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Lawyers Collective HIV / AIDS Unit
RIGHT TO HEALTH AND ACCESS TO MEDICINES

• Access to medicines is an integral part of the right to health.

• Nearly two billion people lack access to essential medicines. [“WHO Medicines Strategy: Countries at the Core, 2004-2007”, (2004).]

• In the case of HIV, it is presently estimated that around 15 million people living with HIV (PLHIV) need ARV treatment (based on revised WHO Guidelines). However, as of end-2010, only 6.65 million PLHIV are receiving treatment.

• Cost of medicines is one of the key factors that affect the access to medicines. In low and middle-income countries, medicines account for 60% of the healthcare cost. [The World Medicines Situation, WHO, 2004].

PATENTS $\rightarrow$ HIGH COSTS OF MEDICINES

• Patent barriers: one of the factors for high cost of medicines.

• Patents $\rightarrow$ monopolies $\rightarrow$ monopolistic prices $\rightarrow$ high costs for medicines

• Examples of prices of patented medicines:
  – Anti-retrovirals (mid-1990s to 2000): USD 15,000 per patient per year
  – *Imatinib mesylate* (*Gleevec*) – Anti-cancer medicine to treat chronic myeloid leukëmia:
    • Novartis’ price = 2400 USD per patient per month
    • Generic version price = 160 to 200 USD per patient per month
  – Tenofovir + Lamivudine / emtricitabine + Efavirenz (*Atripla*):
    • Gilead’s price = 1800USD per patient per month
    • Generic version = 15 USD per patient per month
NO PATENTS $\rightarrow$ COMPETITION $\rightarrow$ DROP IN PRICES

Graph 3: Fall in the prices of first line combination of stavudine (d4T)+ lamivudine (3TC), Nevirapine (NVP). Lowest world price per patient per year since 2000

Source: Untangling Web of Price Reductions, 14 Edn, 2010, Médecins Sans Frontières
COMPETITION REDUCES PRICES: INDIA EXPERIENCE

- Eg: Indian Patent law and Impact
  - 1911: 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.
  - Indian companies supply generic drugs to other countries
2005: PROBLEMS BEFORE INDIA

• 2005: Deadline for India under TRIPS to change its law to grant product patents for medicines.

• Problem 1: Multiple patents for single medicine → patent thickets and evergreening

  2010 study shows that, in the US, the average was nearly 3.5 patents per drug in 2005, with over five patents per drug for the best-selling pharmaceuticals. [Lisa Larrimore Ouellette, 17 Mich. Telecomm. Tech. L. Rev. 299 (2010)].

• Problem 2: Decline in drug approvals despite patent protection

  While patents were supposed to provide an incentive for R&D, data from other countries also showed that such *robust* patent protection did not yield the supposed R&D results. Number of NMEs being approved was on the decline.
PATENTS: PROBLEMS BEFORE INDIA – I

1964
- Zidovudine discovered and patented.

Thereafter
- Explored as anti-cancer treatment and shelved

1984-85
- Discovered to work against HIV

1985
- Patent granted on NEW USE

1964
- Zidovudine patented.

1985
- Zidovudine (new use) patented

1989
- Lamivudine patented

1992
- COMBINATION of Zidovudine + Lamivudine patented

1993 + 20
- Imatinib and all pharmaceutical salts patented.

1995-96
- Mesylate salt of imatinib published

1997 + 20
- Application for different crystal FORMS of mesylate salt of imatinib
PATENTS: PROBLEMS BEFORE INDIA – II

- Multiple patents → Same protection for all “inventions” → me-too drugs → Decline in new molecular entities being approved

- An estimated 12,000 pharmaceutical applications had been filed mostly relating to incremental improvement over existing old drugs.


- Only 15% of new drugs approved between 1989-2000 were highly innovative priority new molecular entities (NMEs).

INDIAN PATENT LAW – HIGHER STANDARDS

• 2005:
  – India required to comply with TRIPS and provide patent protection for pharmaceuticals
  – Parliament deliberated issue of pharmaceutical patents and problem of evergreening
  – Patents (Amendment) Act, 2005: Safeguards introduced to prevent “evergreening”
    • Higher patentability criteria set (SECTION 3(d): no patents on new forms of known substances unless there is a significant enhancement of efficacy)
    • Definition of “inventive step” introduced
    • Patent oppositions (pre-grant retained; post-grant introduced; revocation)
  – Objective of Section 3(d):
    • To prevent frivolous patenting
    • To prevent evergreening
    • To promote access to essential life saving medicines
SECTION 3(d): Higher Patent Standards

SECTION 3 (d)

– 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 ANY NEW PROPERTY OR NEW USE of a known substance ...

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."
STAGES OF GRANT OF PATENT

FILING OF APPLICATION PROVNL. / COMPLETE

PUBLICATION OF APPLICATION

REQUEST FOR EXAMINATION

REQUEST FOR EXAMINATION

EXAMINATION-ISSUE OF FER

DECISION OF THE CONTROLLER

GRANT OF PATENT [NO PRESUMPTION OF VALIDITY]

POST GRANT OPPOSITION (within 12 months)

DECISION OF THE CONTROLLER

REJECTION OF PATENT

REVOCAATION (after 12 months)

APPEALLATE BOARD [IPAB]

PRE-GRANT OPPOSITION

Rejection of pre-grant opposition

Appeal
EXAMPLE I: COMBIVIR

- Combivir is a fixed-dose combination of ARVs
  - Zidovudine (known substance) +
  - Lamivudine (known substance) +
  - “glidant,” an inactive substance (e.g. silicon dioxide (sand), calcium carbonate (chalk), talc, etc) (known substances)
- GlaxoSmithKline (GSK) filed a patent application for combivir.
- Generic version of Combivir is priced at Rs 1,100 per patient per month.
- GSK’s Combivir was not available in the local market.
- 31 March 2006: Manipur Network of Positive People (MNP+) and the Indian Network of People Living with HIV/AIDS (INP+) filed an opposition.
- 7 August 2006: Protests against GSK for exorbitant price and frivolous patenting by patients groups in India and Thailand
- To avoid a precedent of patent rejection, GSK decided to withdraw its patent application for Combivir in India and Thailand.
EXAMPLE II: GLEEVEC NOVARTIS CASE  
... not over yet

- **Imatinib mesylate:**
  - 1998: Patent application filed in India claiming beta-crystal form
  - 2005: Pre-grant oppositions filed
  - 2006: Patent Office rejects on grounds of novelty, inventive step and section 3(d); increase in bioavailability ≠ efficacy

- **Challenge to section 3(d)**
  - 2006-2007: Constitutional validity of section 3(d) upheld; efficacy = therapeutic efficacy

- **Appeal**
    - Novartis failed to satisfy section 3(d); efficacy = therapeutic efficacy
    - Novelty, inventive step recognised

- **Present status**
  - Appeal filed by Novartis in Supreme Court
  - Asking for a re-interpretation of “efficacy”
## USE OF SECTION 3(d) IN OPPOSITIONS

<table>
<thead>
<tr>
<th>Patent applications rejected</th>
<th>Patent applications Withdrawn/Abandoned</th>
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<tbody>
<tr>
<td>- Imatinib mesylate</td>
<td>- Combivir</td>
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<tr>
<td>- Valganciclovir</td>
<td>- Lopinavir/ritonavir soft gels capsules</td>
</tr>
<tr>
<td>- Nevirapine HH</td>
<td>- Abacavir sulphate</td>
</tr>
<tr>
<td>- Lopinavir/ritonavir tablet</td>
<td>- Atazanavir</td>
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<tr>
<td></td>
<td>- Amprenavir agenerase</td>
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<tr>
<td>Drug</td>
<td>Opponent</td>
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<td>-----------------------</td>
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<tr>
<td>Gleevec</td>
<td>Cancer Patients Aid Association</td>
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<tr>
<td>Combivir</td>
<td>MNP+</td>
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<tr>
<td>Atazanavir</td>
<td>INP+ and KNP+</td>
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<tr>
<td>Amprenavir agenerase</td>
<td>INP+ and UPNP+</td>
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<tr>
<td>Drug</td>
<td>Opponent</td>
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| Tenofovir (3 Oppositions) | INP+ and DNP+      | 1 opposition withdrawn  
1 Rejected.  
1 Pending |
| Kaletra (soft gel)    | INP+                | Application deemed abandoned                                           |
| Lopinavir             | INP+, DNP+ and NMP+ | Pending                                                                |
# STATUS OF CIVIL SOCIETY OPPOSITIONS

<table>
<thead>
<tr>
<th>Drug</th>
<th>Opponent</th>
<th>Status</th>
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<tr>
<td>Ritonavir</td>
<td>INP+ and DNP+</td>
<td>Pending</td>
</tr>
<tr>
<td>Abacavir sulfate</td>
<td>INP+</td>
<td>Application deemed abandoned</td>
</tr>
<tr>
<td>Efavirenz</td>
<td>DNP+</td>
<td>Post-grant opposition rejected</td>
</tr>
<tr>
<td>Nevirapine hemihydrate</td>
<td>PWN+</td>
<td>Application rejected</td>
</tr>
<tr>
<td>Pegasys</td>
<td>Sankalp Rehabilitation Trust</td>
<td>Post-grant opposition rejected – Appeal pending</td>
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