



The Impact of India's Amended Patents Act on Access to Affordable HIV Treatment

info@healthgap.org • tel: (267) 475.2645 • February 2005

Background: India is a major source of supply of the world's generic medicines; it exports 66.7% of its products to developing countries.¹ Routine generic production of medicines to treat HIV, both as finished products and as active pharmaceutical ingredients (APIs or raw materials), is the engine driving HIV treatment scale up in sub-Saharan Africa, South America, and Southern and Southeast Asia. Generic competition fueled by Indian production has been largely responsible for reducing the prices of antiretrovirals by as much as 98%.

India's efforts to comply with its WTO obligations to protect product patents on medicines starting January 1, 2005² will prevent routine generic competition for newer, more expensive "second-line" AIDS medicines—as well as other medicines for public health problems. 20-year monopolies will drive up the price of treatment in India and in hundreds of importing countries—the world's source of supply of generic HIV medicines will essentially disappear. A recent case study by a World Bank economist estimates that the cost to consumers in India alone of India's Patents Act amendments will be untenable.³

India passed a decree December 26, 2004 that eliminated 35 years of national exemption of medicines from product patent protection by amending the Patents Act (2003). This governmental decree (called an ordinance) will be put before the Indian Parliament when it reconvenes on February 26, 2005. According to Indian experts, Parliament does not appear prepared to agree to the ordinance. If Parliament does not pass the ordinance within six weeks following the commencement of the Parliamentary session, the ordinance will expire.

Indian lawmakers and politicians therefore have a critical opportunity to amend the Patents Act in a manner that meets India's TRIPS obligations but does not undermine the protection of public health and the promotion of access to medicines for all. Several myths have promoted regarding the impact the amended Indian Patents Act will have on access to medicines. Below is a sample of these myths, side by side with the realities.

Myth: "The fear that prices of medicines will spiral is unfounded....We must realize the fact that 97% of all drugs manufactured in India are off-patent, and so will remain unaffected."⁴

Reality: The Union Minister of Commerce and Industry, Kamal Nath, is correct to state that there are very few patents in force in India—because there has been no product patent regime for medicines in India since 1970. But thousands of medicines that were granted patent protection in other countries between 1995 and 2005, as well as medicines that will become patent protected after January 1, 2005 will be considered for patent protection in India.

In the case of HIV treatment, generic production only of older, pre-1995 generic versions of medicines is not enough to satisfy the treatment needs of people in developing countries. Generic competition is needed to drive down the costs of newer "second-line" antiretroviral treatments that can cost as much as 26 times more than older, "first-line" generic combinations. These are precisely the medicines that will be considered for patent protection in India. These medicines include GlaxoSmithKline's Combivir (zidovudine/lamivudine fixed-dose combination), which is widely used in generic form in India and in African countries, Gilead's tenofovir (TDF), Abbott's Kaletra, and other important antiretrovirals.

¹ The World Health Organization (WHO), *World Medicines Situation*, 2004.

² See TRIPS Art. 65(4).

³ Chaudhuri, S., et al. "Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India." December 1, 2004. (Working paper.)

⁴ "Kamal Nath's statement on the Ordinance relating to Patents (Third) Amendment," *Press Information Bureau. Government of India*. December 27, 2004. <http://nib.nic.in/release/release.asp?relid=6074>.

For drugs like Gleevec (imatinib mesylate), a life-saving treatment for chronic myeloid leukemia (CML), the exclusion of generic competitors from the market through application of exclusive marketing rights (EMRs) increased the price from \$200 for a generic product to \$2000 per month for Novartis' drug. Gleevec access in India is an important illustration of the likely impact of India's Patent Act amendments.

Myth: India's Patents Act amendments are an unavoidable consequence of India's obligations to protect product patents on medicines.

Reality: TRIPS only requires India to establish a product patent regime for medicines. The new amendments to the Patents Act are "TRIPS-plus"—they exceed the standard for patent protection required by the WTO and they fail to utilize fully the public health safeguards available to WTO Member States under TRIPS, which were reaffirmed by the "Doha Declaration on the TRIPS Agreement and Public Health" (Doha Declaration).

The TRIPS-plus provisions of India's Patents Act include:

- Dilution of India's "pre-grant opposition" procedure, which permits a party to challenge a patent application;
- broadening of the scope of patentability;
- And a compulsory licensing regime that is slow moving, bureaucratic, and will prevent the export of compulsorily licensed medicines to poor, importing countries who would qualify for such access.

International experts warn against the adoption of TRIPS-plus patent rules on essential products like medicines in developing countries. For example, the WHO cautions that developing countries that are "establishing standards of patentability for pharmaceuticals...should consider the implications for health of those standards. Standards which are too broad may lead to inappropriate extension of patent life beyond the period required" by TRIPS. Further, WHO states that countries "should recognize that patentability standards which are too broad can contribute to 'evergreening.' This means that the effective patent life for a new medicine is extended beyond the 20-year TRIPS minimum." The amendments to India's Patents Act would require India to grant patents on new uses of known medicines, creating a wide berth of patentability that will cripple competition. India can easily avoid this scenario by agreeing to grant patents only on truly innovative drugs—not for "new uses" on old drugs. It can do this by removing the word "mere" in its proposed amendment to the relevant section of the Patents Act, Section 3(d).⁵ The experience in the U.S. with evergreening has been a sobering—frivolous patents have crowded cost-reducing generic competitors out of the market.

Myth: Patent protection in will stimulate investment into R&D that will benefit Indian consumers and will reward India with increased foreign investment.

Reality: Profits generated by sales in India will not be large enough to affect the R&D agenda of multinational pharmaceutical companies. A recent case study estimates the returns to the pharmaceutical industry after implementation of a product patent regime in India to be only \$53 million per year. According to the recent findings of an international commission, "The evidence suggests that the IP system hardly plays any role in stimulating research on diseases particularly prevalent in developing countries, except for those diseases where there is also a substantial market in the developed world, Nor it is likely that the globalization of IP protection will lead to greater investment by the private sector for the development of treatments for diseases that primarily affect developing countries."⁶

Many industrialized countries only began to implement patent protection on medicines once they had reached a standard of development where it was clear they would benefit from such monopolies. In the case of India, foreign companies will constitute the vast majority of patent filers, as has been the case in other poor

⁵ The proposed amendment by the Government of India states that "the mere discovery of any new property or mere new use for a known substance" is not patentable (emphasis added). Therefore some new uses would be patentable.

⁶ "Integrating Intellectual Property Rights and Development Policy." Final Report of the UK Commission on Intellectual Property Rights. September 2002.

countries that have already come into compliance with TRIPS. Furthermore, compare the elusive promise of increased overseas investment with the concrete reality of decreased patient access to AIDS drugs as prices skyrocket. With 5.5 million HIV positive people in its borders alone, India cannot afford not to amend its Patents Act with public health and access to AIDS treatment foremost in its consideration.

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Recommended areas for action: India should amend its Patents Act in a manner that does not exceed the requirements of TRIPS, and that prioritizes access to medicines and public health. Specifically, India should:

- **Simplify and streamline India’s compulsory licensing procedure.** Routine issuance of compulsory licenses after January 1, 2005 in India is critical if the rapid entry of generic versions of important pharmaceuticals is to continue. The process of compulsory licensing must be changed to facilitate routine and expedited compulsory licensing of important medicines. A strictly enforced deadline of one to three months should be established for the grant of a compulsory license, and rights of appeal should not include permission for injunctive relief that would impede the use of the license. When patent applications in India’s “patent mailbox” are granted for important medicines, rapid compulsory licensing is particularly important in cases where low-cost generic versions of these retrospectively patented products are already available in India and in importing countries,

- **Retain the pre-grant opposition procedure in its original form.** India’s pre-grant opposition procedure permits opposition to potentially frivolous patent applications, protecting consumers against high prices on non-innovative pharmaceutical products under consideration for patent protection. The amended Patents Act would erode the level of transparency and civil society involvement in pre-grant opposition.

- **Remove provisions for the granting of new-use or second-use patents, currently described in Section 3(d) of the Patents Act.** TRIPS does not require the granting of additional patents for new uses or new dosage forms for known medicines. New-use or second-use patents do not reward or encourage true innovation; they will however increase the cost of important medicines, compromise patient access, and extend monopolies over a longer period of time.

- **Fully implement the decision of the WTO General Council on the implementation of paragraph 6 of the Doha Declaration for countries that lack sufficient domestic pharmaceutical manufacturing capacity (the “August 30th Decision”).** The draft amendment to the Patents Act would not permit export of compulsorily licensed medicines from India without a compulsory license granted in the importing country. If the importing countries does not have a patent for the compulsorily licensed medicine in force, it would not be allowed to import compulsorily licensed medicines exported by India, even though the August 30th Decision clearly permits this. Despite its flaws, the August 30th Decision should be implemented in as complete a manner as possible.