

Solving the Innovation-Access Dichotomy

Panel on IP and Access to Medicines

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 **I-MAK** INITIATIVE FOR MEDICINES ACCESS & KNOWLEDGE

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The Story so Far

“10 million lives in the developing world could be saved if we could increase access to currently available medicines”

World Health Organisation



The Story so Far

- TRIPS - promoting the patent system
- Price of medicines unaffordable as patents on pharmaceuticals comes in to play:
 - Studies show increase in prices in developing countries ranging from 26%-760% (*Subramanian*)
 - Intervention of Indian generic companies to reduce prices of ARVs from \$15,000-\$150



The Story so Far

- 1 January 2005 - India introduces pharmaceutical patent protection
- Concerns amongst health advocates that the affordable generics pipeline will be “cut off” (*MSF*)
- India introduces various public health safeguards within its Patents Act: - section 3(d), s11A(7), pre-grant opposition and strong compulsory licence provisions



Solving the Access Problem Within the Current Patent System

- Patient groups/civil society and Indian generic companies intervention into the patent system
- The Glivec case:
 - Novartis drug for myleoid leukemia, imatinib mesylate (Glivec) - \$US 2,500 per month under EMR between 1995-2005. Generic versions \$200 per month
 - Cancer patient group and generic companies file separate pre-grant oppositions against patent application for Glivec.
 - January 2006 -Indian patent office rejects Glivec patent
 - Novartis challenge constitutional validity of s3d - High Court of Madras dismisses case
 - Case on appeal at the patent office appellate board - hearing currently take place



Solving the Access Problem Within the Current Patent System

Drug	Status
Abacavir Sulfate	Withdrawn
Amprenavir	Pending
Atazanavir	Application divided/abandoned - status unclear
Combivir	Withdrawn
Efavirenz	Pending (Post grant opposition)
Lopinavir/Ritonavir	LPV Polymorph - Pending RTV Polymorph - Pending Heat Stable Tablet combination - Pending Soft-gel capsule combination - Withdrawn
Nevirapine	Refused



Solving the Access Problem Within the Current Patent System

Drug	Status
Pegasys	Pending (Post grant opposition)
Tenofovir DF	Ester - Pending Salt - Pending
Valganciclovir	Pre-grant Opposition rejected Post-grant opposition filed



Solving the Access Problem Within the Current Patent System

- September 2008, Brazil rejects patent on ARV tenofovir disproxil fumarate (Viread).
- Brazil's free ARV programme could save millions on one drug.
- Philippines follows India by amending patent law to include section 3d provision and stronger compulsory licensing provisions. Other countries look to follow.



Solving the Access Problem Within the Current Patent System

- Compulsory licensing - difficult to implement:
 - Thailand for efavirenz, lopinavir/ritonavir and plavix
 - Brazil follows suit on efavirenz
 - Other cases include Malaysia, Indonesia, Zambia, Mozambique, Zimbabwe



Re-visiting the Innovation Access Paradigm

- Innovation and access have been in conflict:
 - Health advocates argue that patents impede access.
 - Pharmaceutical companies argue that without patents there are no incentives to innovate

- Not only is access suffering, so is innovation:
 - Seeing fewer new NDA filings for NMEs (U.S GAO Report 2006). Companies appear to rely more on the low hanging fruits of the innovation scale.
 - More poor quality patents being detected that unduly prevent competition and innovation



Prescription for Improving Access and Innovation Within the Current Patent System

- Strengthen patentability criteria - to improve patent quality (section 3d?)
- Increasing public participation in patent examination:
 - requires rectifying information asymmetry
 - strengthening patent challenge procedures pre and post grant
- Predicating patent terms on quality
- Equitable licensing terms from Universities on upstream patents (UAEM)
- Patent Pools
- Patent buy-outs



Alternative Solutions to fostering R&D and Access

- **Public Private Partnerships (PPPs):**

- co-operation between governments, public research institutions, private sector and NGOs. Some 20 different PPPs currently, e.g DNDi, IAVI, MMV, EMVI, IOWH.

- objective to carry out focused research agendas, e.g DNDi and Sanofi-Aventis fixed dose combination of artesunate-amodiaquine for malaria in African countries.

- Concerns over sustainability of PPPs - depend on charitable contributions, still have to overcome patent issues, development/distribution issues (PDPs)



Alternative Solutions to fostering R&D and Access

- **Prizes:**
 - International community i.e governments could provide prizes for development of new therapies for diseases afflicting developing countries
 - Problems - how to define the size of the prize, how to define what is a new therapy and its efficacy, providing big enough prizes for industry
- **Advance Purchase Commitments:**
 - Guarantees future purchase of certain quantities of a product to be developed at an agreed price (with price reductions after time)
 - Problem - likely to require substantial funds to implement and gain commitment from industry
- **Drug Price Control** - Australia's Pharmaceutical Benefit Scheme, pricing based on efficacy (QALYs - Quality of Adjusted Life Years) of new treatment
- **Health Impact Fund** - Incentive system for neglected diseases or more effective medicines (QALYs), fixed fund of \$6 billion of which companies get share based on QALYs



Thank you

