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Intellectual Property and Access to HIV/AIDS Treatment Case Studies

Recent TRIPS-related developments in the rest of the world

In developing countries

Until now, India, Brazil and Thailand have been among the biggest generic ARV producers, both for their own people and for export. This production has been crucial for the supply of affordable treatment in the developing world. It has resulted in competition between producers, which has reduced the price of many ARVs from as much as US$15,000/year per person for a course of combination treatment to as little as US$150/year per person. How have recent outcomes of WTO or bilateral agreements changed the situation?

The Indian case

Until 2005, Indian law did not recognize patents on pharmaceutical products, which enabled Indian companies to make their own generic versions of medicines. India had become one of the world's primary exporters of generic medicines, including AIDS drugs, particularly to many developing countries. As of January 1, 2005 however, the transition period to conform to TRIPS came to an end for a country such as India. In March 2005, the Indian parliament passed amendments to the Patent Act such that pharmaceutical products and processes can now be patented in India.

Some of the first-line ARVs listed on the World Health Organization's model List of Essential Medicines were already in the public domain before the advent of TRIPS in 1995, and therefore no longer patentable. This means Indian generic companies can continue to produce them legally. But this is no longer the case for drugs patented in other countries between 1995 and 2005. Most of the producers of these drugs will have filed for patents in India. As required under TRIPS, those patents have been on hold in a "mailbox" until Indian law was changed in 2005 to comply with TRIPS by recognizing pharmaceutical patents. Under TRIPS, if those patent applications are deemed valid under Indian law, the remainder of the 20 year patent term must now be granted in India to the patent holder. This means that any production of these drugs in India can only legally happen under a compulsory licence or similar authorization. Without such authorization, and hence without competition from generic producers, the price of the drugs will be the monopoly price the patent holder can charge.

Fortunately, the Indian legislation creates a system of automatic compulsory licensing for a generic producer who has made a "significant investment" and is already producing and marketing a drug in India, allowing this production to continue despite a patent. In exchange, as with any compulsory licence, the generic manufacturer must pay a "reasonable royalty" to the patent holder, although the law has not defined what amounts to a reasonably royalty. It remains to be seen what effect this will have on continued production of these generics.

But most drugs will not be covered by this automatic licensing clause – particularly many of the second-line or other new ARVs, which are nearly 10 times more expensive than first-line drugs, and will increasingly be needed as resistance to the first-line ARVs emerges. These drugs will be fully covered by patents. If Indian manufacturers are to be able to export generics of these medicines, the only solution will be to obtain compulsory licenses under the new Indian legislation. In addition to possible procedural hurdles and uncertainty under the new rules on compulsory licensing that now exist in Indian law, this will likely be made difficult by the inevitable political and commercial pressures exerted by both brand-name pharmaceutical companies and countries like the U.S.

India is but one, particularly important, example of how implementing TRIPS will likely restrict the existing sources of supply for lower-cost generic medicines that many developing and other countries need to import. Following the new Indian legislation, access to newer drugs is expected to become more difficult, as these drugs may be subject to at least 20 years of patent protection in all but the least developed countries (and the occasional non-WTO country). Even those countries that are not yet required to give pharmaceutical patent protection under TRIPS will feel the impact, if they need to import medicines from generic producers in countries, such as India, where compulsory licensing is now required in order to export in any significant quantity.

The Brazilian case

Brazil is commonly seen as one of the few countries that will be able to use the exceptions outlined in TRIPS to manufacture patented medications and export them. The Brazilian government's response to HIV is considered a model AIDS program, providing free ARV treatment currently to about 160,000 patients. Part of the reason for this success is Brazil's capacity to manufacture generic ARVs, particularly first-line drugs which were developed before Brazilian law was changed in 1996 to recognize pharmaceutical patents. However, second-line and paediatric therapies are patented and are only available at prices fixed by brand-name companies.

For example, in 2005, the ARV Kaletra® (lopinavir + ritonavir), made by U.S.-based multinational Abbott Laboratories, accounted for a third of Brazil's annual budget for ARVs. The Brazilian government requested that Abbott reduce its price to match what it would cost Brazil to produce it domestically, and also asked Abbott to engage in "technology transfer" by sharing its manufacturing process. Brazil indicated that, without such steps being taken, it would proceed to compulsory licensing of the drug, so that it could be manufactured domestically and more cheaply. Abbott eventually agreed to fix a lower price for a period of 6 years, in exchange for Brazil agreeing to forego using generics or seeking further price reductions.

This was not Brazil's first hard negotiation with multinational brand-name pharmaceutical companies. It has successfully compelled drug companies to lower prices on AIDS medicines several times in recent years by threatening to break their patents and produce generic versions locally. Still, the outcome of this particular negotiation process – i.e., agreeing to forego the use

of compulsory licensing —was disappointing, including for other developing countries, because it abandoned the immediate possibility of manufacturing a second-line generic ARV.

The Thai case

Like Brazil, Thailand has the domestic capacity to manufacture generic medicines, and is producing some ARVs through its Government Pharmaceutical Organization. But a major threat to access to medicines comes from the U.S.-Thailand Free Trade Agreement that is currently being negotiated in secret. As already achieved in a string of similar agreements with other countries and regions (Jordan in 2000, Chile in 2003, Singapore in 2003, Australia in 2004, Bahrain in 2004, five Central American countries in 2004, Morocco in 2004 and Peru in 2005), the U.S. proposals aim to block generic competition and in other ways reduce the ability of governments to control drug prices.

For example, the U.S. is proposing not only stricter limits on compulsory licensing but also extensions of pharmaceutical patent terms beyond 20 years from the date of the patent application. It is also proposing rules on "data exclusivity" would require generic drug companies to conduct their own clinical trials of the safety and efficacy of their "new" drugs, rather than being able to use data submitted by the brand-name company in getting original marketing approval for the originator product. This would create additional expense and delay, and also would unethically require repetition of unnecessary research, when all that should be required is to demonstrate the "bioequivalence" of the generic product to the originally approved brand-name drug. All of these proposals go well beyond what is currently required under TRIPS and would limit further the policy options open to Thailand to promote access to affordable medicines. Thai civil society and international NGOs have mobilized in an effort to block such an agreement that would limit Thai patients' access to lower-cost medicines. At the time of writing, these concerns have been ignored and the Thai/US negotiations are proceeding.

In high-income countries

European Union

In May 2006 , the European Parliament and the Council of the European Union adopted a regulation that provides direction toEU countries in implementing the August 2003 Decision in a uniform manner. This regulation came into force in June 2006

The EU regulation is both better and worse than the Canadian legislation.

- The EU regulation is more flexible in that it does not include a limited list of drugs subject to compulsory licensing for export, one of the flaws of Canada's law.

- Like the Canadian law, it allows export to all least-developed countries regardless of WTO membership. It also allows export to a number of non-WTO developing countries that are "low-income" without some of the additional requirements imposed in Canada's law.

- The EU regulation does not offer the possibility for non-governmental organizations or UN agencies to make use of the system, even though they are often the prime suppliers of medicines, unless they have the "formal authorization" of the government of the

importing country. This same unnecessary restriction was added at the last minute to Canada's law.

- As with the Canadian legislation, the EU regulation limits to 30 days the required period of first attempting to negotiate a voluntary licence with the patent-holder before a compulsory licence may issue. But it also goes further, by waiving this precondition in cases of compulsory licensing for "public non-commercial use" and "national emergencies and other circumstances of extreme urgency", something permitted under TRIPS that the Canadian law fails to include.

- The EU regulation also says that, in these circumstances of public non-commercial use or dealing with emergency or urgent situations, the maximum royalty payable to the patent-holder is 4% of the total price to be paid by the importing country for the EU-made generics – the same cap that is set across the board in the Canadian law. However, the EU regulation is less clear in that it simply says this is a maximum royalty rate, and is silent on how to determine the exact royalty rate applicable in the case of export to any given country, which uncertainty could be an important disincentive to generic manufacturers. Furthermore, the EU regulation does not set any cap on the royalty payable in other circumstances, although it does suggest the 4% figure could be used as a reference point, taking into account humanitarian considerations.

United States

Ironically, the country that has been one of the most ardent proponents of strict patent rules and has pressured other countries to eliminate or refrain from compulsory licensing, has itself regularly issued compulsory licenses. The case of threatening to override Bayer's U.S. patent on the antibiotic ciprofloxacin, during the October 2001 anthrax scare that raised fears of bioterrorism, is probably the most well-known case related to medicines. This incident was an important backdrop to the WTO negotiations that led to the 2001 Doha Declaration affirming the right of WTO member countries to use compulsory licensing. However, the U.S. applies a double standard when assessing its own national interest as compared to the health of patients in developing countries. Countries that have tried to limit or balance patents with other public policy goals such as access to medicines inevitably run into opposition from the U.S. as well as other rich nations, where powerful drug companies are based, including threatened or actual trade penalties.

The Doha Declaration states explicitly that all WTO member countries are free to decide the grounds on which compulsory licensing may occur. Yet, since the Declaration was adopted in 2001, the U.S. has negotiated various free trade agreements with developing countries that restrict the use of flexibilities under TRIPS. The U.S. pharmaceutical industry stands strongly behind these efforts. While the intellectual property provisions of these agreements vary in their specific terms, the U.S.'s common objectives are to limit the potential exclusions from patentability, to prevent parallel importation, and to limit the grounds on which compulsory licenses may be granted (such as allowing this only in "emergency" situations). In addition, the U.S. is negotiating for "data exclusivity" provisions preventing any use of scientific data submitted by the original patent-holding company in getting marketing approval. As explained above, this would preclude the simpler process of demonstrating a generic medicine's bio-equivalence to the already approved product, causing additional expense and delay in generic products entering the market. These U.S. proposals are aimed at eliminating flexibilities that exist under TRIPS, at least in theory.

Conclusion

The recent developments in countries such as India, Brazil and Thailand illustrate how access to lower-cost generic medicines could become dramatically more difficult in the coming years. The WTO Decisions of August 2003 and December 2005, ostensibly aimed at loosening the TRIPS patent rules to help secure access to medicines, are untested as yet and will be worth little if no further action is taken. New trade agreements that impose "TRIPS-plus" restrictions must be rejected. Governments must be willing to use compulsory licensing to secure lower-cost medicines for patients in their own countries and abroad, and make the necessary legislative changes that may be required in their domestic law. For those countries without domestic capacity to manufacture generics, it is important that supplier countries adopt legislation to allow easy compulsory licensing for export, learning from and improving upon models such as the legal reforms adopted in Canada, India, and other jurisdictions.