PROGNOSIS: SHORT-TERM RELIEF, LONG-TERM PAIN

THE FUTURE OF GENERIC MEDICINES MADE IN INDIA

Background

In the midst of civil society protests and international media attention, the Indian Parliament approved and passed the new Patents Act on March 23rd 2005. The Indian Patents Act of 1970 was thus amended to allow for the granting of pharmaceutical product patents – something the country has not done since 1970.

India was obliged to make these changes in its legislation to comply with its obligation under the World Trade Organization's TRIPS[1] Agreement as of January 1st 2005. The previous Indian Patents Act did not allow patents on pharmaceutical products and thus enabled Indian companies to make their own generic versions of medicines. Generic production has been crucial for the supply of affordable medicines in the developing world, especially for newer drugs such as antiretrovirals (ARVs) for the treatment of HIV. It has resulted in competition between producers, which has reduced the price of many ARVs from as much as US$15,000 to as little as US$150 per person per year. In addition, due to the lack of product patents on each separate drug, Indian generic manufacturers have been able to combine three different AIDS medicines in one single pill. The availability of these generic fixed-dose combinations has dramatically simplified AIDS treatment in resource-limited settings.

The bad news: concerns about affordability of new medicines in the long term

Médecins Sans Frontières provides ARV treatment to nearly 30,000 people living with HIV/AIDS around the world. MSF shares concerns expressed by Indian civil society, patients' groups and other international treatment advocates about the consequences of the new Patents Act. The long-term impact of the Indian Patent Act is bad news for those relying on affordable new medicines – in MSF's own HIV/AIDS projects, for instance, approximately 70% of all patients currently take generic ARV medicines made in India. Worldwide, an estimated 350,000 people on ARV treatment depend on Indian generic production – that's half of all those on ARVs in developing countries.

In the future, drugs not yet produced by generic manufacturers - including those for which a patent application has been filed between 1995 and 2005, as well as any drugs invented after 2005 - are likely to only be sold by originator companies. This lack of competition will lead to steep increases in the prices of any new medicines, be it ARVs, antibiotics or new cancer treatments.

The good news: existing generic drugs can still be manufactured

Indian decision makers appear to have listened to some of the concerns voiced by civil society representatives, UN agencies and developing countries. As a result, some of the amendments in the law can protect access to medicines in the short term.

In particular, through a system of ***automatic licensing***, a generic manufacturer who has made a 'significant investment' and is already producing and marketing a drug in India will be able to continue doing so, even if a patent is granted by the Indian patent office (see below). In exchange, it would have to pay a 'reasonable royalty' to the patent holder, but

[1] Trade-related Aspects of Intellectual Property Rights

cannot be stopped from producing and marketing the generic version of the medicine. It is crucial that the Indian government clearly define what a 'reasonable royalty' is to avoid unnecessary price increases.[2]

The new Patents Act will only affect medicines that were invented after 1995. Although India was allowed to delay the patenting of pharmaceutical products until 2005, it had to establish a system for receiving and filing such patent applications starting in 1995. Waiting in the so-called 'mailbox' for examination by the Indian patent office are 8,926 pharmaceutical and agrochemical product applications. A large majority - over 7,000 - of these have been submitted by foreign applicants, with the US multinational Pfizer in the lead.

It will be up to the Indian patent office to decide whether the patent applications in the mailbox meet the patentability criteria laid down in the new Indian Patents Act, and to accept or reject them accordingly. In the new law, the ***scope of patentability*** has been restricted to avoid 'ever-greening' (i.e. the practice of granting secondary patents on existing products) and granting patents on frivolous grounds. For instance, patents on new usage of known compounds should be denied.

Other important amendments in the new Patents Act include the following:

- ***Pre-grant opposition*** has been restored. As under the 1970 Patents Act, any member of the public can oppose the granting of a patent by the patent office once the patent application has been made public.
- ***Export of medicines produced under compulsory license*** will be possible based on the sole notification by the importing country, in accordance with the August 2003 decision of the WTO[3]. India no longer requires that a compulsory license be granted in the importing country. This is important for example in case a patent does not exist, or for least-developed countries which do not need to grant or enforce patents on medicines.

Working to safeguard access

In the long term, a swift system of compulsory licensing will be the only way to ensure generic competition for medicines that are not yet being produced in India. But MSF is concerned that the provisions for compulsory licenses in the Patents Act seem unnecessarily cumbersome and may lead to legal and administrative delays, perhaps even protracted litigation processes between the patent holder and other potential producers of a drug.

The system of automatic licensing that India has put in place offers some immediate relief for generic production of existing medicines. If extended to new drugs, it could also be seen as a model for the future: innovators would be rewarded through a royalty system while competition by generic producers would continue ensuring more affordable prices.

MSF will continue documenting the impact of India's Patent Act on prices of medicines, but we will also work with others to ensure that the mechanisms and provisions allowed for in the law are fully implemented to ensure the widest possible access to affordable life-saving medicines in developing countries.

[2] In the Canadian compulsory licensing provisions in Bill C-9, the royalty rates vary from 0% to 4%.
[3] The "August 30th 2003 decision" of the WTO introduced an exception to the rules of the TRIPS Agreement regarding compulsory licenses. It authorised countries to issue compulsory licenses *mainly for export* to countries with insufficient or no manufacturing capacity.