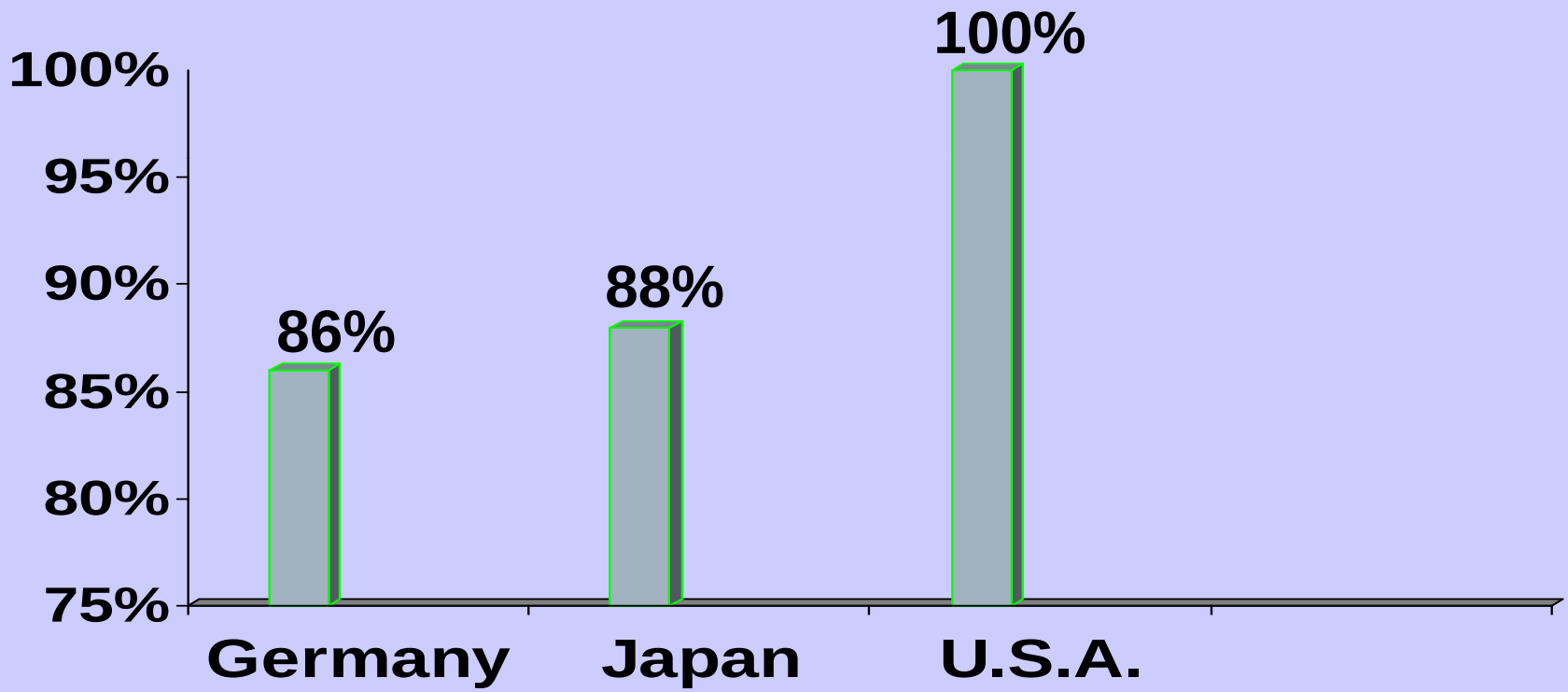
Sector	95-99		99-04	
	Mn $	%	Mn $	%
Indian	740	81	1,302	90
Foreign	179	19	139	10
Total	**919**	**100**	**1,441**	**100**



Source: CMIE, Study Report: 1996-2004

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


Thank You