

Virtual Mentor

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Health law

Intellectual property and access to medicine for the poor

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India is a significant source of affordable generic medicines for developing and least developed countries (LDCs). About 80 percent of the AIDS drugs that the international medical humanitarian organization Medecins Sans Frontieres (MSF)—better known in the U.S. as Doctors without Borders—uses to treat over 60,000 patients in more than 30 countries are generics from India [1]. Novartis, a Swiss pharmaceutical company, has filed a challenge against India's patent law, specifically a part of the law that restricts the patenting of trivial improvements. MSF warns that this case, which is being heard in the Chennai High Court in India, may have widespread implications for India's ability to sell affordable generic drugs.

Many factors affect the procurement of essential medicines at prices people in poor countries can afford, including knowledge and understanding of domestic and international intellectual property law; market intelligence concerning the pricing and supply of medicines and how to forecast demand; global coordination among governmental and nongovernmental agencies; opportunities for local production of medicines in low and middle-income countries; capacities of health systems and budgets; and regulatory capability [2].

Far more critical than these factors in facilitating the global and regional availability of essential medicines, however, is the use of exemptions and amendments, called "flexibilities," in the Agreement on Trade-Related Aspects of Intellectual Property Rights, known as TRIPS.

The TRIPS regime

TRIPS and the patent right. TRIPS, which is part of the Agreement Establishing the World Trade Organization (WTO), is the most comprehensive international agreement on intellectual property protection ever established [3]. Articles 27 to 34 of TRIPS protect patents; that is, they provide the patent owner with the legal means to prevent others from making, using or selling the new invention for a limited period of time, subject to exceptions. Patent protection has to last at least 20 years from the date the patent application was filed [4].

Exceptions to the patent right. Article 27 of TRIPS allows for certain exceptions to patent protection. Governments can refuse to grant patents for three reasons that may relate to public health: (a) when commercial exploitation of an invention must be

prevented to protect human, animal or plant life or health; (b) when new diagnostic, therapeutic and surgical methods for treating humans or animals are invented; and (c) in the case of certain plant and animal inventions [5].

Article 30 of TRIPS allows governments to make limited exceptions to patent rights if certain conditions are met; if, for example, the exceptions do not unreasonably conflict with the normal exercise of the patent. Under this article, researchers may use a patented invention for research in order to understand it more fully, or the patented invention may be used to obtain marketing approval from public health authorities.

Compulsory licensing. Compulsory licensing is the granting of permission by a government to a party or entity (the licensee) to produce the patented product or process without the consent of the patent owner. Although TRIPS does not specify what requirements must normally be met for a party to obtain a compulsory license, Article 31 states that a compulsory license may be granted in an unusual situation (for example, an emergency) without requiring a party to meet requirements that would normally apply.

Parallel imports/gray imports. Parallel importation (also known as participation in the gray market) involves the buying of goods in a foreign country at a price that is lower than the price at which they are sold in the domestic country and the reselling of those goods in the domestic country at a price less than or equal to the market price in that country. For example, the distributor of medicine X in Australia buys medicine X in Thailand at a low price, then re-imports it into Australia to sell at a price that is the same as, or lower than, the price at which it is directly offered to Australian consumers.

Pre-Doha Round: 1995-2001. When TRIPS went into effect in 1995, the LDCs were exempted from TRIPS patent rules, but most of them lacked production capacity and depended on cheap imports from other countries, such as India, where low-cost generics were available. This general shortage of pharmaceutical manufacturing capacity in LDCs meant that once the generic supplier countries (often other developing countries) became subject to TRIPS patent rules, both the developing and LDC countries would be faced with the prospect of unaffordable drug prices. While theoretically TRIPS provided for some flexibilities (for example, compulsory licensing), poorer countries were pressured by more powerful interests against using such mechanisms.

This crisis in drug availability led to another round of multilateral trade negotiations, known as the Doha Round, out of which came the Doha Declaration on the TRIPS Agreement and Public Health or the Doha Declaration on Public Health for short, in November 2001. The Declaration was revised in 2002) [6].

Doha Declaration on Public Health. In the Doha Declaration, ministers of WTO member countries recognized the gravity of public health problems afflicting poor

countries, especially HIV/AIDS, tuberculosis, malaria and other epidemics. They declared that TRIPS should not prevent WTO member countries from taking measures to protect public health and affirmed the right of WTO members to use the exemptions in TRIPS, which provide flexibility for this purpose. They underscored some of the key flexibilities in the agreement, for example, parallel imports and compulsory licenses.

Nevertheless, it was recognized that compulsory licenses remained subject to some conditions in Article 31 of TRIPS, which caused difficulties for developing countries and LDCs that relied on cheap imported medicines. One provision of TRIPS, for example, required that the bulk of all drugs manufactured under a compulsory license be sold only on the domestic market.

Paragraph 6 of the Doha Declaration attempted to override this hurdle by stating:

We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem....

A solution was reached with the 2003 Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health [7]. It took the form of a temporary waiver that was converted to a permanent amendment of the TRIPS Agreement in December 2005. The amendment allows a WTO member country to modify its domestic patent law so that exports under a compulsory license can assist a country that lacks manufacturing capacity. In accordance with this amendment, an exporting country's total production may be exported to meet the needs of an importing country.

TRIPS: post-2005. Despite the TRIPS flexibilities discussed above, WTO member countries cannot avoid their obligations to protect patents in accordance with the provisions of TRIPS. In 2005 the transitional period for developing countries like India to become fully TRIPS-compliant came to an end.

Conclusion

MSF has cautioned repeatedly that if measures are not found to reduce the prices of expensive patented medicines, the ability of those in poor countries to get essential medicines will worsen [8-10]. Swift action is necessary to prevent further crisis in developing countries and LDCs. One solution that has been advanced is the creation of regional pharmaceutical supply centers that can better access affordable medicines by virtue of economies of scale and cooperation. As discussed above, however, the major obstacle to procuring affordable medicines continues to be the TRIPS regime. In the absence of further amendment, developing countries and LDCs should utilize the existing TRIPS flexibilities as far as is possible.

References

1. As Novartis challenges India's patent law, MSF warns access to medicines is under threat [press release]. New Delhi, India, and Geneva, Switzerland: Medecins Sans Frontieres; September 26, 2006. Available at: http://www.doctorswithoutborders.org/pr/2006/09-26-2006_1.cfm. Accessed November 10, 2006.
2. Reichman JH. Procuring essential medicines under the amended TRIPS provisions: the prospects for regional pharmaceutical supply centers. Paper presented at: Intellectual Property, Trade and Development Conference, Chicago-Kent College of Law; October 12-13, 2006; Chicago, Ill.
3. Carvalho NP. *The TRIPS Regime of Patent Rights*. Norwell, Mass: Kluwer Law International; 2002.
4. World Trade Organization. *TRIPS and Public Health: Dedicated Webpage for Notification*. Available at: http://www.wto.org/English/tratop_e/trips_e/public_health_e.htm. Accessed November 10, 2006.
5. World Trade Organization. *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*. Annex 1C. Available at: http://www.wto.org/english/docs_e/legal_e/27-trips.pdf. Accessed November 10, 2006.
6. World Trade Organization Doha WTO Ministerial. *Declaration on the TRIPS Agreement and Public Health*. November 14, 2001. Available at: http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. Accessed November 10, 2006.
7. World Trade Organization WTP General Council. *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*. August 30, 2003. Available at: http://www.wto.org/English/tratop_e/trips_e/implem_para6_e.htm. Accessed November 10, 2006.
8. The second wave of the access crisis: unaffordable AIDS drug prices...again [briefing note]. Medecins Sans Frontieres; December 10, 2005. Available at: http://www.doctorswithoutborders.org/news/hiv-aids/briefing_doc_12-10-2005.cfm. Accessed November 10, 2006.
9. Amendment to WTO TRIPS agreement makes access to affordable medicines even more bleak: MSF concerned that patients the world over will have to pay the price [press release]. Geneva, Switzerland: Medecins Sans Frontieres; December 6, 2005. Available at: http://www.doctorswithoutborders.org/pr/2005/12-06-2005_1.cfm. Accessed November 10, 2006.
10. Testimony of the MSF on IP provisions in DR-CAFTA & consequences for access to essential medicines [speeches and open letters]. Medecins Sans Frontieres; April 2005. Available at: http://www.doctorswithoutborders.org/publications/speeches/2005/testimony_guatemala_4-2005.cfm. Accessed November 10, 2006.

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