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This paper is one in a series of briefing papers by the International Institute for Sustainable Development. Each of the papers focuses on an issue of particular importance for sustainable development in the South in the WTO's current round of negotiations—the so-called Doha Development Agenda. The aim of the series is to set out, in brief and uncomplicated style, what is at stake in those negotiations for those concerned with international development and the environment. The full set of papers, and more information about IISD's work on trade and sustainable development, can be accessed on IISD's Web site at http://www.iisd.org/trade.

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TRIPS and Public Health

1. The genesis of TRIPS

The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was negotiated to address concerns expressed by developed country industries that depend on intellectual property rights (IPRs) to protect investments in innovation. These industries contended that firms in developing countries were depriving them of valuable property rights by copying their inventions without permission. Among the main *demandeurs* of strengthened worldwide protection of IPRs was the research-based pharmaceutical industry (Pharma) centered in the United States, Europe and Japan. This industry, dominated by relatively few firms, controls almost all patents on medicines in force throughout the world.

During the WTO's Uruguay Round of trade negotiations (1986–94), a number of developing countries expressed serious concerns about proposed rules for more extensive patent protection on pharmaceutical products. Many developing countries, following the earlier lead of developed countries such as Switzerland, did not provide patent protection for medicines. Others, following the earlier lead of developed countries such as the United Kingdom and Canada, had provision for so-called "licences of right" that permitted any person to obtain a license for making a patented medicine provided they paid a royalty.

In the end, the Pharma companies were successful in obtaining a commitment from all WTO members to provide patent protection for pharmaceutical products and processes, but developing countries managed to secure several important concessions on flexibilities. These included longer transition periods for implementing product patent protection (Articles 65.4, 66.1, 70.8-9), limited exceptions to patent rights (Article 30), and provisions allowing compulsory licensing (Article 31), and "parallel importation" (Article 6). These last two flexibilities will be explained below.

2. The impact of patents

Although medicines are affected by various forms of IPRs, the most important from the public health standpoint is the patent. Article 28 of the TRIPS Agreement provides that a patent must give its holder the right to prevent third parties from making, using, offering for sale, selling and importing a patented product (or a product produced by a patented process) without its consent. The holder of a patent on a medicine has the right to prevent competitors from entering the market with equivalent products for a period of 20 years from the filing of the patent application (Article 33).

On one hand, patent protection is widely believed to encourage the development of new and useful medicines by offering higher than competitive market returns to those who invest and succeed. For those who can afford the resulting new medicines, patents may serve a public good by encouraging research and development.

On the other hand, competition in the making and selling of products—including medicines—brings prices down. The entry of so-called generic (or off-patent) medicines on the market, particularly with multiple producers, dramatically lowers prices, serving another public good.

There is an evident tension between granting and enforcing patents on medicines and providing access to them. Patents encourage innovation, but keep prices high. The trade-off is different for those living in the developed and developing worlds. In Switzerland, a patent on a medicine might force a consumer to choose between buying the medicine or a new video camera. In Tanzania, there may be no real choice. An on-patent medicine may simply be unaffordable, and the consequence may well be one of life or death.

3. Developing country procurement options

Developing countries seeking to make medicines available to their citizens at low prices have several options, explored below:

Price negotiation

They can attempt to negotiate with originator-patent holders for better prices. Many Pharma companies have already offered poor countries discounts—in some cases dramatic ones—for medicines such as antiretrovirals used to treat HIV-AIDS. Alternatively, procurement authorities in several developing countries might pool their purchasing power to negotiate even better prices.

However, experience to date is that Pharma originator companies do not match the prices offered by successful generic producers from countries such as India. In any case, to the extent that originator prices have fallen, it has been as a result of pressure from generics. There is nothing remarkable about this. In

the absence of competitive pressure, producers have modest incentives to bring prices down.

Buying generic

As another option, procurement authorities and consumers can seek to purchase generic or off-patent medicines. This is a simple matter if there is no patent on a medicine; many important medicines such as older established antibiotics are no longer covered by patents and are available on the world market at low prices. However, for newer medicines, including antibiotics to fight resistant strains of disease and virtually all antiretroviral medicines, the presence of patents will prevent generic producers from entering the market.

India has not yet implemented patent protection for pharmaceutical products and is not expected to do so until January 1, 2005. Until then, many medicines needed to supply developing country demand for low-price generics will be available from Indian producers. After that date, there will be an increasing problem with the availability of newer low-price medicines.

Compulsory licensing

The TRIPS Agreement provides several options for addressing the problem of patents. The most important affords WTO members the right to grant compulsory licences, including "government use" licences. A compulsory licence authorizes a person other than the patent holder to use the patent without its holder's consent. Article 31 of the TRIPS Agreement permits a compulsory licence to be granted for any purpose, with certain conditions such as "adequate remuneration" to the patent holder, and non-exclusive licensing rights. There is also a requirement to make efforts to negotiate an authorization with the patent holder—a requirement that is waived in cases of public non-commercial use and situations of national emergency or extreme urgency.

Parallel importation

Parallel importation occurs when a country imports, without the consent of the patent holder, a pharmaceutical product that was lawfully manufactured and marketed in another country. By allowing parallel importation, countries are able to identify the lowest worldwide price for lawfully marketed medicines and import them without the consent of the IPRs holder in the importing country. There remains one subject of debate regarding parallel imports: that is, whether a medicine lawfully placed on the market in an exporting country, but without the consent of the patent holder (such as by a compulsory licensee), can be parallel imported. There are some who argue that parallel imports are only allowed when medicines are manufactured and first marketed by or with the consent of the patent holder.

4. Post-Uruguay Round developments

During the Uruguay Round negotiations there were good reasons to be concerned about the effects that more restrictive intellectual property rules would have on developing country public health systems. Soon after the TRIPS Agreement entered into force these concerns became reality. The United States, quickly joined by the European Union, launched an aggressive campaign to force the South African government to abandon progressive health care legislation adopted following Nelson Mandela's election as President. The U.S.-EU campaign was based on South Africa's alleged failure to comply with its TRIPS obligations.

South Africa was not violating the TRIPS Agreement, a fact eventually acknowledged even by the U.S. government, which dropped its "TRIPS-Plus" demands under intense public pressure. Pharma companies, however, continued to pursue an aggressive campaign in the courts of South Africa. This legal action was ultimately withdrawn. However, from the standpoint of developing countries an important lesson had been presented. The TRIPS Agreement would be used—and even abused—to prevent them from addressing their public needs.

Following the South Africa experience, the U.S. initiated a complaint at the WTO against Brazil, challenging certain aspects of its compulsory licensing legislation. Brazil has taken the most effective steps of any country to address HIV-AIDS, including showing a willingness to use compulsory licensing to obtain price reductions from pharmaceutical patent holders. (Brazil also locally manufactures its own off-patent antiretroviral medicines.) Although the United Status claimed that its dispute settlement action at the WTO was only intended to address certain aspects of Brazil's legislation, the action was perceived by many developing countries and NGOs as a wider attack on Brazil's system for delivering medicines at low prices. Again under considerable public pressure, the U.S. withdrew its action, after reaching an understanding with Brazil.

As a result of these experiences, developing countries turned to the WTO for some form of systematic relief. In June 2001 the TRIPS Council for the first time was formally convened to address the relationship between the TRIPS Agreement and public health. This effectively began the negotiations that led to the adoption in November that year of the Doha Declaration on the TRIPS Agreement and Public Health.

5. The Doha Declaration on the TRIPS Agreement and Public Health

The Doha Declaration, unanimously adopted by WTO Ministers, includes three preamble statements (Paragraphs 1–3), an agreement on principles for interpretation of the TRIPS Agreement in the field of public health (Paragraph 4), provisions confirming existing TRIPS flexibilities and reaffirming WTO member sovereignty (Paragraph 5), a mandate

for negotiations regarding compulsory licensing for countries with limited or no manufacturing capacity (Paragraph 6) and a further extension of compliance deadlines for least developed WTO members (Paragraph 7).

The critical agreement on principles states:

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' *right to protect public health and, in particular, to promote access to medicines for all.*

The italicized text recognizes that WTO members have a "right" to protect public health. This right must be taken into account when examining claims by IPRs holders. A balancing is envisaged, but that balance must favour promoting "access to medicines for all."

Paragraph 5 in the Doha Declaration

Paragraph 5 of the Doha Declaration affirms the rights of members to grant compulsory licences on any grounds—not only in cases of national emergencies. The requirement to try to negotiate an agreement with the patent holder, found in the TRIPS Agreement, still stands. But this requirement does not apply in cases of national emergency/extreme urgency, and the Doha Declaration makes it clear that it is the sovereign right of each member to judge when these situations exist. (Prior negotiations with the patent holder may also be waived in cases of public non-commercial use, although that aspect was not specifically addressed in the Doha Declaration.)

Paragraph 5 also confirms the right of WTO members to adopt their own policies with respect to "exhaustion of rights," meaning a country could declare that a patent holder's rights are internationally exhausted after the product's initial sale. Under such a regime, the patent holder would have no say in approving or blocking parallel imports, since these take place after the initial purchase. This is an important confirmation of countries' ability to use parallel imports as a tool for public health. The question of whether exhaustion of rights may be based on an initial sale by a compulsory licensee—that is, by a legal producer that does not have the consent of the patent holder—remains debated even after adoption of the Doha Declaration.

The Paragraph 6 negotiations

Article 31(f) of the TRIPS Agreement provides that any compulsory licence shall be issued "predominantly" for the supply of the local market. As of January 1, 2005, all developing WTO members will be required to have pharmaceutical patent protection in place. This means that a reliable supply of "off-patent" versions of newer drugs may no longer be available from countries such as India.

After January 1, 2005, countries with adequate production capacity in the pharmaceutical sector will be able to use compulsory licensing as a bargaining tool with respect to patent holders, and will be able to manufacture drugs themselves if prices are too high. However, countries with limited or no capacity in the pharmaceutical sector will not have the ability to make effective use of compulsory licensing because they cannot manufacture locally. Absent a change to Article 31(f), or a favourable interpretation of Article 30 on limited exceptions, these countries would not be able to obtain supplies from countries with capacity to manufacture and export under compulsory licence.

Negotiations under Paragraph 6 of the Doha Declaration were intended to find a solution to this problem by December 31, 2002, but this goal proved unreachable. As early as December 20, 2002, all WTO members, except the United States (and possibly also Japan), indicated their willingness to accept the text of a waiver of Article 31(f) with various conditions that had been proposed by the Chair of the TRIPS Council (dated December 16, 2002). But the U.S. objected to the fact that the waiver did not include a restriction regarding the "scope of diseases" that might be addressed by compulsory licence. It said that the proposed solution should apply only to HIV-AIDS, malaria, tuberculosis and perhaps also to a limited additional list of infectious diseases. It expressed concern that certain higher income developing members would take advantage of the system to build their own pharmaceutical industries and suggested a limitation on the countries that could use the system as importers or exporters.

Developing countries for their part noted that it made little sense from a public health standpoint to limit the "scope of diseases" which can be addressed by compulsory licence since a condition such as HIV-AIDS (that is, causing an immune system failure) results in a myriad of other conditions (including cancer, diarrheal disease and opportunistic infection), and also that people in developing countries suffer from a wide range of disease conditions (including, for example, coronary disease). Since developed country members with adequate capacity in the pharmaceutical sector do not face a "disease limitation" on the grant of compulsory licences, the system envisaged by the United States would be fundamentally discriminatory.

Not until August 2003, under pressure to produce something meaningful for the WTO's Cancun Ministerial Conference in September, did the members manage to agree to legal changes to make it easier for countries to export generic drugs produced under compulsory licensing. Some critics complain that the accompanying safeguards are onerous, particularly for developing countries with limited administrative capacities. In order to prevent such drugs from being re-exported to developed countries, the drugs must be packaged so as to indicate

they were supplied under a special regime, and recipient governments are expected to take "reasonable measures within their means" to prevent re-exports.

At the time of the agreement, most developed countries pledged not to make use of the provisions as importers, and a number of larger developing countries reserved their use as importers only for cases of national emergency.

Maximum flexibility for least developed WTO members

In addition to recognizing the flexibilities inherent in existing TRIPS Agreement rules, the Doha Declaration granted special flexibility to least developed WTO members. Such members need not adopt patent or data protection for pharmaceuticals at least until January 2016. Perhaps of greater importance, these least developed members need not "enforce" existing patent or data protection rights until that date. (As a result of colonial administration, most least-developed countries already have laws that provide for the grant of pharmaceutical patents. The right to "disapply" existing patents is therefore extremely important for these countries.)

Beyond the WTO: "TRIPS-Plus"

From the standpoint of developing WTO members, the biggest TRIPS and public health challenge may lie outside the framework of the WTO. The United States is negotiating free trade area agreements with an increasing number of countries that include extensive "TRIPS-Plus" commitments on intellectual property rights. In particular, these agreements limit the grounds upon which it is permissible to grant compulsory licences. The recent U.S.-Singapore FTA, for example, allows it only in cases of national emergency/extreme urgency, for public non-commercial use or to remedy anticompetitive practices. These new FTAs also incorporate requirements for extending the term of patents in the event of unreasonable delay by the patent office in granting them. And they mandate that countries provide a five-year period of protection for the data submitted in the course of regulatory approval of a medicine, even if the approval was granted in another country.

The cumulative effect of these provisions is to create significant new impediments to entry of generic medicines on the market, and to diminish the ability of the poor to have access. As the United States is able to obtain concessions outside the WTO from governments that otherwise have resisted making them within the WTO, this weakens the developing countries as a group and undermines the multilateral trading system as a whole.

6. Concluding observation

Developing countries were successful in the Doha negotiations for several reasons. Among the most important is that they were able to identify and pursue a coordinated position. This type of cooperation is surprisingly difficult to maintain as governments seek to maximize their own perceived trade advantages (for example, in concluding a bilateral free trade agreement) and in doing so concede what may be collective best interests. A major challenge for developing country trade specialists, including in the field of public health, is to consider how cooperation and coordination can be carried through to collectively successful results.

The International Institute for Sustainable Development contributes to sustainable development by advancing policy recommendations on international trade and investment, economic policy, climate change, measurement and indicators, and natural resources management. By using Internet communications, we report on international negotiations and broker knowledge gained through collaborative projects with global partners, resulting in more rigorous research, capacity building in developing countries and better dialogue between North and South.

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