Pharmaceutical Patents in India

- Seminar on Global Best IPR Practices

Indo – American Chamber of Commerce

Tapan Ray

March 29, 2008 - Mumbai

INDIAN PHARMACEUTICAL INDUSTRY: 2006-2007

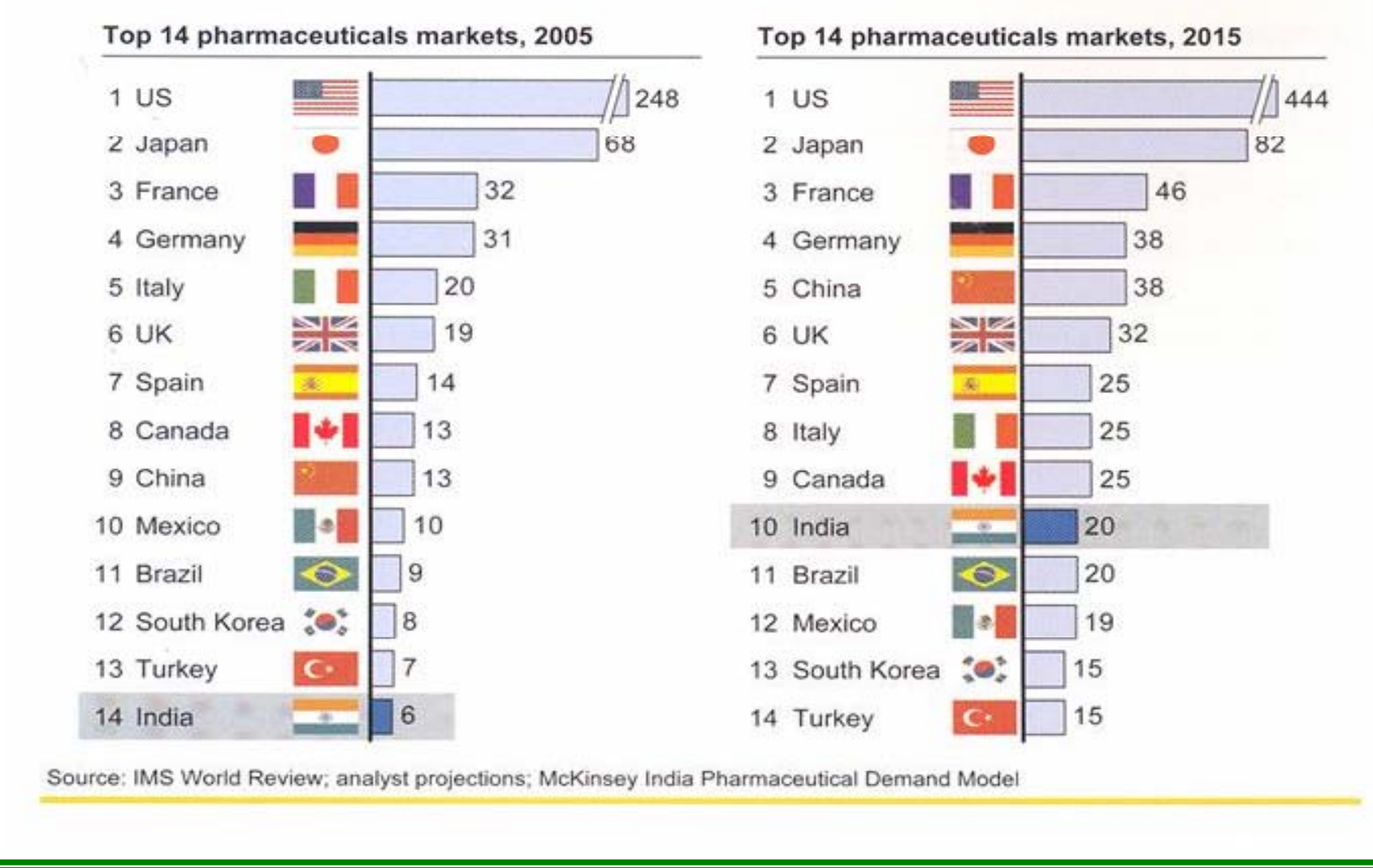
- U.S.$ 8 Bn. Domestic Sales
- U.S.$ 5 Bn. Exports
- Highest number of U.S. FDA approved plants outside U.S.
- Ranks 4th in Volume & 14th in Value
- McKinsey projects U.S.$ 20 Bn. by 2015

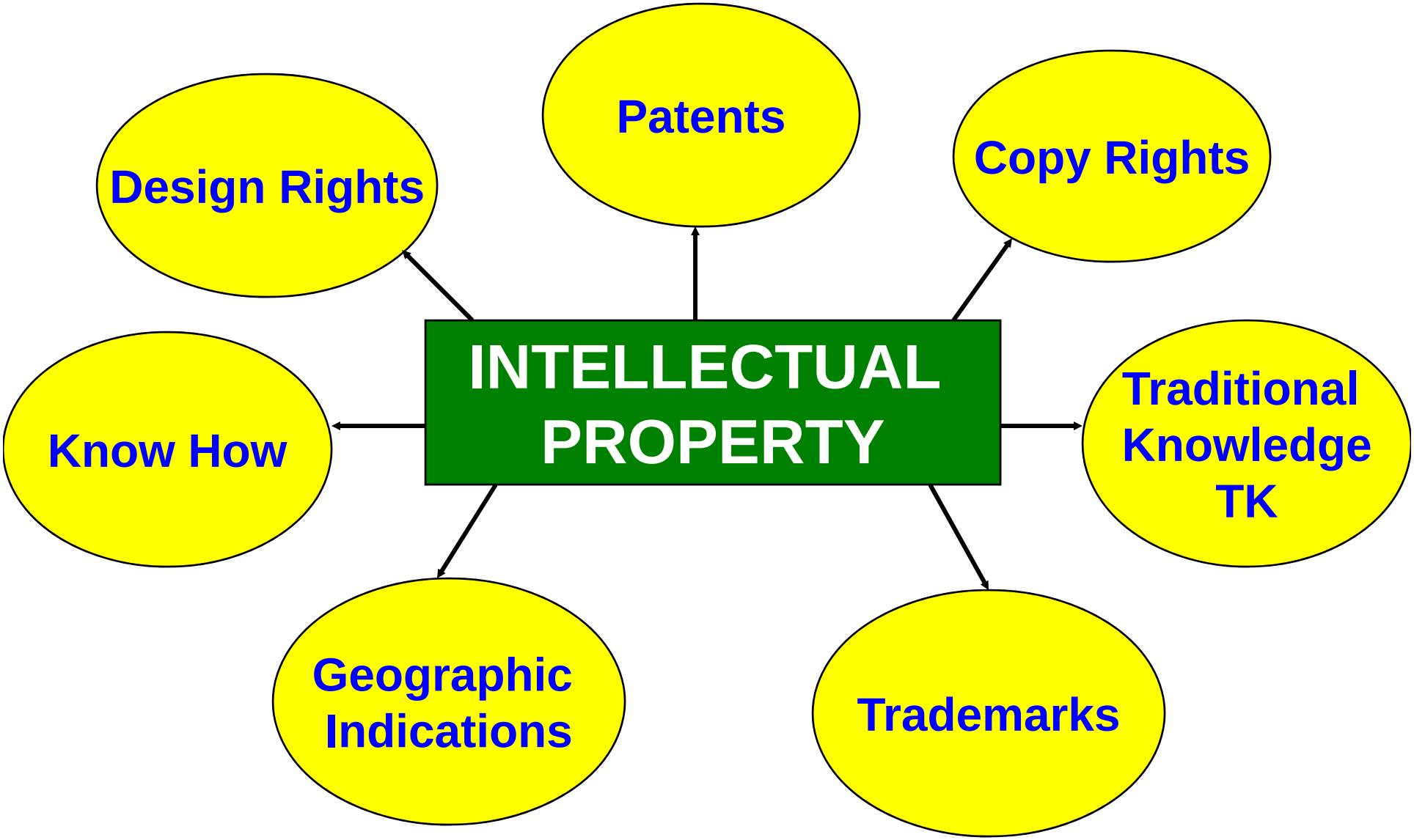
MCKINSEY PROJECTION 2015*

- 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

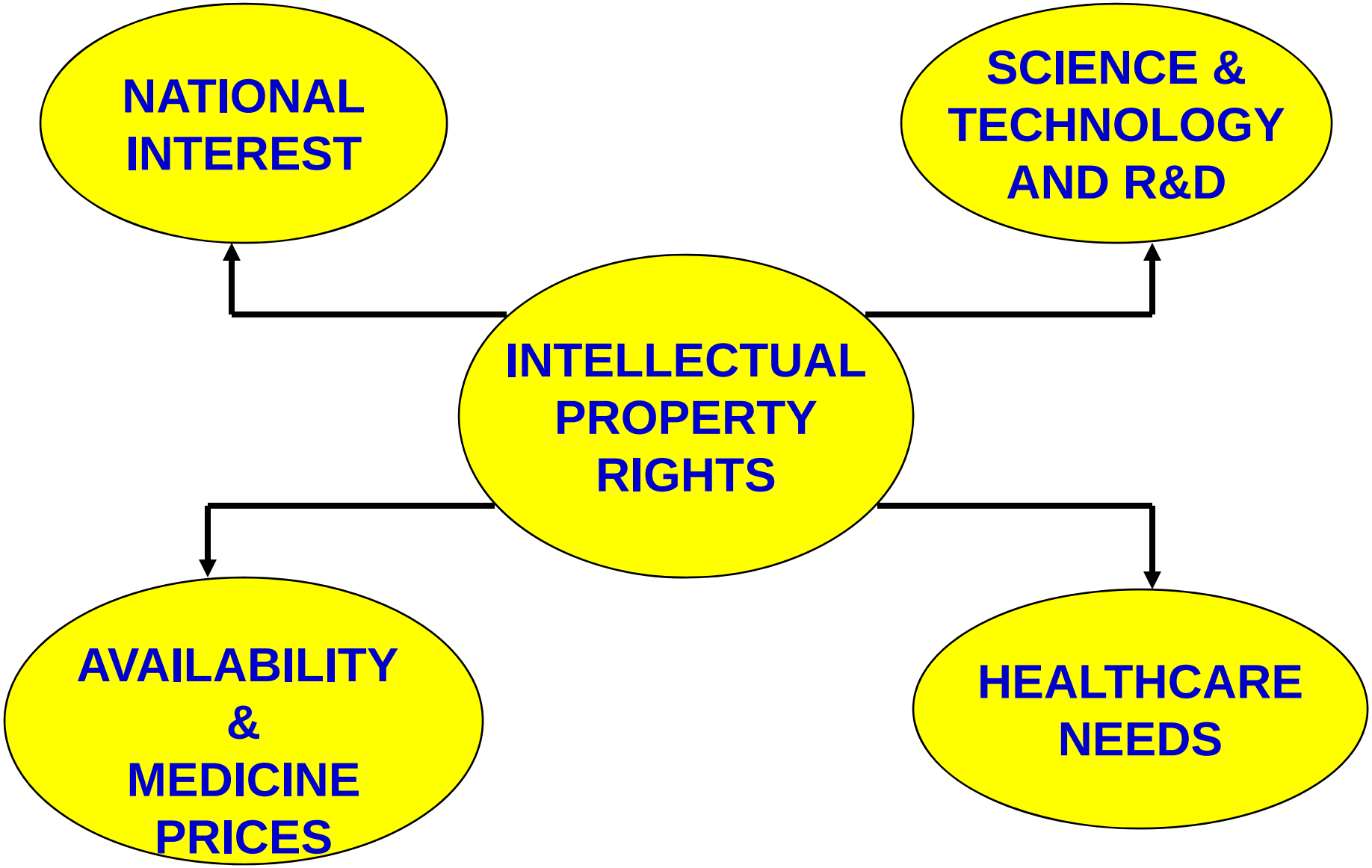
* “Indian Pharma 2015”, McKinsey & Co. – August 22, 2007

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




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

IDEAL IPR POLICY FOR INDIA



IMPACT OF INNOVATION

- Pharmaceutical innovation has produced thousands of medicines to treat and prevent diseases.
- Conditions that not so long ago were fatal can now be managed effectively and safely.
- Epidemics are now becoming distant memories.

EXTENDING LIFE

- New medicines:
  - Helping people to lead healthier more productive lives
  - Cutting costs in healthcare by replacing expensive medical procedures
  - Stimulating the economy with healthier workforce
  - Improving Quality of Life

EXTENDING LIFE

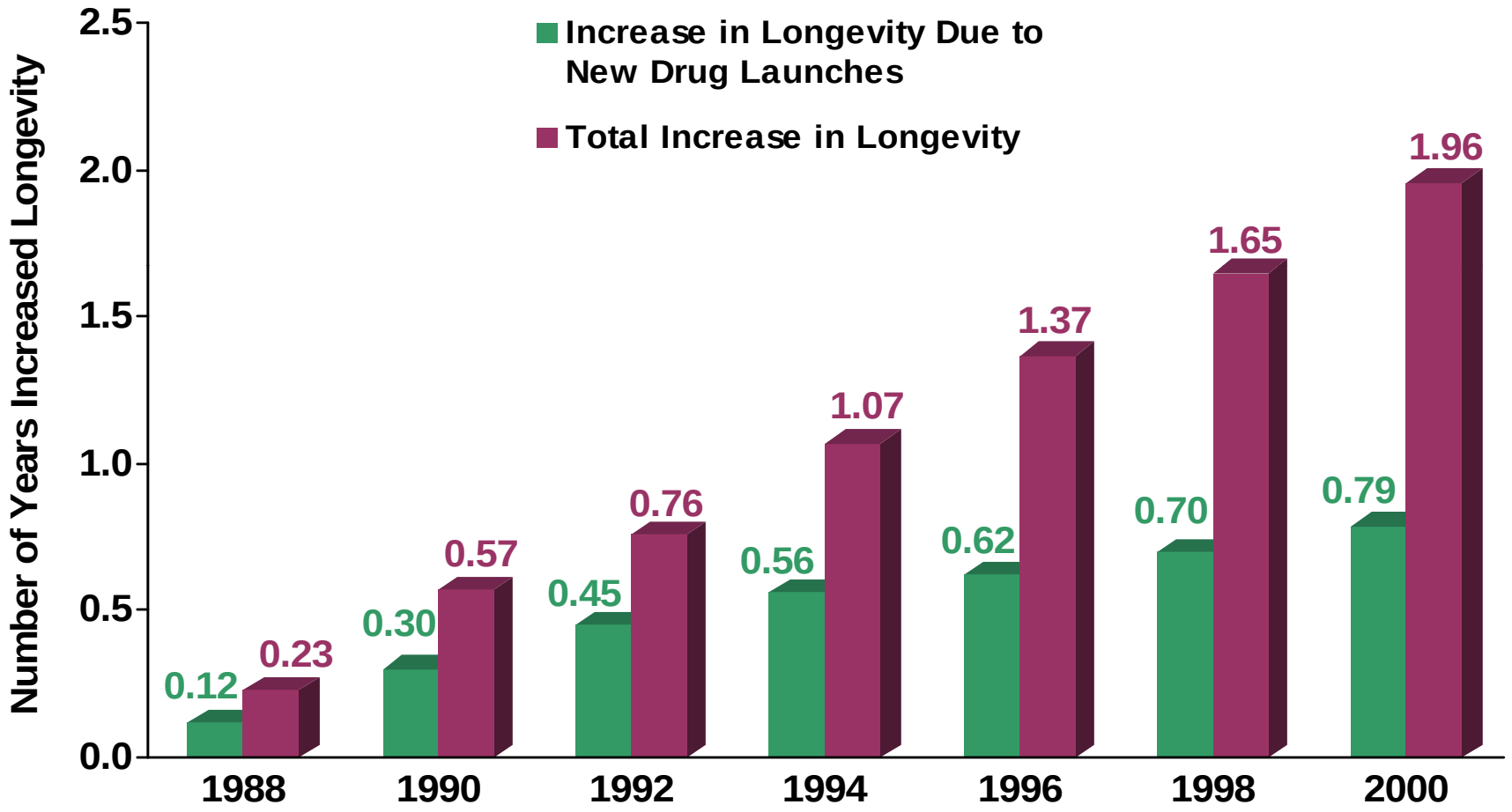
- The pace of scientific discovery has increased exponentially.
- Medicines addressing unmet medical needs continue to be developed and approved.
- In the last 10 years, over 300 new medicines became available, and over 1,000 are in development today.

EXTENDING LIFE

- Since the new HIV/AIDS drugs of the mid-1990s, the U.S. death rate from AIDS dropped about 70%.
- New drugs account for 50–60% of the increase in six-year cancer survival rates since 1975.
- Advances in heart disease and stroke medicines save over 1 million U.S. lives each year.

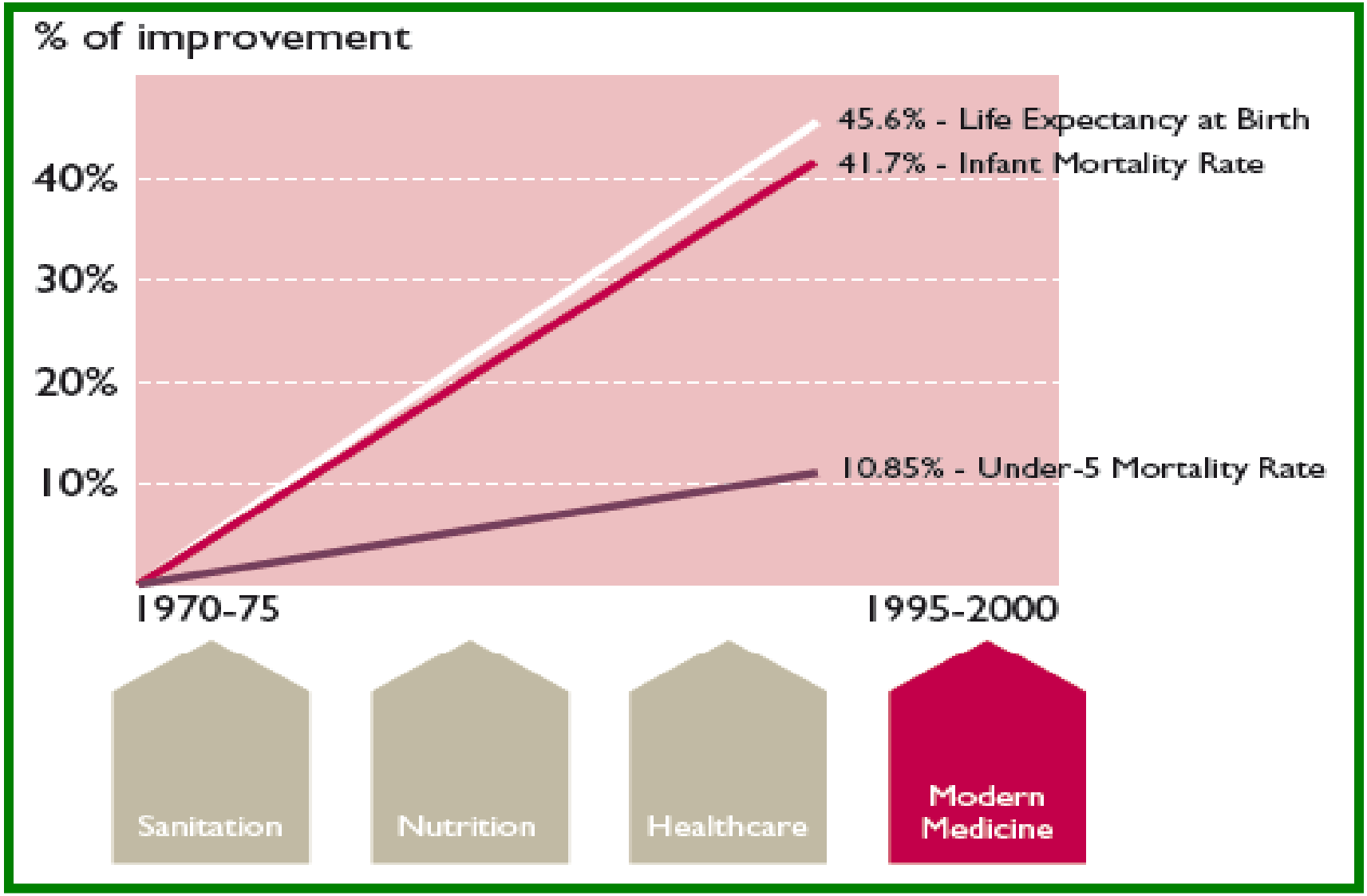
NEW MEDICINES INCREASE LONGEVITY

- ACCOUNT FOR 40% OF INCREASE IN LIFE EXPECTANCY



Data Source: Lichtenberg, PhRMA

GLOBAL HEALTH IMPROVEMENT IN 20TH CENTURY



Source: IFPMA (2007)

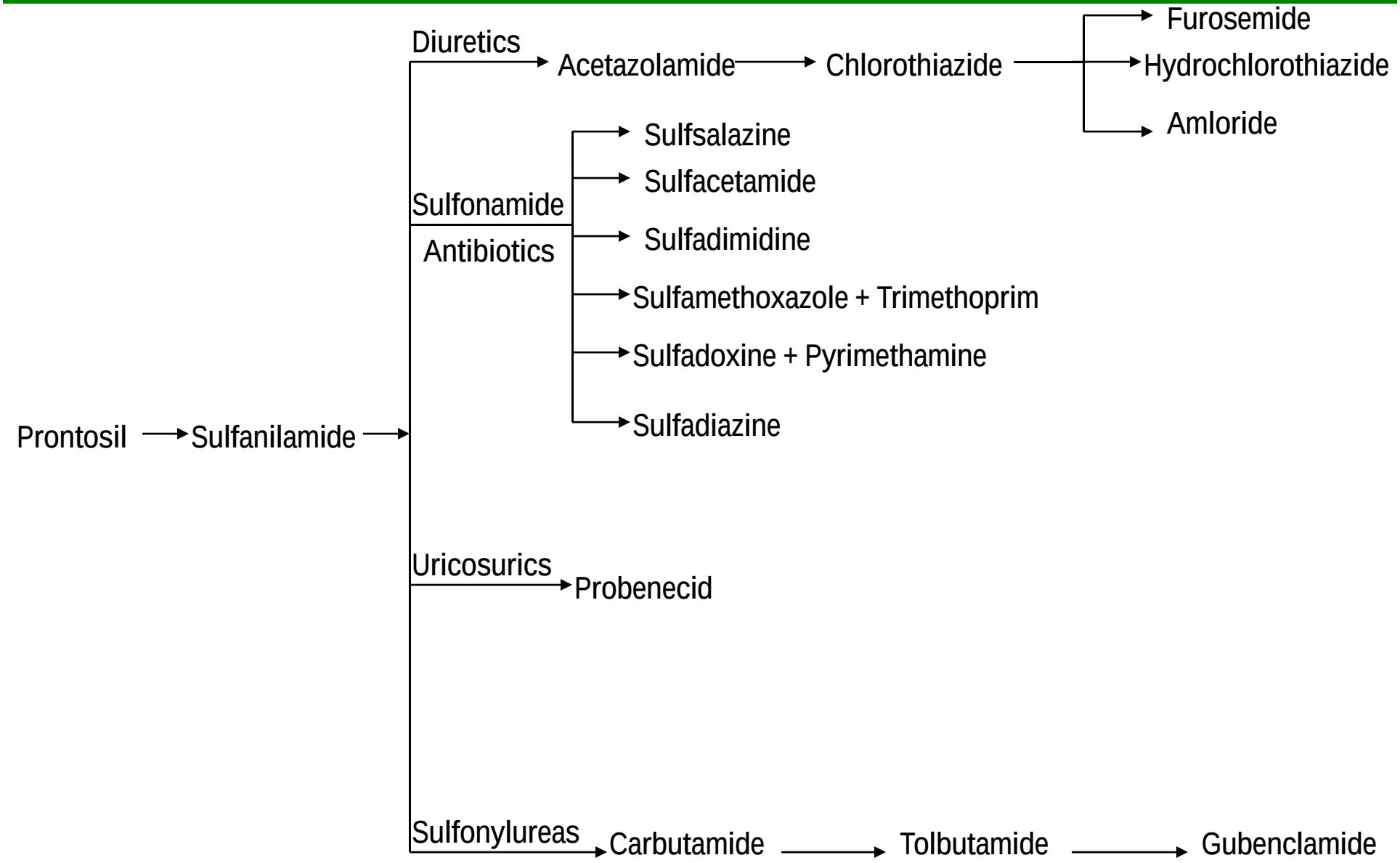
Then….. and… Now

- Treatments we take for granted today did not exist at one time.
- A patient with cancer would consider his diagnosis a death sentence.
- Another patient with arthritis would look forward to a lifetime of pain and disability.
- The contrast between treatments of yesteryear and today highlights the importance of continued innovation.

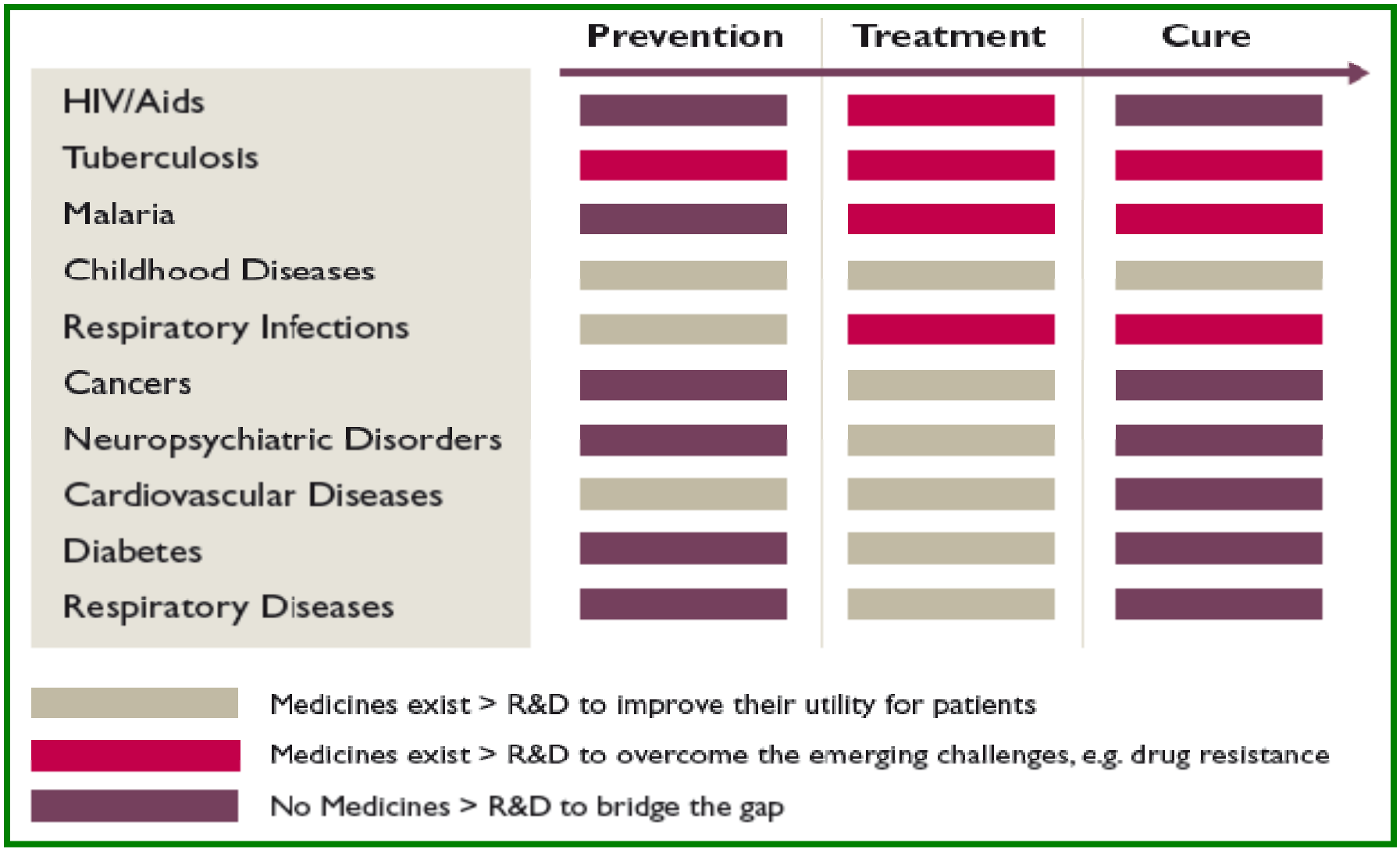
INCREMENTAL INNOVATION

- Some people see incremental changes in medicines simply as “me-too” drugs.
- In fact, having multiple choices of medicines within a class offers many benefits to patients, doctors, and society.

THE EVOLUTIONARY DRUG INNOVATION PROCESS



WHY DO WE NEED MORE INOVATION?



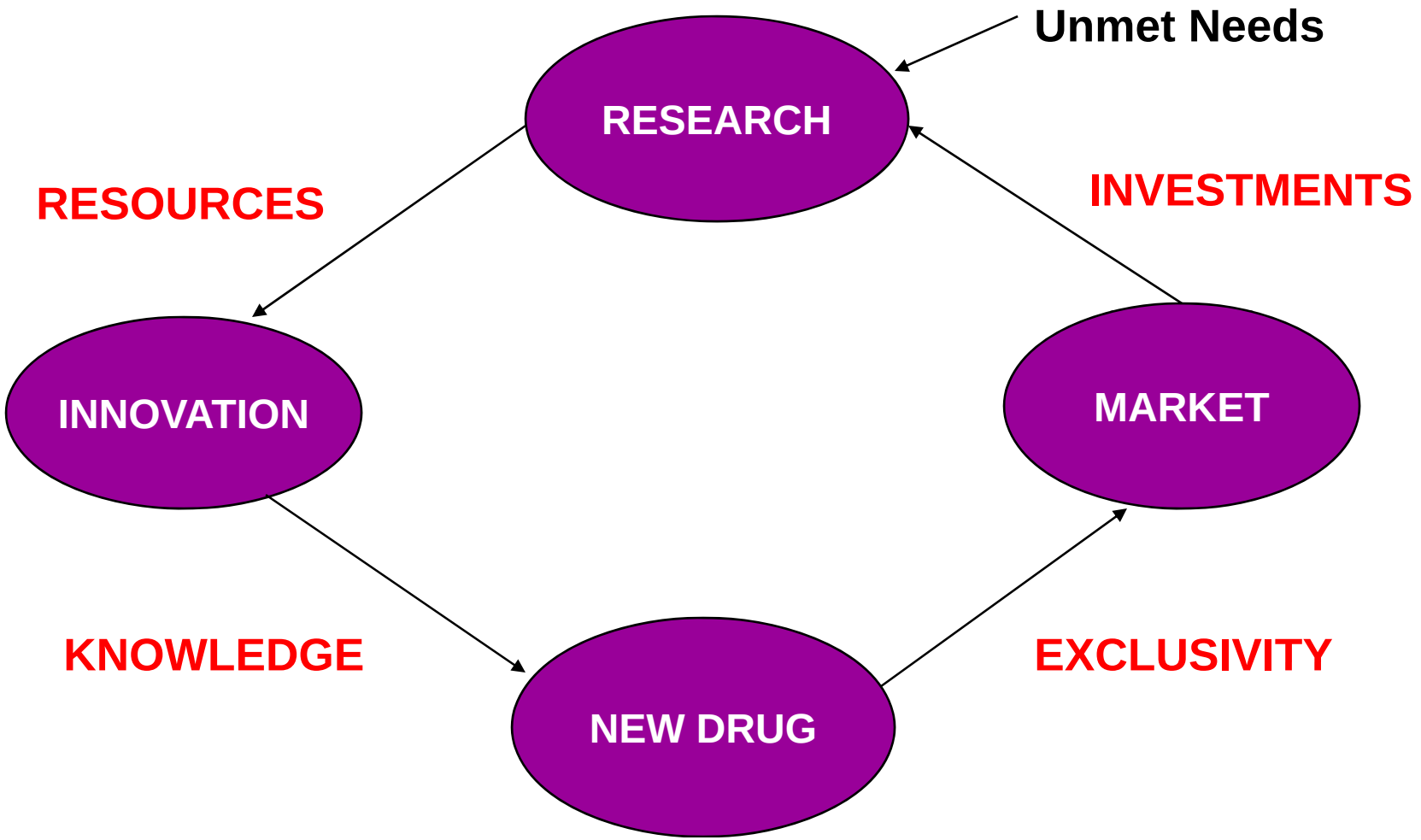
Source: Various WHO & Industry Sources

INNOVATION FOR NEW MEDICINES

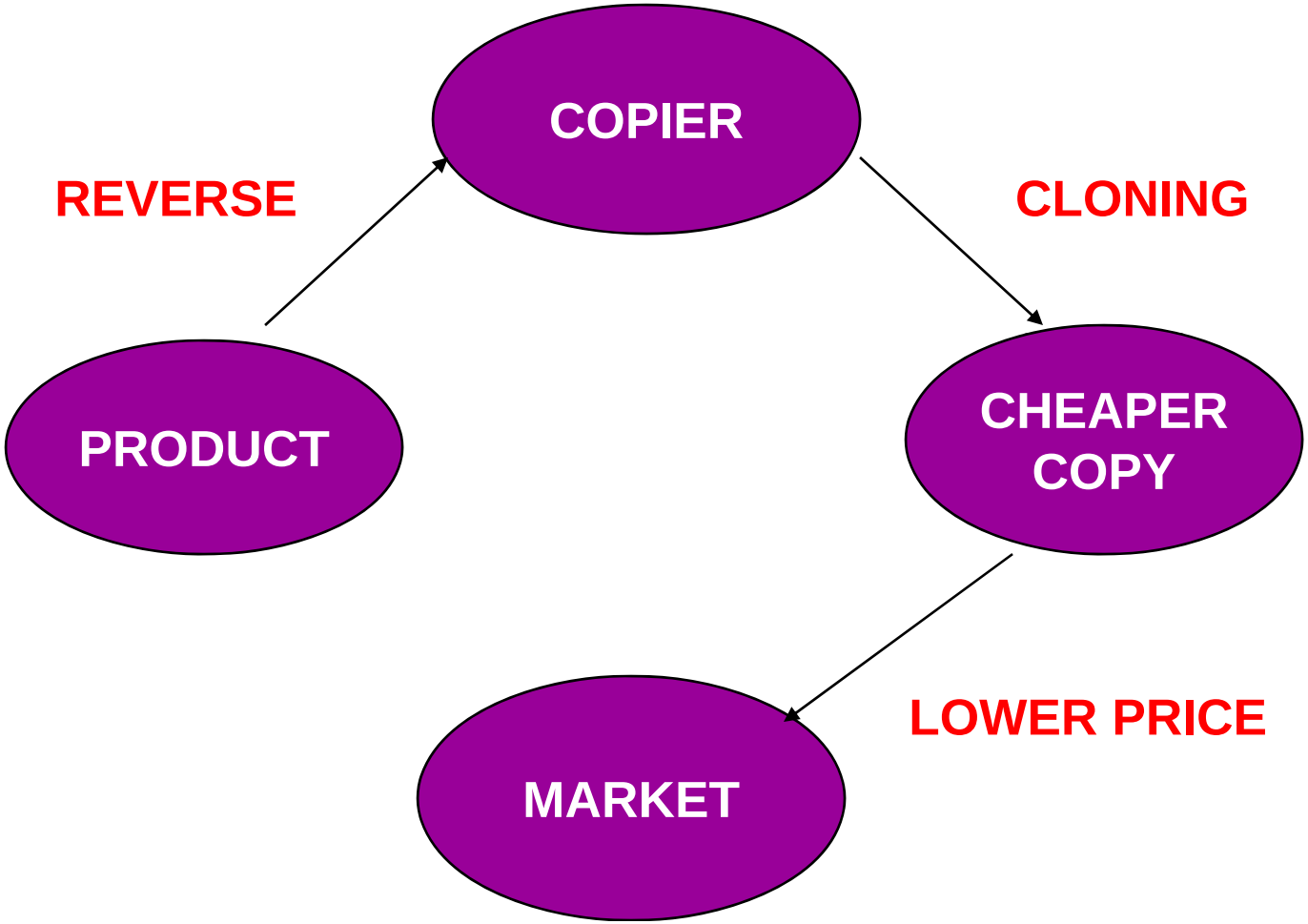
- New medicines play a significant role in the life expectancy gains.

- Research indicates that new medicines generated 40% of the two-year gain in life expectancy achieved in 52 countries between 1986 and 2000.

WHAT IS MEDICAL RESEARCH



…… AND WHAT IS NOT



PRESERVING INCENTIVES FOR INNOVATION

- In an era of new scientific and public policy challenges, preserving a climate that supports innovation is more important than ever.

ENFORCEMENT MEASURES AVAILABLE UNDER THE INDIAN LAW

- A patentee should consider the backlog generally in Indian courts.
- 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 counter-claims is transferred to a High Court for decision.

ENFORCEMENT MEASURES AVAILABLE UNDER THE INDIAN LAW:

- Because defendants invariably counter-claim for revocation, patent infringement suits are typically heard by a High Court.
- High Court may allow the patentee to amend the application in order to preserve the validity of the patent.
- In such an event, the applicant must give notice to the Controller to appear and be heard if so directed by the High Court.

ENFORCEMENT MEASURES AVAILABLE UNDER THE INDIAN LAW:

- If patent infringement is proved and if the defendant does not comply with the judgment, a petition for contempt of court can be filed.
- Contempt of court is a criminal offense, while patent infringement is a civil offense.
- In the event of a contempt of court, Indian law provides for imprisoning the authorised person(s) of the defendant.

ENFORCEMENT MEASURES AVAILABLE UNDER THE INDIAN LAW:

- It is also possible to obtain a preliminary injunction.
- A preliminary injunction is granted if the plaintiff shows a prima facie case and also whether the balance of "convenience" is in the plaintiff's favor.

ENFORCEMENT MEASURES AVAILABLE UNDER THE INDIAN LAW:

- An important consideration before contesting a patent in India is to ensure that the patentee has worked the invention directly or through its licensees in India.
- If a patentee has not worked the invention in India, then the defendant could seek a compulsory license under Section 84(1)(c), if the patent has been in force for more than three years.
- In addition, if a compulsory license is already in place and the patentee has still not worked the invention but yet asserts it, the defendant can seek a revocation of the patent under Section 85(1) of the Patent Act.

ENFORCEMENT MEASURES AVAILABLE UNDER THE INDIAN LAW:

- A new change in the law allows for damages from publication of the application, except for Black Box applications.
- A company, which has made "significant investment" and was marketing the product before January 1, 2005, may continue to do so but must pay a "reasonable royalty" to the patentee.

SHORTCOMINGS OF THE SYSTEM:

- The above-mentioned improvements in the patent regime in India have resulted in a significant up-thrust in the promulgation and enforcement of patents in India.
- The patent regime is plagued with certain major impediments, which continue to hinder the effective enforcement of patents in the country.

SHORTCOMINGS OF THE SYSTEM:

- There is an acute lack of awareness of patent basics in the judiciary and even the legal fraternity.
- A patent infringement is first to be filed in a District Court.
- With a counter-claim of invalidation, the suit moves to the High Court.
- Unlike in advanced patent litigation countries like USA, Europe or Japan, the awareness and understanding of grounds of infringement, exceptions to infringements etc. are inadequate in India.

SHORTCOMINGS OF THE SYSTEM:

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

SHORTCOMINGS OF THE SYSTEM:

- No criminal remedy available for infringement of patents, as opposed to that of copyrights etc.
- Leads to insufficient remedy in the infringement suits.
- The lack of criminal remedies fail to deter potential infringers.
- The patent regime also suffers from certain serious administrative problems.

SHORTCOMINGS OF THE SYSTEM:

- The speed at which a patent application is granted still remains largely slow.
- The Indian Patent Office is faced with a growing backlog of approximately 40,000 unexamined patent applications.
- Subsequent to these amendments, India can boast of one of the best patent law regimes in the world.
- The inadequacy of the enforcement machinery and the slow judicial process is a great problem.

Mint
(20.3.2008)

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
(20.3.2008)

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
(20.3.2008)

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 Erlotnib, 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 (CPAI) 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

CURRENT STATUS

- India still remains weak in many areas largely due to inadequate laws and ineffective enforcement.
- A lot is desired still in order to bring the regime at par with the international standards.
- The reversal of burden of proof provision enables higher rate of success to the patent holder and acts as a deterrent to potential infringers.
- Improving IPR protection will be an important element to increasing and making the climate in India more attractive to private investment.

THE WAY FORWARD

To ensure adequate protection of the patent granted in India we have:

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

STRENGTHENING REGULATORY PROCESS

- DCGI to ensure that marketing approvals shall not be granted to biosimilar and generic versions of products patented in India during their patent life
- If an applicant is relying on research data of another Company, DCGI should ask the applicants to generate their own data for patient safety.

STRENGTHENING REGULATORY PROCESS

- If a patent is granted in India for a particular drug and if the marketing approval for biosimilar or generic versions of a patented drug has already been issued before grant of patent in India, then such marketing approval of the generic / biosimilar should be revoked immediately on intimation of grant of patent by patent holder / licensee / marketing authorisation holder to CDA / DCGI.

Financial Express
(20.3.2008)

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.

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