

Recent Developments in Indian Patent Law and Access to Medicines

Asean Workshop on Compulsory Licensing to
Increase Access to Antiretrovirals (ARVs) and
Diagnostic Reagents

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"Affluent societies are spending vast sums of money understandably on the search for new products and processes to alleviate suffering and to prolong life. In the process, drug manufacture has become a powerful industry. My idea of a better ordered world is one in which medical discoveries would be free of patents and there would be no profiteering from life or death."

Indira Gandhi while speaking at the World Health Assembly in Geneva on 6 May 1981

"The price of medicines will not shoot up due to patents, because of these strong safeguards, checks and balances."

Kamal Nath (Minister for Commerce and Industry) speaking at a meeting on Product Patents: Implications for Pharmaceutical Industry and Consumers, April 2005

Background to the Indian Patents (Amendment) Act 2005 (the “Act”)

- India accedes to the World Trade Organisation (“WTO”) on 1 January 1995.
- Following the decisions of the WTO Dispute Settlement Board and Appellate Board, in April 1999 India officially implements a ‘mailbox’ system for filing product patents and permits the granting of ‘Exclusive Marketing Rights’ (EMRs) during the transition period up to introducing product patent protection.
- After nearly 35 years, on 1 January 2005 India sees the rebirth of the product patent regime in order to meet its obligations under the WTO TRIPS Agreement.
- Pressure from the left leaning parties within the Government coalition and civil society groups leads to some interesting but also “controversial” changes.

Key Amendments to the Act

What are not inventions

- s3(d): The following are not inventions and patentable:

“the mere discovery of a new form of a known substance which does not result in the enhancement of a known efficacy of that known substance

- salts, esters, polymorphs, metabolites, combinations, derivatives of known substance shall be considered the same substance, unless they differ significantly in properties with regard to efficacy.”[excerpt]

Key Amendments to the Act (cont'd)

New Licensing Regime:

- s11A(7) - After a patent is granted in respect of 'mailbox' applications:

“the patent holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to 1 January 2005 and which continue to manufacture the product at the date of grant and no infringement proceedings shall be instituted against such enterprises.” [excerpt]

Key Amendments to the Act (cont'd)

New Compulsory Licensing Regime:

- s92A, incorporating paragraph 6 of the Doha Declaration provides:

“Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems provided such country has, by notification, or otherwise, allowed for importation of the patented pharmaceutical products from India.”[excerpt]

Key Amendments to the Act (cont'd)

Certain acts not to be considered as infringement for the purposes of the Act:

- *s107A(b) - “Importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product shall not be considered as an infringement of patent rights.”*

Key Amendments to the Act (cont'd)

Pre-grant Opposition:

➤ s25(1):

“where an application for a patent has been published but has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of the patent.” [excerpt]

Pre-Grant Opposition in Practice

- The beginning of a new civil society intervention and third party monitoring of questionable patents.
- According to reports, over 100 pre-grant oppositions have been filed by domestic generic companies, but more significantly civil society groups, supported by public interest lawyers, are also using the right.

Pre-Grant Opposition in Practice (cont'd)

Novartis' Patent Application for Gleevec®:

Background:

- Generic version of Gleevec cost a patient approximately Rs 12,000/month (US\$279).
- Novartis granted one of 3 EMRs in India for Gleevec. Novartis brings action against generic producers under its EMR rights. Price of Gleevec goes up to Rs 120,000/month (US\$2,790).

Pre-Grant Opposition in Practice (cont'd)

Patent Application:

- Patent application claiming an invention for a B-crystal form of methanesulfonic acid salt (imatinib mesylate). Invention of the base compound, imatinib, already disclosed in earlier Patent EP A 056409 dated 6 October 1993.

Patent refused because:

- Imatinib mesylate already disclosed in prior publications and patent dated 1993.
- The claimed polymorphic form of imatinib mesylate held not to be a new form of a known substance. An increase in 30% bioavailability over the free base held not to amount to a “significant increase in efficacy.”

Pre-Grant Opposition in Practice (cont'd)

GSK's Application for Combivir®:

- Combination of two known patented substances Lamivudine (3TC) + Zidovudine (AZT), first disclosed as a patent in 1992, but claiming “new invention” for adding a glidant to aid the manufacturing of the tablet formulation.
- s3(d) - **combinations** of known substance shall be considered the same substance, unless they differ significantly in properties with regard to **efficacy**.

Pre-Grant Opposition in Practice (cont'd)

Gilead's Application for Viread®:

- The application claims an invention for the fumaric acid salt (and its crystalline form) of Tenofovir Disoproxil, the ester derivative of the already known Tenofovir molecule (first patented in 1985).
- s3(d) - **new form of a known substance** which does not result in the enhancement of the known efficacy....**salts** of known substance shall be considered the same substance, unless they differ significantly in properties with regard to **efficacy**.

Will India's Patent Act Help to Keep Questionable Patents out and Keep Prices Down?

Example:

- Hoffmann La-Roche granted first product patent in India for Peginterferon alpha-2a for hepatitis C. Current price Rs 250,000 (US\$5,810) for a 24 week course.
- The Act allows for a post-grant opposition.
- Any generic manufacturers of Pegasys before 1 January 2005 can rely on s11A(7) and pay Roche a "reasonable royalty" to continue production. Reasonable royalty yet to be defined by courts.

Lessons To Date From India's New Act

- The definition for what are not inventions could potentially mean questionable patents on important medicines will not be patented e.g Gleevec..
- The pre-grant opposition procedure acts as another safety net to capture questionable patents.
- This will help to encourage true R&D and development in the pharmaceutical industry in India. More importantly, these changes could help to keep many medicines free of patents and more accessible to those in desperate need.