

Putting patients before patents: Protecting the right to access medicines

Tahir Amin

Director and Intellectual Property Lawyer

I-MAK

tahirmamin@gmail.com



A brief history of the Indian Patents Act (the “Act”)

- Ayyangar Committee appointed in 1957 to review the Patent Act, resulting in the Patents Act, 1970 and the end of patent protection on medicines in India.
- India accedes to the WTO and TRIPS on 1 January 1995.
- India officially implements a ‘mailbox’ system for filing patents on medicines and granting interim ‘Exclusive Marketing Rights’ (EMRs).
- 1 January 2005, India required to amend its Act under TRIPS and re-introduces patent protection on medicines.



Amending the Act

- Civil society, health groups and left party members of the coalition fought until the 11th hour to include TRIPS flexibilities and principles of the Doha Declaration.
- Parliament gives assent to the amendments on 4 April 2005, implementing some of the public health safeguards demanded.



Key Amendments to the Act

- Act does not consider new forms of known substances as inventions *unless* they can show a difference in properties with regard to an enhancement of efficacy over the known substance (section 3d).
- Act permits enterprises that invested, produced and marketed a pharmaceutical product prior to 1 January 2005 to continue production on payment of reasonable royalty to the eventual patent holder(section 11A(7)).
- Act permits any person to oppose a patent before its grant (section 25(1)).
- Act implements the paragraph 6 of the Doha declaration (s92 A).



Protecting the Right to Access Medicines: Opposing the Grant of Non-Innovative Patents

- Patient groups and public interest lawyers are challenging patents filed in the mailbox.
- The first successful opposition was by the Cancer Patient Aid Association and generic companies against the application for Glivec® - now on appeal.
- Subsequent targeted oppositions based on legal and scientific merit have been filed by HIV patient groups.



Protecting the Right to Access Medicines: Opposing the Grant of Non-Innovative Patents (cont'd)

These include:

-GSK's Combivir® (combination of Lamivudine(1989) and Zidovudine(1986)). GSK withdraws patent.

-Gilead's Viread® (a salt of the known compound Tenofovir (1985)).

-Abbott's Norvir® (a crystalline form of the known compound Ritonavir (1989-1992)).

- GSK's Ziagen® (a salt of the known compound Abacavir (1988)).



Novartis's Claims

- India's new patent law not TRIPS compliant and unconstitutional - section 3d and section 11A(7)
- Under TRIPS, there is a legitimate expectation of a uniform patent system.
- Gleevec® already patented in 36 countries and is inventive.
- Novartis was granted an EMR for Glivec® in India -therefore its patent application should have been also granted.



Novartis's Claims (cont'd)

- The case is about safeguarding IP and not patient access.
- Novartis is not challenging any provisions of the Indian Patent Law that were put in place to promote access.
- 99% of patients in India receive Glivec® free under its GIPAP programme.
- Novartis's claims around India's patent law are corroborated by the recent report by the Mashelkar committee.
- Indian patent law is likely to jeopardise further development of new medicines because lack of protection hampers innovation.



The Potential Impact of Novartis's Challenge

- A likely increase in prices over time as alternative sources and competition is whittled away. E.g. Pegasys®
- Dependency on unsustainable philanthropic programmes of a handful of producers e.g Tamiflu.
- Directly effect other developing countries seeking to reform patent laws to safeguard public health.
- Continued decline of patenting standards and of true innovation.



Fixing a Broken Patent System

“The privileges granted to inventors by patent laws are prohibitions on other men, and the history of inventions accordingly teems with accounts of trifling improvements, patented, that have put a stop, for a long period, to other similar and much greater improvements. The privileges have stifled more inventions than they have promoted...Every patent is a prohibition against improvements in a particular direction, except by the patentee for a certain number of years; and however beneficial that may be to him who receives the privilege, the community cannot be benefited by it...”

(The Economist, 1851)



Fixing a Broken Patent System (cont'd)

- U.S Government Accountability Office, *New Drug Development, Science, Business, Regulatory and Intellectual Property Issues Cited as Hampering Drug Development Efforts*, November 2006.
- Section 3d
- Pre-grant oppositions/Community Peer to Patent Review.



What is needed

To stand against the infringement of developing countries rights to implement TRIPS flexibilities for the sake of public health.



“In a global economy, a global system of intellectual property rights is needed. This system must reflect the needs both of countries that are developing and those that have developed. The problem is similar to the one concerning which types of knowledge should be in the public domain in the developed world. But the Third World’s need to get low cost pharmaceuticals is not equivalent to its need for low cost CDs. Any system that treats such needs equally, as our current system does, is neither a good nor a viable system.”

(Thurow, L. (1997) Needed: A New System of Intellectual Property Rights, Harvard Business Review, Sept.-Oct. 1997, p.103.)



Thank You

