# INDIAN PATENTS ACT 2005
# &
# PHARMACEUTICAL INDUSTRY IN INDIA

Tapan Ray

2nd Intellectual Rights Conference
Mumbai, October 15, 2008

“A pessimist sees the difficulty
in every opportunity;
an optimist sees the opportunity
in every difficulty.”

-Sir Winston Churchill

# Content

- Economic Scenario of India
- Overview of Indian Pharmaceutical Industry
- Healthcare Policy of India – has it delivered
- IPR Scenario in India & Indian Patents Act 2005
- Key Issues
- The Way Forward
- IP Index

# Economic Scenario of India


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

# Selective Economic Indicators

| | 1990-91 | 2007-08 |
|---|---|---|
| Real GDP | US$ 48 billion | US$ 1174 billion |
| GDP Growth | 5.3% | 8.7% |
| ForEx Reserv. | US$ 1 billion | US$ 290 billion |
| FDI | US$ 0.36 billion | US$ 15.7 billion |
| Inflation | 10.3% | 5.5%** |

# Pharmaceutical Industry & Healthcare Scenario

# The Indian Pharmaceutical Market, the Regulatory Thinking, and Challenges facing the Pharma industry

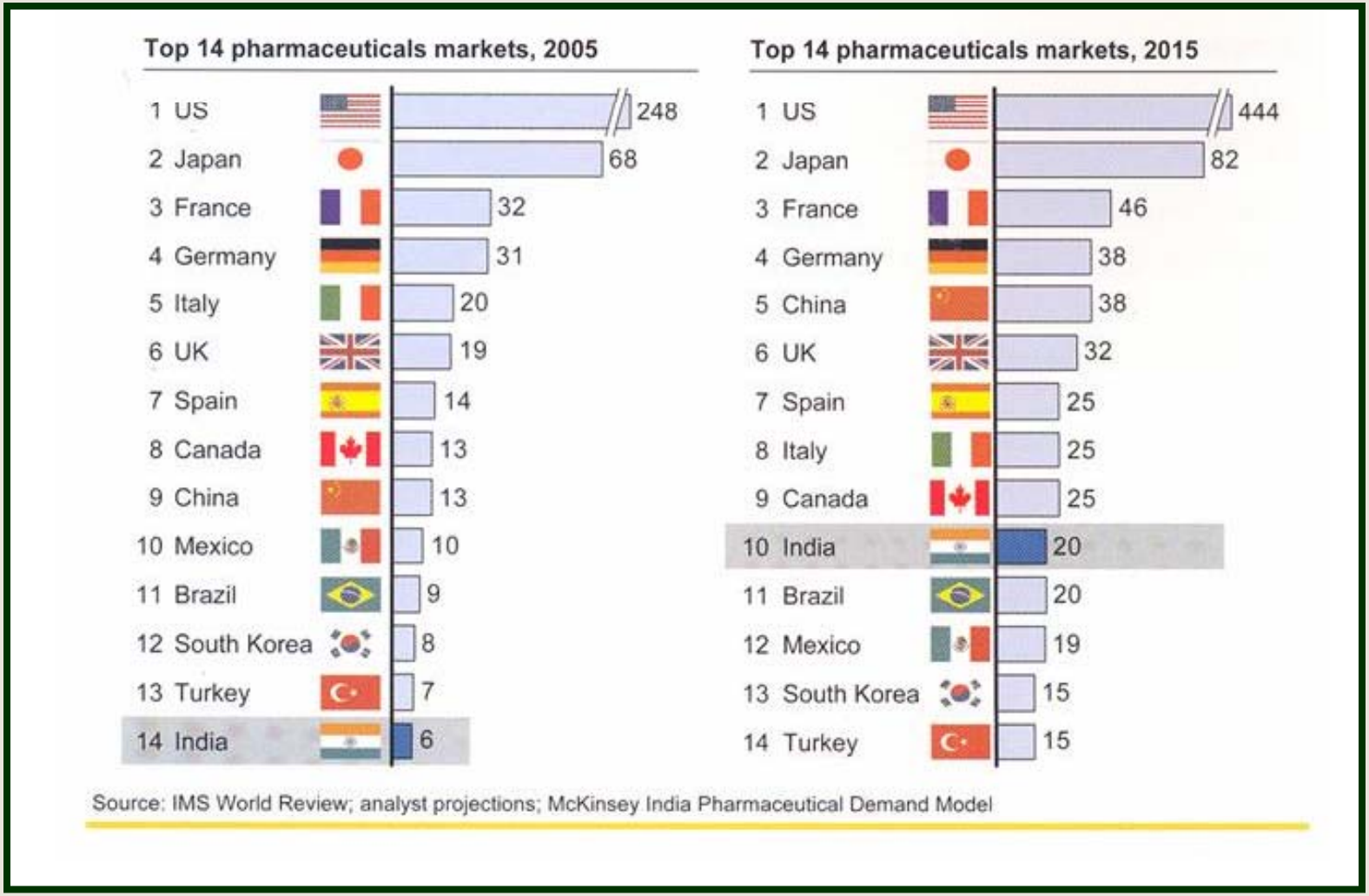
# Indian Pharmaceutical Industry: 2007-2008

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

# McKinsey Projection 2015*

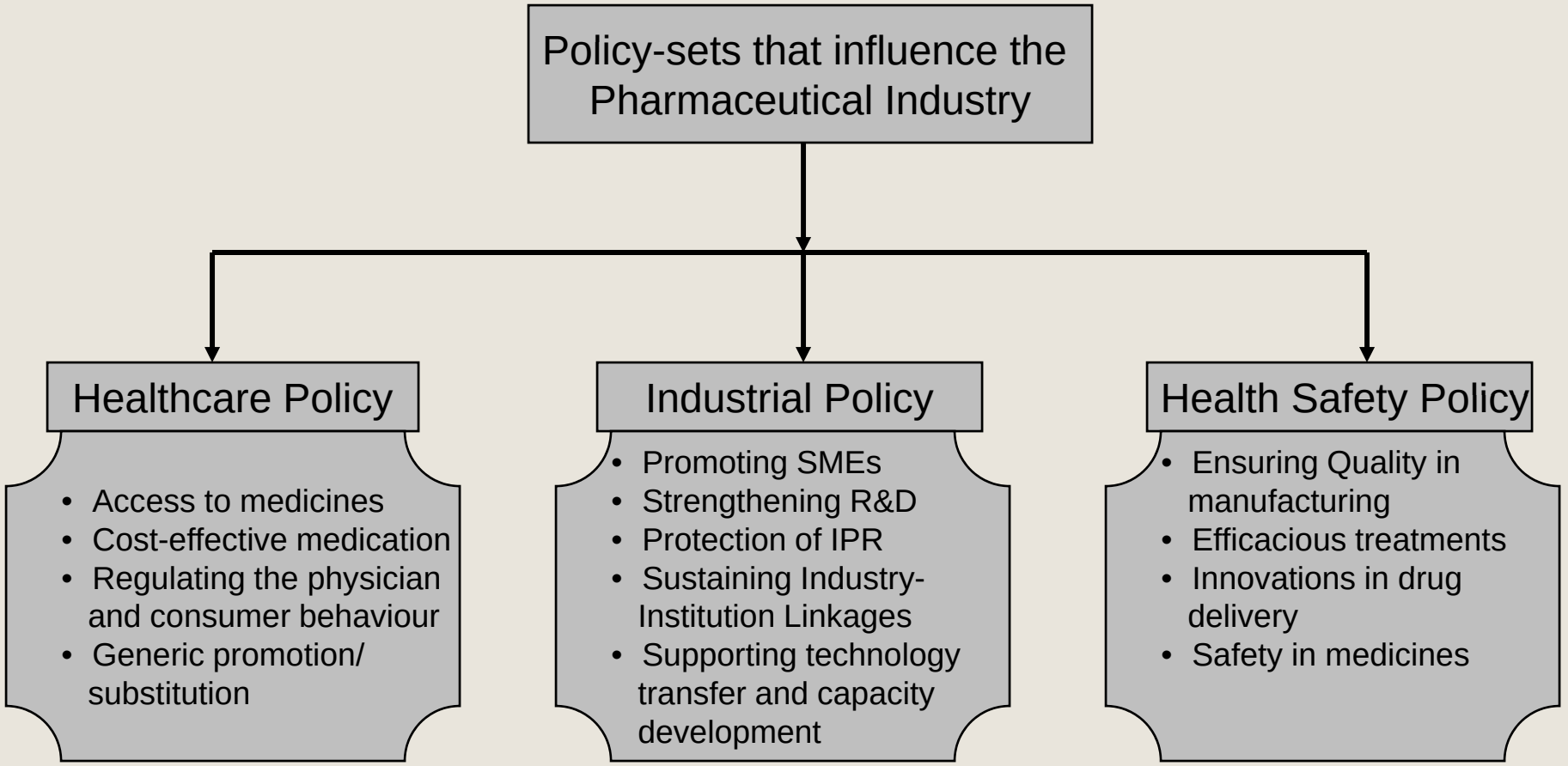
- Domestic Sales to reach U.S.$ 20 Bn.
- Incremental growth between 2005 – 2015, U.S.$ 14 Bn.
- Key Drivers for Growth:
  - Robust Economy
  - Increasing Affordability
  - Deeper Penetration of Health Insurance
  - Increase in Organised Retail Chains
  - Shifting Disease Patterns
  - Increase in Healthcare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

# India is Projected to be the 10th Largest Market by 2015



# Healthcare Policy of India – has it delivered?

# Policy Framework Supporting Pharmaceutical Industry




Source: EXIM Research

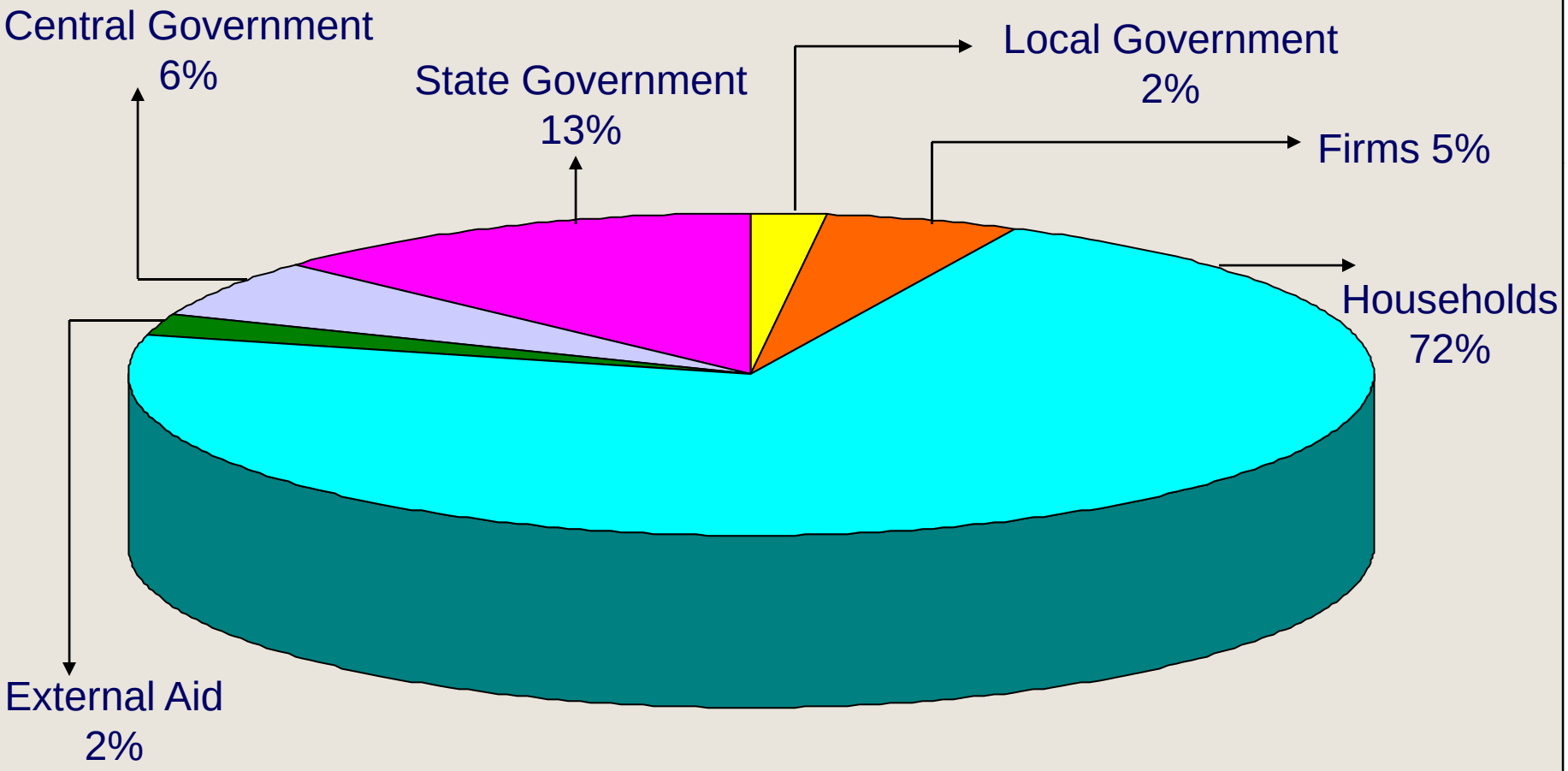
# India's Healthcare Context is Unique

| Countries | Govt. Payment | Out of pocket payment | Insurance | Others |
|---|---|---|---|---|
| United States | 44.3% | 13.7% | 35.8% | 4.9% |
| Japan | 80% | 20% | - | - |
| Australia | 71% | 16% | 7% | 5% |
| France | 77.5% | 20.5% | 2% | |
| Germany | 75.1% | 11% | 13.9% | |
| Canada | 72% | 17% | 11% | |
| UK | 81% | 3% | 16% | |
| Spain | 72% | 20.5% | 7.5% | |
| Italy | 73.7% | 26.3% | | |

India : 72% out of pocket payment and 28% from others

# Sources of Financing Healthcare Services in India

## Proportion of Health Expenditure by Financing Source




Source: National Health Accounts – 2001-02, MoHFW, GoI

# Medicines

| | |
|---|---|
| Doctor’s Fees | 9% |
| **Medicines** | **15%*** |
| Diagnostic Investigations & Pathological Tests | 24% |
| Hospitalization | 17% |
| Transport | 20% |
| Miscellaneous | 8% |
| Others | 7% |

* 60% towards taxes and trade margins

15% of Total Household Cost for Individuals

Source: National Survey of Health, 2003

# Price Control Trend

In the past 30 years, successive Governments have reduced the span of price control on medicines

| DPCO Year | No. of Drugs under Price Control | Percentage of Controlled Market |
|---|---|---|
| 1970 | All | 100 |
| 1979 | 347 | 90 |
| 1987 | 143 | 70 |
| 1995 | 74 | 20 |
| 2002 | 30 drugs proposed | Under review |

Source: ORG-IMS

# Current Price Regulation

| Nature of Price Regulation | Percentage of Controlled Market |
|---|---|
| **Cost based Price Control** | **20** |
| **Price Monitoring with annual price increase ceiling of 10%** | **80** |
| **Total** | **100** |

Source: ORG-IMS/NPPA

# Pharmaceutical Prices in Selected Countries

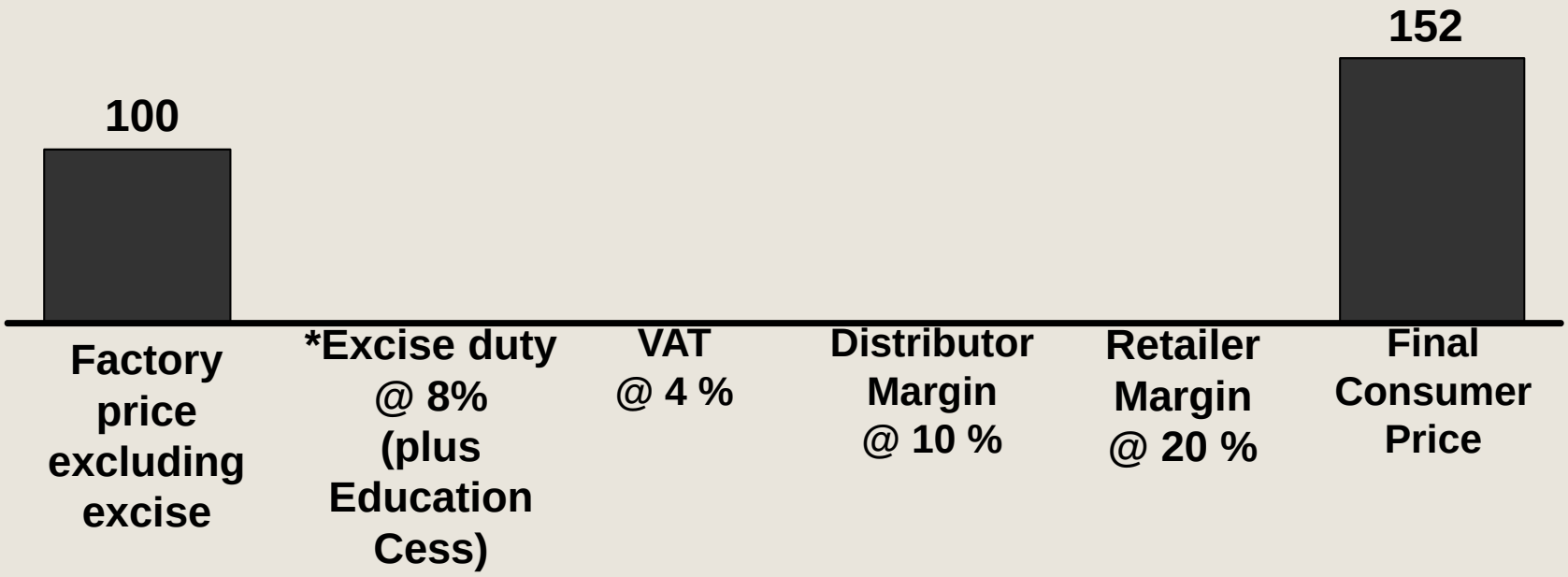
| | Drugs, Dosage Form and Strength | Pack | Prices in India (INR) | Prices in Pakistan (INR) | Prices in Indonesia (INR) | Prices in USA (INR) | Prices in UK (INR) |
|---|---|---|---|---|---|---|---|
| I. **ANTI-INFECTIVES** | | | | | | | |
| 1. | Ciprofloxacin – HCL 500 mg tabs | 10's | **29.00** | 423.86 | 393.00 | 2352.35 | 1185.70 |
| 2. | Norfloxacin 400 mg tabs | 10's | **20.70** | 168.71 | 130.63 | 1843.66 | 304.78 |
| 3. | Ofloxacin 200 mg tabs | 10's | **40.00** | 249.30 | 204.34 | 1973.79 | 818.30 |
| 4. | Cefpodoxime Proxetil 200 mg tabs | 6's | **114.00** | 357.32 | 264.00 | 1576.58 | 773.21 |

# Pharmaceutical Prices in Selected Countries

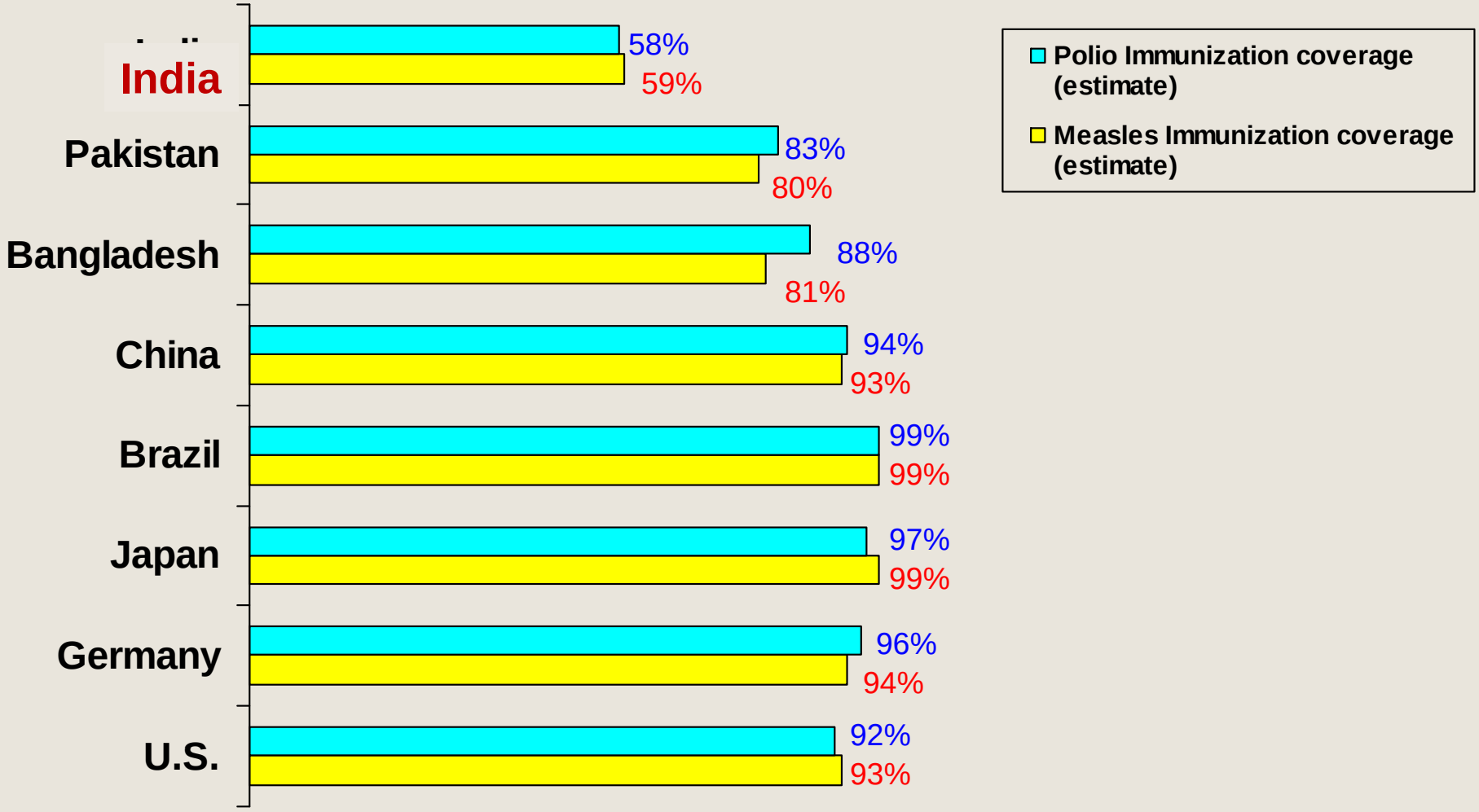
contd…

| | Drugs, Dosage Form and Strength | Pack | Prices in India (INR) | Prices in Pakistan (INR) | Prices in Indonesia (INR) | Prices in USA (INR) | Prices in UK (INR) |
|---|---|---|---|---|---|---|---|
| II. **NSAIDs** | | | | | | | |
| 1. | Diclofenac Sodium 50 mg. tabs | 10's | **3.50** | 84.71 | 59.75 | 674.77 | 60.96 |
| III. **ANTI-ULCERANTS** | | | | | | | |
| 1. | Ranitidine 150 mg. tabs | 10's | **6.02** | 74.09 | 178.35 | 863.59 | 247.16 |
| 2. | Omeprazole 30 mg. caps | 10's | **22.50** | 578.00 | 290.75 | 2047.50 | 870.91 |
| 3. | Lansoprazole 30 mg. caps | 10's | **39.00** | 684.90 | 226.15 | 1909.64 | 708.08 |

# High Transaction Cost

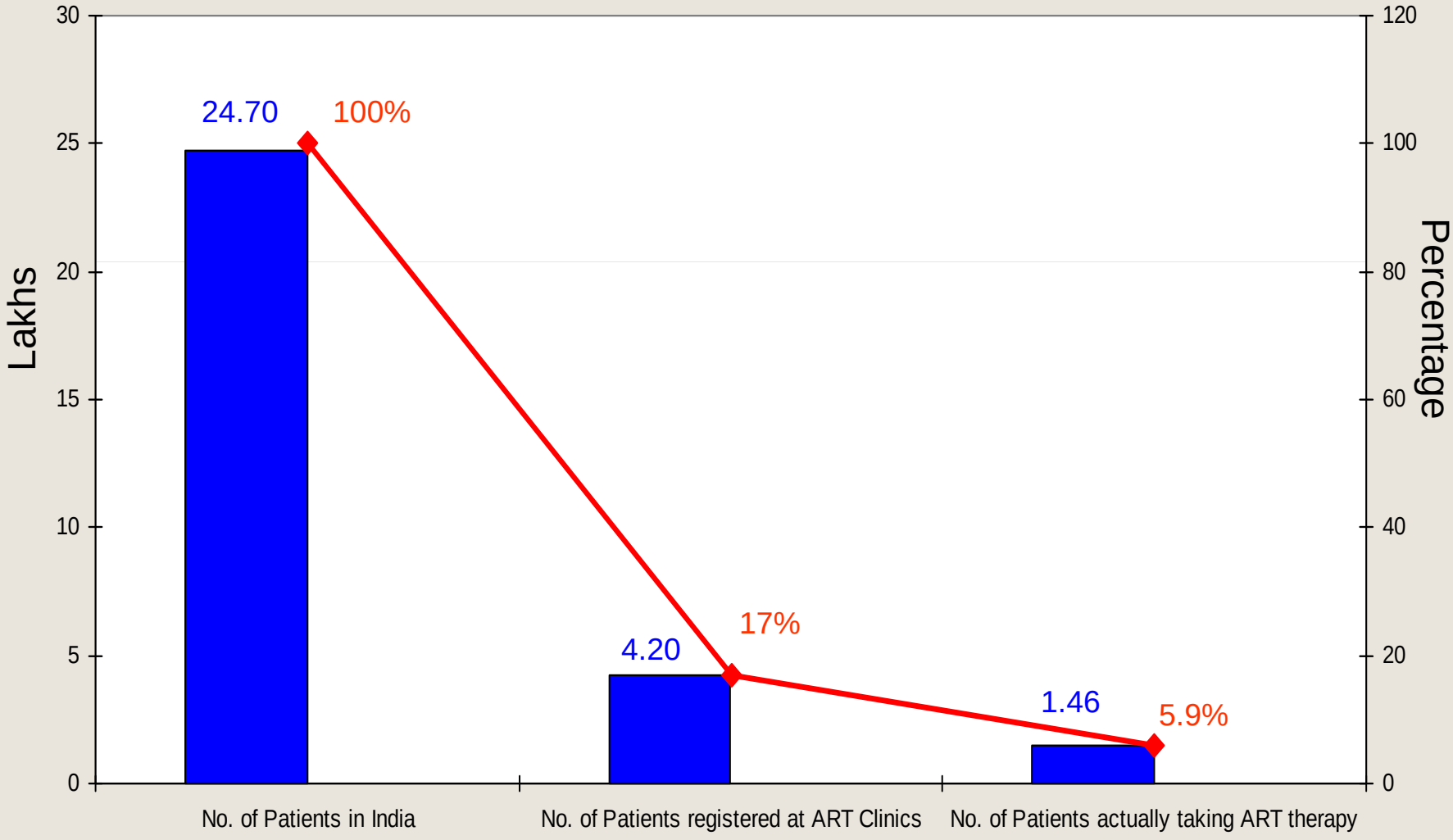


# Many Children not getting Primary Vaccination



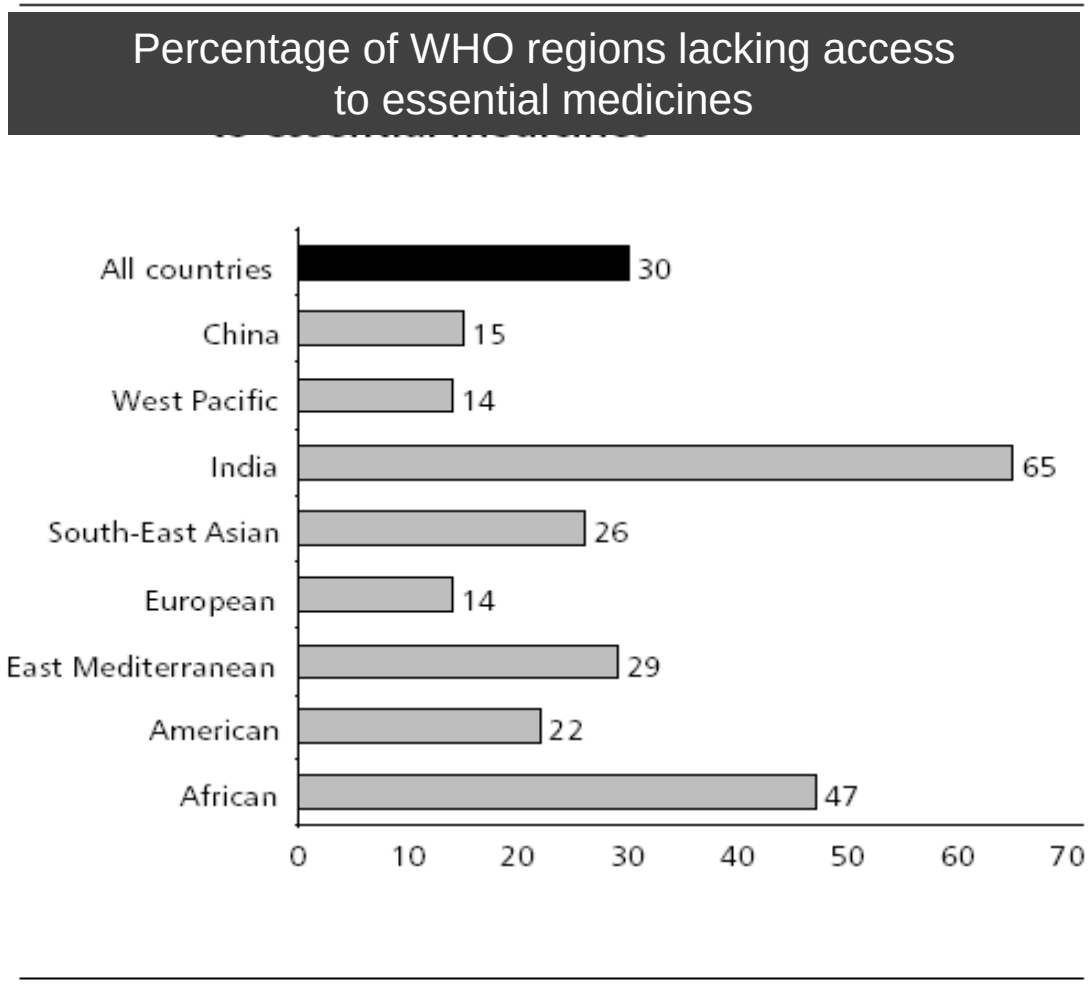

Source: World Health Organisation

# HIV Patients: Access to ART




Source: NACO, INDIA

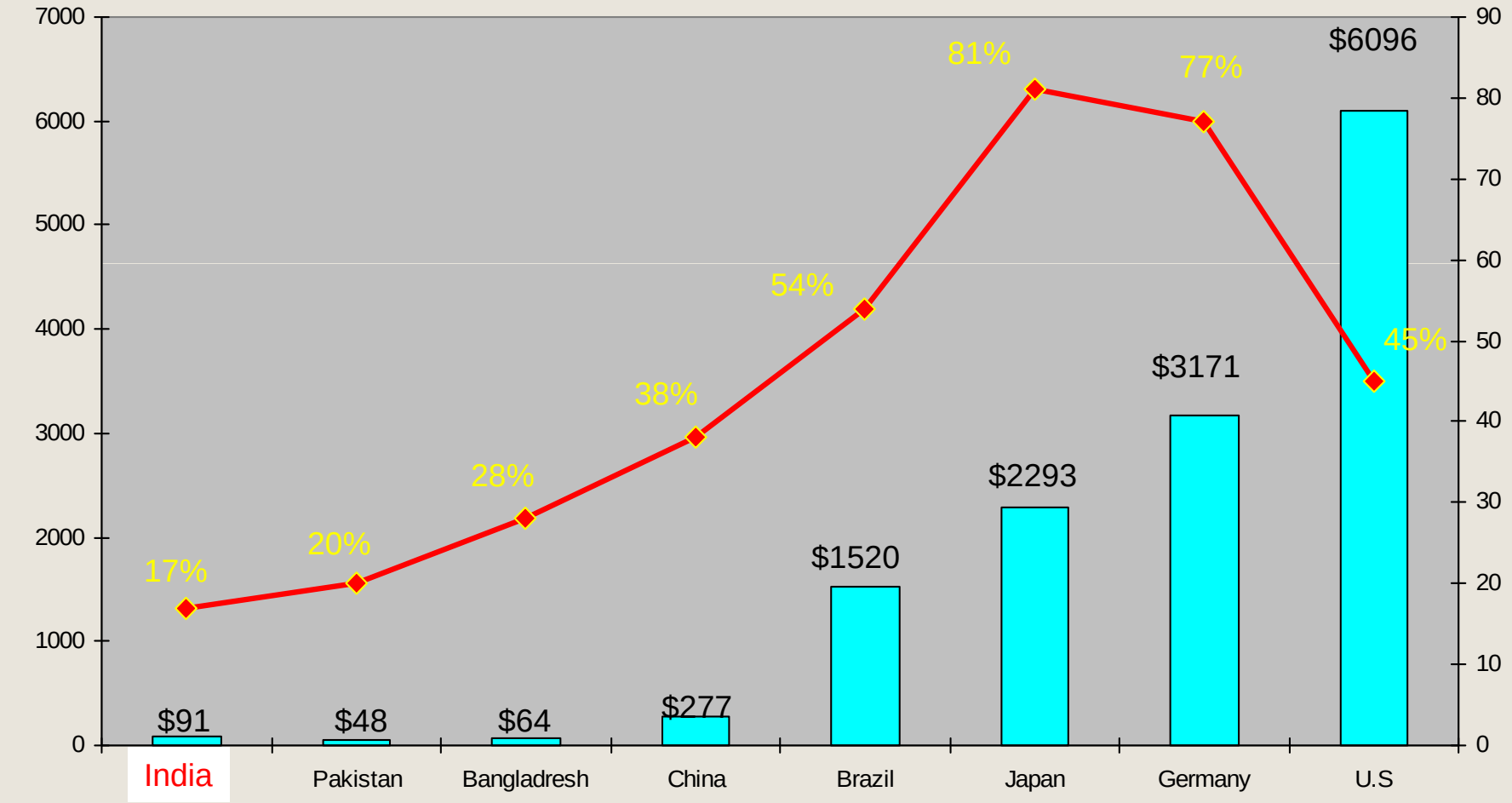
# Access to Modern Medicine – A Challenge




- This 350 mn. people are largely clustered around urban centres where health care facilities exist

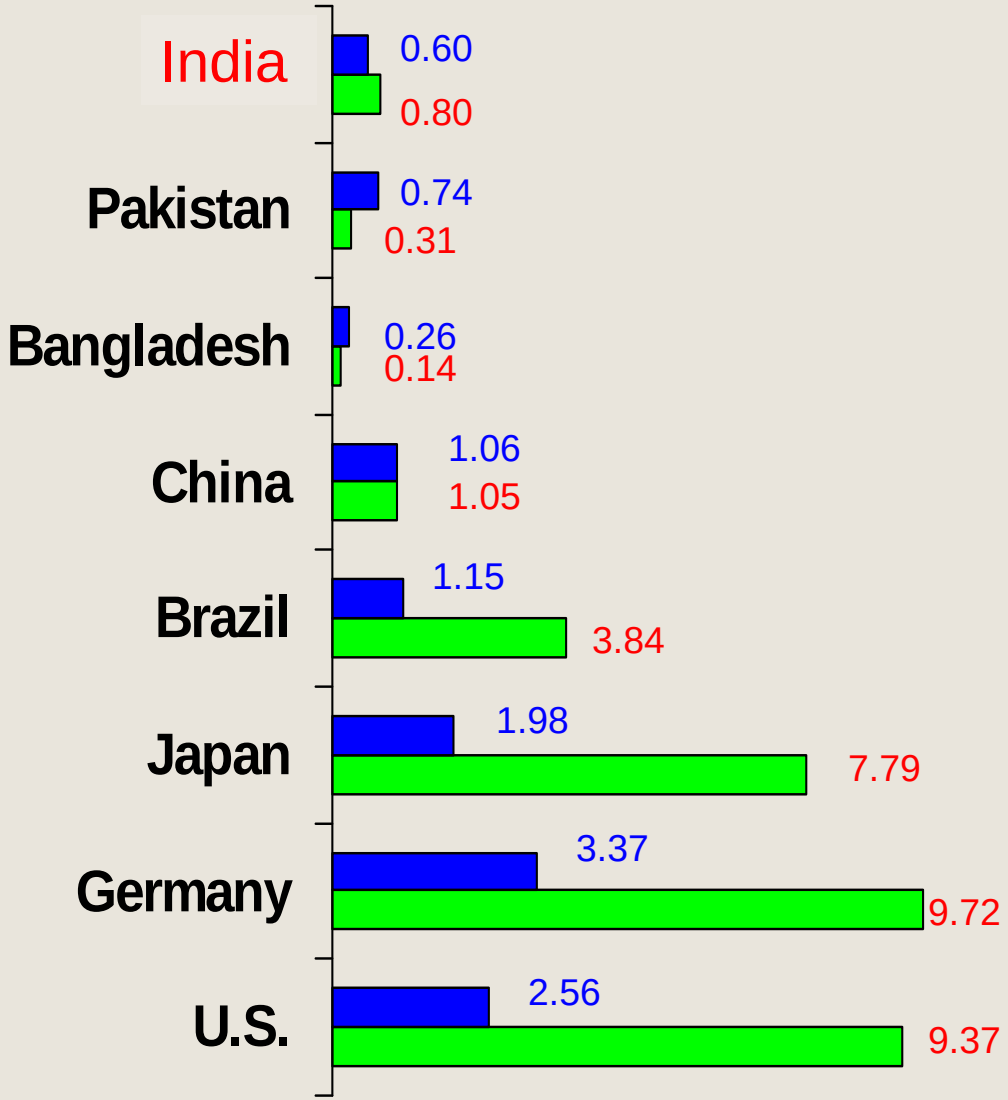
Source: Network, November 2004

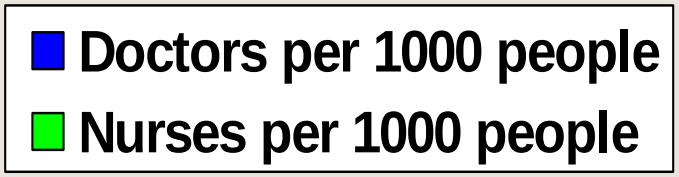
# India Spends Relatively Less on Healthcare




Source: World Health Organisation

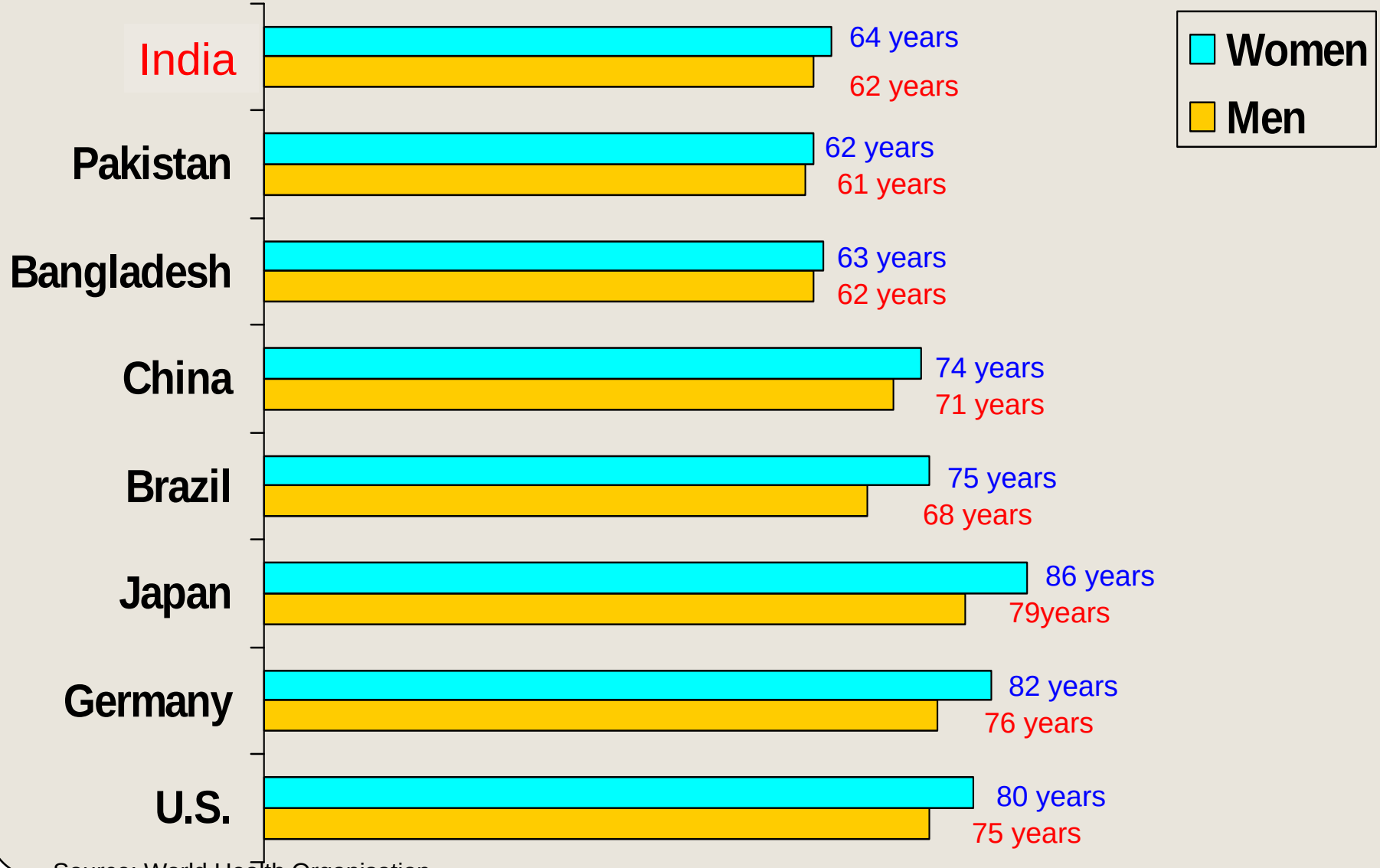
# Shortage of Doctors and Nurses in India



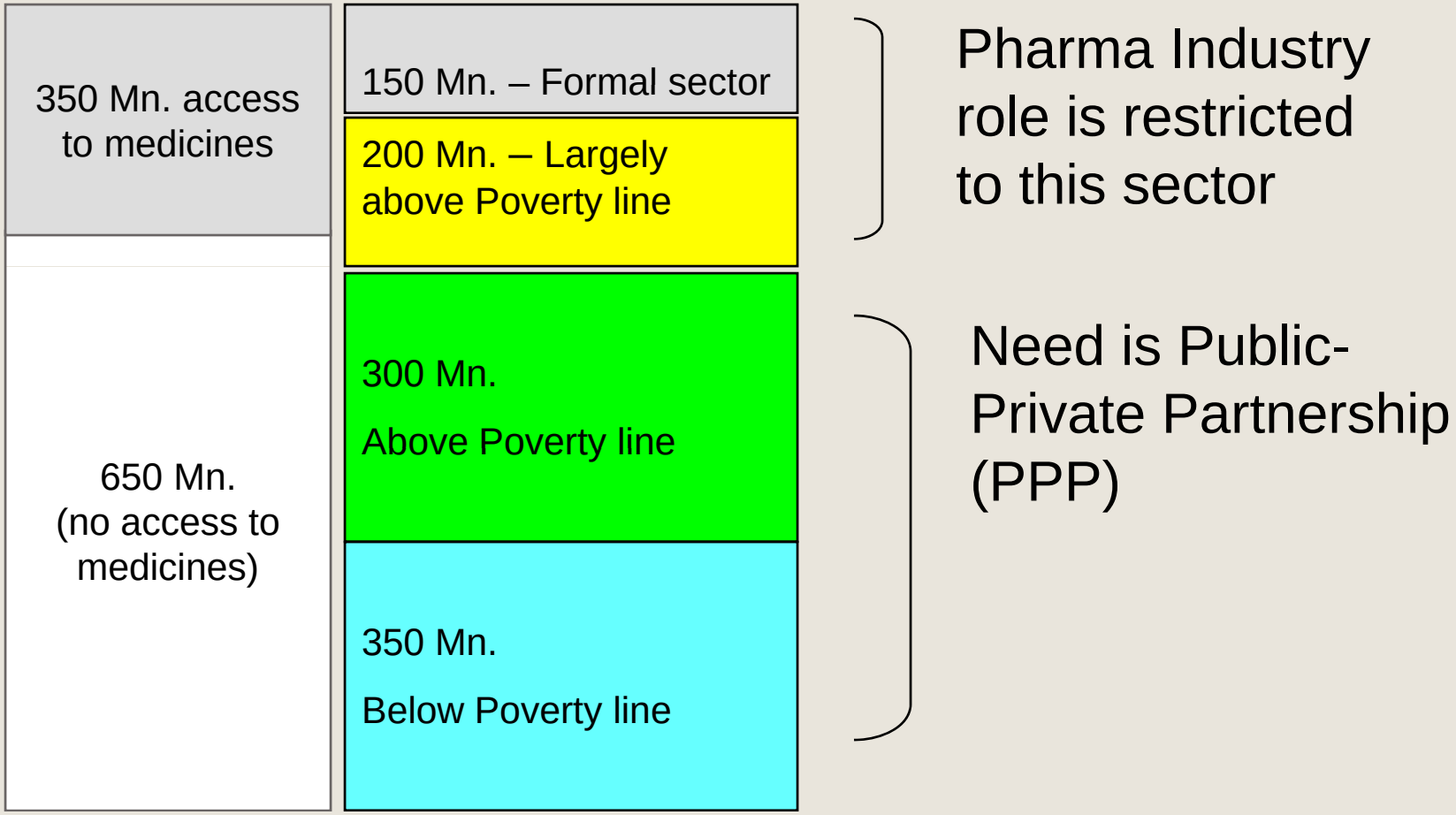

Source: World Health Organisation

# Life Expectancy in India




Source: World Health Organisation

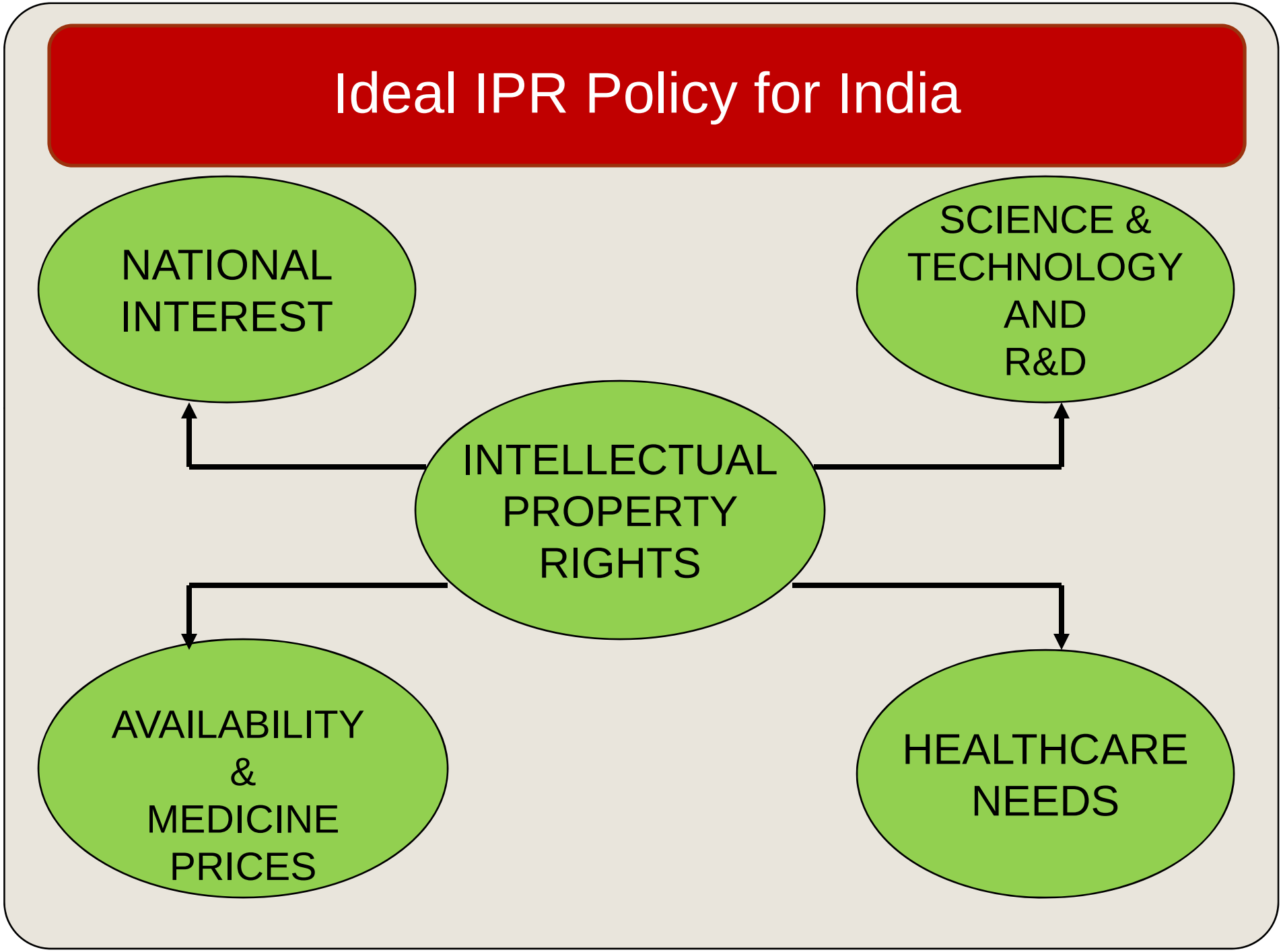
# Access to Innovative Medicines




Formal Sector: Those employed with the Public or Private Sector

# IPR Scenario in India & Indian Patents Act 2005

# Ideal IPR Policy for India

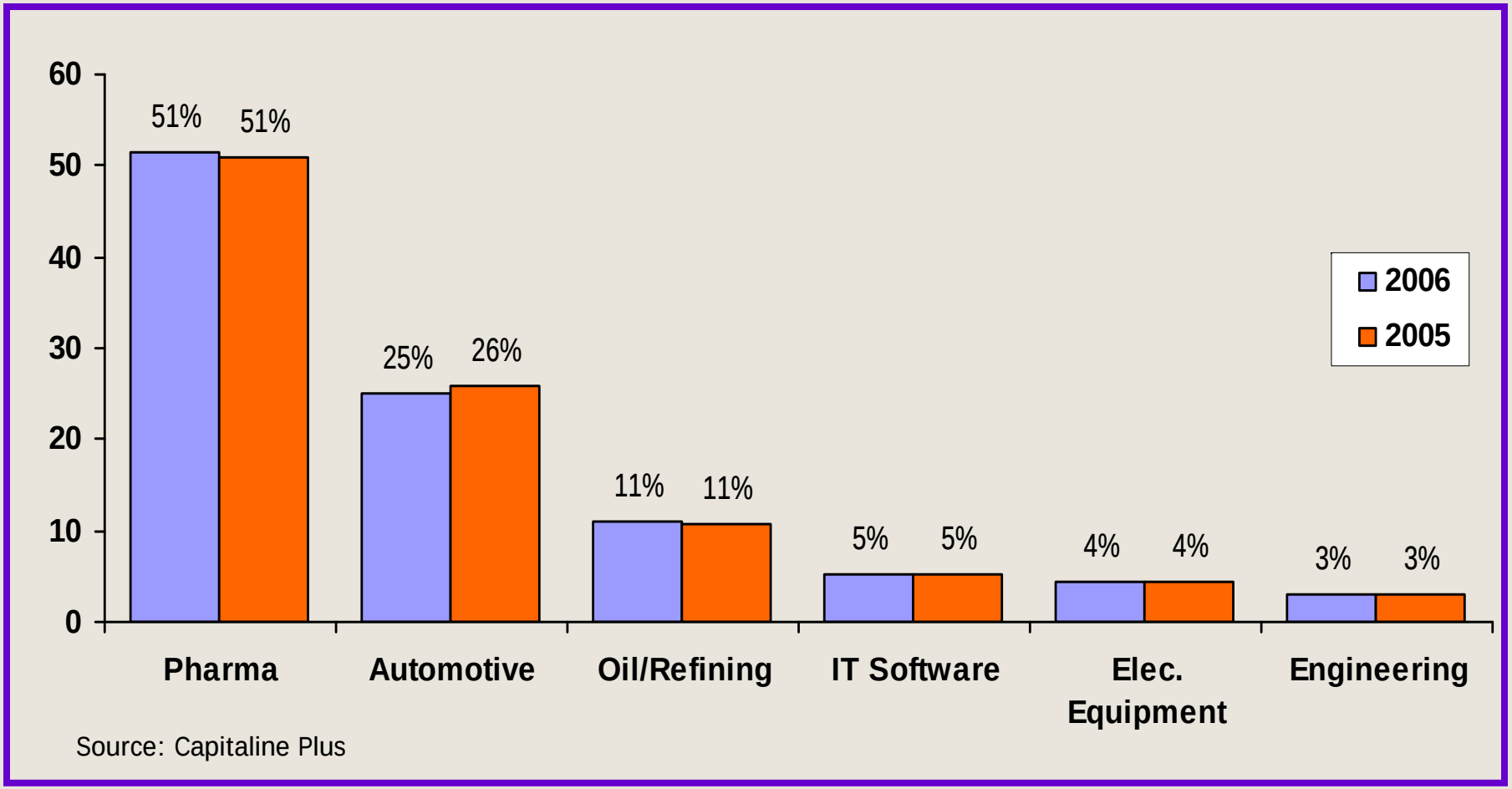


# Patents in India – Historical Perspective

| 1911 | 1970 | 1999 | 2002 | 2004 |
|---|---|---|---|---|
| Indian Patents and Design Act | Indian Parliament enacted the Patents Act | First Amendment to the Patents Act | Second Amendment to the Patents Act | Patents Ordinance passed on December 26, 2004 |
| Product Patents | Process Patents | EMR and Mailbox provided | Patent term extended to 20 years | In technical compliance with the commitment made under the WTO Agreement |

# Indian Industry – R&D Spend

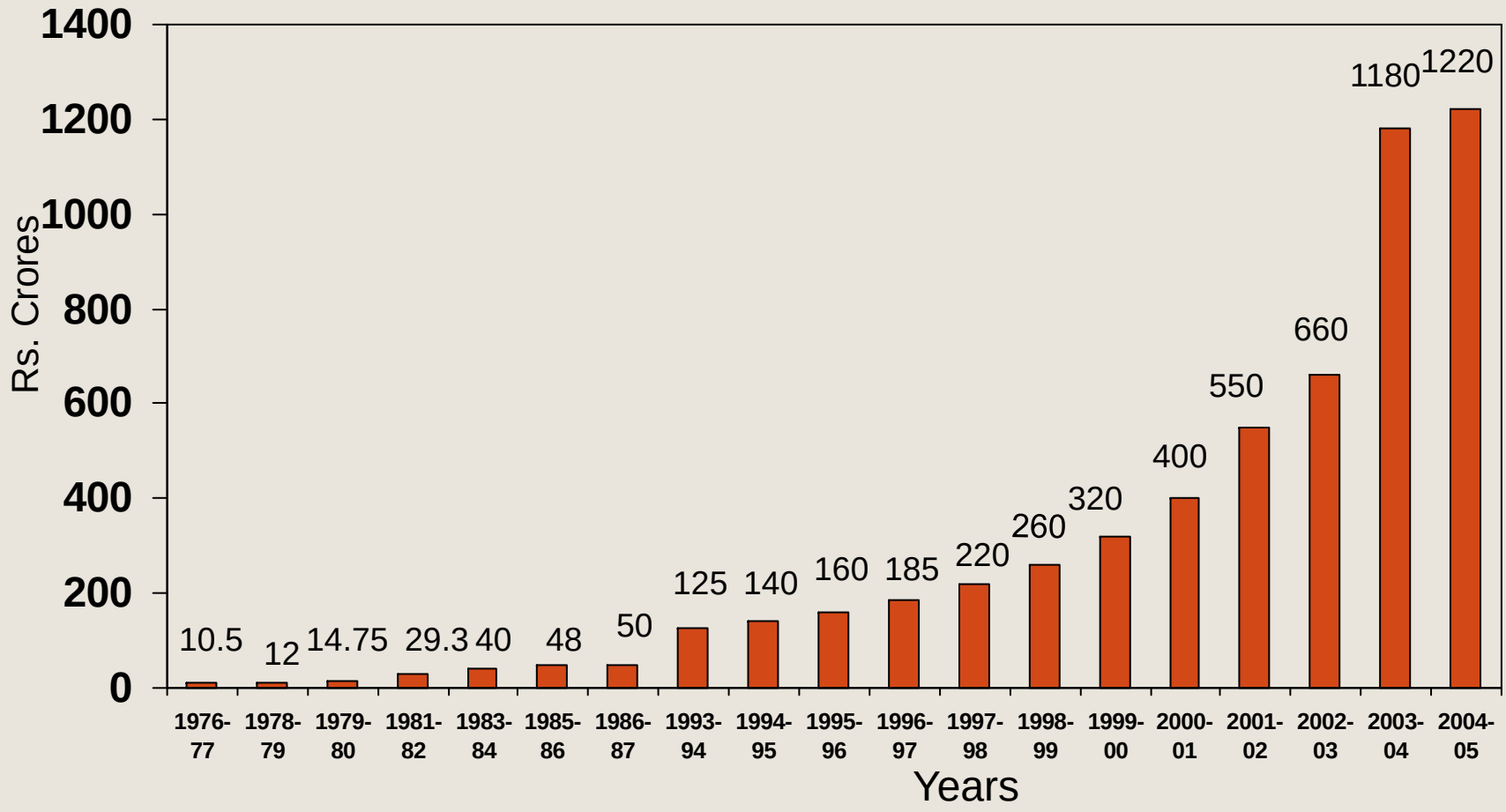
## R & D Spend: How Top Sectors Fare




Source: Capitaline Plus

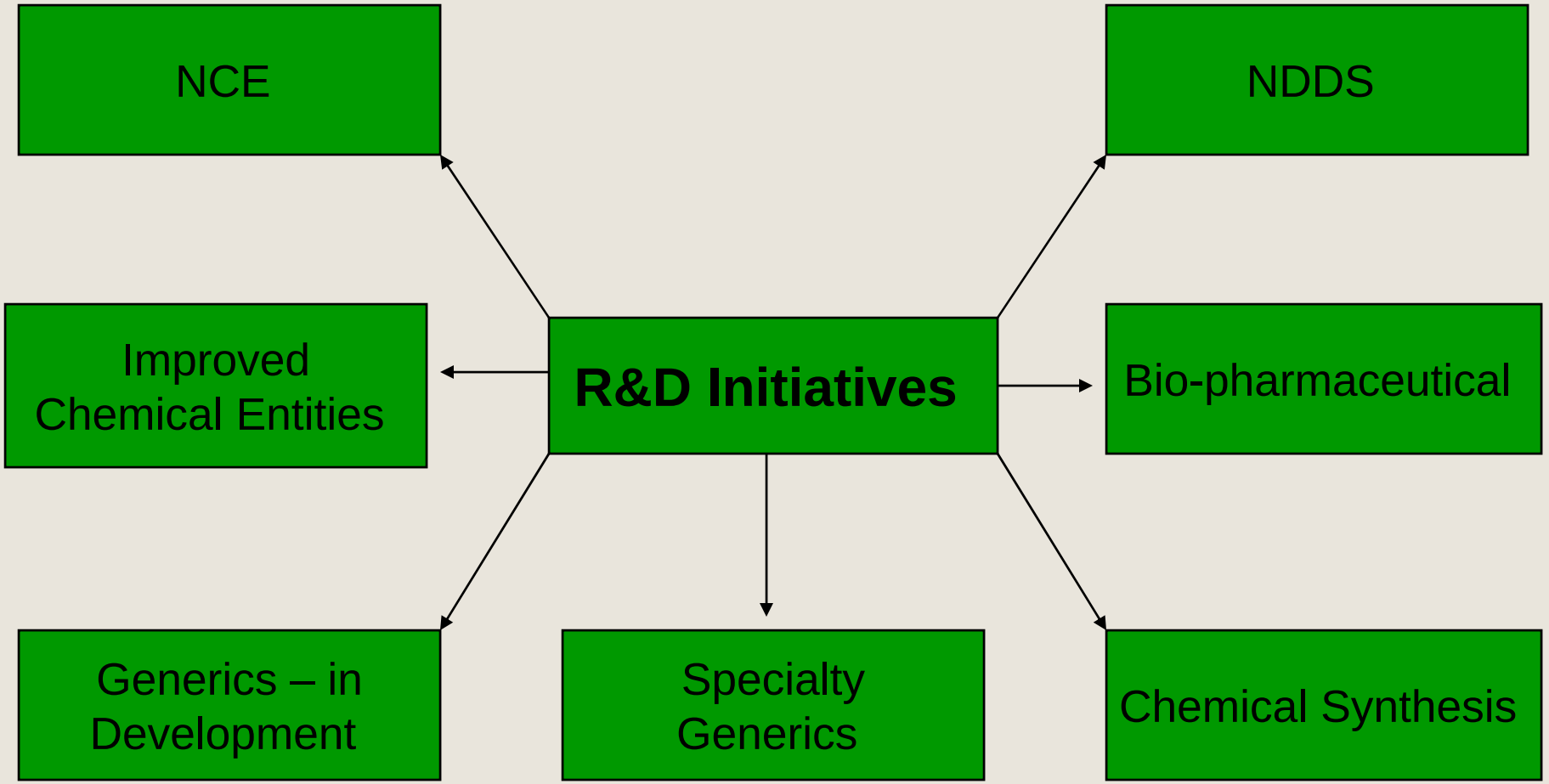
Pharma Spends More Than All Industries Put Together

# Trends in R&D Expenditure in Indian Pharmaceutical Industry (1976-77 to 2004-05)



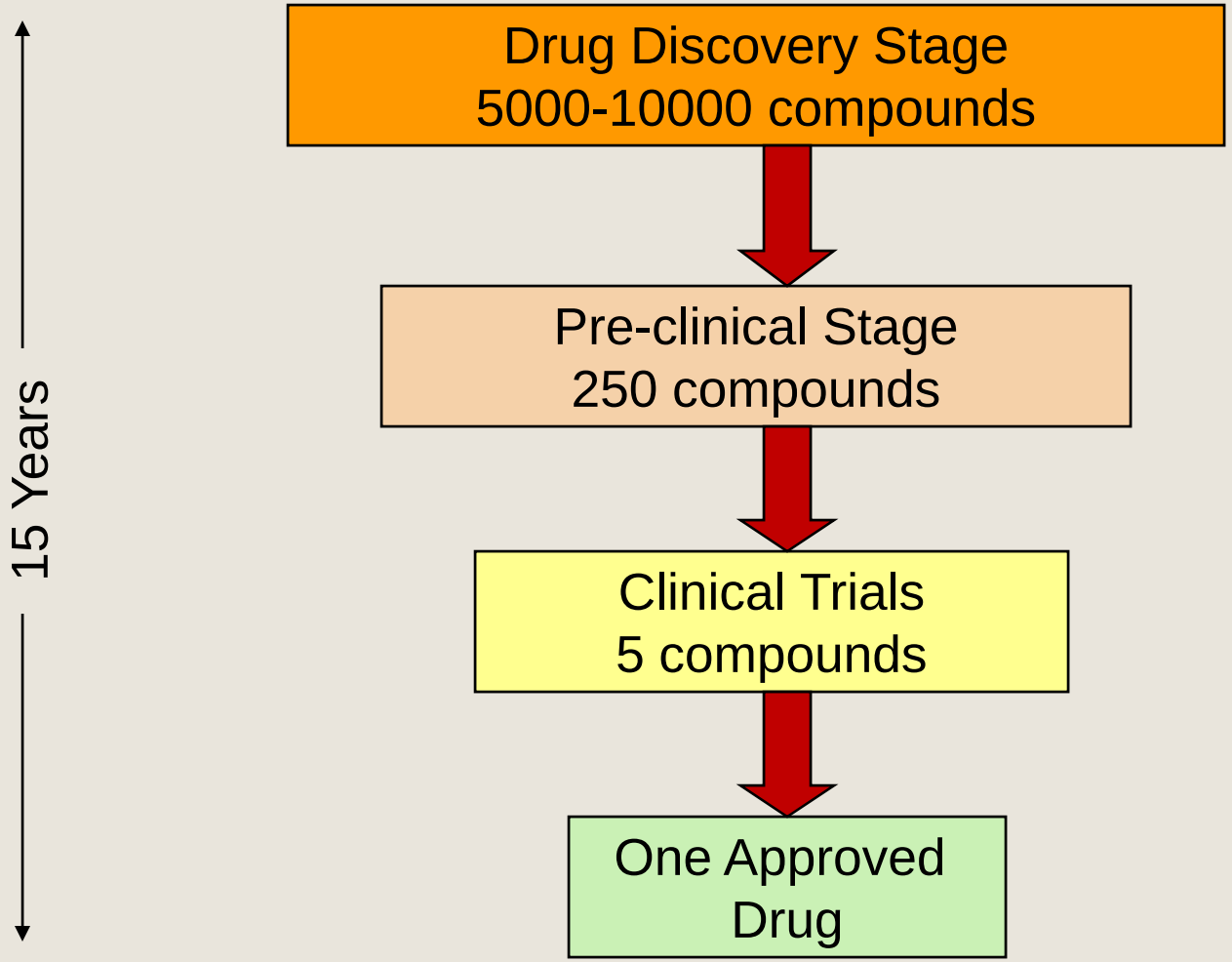

Source: Organisation of Pharmaceutical Producers of India

# R&D Status of Indian Pharmaceutical Industry




Source: Indian Pharmaceutical Industry, ICRA, 2004

# Research & Development Process in Pharmaceutical Industry

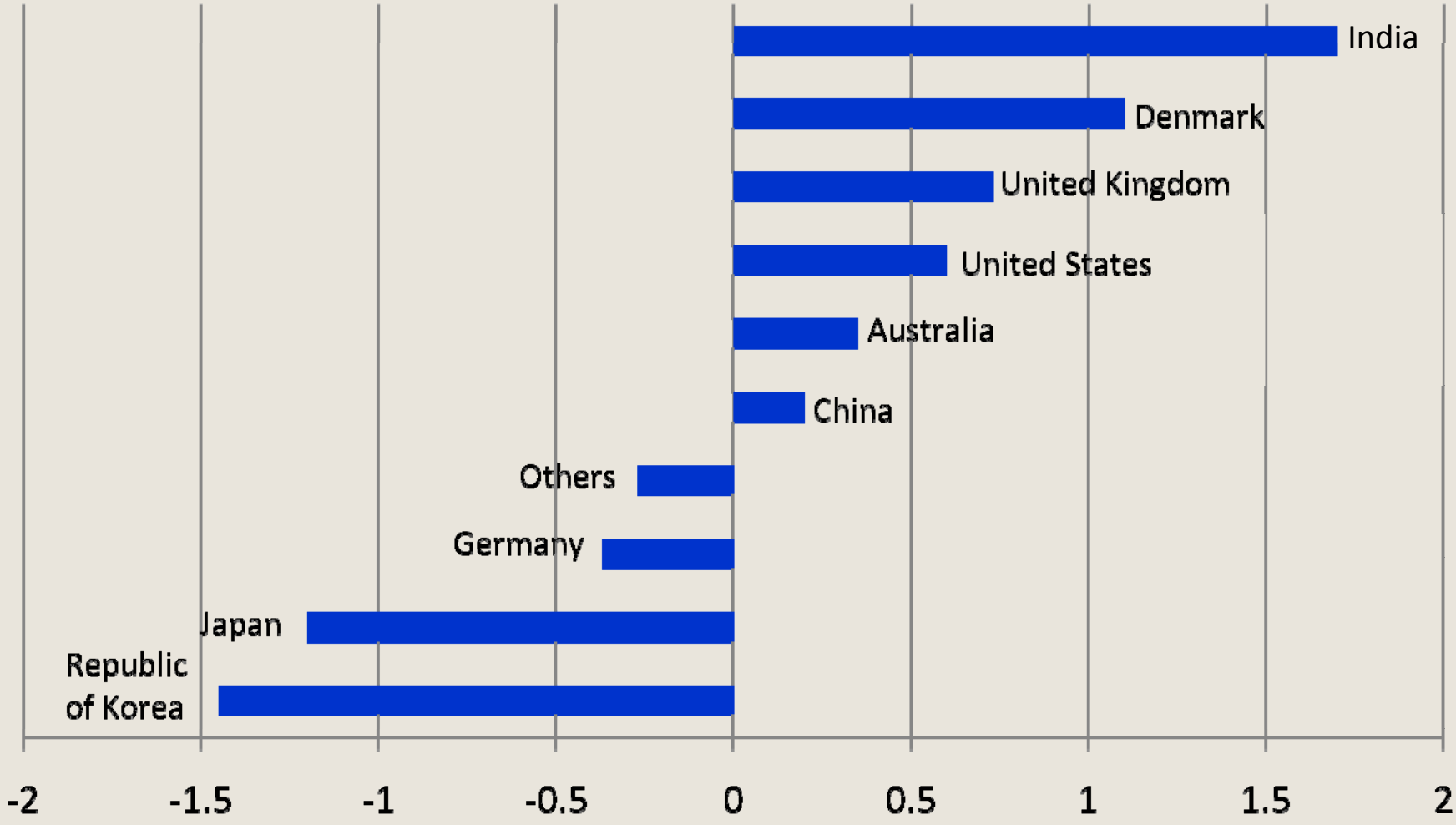



Source: PhRMA

# Relative Specialization Index (RSI)

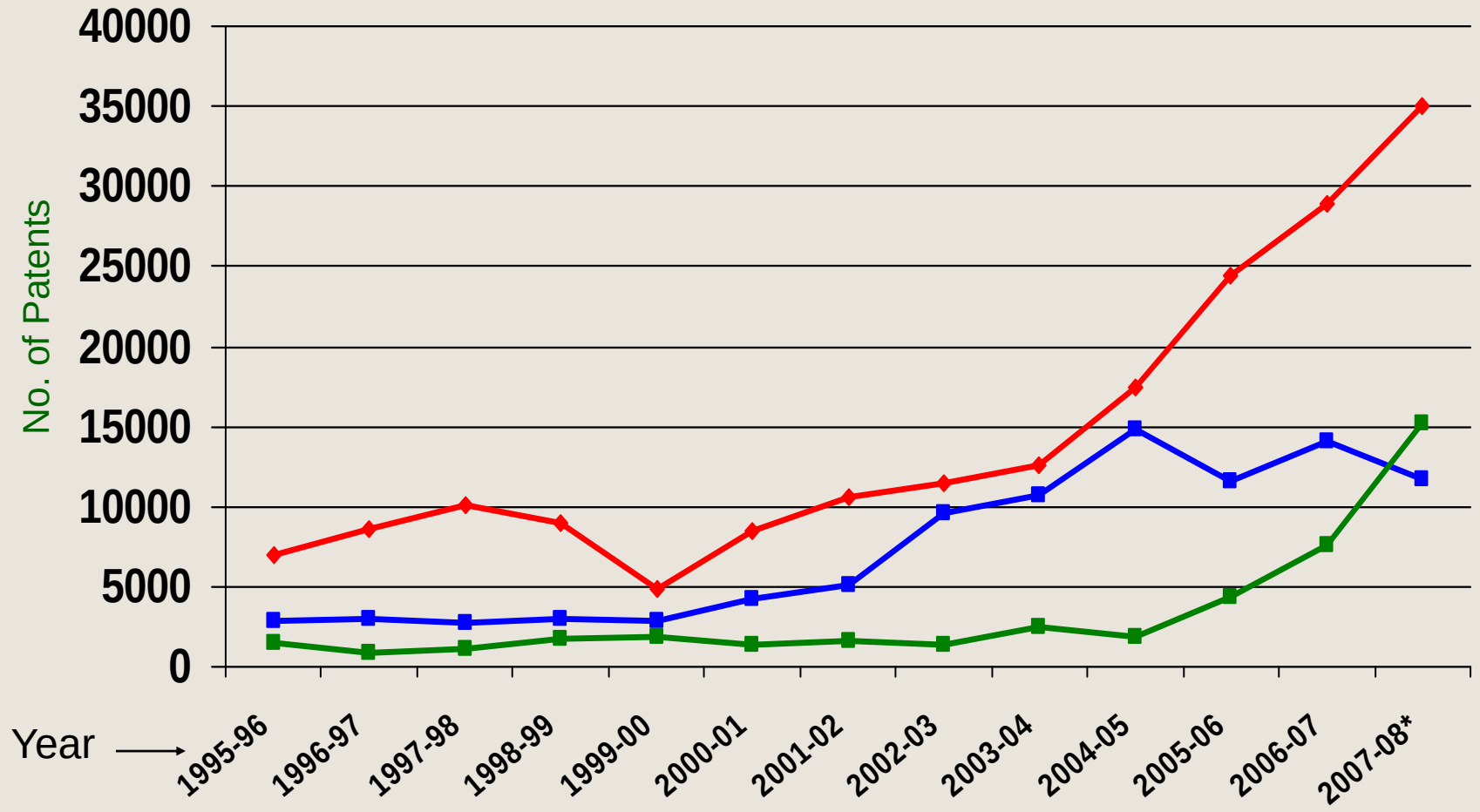
- Relative Specialization Index (RSI) compares the number of patents originating from a given country in a specific technology to the total number of patents in all areas.

# Relative Specialization Index (RSI) - Pharmaceuticals (2001-2005)




Source: World Patent Report – A Statistical Review, 2008, World Intellectual Property Organisation

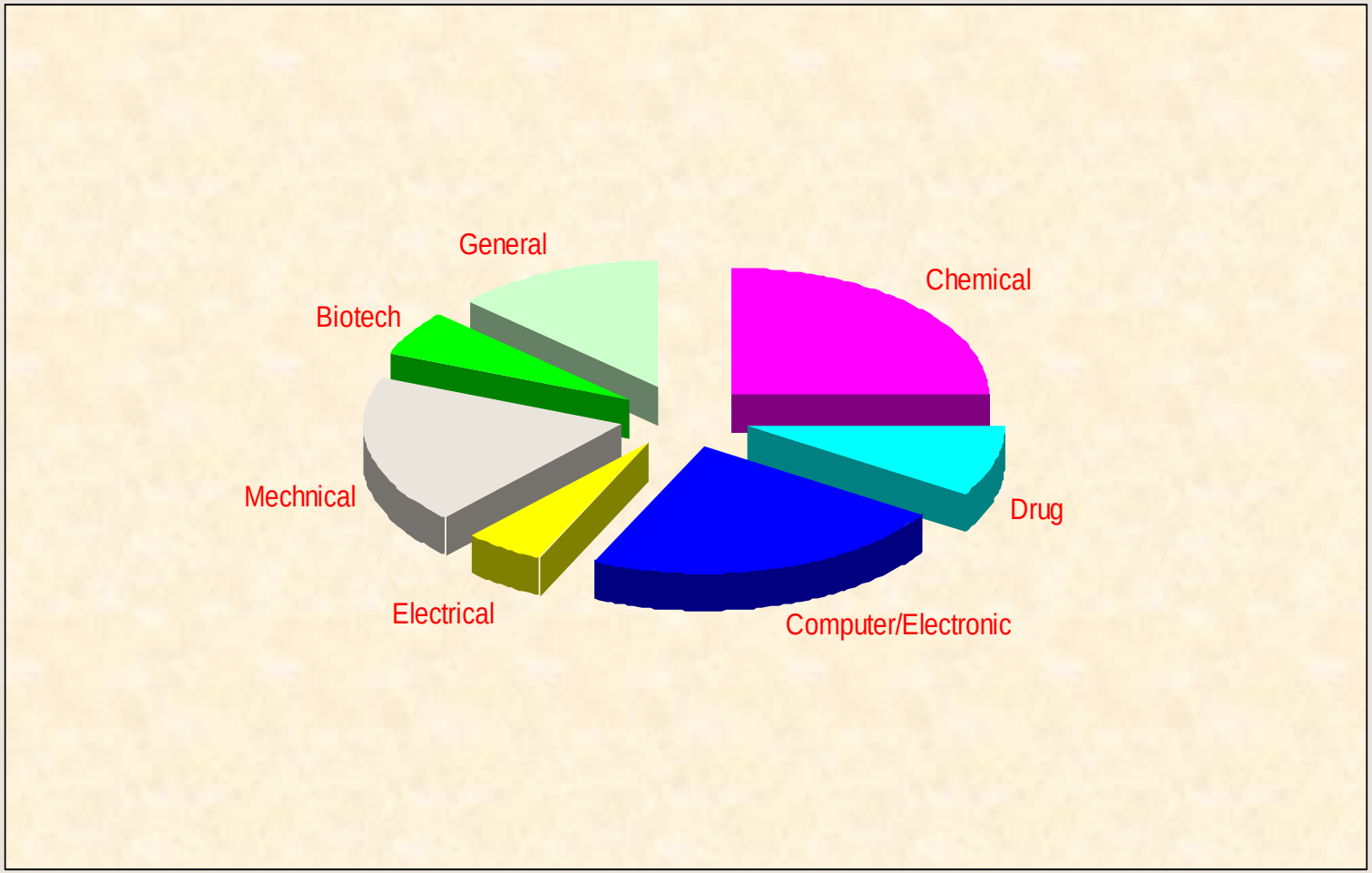
# Patents Filing Trends at the IPO (from 1995-96 to 2007-08*)




2007-08* provisional figures

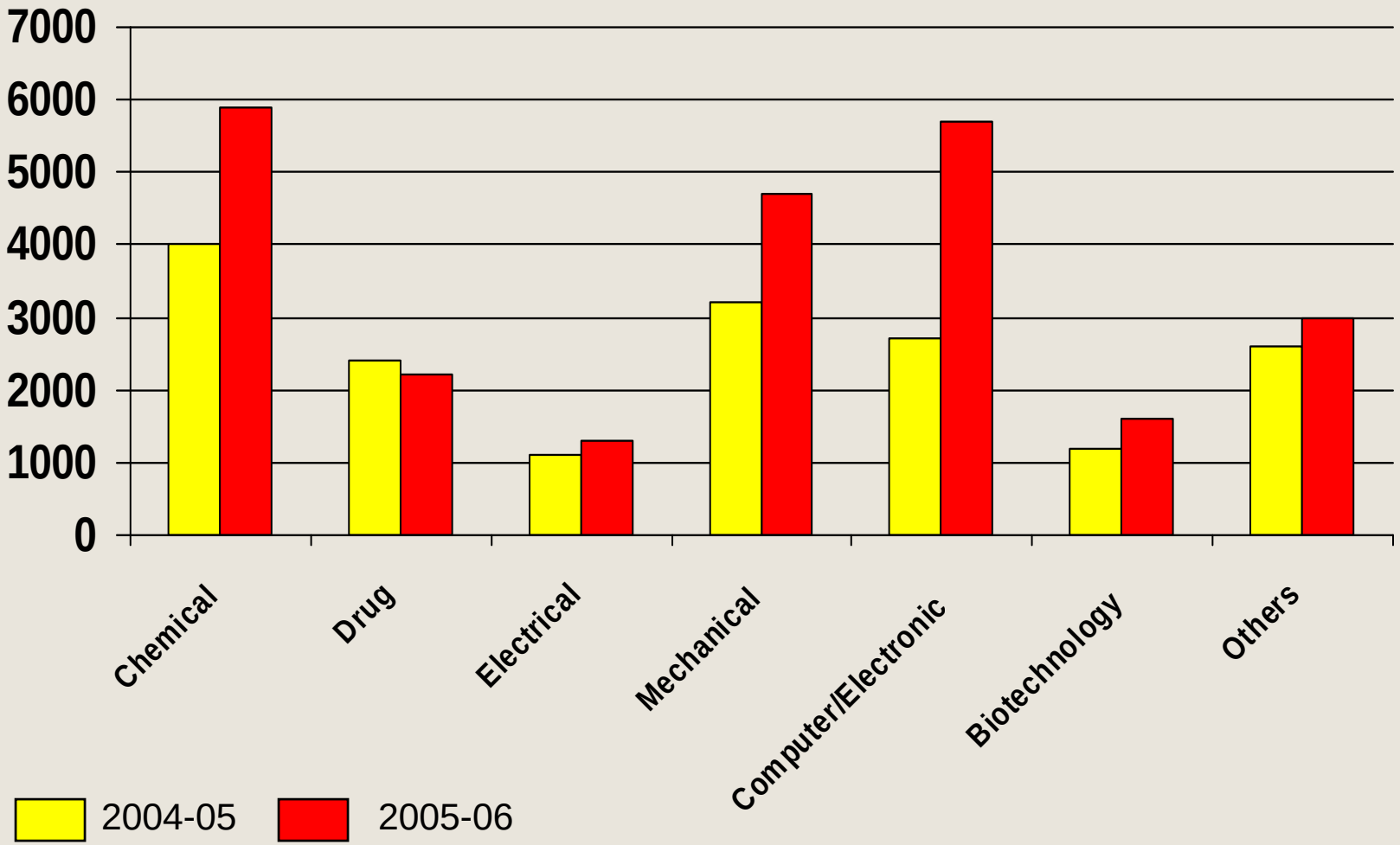
Source: IPO

# Domain-wise Breakdown of Patent Applications Filed at the IPO (2005-06)



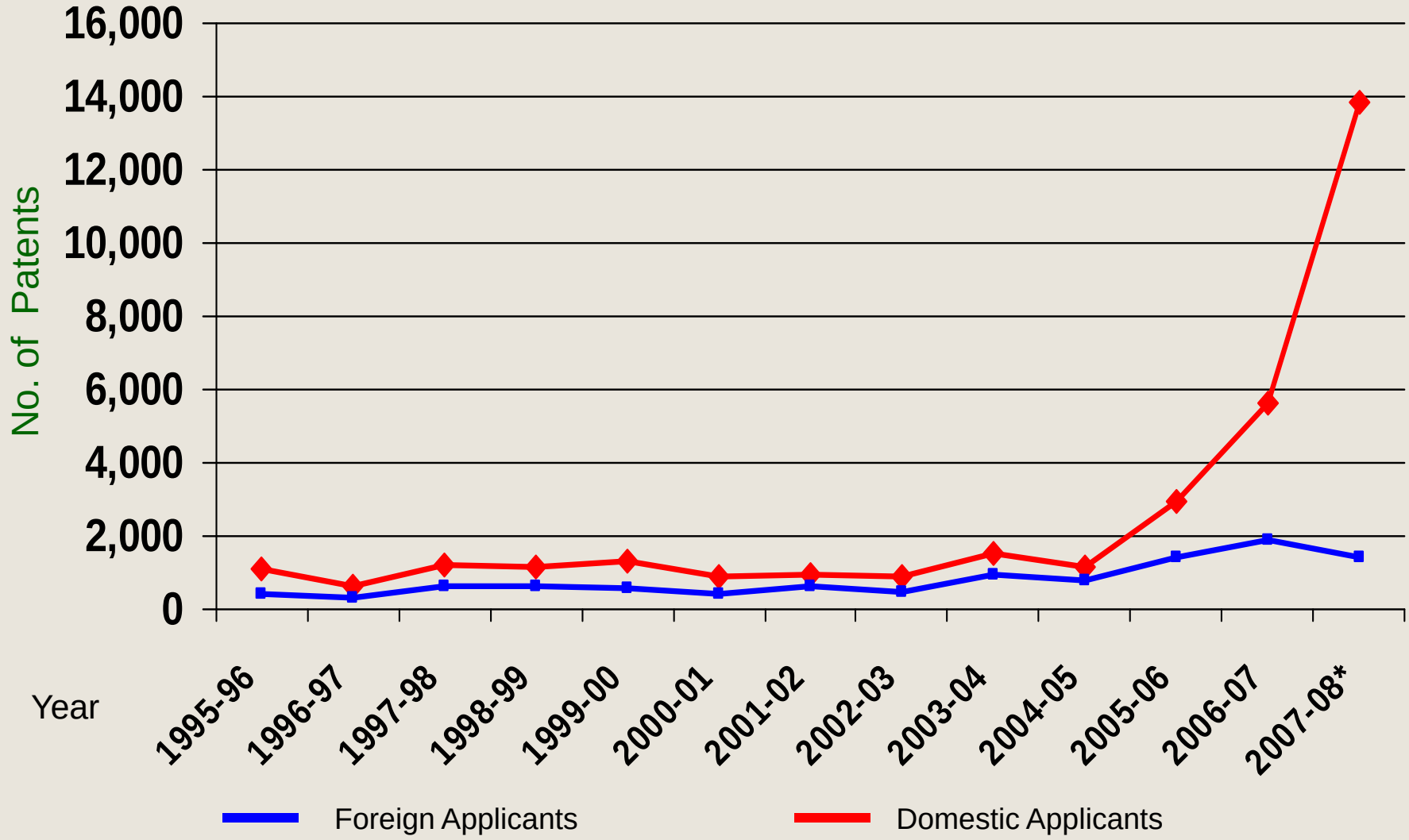

Source: 2005-06 Annual Report, IPO

# Growth of Patent Applications Filling in Different Domains (from 2004-05 to 2005-06)




Source: 2005-06 Annual Report, IPO

# Trend of Patent Applications Granted by Domestic Applicants & Foreign Applicants at the IPO




Source: IPO

2007-08* provisional figures

# Patent Applications Status Pharmaceuticals

| | 2002-03 | 2003-04 | 2004-05 | 2005-06 | 2006-07 |
|---|---|---|---|---|---|
| **Filed** | **11,466** | **12,613** | **17,466** | **24,415** | **28,882** |
| **Examined** | **9,538** | **10,709** | **14,813** | **11,569** | **14,119** |
| **Granted** | **1,379** | **2,469** | **1,911** | **4,320** | **7,359** |

Source: Commerce Ministry, GoI

# Key Issues

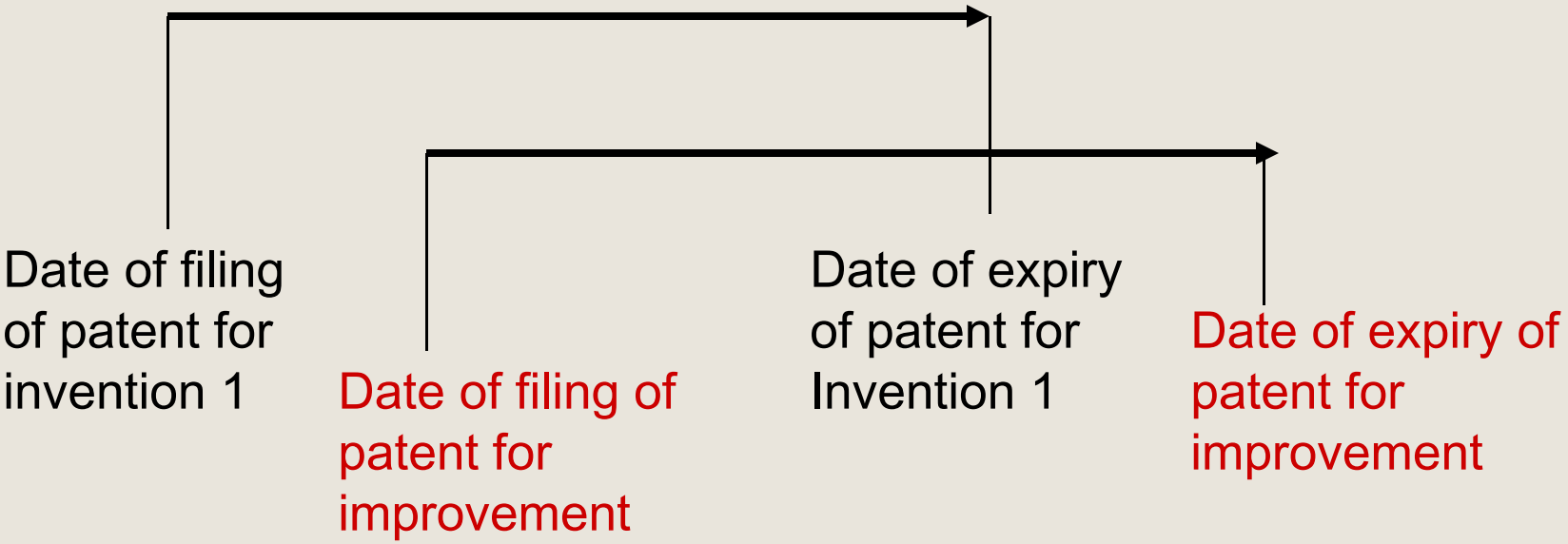
# Indian Patent Law
# - Areas of Concern

- Definition of Patentability
- Data Protection
- Scope of Compulsory Licensing
- Pre-Grant Opposition
- Enforcement of Patent Act

# 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.**"

# Evergreening… A Misconception



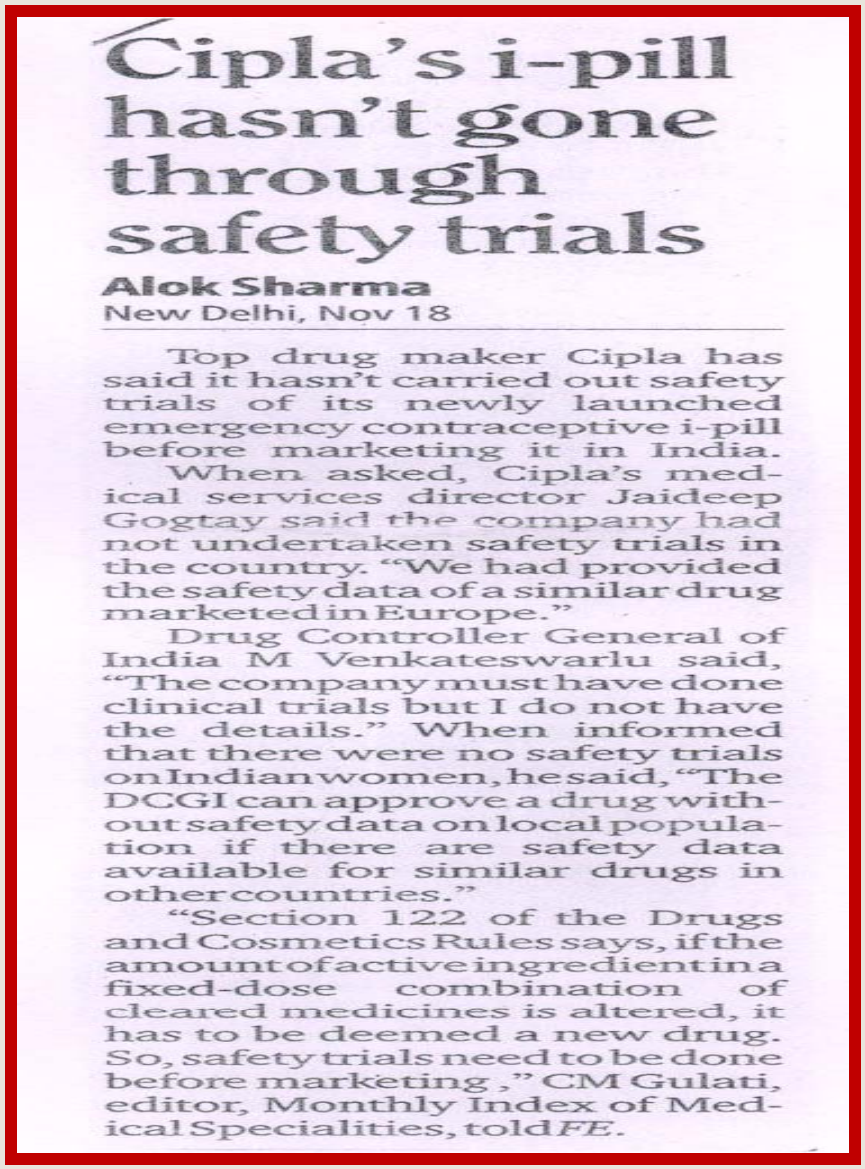

Anyone is free to use the patent of invention 1 when the term for that is over. The innovator or anyone else who has patent for the improvement will have rights to his patent only. There is no extension of patent term as per the Indian Patent Act.

# 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 utilize *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*."

# 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*.

# Regulatory Data Protection

The key issue: Need for strong provisions for protection of undisclosed information against “unfair commercial use”.

Recommendations:

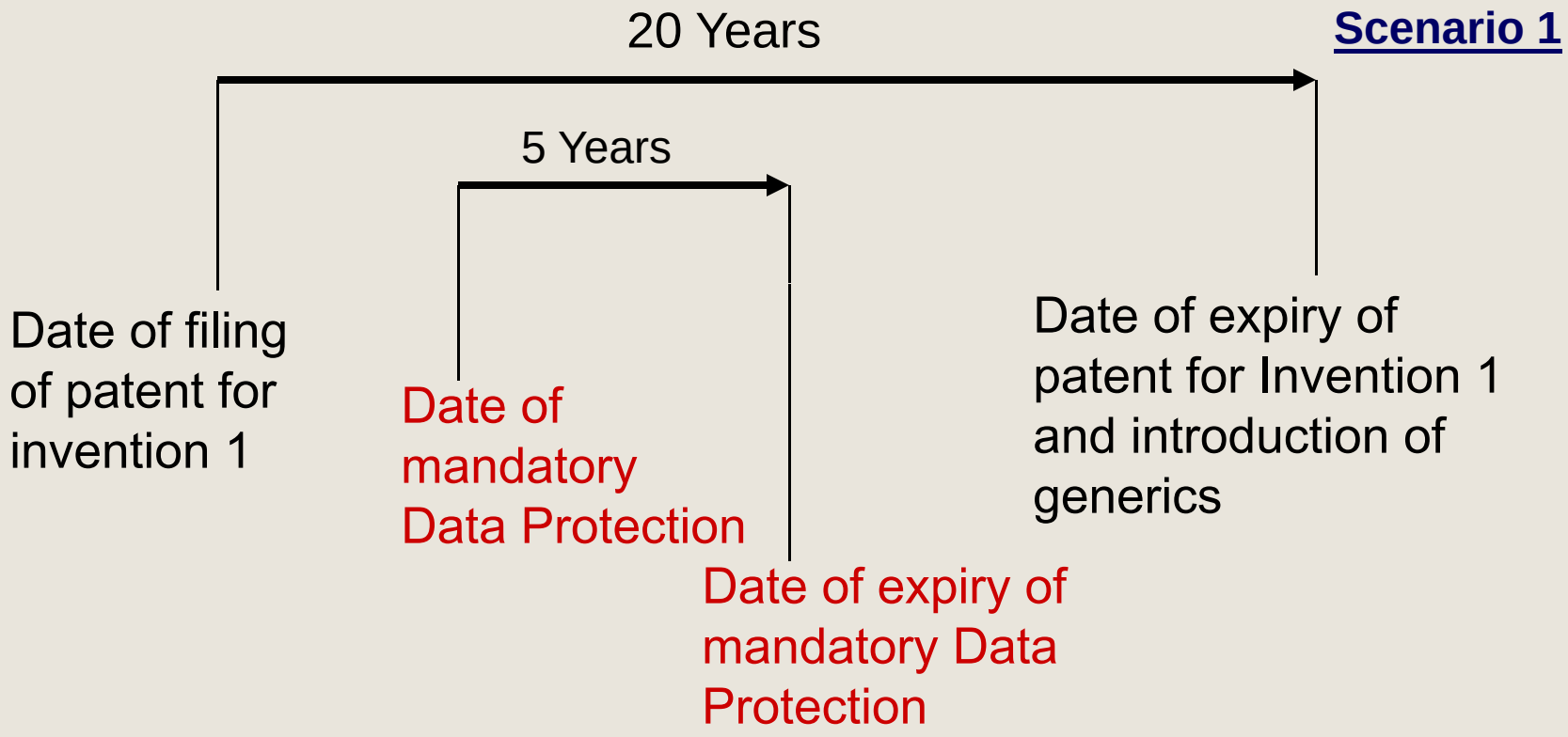
- No need for new law.
- Safety testing provided in law to be insisted on.
- Requirement can be met with appropriate executive order adding the following text in Schedule Y under ‘Application for Permission’

# Regulatory Data Protection

**Recommendations:**

- **Ensure a minimum five-year exclusivity period** for new drug products (beginning from the date of market approval in the country).

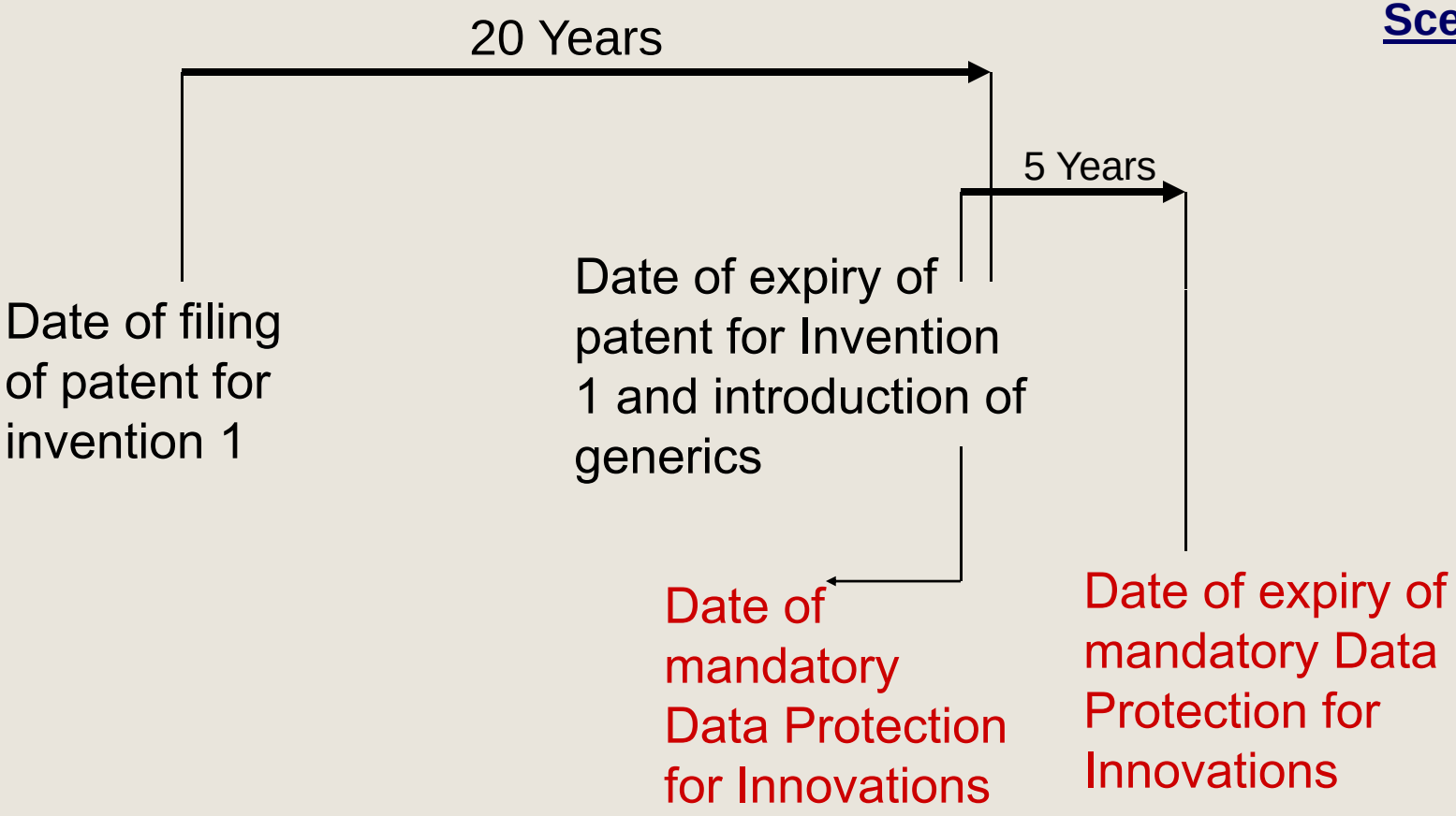
# Regulatory Data Protection – Is 'Evergreening' … A Misconception




*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.

# Regulatory 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.

# 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 2 months of commencement of pre-grant proceedings.
  3. If not concluded within 12 months, provide equivalent Patent Term Restoration.

# The Economic Times (May 29, 2008)

# Cipla to oppose 60 drug patents of global cos

## Files Pre-Grant Opposition For 50 Drugs

Khomba Singh
NEW DELHI

DRUG major Cipla, which has been at the forefront of fighting drug patents in the domestic market, has filed pre-grant oppositions for over 50 drugs in various patent offices in India. If the pre-grant oppositions are successful, it will pave the way for introduction of cheap drugs in the country.

Cipla head of R&D Gopalakrishnan told ET, "The company plans to challenge over 60 drug patents of global majors in cardiology, oncology, antibacterial and psychiatric segment. We have filed pre-grant applications for about 90% of them." He, however, declined to share the details of the patent challenges. Although the exact number of drug patent applications are not known, according to industry estimates, there are about 10,000 patent applications in India. Global companies have been quick to file patent applications for a large number of drugs since India became TRIPS compliant in 1995. Drug MNCs such as Merck, Gilead, Novartis, Pfizer, Abbot and Amgem, among others have been filing applications in India.

**Cipla files patent pleas**

**Domestic drug maker** Cipla has filed pre-grant oppositions for over 50 drugs. Global drug giants had filed patent applications for numerous since India became TRIPS-compliant in 1995.

The Mumbai-based company is also fighting two fighting court cases against Roche anti-cancer drug Tarceva and Gilead's anti-HIV drug Viread. India-based patent lawyers and healthcare groups say that most of these applications do not merit a patent in India. "About 60%-70% of these patent claim are for new method of treatment or new usage of a known drug which cannot be granted patent in India, unless there is significant new thereupatic benefit, " says Mumbai-based patent attorney Gopa Nair.

In oncology alone, global companies have filed over 400 claims for patent protection. Other drug majors are learnt to have filed several oppositions. Other Indian company have also challenged patentsof global MNCs. Ahmedabad-based Torrent Pharmaceuticals is learnt to have filed about 45 oppositions. Besides Indian generic drugmakers, a host of healthcare groups and NGOs are also aggressively challenging exclusivity attempts of discovery companies.

khomba.singh@timesgroup.com

# Compulsory Licenses

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

# Enforcement of Patent

- Preserving a climate that supports Innovation is more important than ever.

# Enforcement Measures Available Under the Indian Law

- The patentee may file an action for patent infringement in either a District Court or a High Court.
- Whenever a defendant counter-claims for revocation of the patent, the suit along with the counterclaims is transferred to a High Court for decision.

# Enforcement Measures Available Under the Indian Law

- It is possible to obtain a preliminary injunction.
- The basis upon which a preliminary injunction is granted is:
  - ✓ Plaintiff shows a prima facie case.
  - ✓ Balance of "convenience" is in the plaintiff's favor.

# Shortcomings of the System

- No time frame is prescribed for legal recourse, unlike in EU & US.
- Judicial delays: can take up to ten years for resolution and payment of damages on patent infringements.
- The pendency of patent cases, especially of the main suit, is likely to remain a deterrent for enforcement.

# Shortcomings of the System

- No criminal remedy available for infringement of patents
- Often leads to insufficient remedy in the infringement suits
- Lack of criminal remedies fail to deter potential infringers

# Mint
# (March 20, 2008)

PATENT ROW

## Cipla gets HC breather to sell copycat version of Roche drug

**Ruling says irreparable damages would accrue to patients if a cheaper version of the lung cancer drug was denied**

By Bhuma Shrivastava
*bhuma.s@livemint.com*

NEW DELHI

In a judgement cheered by public health advocates, the Delhi high court refused to restrain Indian drug maker **Cipla Ltd** from selling cheaper copies of a patented lung cancer drug, quashing a plea from its patent holder, Swiss drug maker **F. Hoffman La Roche**.

The ruling stated that irreparable damages would accrue to the patients who will have their lives cut short if a cheaper version of the drug was denied to them. The litigation was being seen as a test case on how strictly the Indian courts will read the patent law and rights granted under it versus the wider public health concerns in a situation when a patent had already been granted.

As part of the verdict, delivered on Wednesday by justice Ravinder Bhatt, Cipla has been allowed to manufacture and sell copies of the drug, erlotinib, sold as Tarceva by the Swiss company in India. Cipla has also been instructed by the court to maintain "faithful accounts" of earnings from the drug in case there is an adverse ruling later and damages need to be paid.

Cipla's chairman Yusuf Hameid said it was "a boon for cancer patients in India who need affordable drugs".

**Cautious step:** *A file photo of Cipla's Kurkumbh plant. The firm has been instructed by the Delhi high court to maintain 'faithful accounts' of earnings from the lung cancer drug in case there is an adverse ruling later.*

Hailing the ruling as "excellent news", Cancer Patient Aid Association president Y.K. Sapru said "the human approach, the fact that harm to patients was recognized in the ruling, is a welcome move."

Roche got a patent for erlotinib in February 2007 and, later that year, ignoring the patent, Cipla announced that it was going to sell the drug under the label Erlocip at Rs1,600 per tablet, or one-third of Roche's price. Roche then sued Cipla for allegedly infringing on its patent.

Cipla's move, seen as being risky by some, hinged on the argument that Roche's patent was invalid as the drug was a tweaked version of an older drug and that its prices were out of reach for most Indian patients. Roche was contesting it as "plain and simple indemnity" case, as its counsel Abhiskeh Singhvi said during the hearings, and wanted its rights to be protected as per the patent law. While the injunction has been denied, the hearing on the revocation of patent—filed for by Cipla—will go on.

Girish Telang, managing director of Roche's Indian arm, **Roche Scientific Co. (India) Pvt. Ltd**, expressed disappointment at the ruling. "It is a disappointment because we have a patent and patent should be respected. That has not come by with the refusal of the injunction," he said, while declining to say if Roche will appeal.

According to a report by the Indian Council of Medical Research, at least 90,000 men and 79,000 women are diagnosed each year in India with cancer of the lungs and bronchitis. Sapru estimates that at any point of time, there would be more than 100,000 patients with lung cancer in India.

Another expert dealing closely with the Roche litigation, who did not want to be identified, said: "What was the use of amending the Patent Act in 2005 if the patent is not to be respected? A benchmark for pricing is not fixed by the patent office when a patent is given, so why is that a valid ground now?" Moreover, added the expert, this was an infringement lawsuit and not a writ petition where issues of public interest are considered thoroughly.

ALSO SEE
>US' stand on patent issue >P11

Financial Express
(March 20, 2008)

# HC: Cipla can sell Roche drug generic

**Corporate Bureau**
Mumbai, Mar 19

In what could be a setback to multinational pharmaceutical companies, the Delhi High Court has allowed Indian firm Cipla to manufacture and sell a copycat version of the patented drug, Tarceva, in India. The patent holder, Swiss pharma major Hoffmann La Roche, had earlier filed for a temporary injunction to block Cipla from launching the anti-cancer drug erlotinib. Cipla sells a generic version of the lung cancer drug at one-third the price of Roche's patented drug.

Delivering the verdict, Justice S Ravindra Bhatt directed Cipla to keep an account of sales for deciding damages if Roche wins the case. Noticing the price differences, Justice Bhatt said Indian cancer patients would be affected if the generic drug is withdrawn from the market. Treatment with Roche's Tarceva reportedly costs over Rs 1 lakh a month. The once-a-day tablet costs about Rs 4,800, while Cipla's copycat version costs Rs 1,600.

**BREAKING THE SEAL**

- Cipla can produce and sell copycat version of Roche's patented drug, Tarceva
- The once-a-day Tarceva costs Rs 4,800 while Cipla's version costs Rs 1,600
- HC said cancer patients would be affected if generic drug is withdrawn from market
- Cipla has to keep account of sales till the case is finally settled issue and listing

YK Hamied, chairman of Cipla, termed the verdict as a victory for cancer patients in India. "We supply the drugs at the cheapest rate. We continue to challenge trivial patent applications on life-saving drugs."

In January this year, Roche filed a patent infringement suit against Cipla in the high court, following Cipla's launch of the generic version of Tarceva. Roche, which has been granted a product patent for Tarceva, can enjoy a 20-year monopoly if it wins the patent oppositions.

Meanwhile, the Hyderbad-based Natco Pharma has applied to the Delhi patent office seeking a compulsory licence on Tarceva to export the drug to Nepal.

While the patient's associations welcomed the HC verdict, YK Sapru, founder-chairman of the Cancer Patients' Aid Association (CPAA), told *FE*, "The judiciary has acted in the right way. They supported the human beings' right to live."

There are about 30,000-40,000 lung cancer patients in India who cannot afford high-priced cancer drugs, Sapru added.

# Business Standard (March 20, 2008)

# Court allows Cipla to market disputed drug

*Roche given four weeks to reply to counter-claim*

BS REPORTER
New Delhi, 19 March

The Delhi High Court today passed an interim order allowing domestic drug firm Cipla to market its version of a lung cancer treatment drug for which Swiss multinational Roche Scientific holds the India patent, pending another hearing scheduled for August 6.

The interim order was passed by the court today on a plea filed by Roche Scientific on January 19 this year. The generic name of the drug is Erlotinib, which Roche markets as Tarceva and Cipla as Erlocip.

Ahead of the next hearing, the court has asked Cipla to maintain records of sales of Erlocip.

It has also admitted the counter-claim filed by Cipla that questions the validity of the Roche patent and asked the latter to respond within four weeks from today.

The case, which is being keenly watched by global and Indian drug firms and consumer interest groups, is the first test case of India's new patent regime.

The new patent law came into effect on January 1, 2005, and offers firms product patent protection against the earlier practice of process patent protection, which effectively allowed firms to make the same drug through a different process.

Days before Roche sought legal redress, Cipla started marketing the drug for Rs 1,600 a tablet, one-third the price Roche charges (Rs 4,800 a tablet). Roche has been selling Erlotinib under the brand name Tarceva in India since 2006.

The crux of Roche's argument is that the product patent right it has for Tarceva prevents competition from manufacturing a copy-cat version of the drug.

In response, Cipla has claimed that the Indian patent is not valid and argued that it was well within its rights to manufacture and market the medicine in the country.

The counsel for Cipla said the high court's order today made special mention of the life-threatening nature of cancer and the life-saving properties of this drug.

"Given the price difference, the court did not want patients to be deprived of a low-cost alternative by staying sales of the generic product," the counsel claimed.

Today's decision will ensure uninterrupted supply of a low-cost medicine for treating lung cancer. Nearly 160,000 people in the country are estimated to be suffering from the disease, which has a high fatality rate.

Welcoming the interim verdict, the Cancer Patients Aid Association (CPAA) Chairman Y K Sapru said he was glad to note "the judiciary has given preference to the right of a human being to live over all other rights enshrined under the Constitution of India".

Cipla's manufacturing facility in Kurkumb, about 70 km from Pune BLOOMBERG PHOTO

**PATENT WAR**

- March 13, 1996: Roche files patent application in India
- July 13, 2005: DCGI gives approval to Roche for marketing Tarceva in India
- July 13, 2007: Patent granted for Tarceva in India
- January 2008: Cipla launches generic version of Tarceva
- January 19, 2008: Roche files infringement lawsuit at Delhi High Court
- March 19, 2008: HC allows Cipla to sell version of Roche drug

Business Standard
(September 27, 2008)

# Roche files two petitions against Cipla copycat drug

**THE PETITIONS ALLEGE THAT CIPLA VIOLATED ROCHE'S PATENT by launching a generic version of Valcyte and also with a phonetically similar name, 'Valcept'**

JOE C MATHEW
New Delhi, 26 September

The Indian arm of Swiss drug maker F Hoffman-La Roche Scientific has filed two separate petitions against Cipla in the Bombay High Court alleging patent and trademark infringements over its anti-infection drug "Valcyte".

The first petition alleges that Cipla Ltd, India's second largest pharmaceutical company, violated Roche's patent by launching a generic version of Valcyte. The second petition says Cipla violated the Swiss drug maker's trademark by launching the product in a phonetically similar name, "Valcept".

A generic is a drug that is chemically equivalent to an innovator's medicine and the drug is not protected by patent.

According to legal sources tracking the development, the trademark infringement suit was filed last week and the case against alleged patent right violations early this week.

Roche officials confirmed the development but declined to provide more details. When contacted, Amar Lulla, joint managing director of Cipla, refused to comment.

This is the second product in which Roche and Cipla are locked in a legal battle on patent issues. The Delhi High Court is expected to give its verdict on the first case — involving Roche's cancer medicine Tarceva — in two months.

*Continued on Page 2*

The Economic Times
(September 27, 2008)

# Roche sues Cipla over Valcyte patent breach

## Second Instance Of Swiss Co Dragging Cipla To Court

Khomba Singh
NEW DELHI

SWISS major Roche has moved the Bombay High Court (HC) against domestic major Cipla for allegedly infringing both the patent and trademark of its patented drug Valcyte in India. Cipla had recently launched the low-cost version of the drug under the brand name Valcept.

This is the second time that Roche has taken Cipla to court. In the earlier instance, Roche had contested the launch of a generic version of its lung cancer drug Tarceva. That case is pending in the Delhi High Court.

When contacted, Cipla joint MD Amar Lulla said, "I don't have the details but Roche has filed a patent and trademark case against the company." Roche India MD Girish Telang said he could not comment over phone. Valganciclovir is used to prevent eye infections in people who have less immune power, such as people living with HIV and AIDS.

Industry sources said that Cipla has been emboldened as the Delhi HC had refused to give injunction in the pending Tarceva case. "Besides the patent infringement, Cipla's drug name is phonetically similar to Roche's patent protected drug," the source added.

**BITTER PILL**

- **Roche alleges** violation of patent and trademark of its patented drug Valcyte
- **Cipla had** recently launched low-cost version of the drug under brand name Valcept
- **Valganciclovir is** used to prevent eye infections in people who have less immune power, such as people living with HIV & AIDS

Industry sources say Cipla's drug Valcept is priced at Rs 245 per tablet, compared to Roche's maximum retail price for Valcyte at over Rs 1,000. Cipla had filed its generic version of Tarceva at about one-third the price of Roche's patented drug. The Delhi HC had refused to grant injunction against Cipla's drug citing public interest, given the significant price difference between the two drugs.

Patent expert Shamnad Basheer says that Roche received the patent for the drug in June last year from the Chennai patent office. However, Indian companies Ranbaxy, Cipla and patient group Delhi Network of Positive People (DNP+) living with AIDS have filed post-grant opposition against the drug. They say that Roche's drug is an obvious compound, which cannot be granted patent under the section 3(d) of the Indian patent law. The decision on the post-grant opposition is still pending, Mr Basher said in his blog.

# How to Address?

1. **Remedy through Judicial Process**
   - Overburdened system may result in long pending disputes
2. **Remedy through Regulatory Process**
   - Could help pre-empting disputes in most cases

# Strengthening Regulatory Process

- No ‘Marketing Approval’ to biosimilar and generic versions of products patented in India during their patent life.
- Protect innovators’ data.
- Ask applicants to generate their own data for patient safety.

Financial Express
(March 20, 2008)

# Pharma MNCs ask DCGI to liaison with patent offices

**Reghu Balakrishnan**
Mumbai, Mar 19

In the backdrop of Wednesday's Delhi High Court verdict that allowed Cipla to manufacture and sell a patented cancer drug in India, multinational pharma companies plan to urge the Drug Controller General of India (DCGI) to improve its co-ordination with patent offices across the country. Cipla has been granted marketing approval for Erlotinib, copycat version of Roche's Tarceva, as DCGI was not aware that Roche had been granted patent for Tarceva, MNCs argue.

Dismissing the injunction filed by Swiss major Hoffmann La Roche, the Delhi High Court allowed Cipla to manufacture and sell a generic version of the Roche's cancer drug, Tarceva, in India.

Tapan Ray, director general, Organisation of Pharmaceuticals Association of India (OPPI), the body for MNC having presence in India, told FE, "In Cipla's case, the DCGI has given the marketing approval without cross checking whether any product patents have been granted over the drug.

DCGI gave the marketing approval to Cipla while the patent for Erlotinib had been granted to Roche by Delhi patent office one year back." The marketing application that is submitted to the DCGI must contain the details of whether any patent application has been granted over the same molecule," he added. The Swiss major had been granted patent for Erlotinib hydrochloride by Controller General of Patents, Trademarks and Designs, New Delhi in February 2007.

**"Cipla has been granted marketing approval for Erlotinib, copycat version of Roche's Tarceva, as DCGI was not aware that Roche had been granted patent for Tarceva"**

"This is a procedural flaw. When the DCGI comes to know the product patent has been granted over the same molecule, the DCGI must ask the generic player to withdraw the drug from the market. We have already brought the issue in DCGI's notice. However, we want to reinforce in the backdrop of Delhi HC verdict," they said.

However, Gopakumar Nair, Mumbai-based patent attorney, points out that the MNCs' demands are not viable. "In US, there is a requirement for orangebook listing of patent before applying for the marketing approval of a drug. But in India there is no law to insist that DCGI should be aware of the patents granted before."

The Orange Book with the US FDA contains the approved drug list by active ingredient, proprietary name, applicant holder or applicant number. The data is updated concurrently with the publication of the annual edition or cumulative supplements.

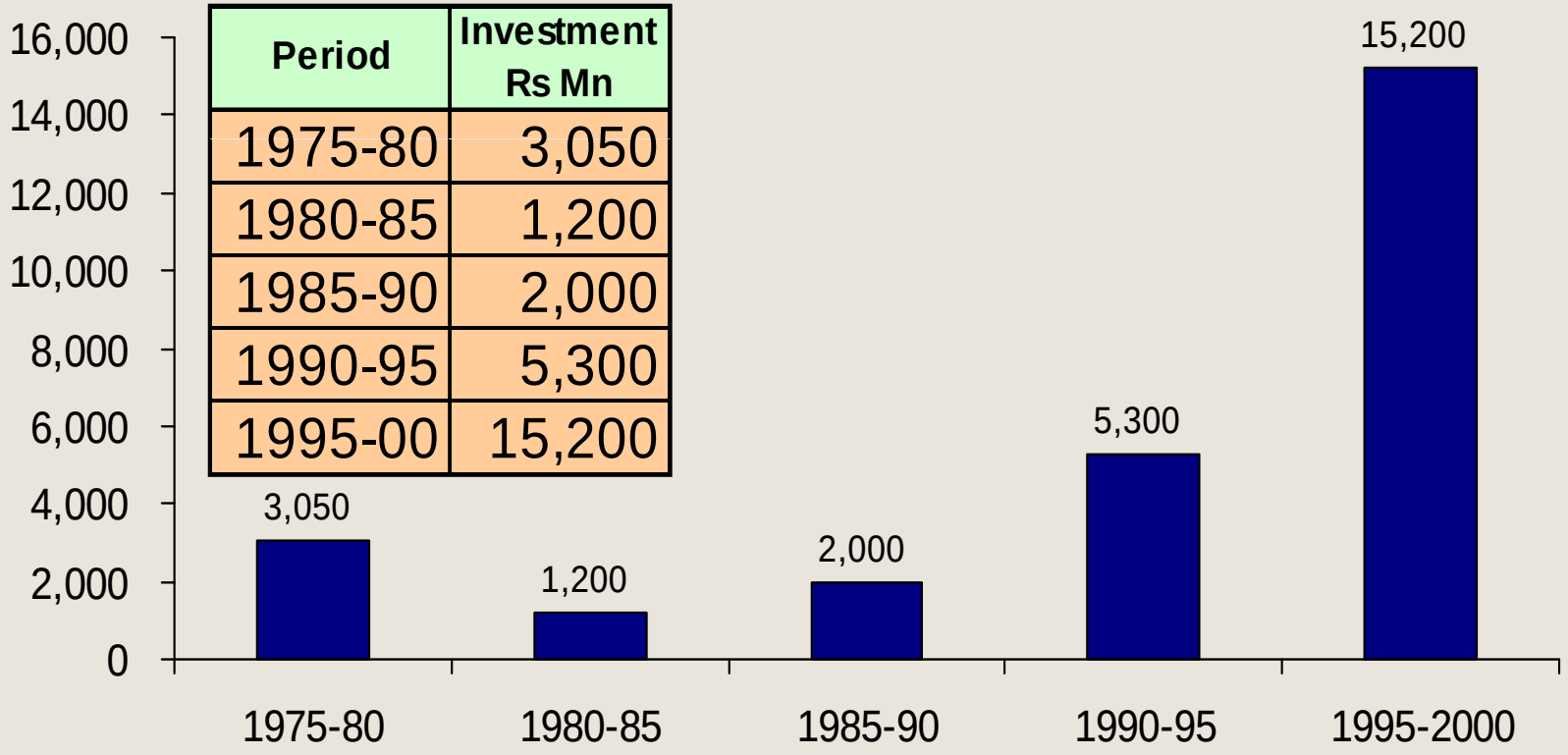
# Shortcomings of the System

- Patent regime also suffers from certain serious administrative problems.
- The speed at which a patent application is granted largely slow.
- The Indian Patent Office is faced with a backlog of over 1,09,000 unexamined patent applications.

# IPR & Investment

## Protection of IPR a MUST for Investment

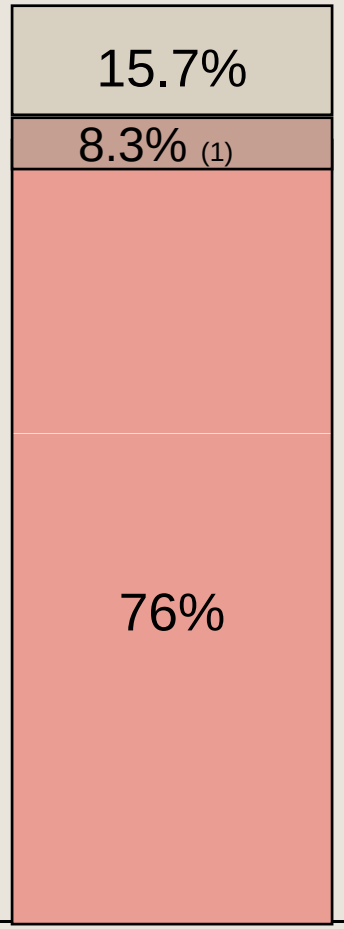
| Period | Investment Rs Mn |
|---|---|
| 1975-80 | 3,050 |
| 1980-85 | 1,200 |
| 1985-90 | 2,000 |
| 1990-95 | 5,300 |
| 1995-00 | 15,200 |




*Reality: Maximum FDI took place between 1995 & 2000*

# Will Patent Laws Fuel Price Increases?

- Post 2005 only 2.3% of the Indian pharma market l consists of drugs that have no therapeutic equivalent.
- 97.7% of the market will be generic or the products will have therapeutic areas.




Empirical evidence suggests ~15% of new patented drugs are NMEs with significant therapeutic advantage.

Therapeutic Equivalents will exist.

~85% of All Patented Medicines will have a Therapeutic Equivalent

(1) Includes new salt, new formulations, new combinations, new manufacturer or patents for new indications

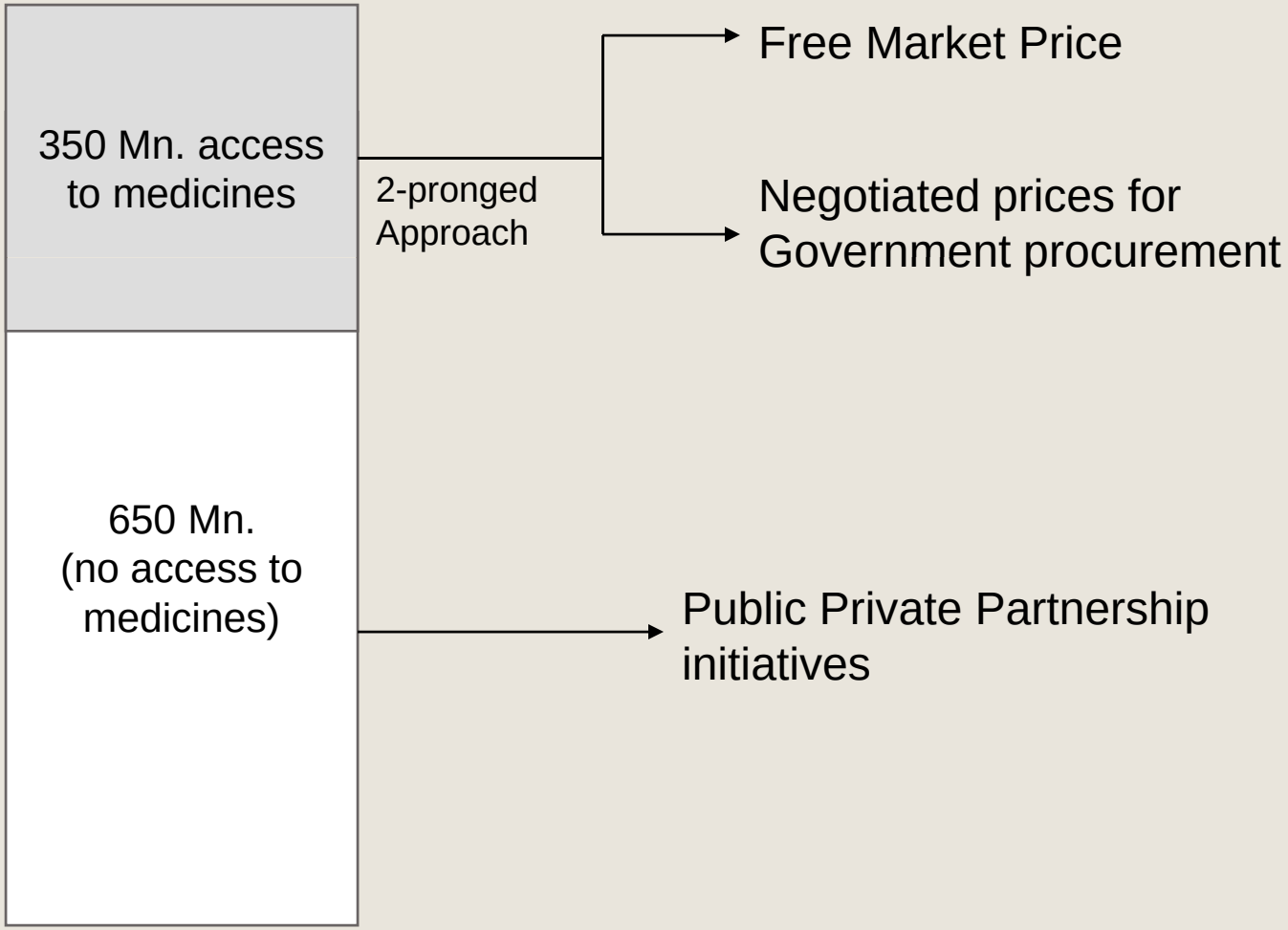
Source: Lu and Comanor (1998), OPPI, FDA, BCG Analysis

# The Way Forward

# How to Improve Access to Modern Medicines

- Robust Healthcare Infrastructure.
- Improved Healthcare System and Delivery.
- Introducing a sound Healthcare Financing Model for all.
- Meet unmet need through robust IPR regime.

# The Way Ahead…
# Ensuring Access in Control Free Pricing Regime….



# Promote Health Insurance

- Hasten reforms to attract players.
- Mandatory insurance in organized sector.
- Health insurance for farmers, labourers.

# IP Index

# 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

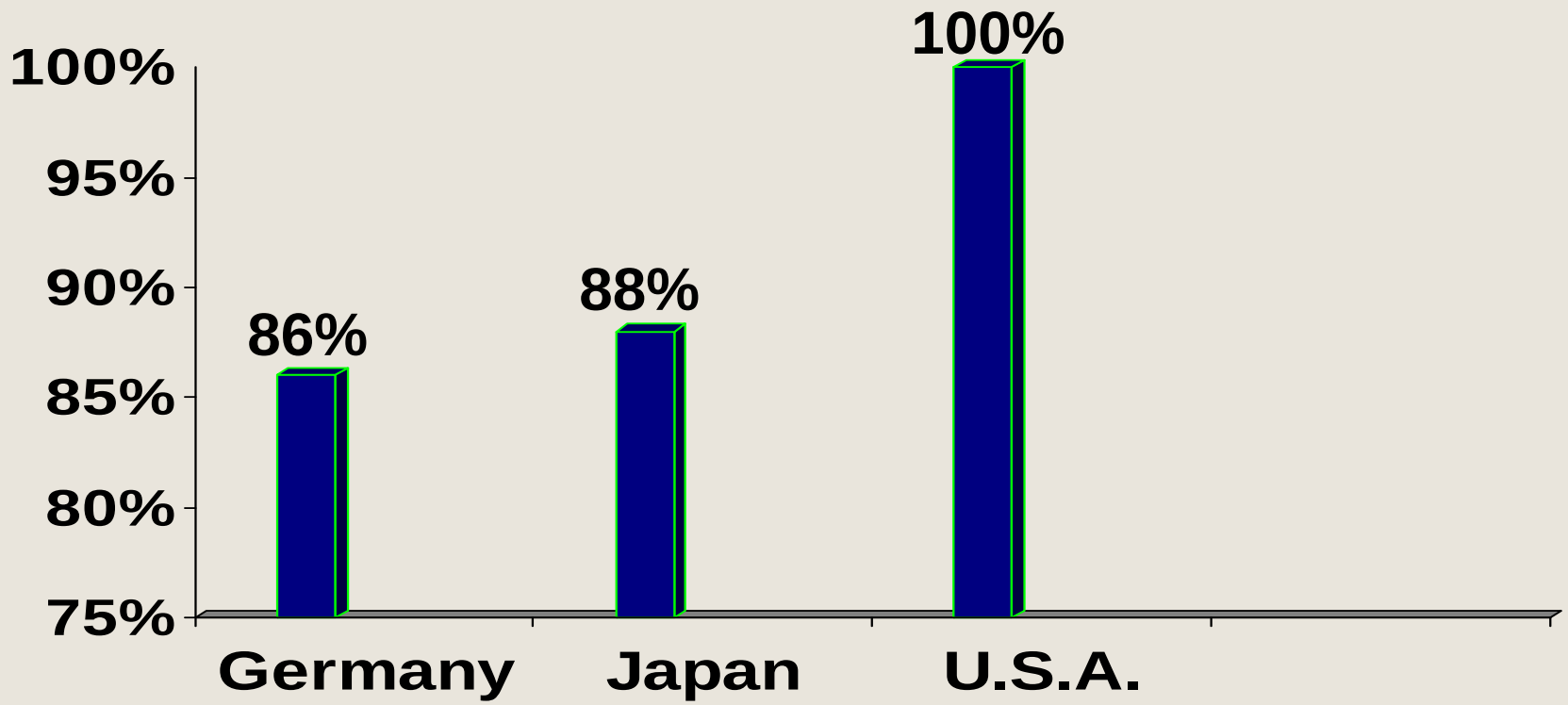
# Pharmaceutical I.P. Index

| 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

# 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

“We cannot solve our problems
with the same thinking we used
when we created them.”

- Albert Einstein

Thank You