

# TRIPS Patent Law & Access to Medicines

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# Patents

- Patents: Products & Process
- Statutory Right, not a common law right.
- No cross border reputation (cf: trademark, copy right)
- Negative Right: Exclude others from use, manufacture, offer for sale, sell, import, export
- Creates monopoly: No competition: Prices up:
- No monopoly: Competition: Prices down
- Product and Process patent monopolies

# Patents in India

India supplies 50% of the medicines in the developing countries

## *Patents and Designs Act, 1911*

Product and process patent : protection

Term of patent: 16 years

## *Patents Act, 1970 (For pharmaceuticals and agrochemicals):*

No product patent protection, only process patent

Process patent for best process known to inventor

Maximum term of patent: 7 years

## *Consequence:*

No monopoly on pharmaceutical products

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

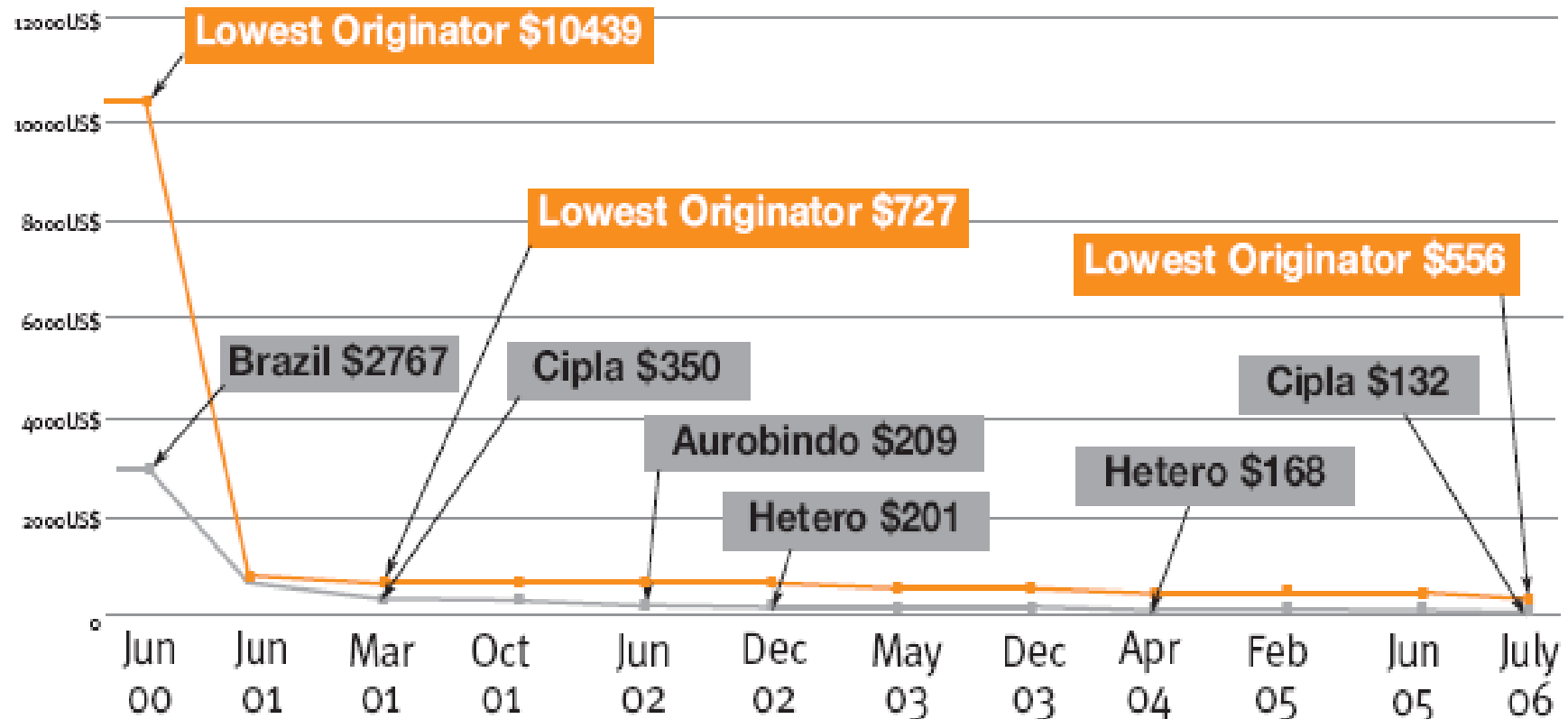
> 1 manufacturer of drug → competition → lower prices

Prices of medicines in India are the lowest in the world.

# EFFECT OF COMPETITION ON PRICES

**Graph 1:** Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year.

## The Effects of Generic Competition June 2000-June 2006



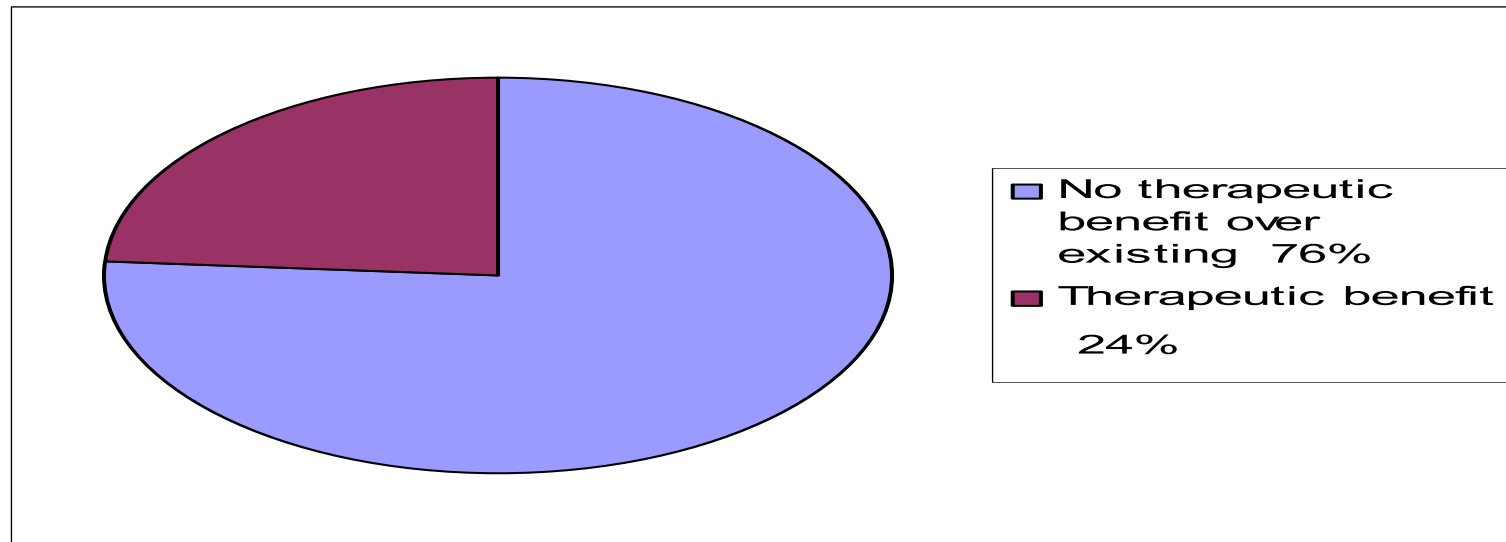
Generic competition has shown to be the most effective means of lowering drug prices.

*Courtesy : Médecins Sans Frontières*

# TRIPS Regime

- Minimum standards of intellectual property protection with effect from 1 January 1995.
- What is patentable?: Invention which
  - is *new*,
  - involves an *inventive step* and
  - is *capable of industrial application*. [Article 27]
- Protection to both products and processes [Article 27]
- Period of protection: Minimum 20 years [Article 33]
- Varying deadlines for developing and least developed countries on condition of provisions for Exclusive Marketing Rights and mailbox facility [Article 70]
- Prospective operation: Inventions on or post 1 January 1995
- Dispute settlement mechanism [Article 64]
- Non-compliance can lead to imposition of sanctions.
- 1 January 2005: India to provide product and process patent protection to all fields of technology [Article 65]

# NEW DRUG APPROVALS [1989-2000]



- 1,035 new drugs approved by US FDA (1989-2000)
- Only 15% of new drugs approved in 1989–2000 were highly innovative priority NMEs (New Molecular Entities)
- India estimates 12,000 pharmaceutical applications have been filed mostly relating to incremental improvement over existing old drugs.

“Changing Patterns of Pharmaceutical Innovation”, National Institute for Health Care, Management Research and Educational Foundation, May 2002

# EVERGREENING

- Pharmaceutical companies obtain patents on different aspects of the same drug to extend their monopoly. Eg: formulations, salts, esters dosages, combinations, etc.
- Due to this, a single drug has multiple patents: Originating patenting and derivative patent
- This prevents introduction of generic versions of the drug even after the expiry of the original patent.
- Eg: Combivir is a combination of Zidovudine and Lamivudine.

# INDIAN PATENT LAW AMENDMENTS

- March 2005:
  - Parliament deliberated the issue of pharmaceutical patents and acknowledged problem of ever greening.
  - Patents (Amendment) Act, 2005 passed.
- Introduced 20-year product patents for pharmaceutical products.
- Included key protections:
  - Section 3(d) amended to exclude patentability of new forms of known substances unless there is significant enhancement of efficacy;
  - Pre-grant opposition retained;
  - Post-grant opposition introduced.
  - Review retained
  - Revocation retained
  - Compulsory licenses

# RELEVANT PROVISIONS

- “invention” means a new product or process involving an inventive step and capable of industrial application [Section 2(1)(j)]
- “inventive step” means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art [Section 2(1)(ja)]
- “capable of industrial application”, in relation to an invention, means that the invention is capable of being made or used in an industry [Section 2(1)(ac)]

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- “inventive step” means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art [Section 2(1)(ja)] {**Non-Obviousness**}
- “capable of industrial application”, in relation to an invention, means that the invention is capable of being made or used in an industry [Section 2(1)(ac)]

# RELEVANT PROVISIONS

What are not inventions (Section 3):

- An invention the primary or intended use or commercial exploitation of which could be **contrary to public order** or morality or which **causes serious prejudice to human, animal or plant life or health** or to the environment [section 3(b)]
- The mere discovery of a scientific principle or the formulation of an abstract theory or **discovery of any living thing or non-living substance** occurring in nature [section 3(c)]
- A substance obtained by a **mere admixture** resulting only in the aggregation of the properties of the components thereof or a process for producing such substance [section 3(e)]
- Any **process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings** or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products [section 3(i)]

# RELEVANT PROVISIONS

- What are not inventions (Section 3):
  - The **mere discovery of a new form of a known substance** which does **not result in the enhancement of the known efficacy** of that substance or the **mere discovery of a new property** or a **new use of a known substance** or of the mere use of a known process, machine or apparatus unless such know process results in a product or employs at least one new reactant [Section 3(d)]

*Explanation:* “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 regard to efficacy.** [Explanation to Section 3(d)]

# *GLEEVEC CASE* – HISTORY

- March-April 2005: *Patents (Third Amendment) Act* was passed and came into force.
- 18 July 1997: Novartis AG filed a patent application for  $\beta$ -crystal form of imatinib mesylate in Switzerland
  - Base + Acid = Salt + Water
  - imatinib free base + methane sulphonic acid = Imatinib mesylate + water
- September 2005: CPAA filed a pre-grant opposition to Novartis' patent application.
- January 2006: Patent Controller rejected Novartis AG's patent application holding that the  $\beta$ -crystal form of imatinib mesylate is:
  - not novel,
  - does not involve an inventive step,
  - Is a crystalline form (imatinib mesylate) of an already known substance (imatinib) with no significant difference in efficacy

# *GLEEVEC CASE* – MADRAS HIGH COURT

May 2006:

- Novartis AG and Novartis India filed writ petitions (judicial review actions) challenging Section 3(d) of the *Patents Act, 1970* on the grounds of:
  - TRIPS non-compliance, and
  - Violation of equality provision of the Constitution (Article 14)
  - Violation of right to profession, trade and business provision of the Constitution (Article 19) [subsequently dropped]

# *GLEEVEC CASE* – MADRAS HIGH COURT

Issue of TRIPS non-compliance cannot be examined.

- Domestic courts do **not** have jurisdiction to decide whether a domestic law is in violation of an International Treaty or not.
- Exclusive forum for determining TRIPS-compliance is the WTO Disputes Settlement Body by a Member State.
- Because it found that it lacked jurisdiction to decide such issues, the Court declined to address the issue of whether section 3(d) was in compliance with the TRIPS Agreement.
- The Court refused to grant any declaratory relief.

# *GLEEVEC CASE* – JUDGMENT

## **Section 3(d) is not vague or arbitrary and therefore does not violate Article 14**

- Concept of “efficacy” has a clear meaning in the pharmaceutical field.
- Efficacy is to be understood as therapeutic efficacy.
- Concept of “enhancement of efficacy” too has a clear meaning in the pharmaceutical field. Therefore, a patent applicant can place on record the therapeutic effect/efficacy of a known substance and the enhancement in that known efficacy;
- Parliament can use broad, undefined terms which are to be interpreted and applied by the Patent Offices in different factual circumstances.

## *GLEEVEC CASE – JUDGMENT*

*“We have borne in mind the object which the Amending Act wanted to achieve, namely ... to provide easy access to the citizens of this country to life saving drugs and to discharge their Constitutional obligation of providing good health care to its citizens.”*

# STATUS OF CIVIL SOCIETY OPPOSITIONS

<i>Drug</i>	<i>Opponent</i>	<i>Status</i>
Gleevec	Cancer Patients Aid Association	Application rejected
Combivir	MNP+	Application withdrawn
Atazanavir	INP+ and KNP+	Application deemed abandoned
Amprenavir agenerase	INP+ and UPNP+	Pending

# STATUS OF CIVIL SOCIETY OPPOSITIONS

<i>Drug</i>	<i>Opponent</i>	<i>Status</i>
Valganciclovir	INP+ and TNNP+	Patent granted without hearing [Challenged in the Madras High Court]
Tenofovir	INP+ and DNP+	1 opposition withdrawn 2 pending
Kaletra (soft gel)	INP+	Application deemed abandoned
Lopinavir	INP+, DNP+ and NMP+	Pending

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Ritonavir	INP+ and DNP+	Pending
Abacavir sulfate	INP+	Application deemed abandoned
Efavirenz	DNP+	Post-grant opposition pending
Nevirapine hemihydrate	PWN+	Application rejected
Pegasys	Sankalp Rehabilitation Trust	Post-grant opposition pending

# Community Led Movement

- The Oppositions are with the full involvement of the Community of PLHA networks and other patients rights groups
- From 2000 onwards Lawyers Collective has been building the capacity of PLHA networks and other patients rights groups by building capacity on rights based strategies and patent issues
- The decision to oppose or not oppose patent applications is done collectively [without the drug companies knowing about them]
- In key cases [e.g. Novartis] the community takes the decision of advocacy, involved in deciding the strategies of advocacy and holding demonstrations, sit-ins etc
- The opposition work also involves the building the capacity of lawyers who want to work for the people

# DATA EXCLUSIVITY (DE)

- Article 39 of TRIPS requires protection of data submitted to regulatory authorities for approval of pharmaceuticals and agrochemicals.
- Multinational pharmaceutical companies have been lobbying with the Government for DE which will restrain the drug regulatory authority from relying on test data submitted by pharmaceutical companies to approve generic versions of the same drug.
- DE will allow monopolies to be created even in case of non-patentable or off-patent drugs.
- It may also extend the monopoly beyond patent term in some cases.
- Satwant Reddy Committee Report (2007): With respect to pharmaceuticals,
  - Provide minimum standards of data protection during a transitory period.
  - In the post-transition period, higher standards of data protection can be considered for “new chemical entities”.

# FREE TRADE AGREEMENTS (FTAs)

- FTAs are bilateral and regional trade agreements generally between two countries.
- Due to the reluctance of the multilateral system in the WTO to introduce new changes providing higher levels of IP protection, the US has chosen to rely on the bilateral approach.
- A significant number of countries have signed or are negotiating Free Trade Agreements with US. **For example** US-Singapore FTA, provides for data exclusivity period for 5 years after the approval of the drug. US- Morocco FTA, Art.15.9.2 requires patents to granted for any new uses or methods of using a known product, including new uses of a known product for treatment of humans and animals.
- These measures are termed as TRIPS- plus provisions- as these are not covered by the TRIPs agreement. These bilateral agreements require higher IP standards. For instance, Article 17.9.6 of US-Chile FTA provides for provides for patent terms extension in case of delay in examining the patent applications or granting patents.