

# UPDATE 4



## PATENTS, INDIA, AND HIV/AIDS TREATMENT

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When India's Parliament passed an amendment to the Patent Act in March 2005, the legislation change drew global attention. The reason why a change to India's intellectual property system became major news around the world is because, prior to January 2005, India was the last country in the world with an advanced pharmaceutical sector that did not offer product patents on drugs. Indian firms had served as the principal suppliers of affordable antiretrovirals (ARVs) to developing countries, and the subsequent competition encouraged brand-name producers to lower the prices of their patented drugs as well. Thus, India's patent system contributed to the growth of a pharmaceutical sector whose active presence in the global ARV market had greatly increased the feasibility of extending treatment of people living with HIV/AIDS in poor countries, directly, through the supply of affordable ARVs, and indirectly, by placing pressure on brand-name firms. This update reviews the implications for AIDS treatment of the amended Patent Act, which extends patent protection to new pharmaceutical products.

First, the background. The World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets new and universal standards to which IPR systems in all countries that are members of the WTO must conform. TRIPS requires countries to grant patents in all fields of technology, including pharmaceuticals. Historically, many countries did not offer patents on pharmaceutical products; only recently, in compliance with TRIPS, have they begun to do so. However, countries that did not grant patents to pharmaceuticals prior to 1995, when TRIPS entered into effect, were not obligated to begin doing so for another ten years. India took full advantage of this transition period, delaying the availability of product patents on pharmaceuticals until 2005.

The fact of the matter is that pharmaceutical patents remain rare in most developing countries: "least developed countries" have until 2016 to issue pharmaceutical patents; where patents are available, originator firms often chose not to bother patenting their drugs in a given country; and even where patents are available and sought, drugs that were already on the market prior to a country changing its patent laws typically cannot be patented. Thus, many drugs that are patented throughout the developed world are still not patented in many developing countries.

But few developing countries have the economic and technological capacity to produce their own ARVs, regardless of the patent situation. Thus, many countries in the developing world have relied on Indian firms' ability to produce generic versions of modern drugs, especially ARVs. In fact, of the roughly 700,000 people in the developing world receiving antiretroviral therapy, it is estimated that more than half of those are treated with Indian ARVs.

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The amended Patent Act potentially complicates the global supply of ARVs, for the simple reason that importing drugs requires that someone export the drugs, and there is some question as to the long-term reliability of Indian pharmaceutical firms to continue playing this role. Once drugs become patented in India (and now that patents are available in India virtually all new drugs will eventually be patented there), then Indian firms will face legal obstacles to producing generic versions for export.

That's the simple version. Reality is a bit more complex, though the end point is the same.

Under certain conditions, governments can issue "compulsory licenses," which allow local firms to produce patented goods without the patent-owner's permission. According to TRIPS, however, goods produced under a compulsory license must be "predominantly" for domestic use. To the extent that new ARVs will now be patented in India (and, thus, in all countries with advanced pharmaceutical sectors), TRIPS can impede provision of generic versions of such drugs to developing countries.

In August 2003 WTO members agreed on a waiver to this clause that could facilitate the export of generic drugs to countries lacking domestic manufacturing capacity. Though a formal amendment to TRIPS is still being negotiated, a number of export-capable countries have since revised their patent laws in response to the waiver. Canada was the first, the European Union is in the process of doing so, and India's amended Patent Act also permits compulsory licensing for export.

Although the problems that TRIPS poses to poor countries' access to affordable ARVs have been recognized and addressed, significant obstacles remain. The waiver permitted by the WTO and introduced in subsequent national legislation are extraordinarily complex and are likely to be difficult to use in practice.

Most critically, there may be few incentives for potential exporters to bother doing so. Exporting generic drugs to poor countries is a low-margin activity. To the extent that patent rules make producing and exporting generics more laborious (i.e. raise the legal and transaction costs), they may encourage Indian pharmaceutical firms to abandon this line of business. Note that India's generic exports mean much more to the world than they do to Indian pharmaceutical firms: while Indian generics account for roughly fifty percent of ARVs used in developing countries, that is roughly four to ten times the importance of these exports to the firms themselves. The developing world relies on India, but Indian firms do lots of things besides produce generic ARVs for the developing world. The alarming scenario, then, is that the incentives faced by India's pharmaceutical firms will encourage them to dedicate fewer and fewer resources toward producing and distributing generic ARVs in the years to come (indeed, that is precisely one of the central objectives of TRIPS and the amended Patent Act). When new ARVs are introduced in coming years, drugs that will be essential as ARV resistance develops, there may be few firms that are legally, financially, and technically capable of producing generic versions for export.

What, then is the outlook? For the time being efforts to scale-up treatment of people with HIV/AIDS should not be affected by India's amended Patent Act. Indian firms can continue to produce and export the ARVs that are currently used throughout the developing world. The problems lie just over the horizon, for it will be much more difficult for Indian firms to produce and export generic versions of subsequent generations of ARVs. This, in turn, could have serious ripple effects, for in the absence of competition from generics, brand-name firms face fewer incentives to lower their prices. The importance of increasing the availability of affordable ARVs has never been greater; the challenges to doing so have been made significantly more complex.