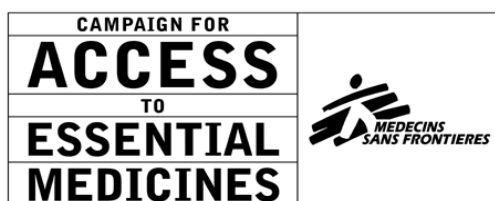


Will the lifeline of affordable medicines for poor countries be cut?

Consequences of medicines patenting in India

Briefing document

Médecins Sans Frontières
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Médecins Sans Frontières is an independent humanitarian medical relief organisation providing assistance to victims of epidemics and natural or man-made disasters in nearly 80 countries around the world (including India). MSF was awarded the 1999 Nobel Peace Prize.

Why are medicines expensive? The role of patent protection

The patent system is social policy tool that aims to stimulate innovation. Internationally, patent protection is governed by the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. TRIPS does not establish a uniform international law, but sets out minimum standards of patent protection that must be met by all WTO members. Developed countries have already implemented the agreement, and other countries such as India are implementing it now, in 2005. Least-developed countries are not obliged to do so until 2016.

Medicines are expensive when they are protected by patents. The patent holder has a monopoly on the drug for a minimum of 20 years, and uses that period to maximize profit. But as soon as generic competition is possible, prices of medicines plummet: for instance, after the Brazilian government began producing generic AIDS drugs in 2000, prices dropped by 82%.

PURPOSE OF THE DOCUMENT

2005 marks a fundamental and potentially dramatic change in access to medicines in developing countries: countries which do not yet grant patents on medicines, such as India, now have to implement patent laws in compliance with the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Indian parliamentarians meet in February 2005 to begin discussing the President's Patent (Amendment) Ordinance of December 2004.

This document briefly outlines the issues at stake and the choices available to Indian policy makers to ensure access to affordable and effective medicines for millions of people in developing countries - as seen from the perspective of Médecins Sans Frontières, a humanitarian medical organisation working in nearly 80 countries worldwide. This paper is aimed at political decision-makers, but also journalists, care providers, medicine suppliers, non-governmental organisations and any other groups and individuals interested in improving access to medicines.

OBSTACLES TO TREATMENT IN POOR COUNTRIES

Many factors influence access to life-saving medicines in developing countries. Quality of diagnosis, prescription, selection, distribution and dispensing of medicines, drug quality, capacities of health systems and budgets, and lack of research and development all play a role. However, the price of medicines remains one of the most formidable barriers.

The media spotlight continues to focus on AIDS, but the prices of medicines affect people suffering from other diseases too. Many African countries continue to rely on chloroquine, an outdated drug, to treat malaria because the newer, more effective artemisinin-based treatment costs as much as twenty times more. Hepatitis C, a lifelong infectious liver disease causing cirrhosis and liver cancer, affects 170 million people worldwide, but the cost of treating one patient is 30,000 US\$ per year. Governments of poor countries cannot afford such high prices for medicines when running a health system on very limited resources. High prices also create barriers to research: for example, the high cost of the new quinolone class of antibiotics has prevented sufficient research into whether such drugs could be used to reduce the length of tuberculosis treatment, which currently takes six to eight months.

INDIA: A LIFELINE OF MEDICINES FOR POOR COUNTRIES

Since 1970, India's Patent Act has allowed Indian manufacturers to legally produce generic versions of medicines patented in other countries. India's expertise in reverse drug engineering and the efficiency of its pharmaceutical manufacturing industry fast established it as the prime source of generic medicines in the world. Thanks to India's generic antiretroviral drugs, for example, AIDS triple therapy - which costs US\$10,000 per patient per year in the West - was made available at less than US\$200 per year a few years ago. These discounts allowed life-saving treatment programmes to see the day in several developing countries. An estimated 70% of the 25,000 AIDS patients treated by Médecins Sans Frontières in 27 countries are taking Indian generics.

The absence of drug product patents has also allowed Indian generic manufacturers to develop fixed-dose combinations of AIDS drugs, combining several pills originally produced by different companies into one tablet that is easy to take. This simplification of treatment regimens has been crucial to the scale-up of AIDS treatment programmes in poor countries.

TRIPS IMPLEMENTATION IN INDIA

On December 26th 2004, to comply with the terms of the TRIPS Agreement, the President of India issued the Patents (Amendment) Ordinance, which requires patents to be granted on new medicines as from January 1st 2005, and on medicines for which companies filed a patent application after 1995 (see explanation of the "mailbox" system on page 4).

This is potentially very bad news for Indian patients. If the government does not establish measures to bring prices down, the cost of new drugs will remain very high, because patents prevent competition. Estimates suggest prices of new drugs will increase by a mean of 200%¹. It is also a devastating development for many poor countries that rely on India as a source of affordable quality medicines. Although least-developed countries are not obliged to grant patents on pharmaceuticals until 2016², they do not have the technical and financial capacity, nor the economies of scale to produce their own generic medicines. TRIPS implementation in India and other manufacturing countries will effectively cut the lifeline of affordable drugs unless safeguard measures are implemented to prevent this.

The effects are already visible: second-line antiretrovirals³ which are under patent in Brazil⁴ such as nelfinavir or the fixed-dose-combination of lopinavir/ritonavir are available at exorbitant prices as compared to the first-line drugs which are not patented in any of the big developing country markets. It is the lack of patents combined with the existence of attractive markets that made the prices of first-line antiretrovirals come down. Table 1 below illustrates the difference between first-line and second-line treatment prices in developing countries around the world.

Country	First-line regimen	Price in US\$ per patient per year (generics available)	Second-line regimen	Price in US\$ per patient per year (no generics available)
Cameroon	3TC/d4T/NVP	277	AZT+ddl+NFV	4,763
Malawi	"	288	"	1,875
Kenya	"	292	"	1,594
Cambodia	"	350	AZT+ddl+LPV/r	1,215
Thailand	"	352	AZT+ddl+SQV/r	3,500
Honduras	"	426	D4T+ddl+NFV or AZT+ddl+NFV	3,796 for NFV only

Table 1: Comparing prices of first- and second-line AIDS triple therapy regimens in a selection of developing countries (as at June 2004).

INDIA, THE NUMBER ONE SOURCE OF AFFORDABLE MEDICINES

Sick people in India and around the world depend on the willingness of Indian producers to carry out the research to develop and manufacture affordable generic versions of second-line AIDS drugs and other new medicines. India

¹ F. M. Scherer, Jayashree Watal. "Post-TRIPS Options for Access to Patented Medicines in Developing Countries." Commission on Macroeconomics and Health, Working Paper Series, Paper No. WG4:1, June 2001, 15-16.

² Doha Declaration on TRIPS and Public Health, paragraph 7. The declaration is available at: www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

³ I.e. the drugs patients take when first-line drugs start to fail.

⁴ Brazil amended its patent law to start granting patents on medicines in 1996.

has a long history of fighting for protection of public health over intellectual property: it led developing countries' resistance to the TRIPS Agreement during the Uruguay Round of WTO negotiations, and also played a key role during the 2001 WTO ministerial conference in Doha, which resulted in the adoption of the Doha Declaration on TRIPS and Public Health⁵. Unlike other developing countries, it has also waited as long as was permitted by TRIPS before introducing patents on pharmaceutical products. In the new post-2005 TRIPS context, it is crucial that India continue to develop policies that promote access to medicines, not just out of responsibility to its own people, but as a lifeline to patients in other developing countries.

The Indian parliament will soon discuss the President's Patent (Amendment) Ordinance. At this stage it is still possible to alter some of the details of the legislation, and thus determine the scope of patent protection on medicines in the future.

MÉDECINS SANS FRONTIÈRES URGES INDIAN POLICY MAKERS TO:

1. Provide a system for fast-track implementation of compulsory licensing

India, like all WTO members, can ensure continuing access to affordable medicines by making use of the flexibilities included in the TRIPS agreement. For instance, TRIPS allows countries to overcome patent barriers by issuing *compulsory licenses* or *licenses for government use*, which allow the production or importation of generic medicines without the consent of the patent holder. These policy tools are commonly used by developed countries, mostly in cases of anticompetitive practices. As the TRIPS Agreement becomes progressively implemented worldwide, developing countries are also making use of TRIPS flexibilities to ensure access to AIDS medicines at affordable prices: Malaysia and Indonesia have both issued a government use order to allow respectively the importation and local production of generic antiretrovirals for use in public services. Similarly, the government of Cameroon has authorized its central procurement agency to import generic versions of patented medicines for the supply of the non-profit sector⁶. Zimbabwe, Mozambique and Zambia also issued compulsory licences for the local production of generic versions of patented antiretrovirals.

The "mailbox" system

Although India and other developing countries were allowed to delay implementation of the TRIPS Agreement until 2005, they had to establish a "mailbox" system to receive and file patent applications from the beginning of 1995. Around 9,000 of them have been filed since 1995. In accordance with TRIPS, India is now opening the mailbox to consider these pending applications. The Ordinance provides a special regime for them¹: although the 20-year term will be counted from the date of the patent application, the protection will be effective only from the date the patent is granted.

This means that products in the mailbox will be protected by patents for less than the usual 20 years. In fact, as long as the application remains in the mailbox and the patent is not granted, generic manufacturers can freely produce the drug without fear of legal action. Once the patent is granted, however, generic manufacturers will have to either obtain a voluntary license from the patent-holder or a compulsory license from the Patent Office, and pay royalties to the patent-holder - in the absence of either, they will be forced to stop production.

India's 1970 Patent Act and subsequent amendments contain 19 sections on compulsory licences⁷. These provisions are explicitly based on the TRIPS Agreement objectives and principles⁸ and on the Doha Declaration of TRIPS and Public Health. It is crucial that the Indian government make full use of these provisions in order to promote access to medicines in India and other developing countries. It would be important to have swift procedures and clear guidance for royalty rates so that the granting of compulsory licenses is not held up in legal appeals and squabbles over royalties.

⁵ The Doha declaration is available at www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

⁶ "Determining the patent status of essential medicines in developing countries". Health Economics and Drugs, EDM Series no. 17. WHO, 2004.

⁷ India's 1970 patent act and subsequent amendments are available at www.patentoffice.nic.in. References to compulsory licence provisions in the Patent Act are contained in Chapters XVI and XVII.

⁸ TRIPS Agreement Articles 7 and 8.

To fulfil its leading role as supplier of affordable medicines to other developing countries, India must also put in place legislation that will facilitate generic production for export. According to the TRIPS Agreement, compulsory licensing must be used “predominantly for the supply of the domestic market”, i.e. countries cannot issue a compulsory license in order to produce for export only⁹. At the Ministerial conference in Doha, WTO members recognised that this limitation has a direct effect on countries which do not have the capacity to produce their own medicines, since their only chance of gaining access to a given generic would be if India or another manufacturing country were able and willing to issue a compulsory license for that medicine *and* could dispose of the majority of the production within its national boundaries. Subsequent discussions of this issue at the WTO concluded in a statement known as the “August 30th decision”¹⁰: countries that do not have capacity to manufacture generics themselves will be able to import from another country if that country issues a compulsory license and if both parties inform the WTO of the nature and duration of the licence and the product quantities involved.

In accordance with the August 30th decision, India’s Patent Ordinance includes a provision on compulsory licensing for export¹¹. However, it requires a compulsory license to be granted by the importing country - this may unwittingly bar many least-developed countries from gaining access to Indian generics¹²: a compulsory license can only be issued for a product that is patented in that country, and pharmaceutical companies tend not to file patents in all least-developed countries, since these countries do not have to grant or enforce drug patents until 2016 and have no production capacity. The Indian parliament should delete all reference to compulsory licencing in importing countries, a specification that is in any case more restrictive than the WTO text itself.

The WTO August 30th decision contains layers of complex requirements which will pose hurdles to companies seeking to produce generic medicines for export. It is vital that the Indian government create a fast and automatic system for granting compulsory licences to ensure that generic manufacturers are not dissuaded from producing medicines for export to other countries.

2. Prohibit patenting of “new use of a known substance”

According to the TRIPS Agreement, patents can be granted on any inventions that are “new, involve an inventive step and are capable of industrial application”¹³. Patents are granted for twenty years. However, pharmaceutical companies use deliberate strategies to prolong their patents, known as “evergreening”. One of these methods is applying for another patent on a previously patented product, claiming “new use” of the drug. For instance, the AIDS drug AZT’s patent is about to expire in 2005. Let us imagine that scientists discovered that AZT could also be used against some other disease. If countries agreed to grant “new use” patents for AZT, they would not be able to benefit straight away from lower prices of generic AZT for this other disease but would have to wait another 20 years. Although the TRIPS Agreement does not require WTO members to grant patents on these new uses, many countries do so anyway.

Section 3 of India’s original 1970 Patent Act stated that “new use for a known substance” was not sufficient basis for granting a patent. But the December 2004 Ordinance replaces “new use” with “mere new use”¹⁴. This revised definition widens the scope of patentability, as it does not elaborate on what type of “new use” *is* patentable. The term “mere” should be removed from the text in order to limit excessive patent protection. India can also restrict the number of patents granted by refusing to grant new patents for other secondary inventions, such as “new formulation” or “new combination” of known molecules.

⁹ TRIPS Article 31(f).

¹⁰ WTO Decision of the General Council on the Implementation of paragraph 6 of the Doha Declaration, 30 August 2003. http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

¹¹ Patent (Amendment) Ordinance, paragraph 54, section 92A.

¹² See “Indian TRIPS - Compliance legislation under fire”, BRIDGES, vol.9(1), 19 January 2005.

¹³ TRIPS Agreement Art. 27.1.

¹⁴ Patent (Amendment) Ordinance 2004, section 3(a).

3. Opt for a system of "pre-grant opposition" of patents

India's 1970 Patent Act contained a system of checks and balances to prevent granting of illegitimate patents: in particular, it allowed a patent application to be contested by any interested third party before the patent was granted (so-called "pre-grant opposition"). Unfortunately, in order to streamline the patenting process, the December 2004 Ordinance reduces pre-grant scrutiny in favour of "post-grant opposition" (challenging a patent once it has been granted). This system unfairly favours brand-name companies: even if a patent is eventually found to be invalid, generic competition will be effectively prevented during the time that it takes to oppose it. Challenging an existing patent can take many years¹⁵.

The TRIPS Agreement does not prescribe a specific type of opposition system, and many WTO Members, such as Canada, Australia and Japan, allow pre-grant opposition. In order to limit the granting of illegitimate patents and contribute to improving access to affordable medicines, the Indian parliament should withdraw this new amendment and return to the text of the 1970 Patent Act.

4. Resist pressure to provide exclusivity to pharmaceutical test data

Although the TRIPS Agreement does not require any *exclusivity* on pharmaceutical test data, it is increasingly being used by developed countries as a new mechanism to delay competition of generic medicines, and developing countries are coming under pressure to provide it. This practice prevents national drug regulatory authorities from using an originator company's data to register a therapeutically equivalent (or "bioequivalent") generic version of that medicine during a fixed period of time. It is completely separate from patent protection, yet it creates a patent-like monopoly during the period of data exclusivity, which usually lasts from five to 10 years.

Thankfully, this type of data exclusivity does not exist in India today. TRIPS only requires WTO countries to protect pharmaceutical test data against "unfair commercial use"¹⁶ - but this gives full permission to national drug regulatory authorities to register/authorize the marketing of generic medicines on the basis of the pharmaceutical tests submitted by the originator company¹⁷. It is important that India continue to resist pressure to provide exclusivity on pharmaceutical test data.

INDIA HAS A CHOICE - AND A RESPONSIBILITY

Five years ago, after increasingly bleak statistics about the scale of the AIDS pandemic, hopeful stories at last started to emerge: as the price of first-line AIDS drugs came down, thanks in major part to competition from Indian pharmaceutical manufacturers, treatment came within reach of developing countries. Today, an estimated 700,000 people have access to treatment in developing countries - a fraction of those who need it, but the beginning of what could be remarkable progress. But when these patients start requiring second-line treatments, prices per treatment per individual will shoot up due to lack of generic competition, and many of the patients and communities will no longer be able to afford the much-needed medicines.

India is the leading global supplier of affordable antiretrovirals and other essential drugs. It is crucial that it allow production and export of generic versions of new medicines to continue. Médecins Sans Frontières urges the Indian Parliament to ensure that the amendments to the 1970 Patent Act incorporate the full flexibilities and safeguards of the TRIPS Agreement and reflect the hard-fought outcome of the Doha Declaration on TRIPS and Public Health, which affirmed that "*the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health and, in particular, to promote access to medicines for all.*" All over the world, lives of people living with HIV/AIDS and other diseases depend on it.

¹⁵ In the United States, where a post-grant opposition system is favoured, studies have found that the quality of patents has been affected. According to the Federal Trade Commission, the US patent and trademark office has been working under the assumption that "...once an application is filed, the claimed invention is effectively presumed to warrant a patent unless the PTO can prove otherwise." See also "*India: Third Amendment of the India Patents Act*" by Dear, B. and Iranian Rao C., 10 January 2005, available at www.asead.org

¹⁶ TRIPS Article 39.3.

¹⁷ Correa, C. "*Protection of data submitted for the registration of pharmaceuticals - Implementing the standards of the TRIPS Agreement*", South Centre, 2002.