Implementing the Doha Mandate on TRIPS and Public Health

Recent negotiations at the World Trade Organization (WTO) on patents and public health have sought to implement the work program agreed in Doha in 2001 on improving access to generic drugs for poor countries. Promoting poor people’s access to medicines and vaccines is central to the alleviation of poverty. This is most urgently the case for fighting the HIV/AIDS epidemic. Currently, only six in a thousand of infected patients in the developing world receive the anti-retroviral (ARV) drugs that have made AIDS a treatable disease in rich countries. It 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 reviews what is at stake in these negotiations and how an agreement at the WTO may affect access to medicines in poor countries.

**Patents, generics and drug prices**

Newly developed medicines are protected by patents that extend time-bound market exclusivity to research-based pharmaceutical companies. 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—when three billion people live on less than two dollars a day.

A number of initiatives have been launched 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 have also offered drugs for free and provided the supporting health infrastructure to make anti-retroviral treatments effective. While such actions are laudable, they are not systematic and depend on the goodwill of private firms. Clearly, the scale of the health crisis in the developing world is too large to be solved by private sector philanthropy alone.

Another strategy is to rely on generic manufacturers to produce copycat versions of drugs and force down prices through market competition. Indeed, the price discounts on ARVs offered by the drug originator companies were probably brought about by competition from generic producers as much as they were voluntary (see Figure 1). Today, for a number of AIDS drugs, generic manufacturers from Brazil, India, and Thailand offer the lowest prices, although the originator drugs remain the cheapest for other ARVs.¹

**TRIPS, compulsory licenses, and the Doha Declaration**

Generic production is possible for the great majority of essential medicines that currently are not protected by patents in developing countries.² However, this practice may become difficult in future as stronger patent rules required by the WTO 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 Intellectual Property Rights (TRIPS). This 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 (see 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 explicitly allows the use of compulsory licenses and, in case of “national emergency or other circumstances of extreme urgency,” does not even require a government to make efforts to obtain a voluntary license from the patent holder. Responding to concerns that the TRIPS patent rules could undermine access to medicines in poor countries, members of the WTO issued a Declaration at the Ministerial Meeting in Doha, Qatar in 2001, which reaffirms the right of governments to use compulsory licenses. In practice, few compulsory licenses have been issued, for several reasons. First, as pointed out above, most medicines in developing countries have been free of patents, such that there has been little need to issue compulsory licenses. Second, the granting of such a license can involve complex administrative processes and can be subject to political pressures. Third, the threat of permitting the production of competing generic medicines has led pharmaceutical companies to offer the drugs at cheaper prices themselves. This was arguably the case when some in the United States Government advocated the grant of a compulsory license on the patented drug Ciprofloxacin during the 2001 anthrax crisis. Similarly, the pharmaceutical company Roche offered a 40 percent price reduction on its AIDS drug Viracept to Brazil, after the Government publicly announced in 2001 that it would issue a compulsory license to a local laboratory.

In the future, granting a compulsory license to a local producer may emerge as an effective strategy to promote generic competition in developing countries that have the capacity to manufacture pharmaceuticals. For example, well-developed pharmaceutical industries can be found in Brazil, China, India, or Thailand. Yet many other developing countries—especially the least developed countries in 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 is legally uncertain whether current TRIPS
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. However, developing countries can delay the introduction of pharmaceutical patent protection to the beginning of 2005 and least developed countries are 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 obliges developing countries to accept patent applications for pharmaceutical products during the transition period (so-called ‘mailbox’ patents) and grant ‘exclusive marketing rights’ to these products for five years or until the patent is granted or rejected, whichever is shorter.

In practice, these transition periods mean that pharmaceutical compounds patented before developing countries implemented their TRIPS obligations will never receive patent protection in those countries and are thus open to generic competition. These include the great majority of medicines on essential drug lists, including 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 progressively coming onto the market and will constitute an increasing share of marketed drugs as time goes by. A substantial change is likely to occur in 2005, when all developing countries will be required to protect pharmaceutical product patents and the ‘mailbox’ drug patents will be processed. Least developed countries in Africa and elsewhere will not be required to protect drug patents for the foreseeable future, but this is of minor relevance as most of these countries do not possess generic manufacturing capabilities in the first place.

rules allow importation in such a case (see Box 2). The ‘Doha Declaration’ acknowledged the difficulties countries with insufficient or no manufacturing capacity face in effectively using the compulsory licensing mechanism and called for negotiations “… to find an expeditious solution to this problem … before the end of 2002.”

Post-Doha negotiations

Post-Doha discussions on implementing the Declaration’s work program focused on a number of rules that would govern the new importing mechanism. Which countries should be eligible importers? From a purely economic perspective, there is little reason to prevent any country from importing generic drugs under a compulsory license. If a government decides to dilute the exclusive rights conferred by a patent, it seems best to purchase drugs from the most efficient source, regardless of where this source is located. This type of economic reasoning played little role in the negotiations, however. The eventual compromise text put forward by the Chairman of the TRIPS Council in December 2002 defined ‘eligible importing Member’ as any least-developed country as well as any other Member that has found that it has insufficient pharmaceutical manufacturing capacity. Another focus of negotiations was the development of safeguards to minimize the risk that drugs destined for poor countries leak into rich countries’ pharmaceutical markets. This is a legitimate concern. Sharp price differences between developed and developing countries create immense profit opportunities from smuggling of drugs. The December compromise text required, for example, that importing countries make a notification to the WTO, detailing the names and expected quantities of imported drugs, and that generic drugs benefiting from the system are appropriately labeled. While developing countries were concerned that some of the safeguards could be too burdensome to allow effective use of the mechanism, they supported them. Clearly, every government has an interest that an instrument designed for poor countries does not undermine pharmaceutical companies’ primary markets.

Nonetheless, WTO Members were not able to strike a deal by the agreed December 2002 deadline. In the end, the United States alone opposed the proposed compromise. It was concerned that the solution could be abused by developing countries to pursue industrial policy objectives and reduce the value of patents and the incentives for future drug research. The US Government sought to restrict an
Box 2: Why importation of generic drugs under a compulsory license may conflict with TRIPS rules

The TRIPS Agreement does not explicitly prohibit governments that wish to grant a compulsory license from importing generic drugs. Instead, the conflict arises in the exporting country. Article 28 of TRIPS confers patent holders the exclusive right to make patent protected products. Thus if a generic producer in country A wishes to produce the drug for export to country B (where the Government has issued a compulsory license), this producer may violate the patent rights in her home country A.

Some legal scholars have argued that the Government in country A could invoke Article 30 of TRIPS, which provides for limited exceptions to conferred patent rights, and thus allow the producer to make and export the drug to country B. But it is uncertain whether such an interpretation of the TRIPS Agreement would be upheld in WTO dispute settlement. The risk of litigation may deter generic manufacturers from producing drugs and governments from allowing such production in the first place.

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.” If compulsory licenses are granted in large developing countries such as Brazil, China or India, a “non-predominant” share of production could still represent a significant supply for least developed countries. However, there may well be cases in which a Member is requested by another Member (with insufficient capacity) to fulfill a compulsory license when the prospective exporter would not intend to provide a predominant part to its local market. The current legal uncertainty is therefore unsatisfactory.

agreement to HIV/AIDS, tuberculosis, malaria and other infectious diseases of comparable concern to public health. This was unacceptable to developing countries. They saw such a restriction as a retreat from the Doha consensus which, in their view, did not impose a limitation on the diseases covered. The text of the Doha Declaration recognizes “… 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.”

From the viewpoint of public health policy, limiting the scope of diseases also seems a costly way of addressing concerns over the possibility that an agreement might be abused. While HIV/AIDS, malaria and tuberculosis undoubtedly represent grave public health concern in the developing world, certain non-infectious diseases, such as cancer, heart disease, asthma and diarrhea are major causes of mortality among poor people. For example, according to data from the World Health Organization (WHO), non-infectious diseases account for 47.2 percent of Africa’s disease burden, as measured by disability-adjusted life years. Since December 2002, several compromises have been proposed to overcome the negotiating deadlock.

The European Union suggested assigning a role to the WHO to assess which diseases constitute a public health concern in a developing country. The Chairman of the TRIPS Council proposed limiting an agreement to “national emergencies or other circumstances of extreme urgency.” Developing countries have opposed these proposals, expressing concerns that such requirements would create a two-tier system whereby the poorest countries with insufficient manufacturing capacity would face a greater barrier for using compulsory licenses than other WTO Members. Recall that the TRIPS Agreement already allows OECD countries and middle income countries such as Brazil, China or Thailand that possess pharmaceutical manufacturing capacity to use compulsory licensing without any scope of diseases limitation or the need to declare a national emergency.

Moving forward: the need for complementary action

Finding a practical solution to the current negotiating impasse would be desirable—not least because the lack of progress on TRIPS has negative implications for advancing the broader Doha Development Agenda. Yet progress at the WTO alone is
not sufficient for effectively promoting access to medicines in poor countries. Complementary action is needed in several areas.

First, governments in both developing and developed countries need to offer incentives for pharmaceutical patent-holders to systematically differentiate prices for new medicines according to ability to pay—beyond the voluntary price discounts seen so far. For example, rich countries already prohibit the parallel importation of patented medicines sold in the developing world and such rules need to be rigorously enforced. Policymakers in the developed world should also abstain from using prices observed in poor nations as implicit or explicit reference values for price regulations in rich country markets. With such guarantees, pharmaceutical companies would be in a better position to establish differentiated pricing structures that are sustainable in the long term and that extend to developing country retail markets.

Second, funding for fighting the developing world’s health crisis needs to be scaled up. For example, the latest projections by UNAIDS put the cost of the global struggle against AIDS at $10.5bn a year by 2005 and $15bn a year by 2007, up from estimated aid flows of just $3bn in 2002. The Global Fund to Fight AIDS, Tuberculosis and Malaria remains cash-strapped. The US Senate recently passed a five-year, $15 billion bill to fight HIV/AIDS in Africa and the Caribbean. This significant commitment may inspire other countries to increase their own contributions.

Third, to effectively treat patients in poor countries, large investments in complementary health infrastructure are necessary, including hospitals, roads, warehouses, doctors and nurses. In addition, the procurement of generic drugs requires the development of quality control mechanisms. In the case of ARVs, sub-standard quality drugs can lead AIDS patients to quickly become resistant to drugs. A WHO program of pre-qualifying generic producers of ARVs already helps governments selecting quality generic producers. This program has been financed by donor contributions from a number of governments, but these resources have recently dried up. It is important to ensure the financial sustainability of this international public good. In addition, the WHO program may need to be complemented with quality assurance regulations and increased capacity for implementing and monitoring them at the national level.

Finally, relatively little research has been undertaken into diseases prevalent in the developing world, but not common in rich countries. Even if patents were not diluted by compulsory licensing, the low purchasing power of patients in poor countries would limit the incentives for research-based pharmaceutical companies to invest in such research. In the 12 months to October 2002, developed countries accounted for more than 95 percent of the $270 billion of sales in the world’s leading 20 country markets worldwide. The group of developing countries that may benefit from a WTO agreement on importing generic drugs under compulsory licensing probably accounts for less than 1 or 2 percent of global pharmaceutical sales. It is therefore important to find alternative incentive mechanisms and funding sources to encourage more developing-country specific R&D.

It is likely that the discussions on TRIPS and public health will stretch out until the WTO Ministerial Meeting in Cancun, Mexico in September 2003. Developing countries have a legitimate case to argue for a practicable and long-lasting solution that addresses public health concerns of poor countries with insufficient manufacturing capacity. Yet it is equally important to address the other barriers to promoting access to medicines that are more binding in the short term.

This Trade Note was written by Carsten Fink, Economist in the Development Research Group. Comments by Frederick Abbott, Philip John Hedger, Manjula Luthria, Richard Newfarmer, Juan Rovira, Beata Smarzynska Javorcik and Arvind Subramanian are gratefully acknowledged. It draws on Chapter 5 of Global Economic Prospects 2002, and an Op-ed by M. Ramphele and N. Stern “The new AIDS fight; Generic Drugs can Make the Money Last” in the New York Times (March 1, 2003).
Endnotes:

1 Comparing prices of originator and generic drugs is a tricky business. For example, the pricing guide published by Médicins Sans Frontières shows that originator drugs are the cheapest for the majority of ARVs among producers pre-qualified by the WHO as meeting standards of quality and compliance with Good Manufacturing Practices. In many cases, however, generic producers not pre-qualified by the WHO offer the cheaper prices. These generic drugs are not necessarily sub-quality products, as exclusion from the WHO list does not mean that a drug has not been approved by one or more national drug regulatory authorities. Different price quotation practices with regard to transportation and distribution costs as well as currency fluctuations often further complicate price comparisons.

2 The World Health Organization’s Model List of Essential Drugs has customarily not included many drugs protected by patents, as affordability is one of the criteria used in designating medicines as ‘essential.’ However, the WHO has recently revised its Model List, and the latest list includes a significant number of patented drugs (particularly in respect to HIV/AIDS).

3 According to a October 2001 press release of the US Department of Health and Human Services (HHS), Bayer agreed to supply ciprofloxacin at 95 cents per tablet to the HSS, which compares with a previously 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 US Securities and Exchange Commission (SEC), 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.”

4 See the August 2001 press release by the Brazilian Ministry of Health (http://portalweb02.saude.gov.br/saude/aplicacoes/noticias/noticias_detalhe.cfm?co_seq_noticia=462).

5 However, the majority of OECD countries pledged not to use the system.

6 Following the breakdown of the negotiations in December 2002, the United States declared a unilateral moratorium confined to HIV/AIDS, malaria, tuberculosis and other infectious diseases. It pledged to not take any developing country that imported generic drugs under a compulsory license to WTO dispute settlement. Switzerland joined this moratorium. The European Union adopted its own moratorium based on the December 2002 text. In addition to the scope of diseases limitation, this sort of moratorium seems unsatisfactory to developing countries. It does not protect developing country governments from private litigation and can be unilaterally revoked. At the same time, the United States itself does not regard this moratorium as a permanent solution and has declared its preference for concluding a multilateral agreement.

Data Sources

Data on the number of people infected by HIV/AIDS and those that receive anti-retroviral drugs are from the WHO. 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 information on Roche’s 40 percent price discount is based on several newspaper articles published in August 2001. The pharmaceutical sales figures in the world’s leading 20 country markets are published by IMS Health Global Services.

Further Reading

