
Intellectual Property and Public Health: The WTO's August 2003 Decision in Perspective

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Carsten Fink

In August 2003, members of the World Trade Organization (WTO) agreed on a waiver to certain WTO intellectual property rules. The waiver was designed to improve access to generic drugs for countries in need. Promoting poor people's access to medicines and vaccines is central to alleviating poverty and fighting the HIV/AIDS epidemic. Only 5 percent of infected patients in the developing world receive the antiretroviral (ARV) drugs that have made AIDS a treatable disease in rich countries. Better access to drugs is equally important for combating malaria, tuberculosis, diarrhea, cancer and many other diseases that annually kill millions of children and working-age adults in poor countries. This note outlines the main elements of the so-called August 2003 Decision and explores how it may affect access to medicines in poor countries.¹

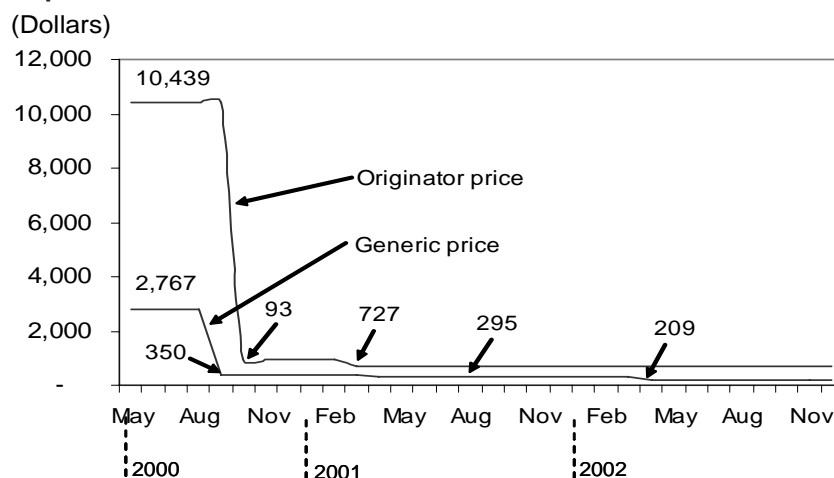
Patents, generics, and drug prices

Newly developed medicines are generally protected by patents that offer time-limited market exclusivity to the patent holder, usually a research-based pharmaceutical company. The patent system provides incentives for pharmaceutical innovation. It allows patent holders to charge prices in rich-country markets that recoup investments in research and development (R&D). But rich-country prices for new drugs can be unaffordable to poor people in the developing world. For example, the cost of an ARV drug therapy in developed nations can easily exceed \$30 a day, whereas three billion of the world's people live on less than two dollars a day.

Efforts have been made to reduce drug prices in poor countries. In the case of ARVs, pharmaceutical companies have offered steep price discounts to developing-country governments. In selected countries, they also have offered drugs for free and provided the health infrastructure needed to make antiretroviral treatments effective. While such actions are laudable, they are not systematic and depend on the good will of private firms. Clearly, the scale of the health crisis in the developing world is too large to be solved by private philanthropy alone.

Another strategy is to rely on manufacturers of generic drugs to produce copycat versions of patented products and so force down prices through market competition. Indeed, the price discounts on ARVs offered by the originator companies were probably brought about as much by competition from generic producers as by voluntary decision (figure 1). As of June 2005, generic manufacturers—especially from India, but also from other developing countries—offered the lowest prices for most AIDS drugs.²

Figure 1: Originator and Generic Drug Prices for a Sample ARV Triple - Combination



Notes: Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year.

Source: Médecines sans Frontières, "Untangling the Web of Price Reductions," various editions, available at www.accessmed-msf.org.

TRIPS, compulsory licenses, and the Doha Declaration

Generic production is possible for the great majority of essential medicines, which currently are not protected by patents in developing countries.³ However, this practice may become more difficult as stronger patent rules required by the WTO have come into effect. As part of the Uruguay Trade Round (1986–94), members of (what is now) the WTO negotiated the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). That agreement obliges countries to extend patent protection to pharmaceutical products and processes. While TRIPS foresees various periods of transition for developing countries, the supply of generics may be significantly curtailed in the near future (box 1).

In principle, governments have the option of overriding the market exclusivity of patents by granting so-called compulsory licenses to generic manufacturers. TRIPS allows the use of compulsory licenses. In cases of "national emergency or other circumstances of extreme urgency," and in cases of public, noncommercial use, it does not even require that the proposed user first make efforts to obtain a voluntary license from the patent holder.⁴

Responding to concerns that the TRIPS patent rules could undermine access to medicines in poor countries, WTO members issued a declaration at their ministerial meeting in Doha, Qatar in 2001, reaffirming the right of governments to use compulsory licenses. Indeed, several developing country governments have granted

compulsory licenses on different AIDS drugs in the past few years—for example, Malaysia, Mozambique, and Zambia.⁵ Notwithstanding these recent cases, compulsory licenses have not been used frequently in the past, for two reasons. First, as pointed out above, most medicines in developing countries have been free of patents, so there has been little need to override market exclusivity. Second, the threat of permitting the production of competing generic medicines has led pharmaceutical companies to offer the drugs at cheaper prices. This arguably happened when some in the U.S. government advocated overriding the patent of the drug Ciprofloxacin during the 2001 anthrax crisis.⁶ Similarly, the pharmaceutical company Roche offered a 40 percent price reduction on its AIDS drug, Viracept, to Brazil after the Brazilian government publicly announced in 2001 that it would issue a compulsory license to a local laboratory.⁷

In the future, as more products in more places will be protected by patents, granting compulsory licenses to local producers may emerge as an effective strategy to promote generic competition in developing countries that have the capacity to manufacture pharmaceuticals. Well-developed pharmaceutical industries can be found, for example, in Argentina, Brazil, China, India, and Thailand. Yet many other developing countries—especially the least developed countries of Africa—do not possess pharmaceutical manufacturing capabilities. These countries can effectively use the compulsory licensing option only if they are allowed to import generic drugs. Yet it was legally uncertain whether this would be allowed under TRIPS (Box 2). Acknowledging the difficulties that countries with insufficient or no manufacturing capacity face in using the compulsory licensing mechanism, the Doha Declaration called for negotiations to solve the problem.

The August 2003 decision

Post-Doha negotiations on implementing the declaration lasted almost two years and were marked by acrimonious debate. Several points of contention emerged—among them which countries should be eligible importers, whether to limit the range of diseases to which the new system would apply, and what kind of reporting requirements and safeguards should be established (Abbott 2005). WTO members were not able to strike a deal by the December 2002 deadline specified in the Doha Declaration, with the United States alone blocking the proposed compromise. Another attempt at consensus failed in February 2003. But in August, amid concerns that the stalled negotiations would risk failure of the September 2003 WTO Ministerial Meeting in Cancún, Mexico, an agreement was reached.⁸

The August 2003 deal consists of a decision by WTO members, accompanied by a statement from the chair of the WTO General Council that spelled out certain shared understandings on the interpretation and implementation of the decision. Key elements of the new system are as follows:

Box 1. Untangling the TRIPS transition periods

The provisions of TRIPS entered into force on a staggered schedule—with the main obligations applicable to developed countries at the beginning of 1996, and most obligations applicable to developing countries as of January 1, 2000. Developing countries were allowed to delay the introduction of pharmaceutical patent protection until the beginning of 2005, and the least developed countries are still entitled to a transition period ending in 2016 (with the possibility of a further extension). At the same time, a convoluted compromise negotiated during the Uruguay Round obliged developing countries that did not immediately provide for patent protection to accept applications for pharmaceutical product patents during the transition period (so-called mailbox patents) and grant “exclusive marketing rights” to those products for five years or until the patent is granted or rejected, whichever is shorter.

In practice, these transition periods mean that pharmaceutical compounds for which patents were filed before the entry into force of the TRIPS agreement (January 1, 1995) will not receive patent protection in those countries that previously excluded pharmaceutical products from the scope of patentability. The compounds that will remain open to generic competition include the great majority of medicines on essential drug lists, among them a number (but not all) of the ARVs. Drugs patented after developing countries implemented their TRIPS obligations—including some of the most effective new treatments to combat HIV/AIDS, malaria, and tuberculosis—are now coming into markets. As time goes by, they will make up a growing share of pharmaceutical sales.

Of special relevance is the situation of India—the most important supplier of generic drugs. Following the conclusion of the Uruguay Round, India opted for the mailbox transition mechanism to fulfill its TRIPS obligation. Full pharmaceutical product patent protection became available only with the 2005 amendments to the Indian Patents Act. However, the March 2005 amendment contains a provision allowing Indian manufacturers to continue generic production of drugs for which mailbox patents are granted. This provision would appear to delay the arrival of medicines supplied under market exclusivity in India.

Least developed countries in Africa and elsewhere will not be required to protect drug patents for the foreseeable future. While many of these countries do not possess generic manufacturing capabilities in the first place, some do, and the staggered structure of the TRIPS transition periods may encourage generic pharmaceutical production in the least developed countries. Pharmaceutical manufacturers in Bangladesh, for example, are seeking to build on this advantage.

- Its applicability is not limited to a predefined set of diseases (as was favored by some WTO members during negotiations) or to emergency situations.⁹ At the same time, members acknowledged that the system should not be used “as an instrument to pursue industrial or commercial policy objectives.”
- Eligible importing members are defined as any least developed country as well as any other member that finds that it has insufficient pharmaceutical manufacturing capacity for the product in question. However, several developing countries indicated that they would use the system only in situations of national emergency or other circumstances of extreme urgency.¹⁰ The majority of OECD countries and the countries that recently acceded to the European Union opted out of the system altogether.¹¹
- The importing member must notify the WTO of its grant of a compulsory license (or its intention to make such a grant) and the names and expected quantities of the pharmaceutical products needed.¹² The exporting member must notify the WTO of the name of the generic manufacturer(s), the products and quantities for which the license is granted, and the countries to which generic drugs are to be exported. In addition, the exporting manufacturer has to post detailed information about its shipments on a dedicated website.
- A number of safeguards minimize the risk that drugs produced under the system and destined for poor countries should leak into rich countries’ pharmaceutical markets. Prices of patented medicines are substantially higher in the developed world, creating opportunities to profit by illegally diverting drugs. Thus, pharmaceutical products produced under the system have to be appropriately labeled and, to the extent possible, distinguished through special packaging, coloring, and shaping (provided this does not significantly affect prices). In addition, importing countries must take reasonable measures to prevent reexportation of the products in question.

The August 2003 Decision takes the form of a waiver of existing TRIPS rules. It also instructs WTO members to adopt a permanent amendment to the TRIPS agreement that would be based, “where appropriate,” on the decision. This has not happened, because WTO members still hold different views on the amendment. The United States—supported by Japan and Switzerland—would like it to include a reference to the statement by the chair of the General Council, a step opposed by many developing-country members, which argue that such a reference would elevate the legal status of the chair’s statement, which they view as separate from the decision.

Several of the members that said they would use the system only in emergencies have emphasized that their undertaking was voluntary. They oppose an amendment that would formally incorporate a list of countries opting out of the system. The group of African WTO members has proposed an amendment that does not refer to the chair’s statement and that eliminates several provisions of the decision that the

group views as redundant—for example, certain notification requirements. Several developed-country members have criticized the proposal as upsetting the delicate balance achieved in the August 2003 Decision.

Meanwhile, the August 2003 Decision retains its full legal effect. Several WTO members have begun to implement it in national laws and regulations. Canada and Norway were the first countries to amend their patent laws in 2004, allowing generic manufacturers from these countries to become exporters under the new system. India also implemented the decision as part of its March 2005 amendment to its patent act—an important step because some of the world’s most competitive generic manufacturers are located in there. In addition, legislative changes are under way in the European Union, Republic of Korea, Switzerland, and elsewhere.

How important is the new system?

To date, the system has not been used, and it may not be used for some time, as most drugs are not covered by patents in key producer countries—notably India (see box 1). In addition, there is no need to invoke the system if an exporting

Box 2. Imports of generic drugs under compulsory license and TRIPS rules

The TRIPS agreement does not prohibit governments from *importing* generic drugs under a compulsory license. Instead, the conflict arises in the exporting country. Article 28 of TRIPS confers on patent holders the exclusive right to *make* patent protected products. Thus if a generic manufacturer in country A produces a drug for export to country B (where the government has issued a compulsory license), it may infringe on the rights of the patent holder in country A.

A special case arises if the drug in question is already produced under a compulsory license in country A. Article 31(f) of TRIPS mandates that compulsory licenses “shall be authorized *predominantly* for the supply of the domestic market of the Member authorizing such use.” (Emphasis added.) If compulsory licenses are granted in large developing countries such as Brazil, China, and India, a nonpredominant share of production could still represent a significant supply for least developed countries. However, there may well be situations in which an exporter in a member country, acting in response to a compulsory license issued by another member (with insufficient capacity), would not intend to sell a predominant part of its production in the local market. Finding a solution to that problem was the crux of the post-Doha negotiations on TRIPS and public health.

country grants a compulsory license to supply the domestic market and a “nonpredominant share” of production is exported (see box 2).

But as more patented drugs come onto developing-country markets, there may well be situations in which countries with no or insufficient manufacturing capabilities seek to import under compulsory license medicines that are not available abroad as generics. While compliance with the decision’s notification and safeguard requirements seems manageable, there are other barriers to overcome. In particular, it may take more than a year and significant up-front investments for a generic supplier to deliver quality medicines. Ensuring interim supplies from the patent holders and finding foreign manufacturers willing to take on the business risk involved—especially if the quantities involved are small—may not be easy. In any case, even if the system is not used frequently, countries with insufficient manufacturing capability are now in a more credible position to break the price hold of pharmaceutical patents when negotiating drug prices. As pointed out above, the threat of compulsory licenses has been a valuable bargaining tool for governments in the past.

Moving forward: the need for further action

The August 2003 Decision was an important landmark in ensuring consistency between multilateral intellectual property rules and public health objectives. Yet progress in resolving intellectual property–related conflicts is insufficient to widen access to medicines in poor countries. Complementary action is needed in several areas.

First, sufficient financial resources are needed to fight the developing world’s health crisis. While substantial funding has become available in recent years, UNAIDS projects a gap between pledged funds and real needs totaling more than \$18 billion over the next three years. The agency says that annual spending of \$22 billion will be needed by 2008.¹³

Second, to effectively treat patients in poor countries, large investments in complementary health infrastructure are necessary, including hospitals, roads, warehouses, and medical personnel. In addition, the procurement of generic drugs requires the development of quality control mechanisms. In the case of ARVs, drugs of inferior quality can cause AIDS patients to become resistant, even to drugs of better quality. A WHO program to prequalify generic producers of ARVs already helps governments in selecting quality generic medicines. That program needs to be complemented by quality assurance regulations at the national level—and by greater capacity to implement and monitor those regulations.

Third, relatively little research has been done on diseases that are prevalent in the developing world but not common in rich countries. For such diseases, the low purchasing power of patients in poor countries limits the incentives for research-based pharmaceutical companies to invest in such research (even if the economic

value of patents remained undiluted by compulsory licenses.) In 2003, North America, the European Union, and Japan alone accounted for 88 percent of the \$466 billion of global pharmaceutical sales. The low-income countries with the heaviest disease burden probably account for less than 2 percent of global sales. It is therefore important to find alternative incentive mechanisms and funding sources to encourage more R&D specific to developing countries.¹⁴

Conclusion

The WTO's August 2003 Decision has established a new system for countries with insufficient manufacturing capabilities to import generic medicines under compulsory licenses. Fully operational until replaced by a formal amendment to the TRIPS agreement, it may develop into a useful policy option as the share of drugs patented in the developing world grows over the next five to ten years. Meanwhile, it will be important to address other barriers to promoting access to medicines—notably insufficient funding, weak health infrastructures, and inadequate incentives to engage in R&D specific to the diseases of the poorest countries.

Notes

1. This Trade Note was written by Carsten Fink, Senior Economist at the World Bank Institute. It is a revised version of Trade Note No. 5, which was published in May 2003. Comments by Frederick Abbott, Carlos Braga, Philip John Hedger, Manjula Luthria, Richard Newfarmer, Juan Rovira, Beata Smarzynska Javorcik and Arvind Subramanian are gratefully acknowledged.

2. Comparing prices of originator and generic drugs is a tricky business. For example, some of the generic manufacturers listed in the pricing guides published by Médecins Sans Frontières are not prequalified by the WHO as meeting standards of quality and compliance with good manufacturing practices. These manufacturers do not necessarily produce substandard medicines, as exclusion from the WHO list does not mean that a drug has failed to gain approval from a national drug regulator. Different price quotation practices with regard to transportation and distribution costs, as well as currency fluctuations, further complicate price comparisons.

3. The World Health Organization's Model List of Essential Drugs has excluded many drugs protected by patents, as affordability is one of the criteria used in designating medicines as essential. However, WHO's latest list includes a significant number of patented drugs (particularly for treatment of HIV/AIDS).

4. The term "compulsory license" is often used loosely. As a matter of domestic policy, there is an important distinction between use of a patent by third parties (private firms) and use by governments.

5. See WHO Document EB115/32 ("Antiretrovirals and Developing Countries"). In the case of Malaysia, the license in question was for the import of antiretroviral drugs from India for use in public hospitals only.

6. According to a October 2001 press release of the U.S. Department of Health and Human Services, Bayer agreed to supply ciprofloxacin at \$0.95 per tablet, much less than the previous discounted price of \$1.77 (<http://www.os.dhhs.gov/news/press/2001pres/20011024.html>). In a January 2002 "Form 20-F" filing with the U.S. Securities and Exchange Commission, Bayer informed investors that "in response to the recent bioterror attacks in the United States, the

U.S. and Canadian governments contemplated compulsory licensing of our ciprofloxacin antibiotic—in effect, permission to generic manufacturers to market ciprofloxacin before the expiry of our patent rights.”

7. See the press release by Roche, dated August 31, 2001. <http://www.roche.com/media-news-2001-08-31-e.pdf>.

8. The Cancún WTO Ministerial Meeting failed anyway, for different reasons.

9. The decision refers to the public health problems recognized in paragraph 1 of the Doha Declaration. That paragraph reads: “We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”

10. These countries are Hong Kong (China), Israel, Republic of Korea, Kuwait, Macao (China), Mexico, Qatar, Singapore, Taiwan (China), Turkey, and the United Arab Emirates.

11. These countries include all 30 members of the OECD (except Republic of Korea, Mexico, and Turkey) as well as Cyprus, Estonia, Latvia, Lithuania, Malta, the Slovak Republic, and Slovenia

12. This notification is required only if the drug in question is protected by patent in the importing country.

13. See “Resource Needs for an Expanded Response to AIDS in Low and Middle Income Countries,” presented to the UNAIDS Programme Coordinating Board in 2005 (available at www.unaids.org).

14. The World Health Organization’s Commission on Intellectual Property Rights, Innovation, and Public Health is collecting proposals to this effect (see [www.who.int/intellectual property](http://www.who.int/intellectual%20property)).

References

Abbott, Frederick M. 2005. “The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health.” *American Journal of International Law* 99: 317–58.

Data sources

Data on the number of people infected by HIV/AIDS and the number who receive antiretroviral drugs are from UNAIDS. The \$30 figure on the estimated costs of antiretroviral therapy in developed countries is approximately equivalent to the \$10,439 figure shown in figure 1. The figure on global pharmaceutical sales in 2003 and the share of North America, the European Union and Japan in these sales are from the IMS Health Review 2004.

