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The WTO, Intellectual Property Rights, and the Access to Medicines Controversy

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Summary

On August 30, 2003, World Trade Organization (WTO) negotiators agreed to enable developing and least developed countries to access medicines to fight public health epidemics such as HIV/AIDS, tuberculosis, malaria, and other infectious diseases within the context of the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement. In December 2005, WTO members agreed to a permanent amendment to TRIPS to incorporate this decision. The WTO Decision will allow poor developing countries to issue a compulsory license to a third-country producer to manufacture generic drugs at an affordable price. The accord reflects contentious issues in the negotiations including the scope of diseases, country eligibility, and diversion safeguards. Some have questioned the economic utility of issuing compulsory licenses. This report will be updated as necessary.

Issue

In August 2003, the WTO reached an agreement on the use of compulsory licenses by developing countries without manufacturing capacity to access life-sustaining medicines. This agreement was incorporated as an amendment to TRIPS on the eve of the Hong Kong Ministerial in December 2005. The issue of access to affordable medicines is one of great concern to developing countries whose health-care systems are often overwhelmed by HIV/AIDS and other infectious diseases. Some developing countries have viewed the TRIPS agreement as an impediment in their attempts to combat such public health emergencies by restricting drug availability and by transferring scarce resources from developing countries to developed country manufacturers. For the developing world, the issue of compulsory licenses is an important test as to whether the WTO can meet the development needs of its members, and conversely, whether the developing world can influence the actions of the world trading system.

Developed country pharmaceutical industries view the TRIPS agreement as essential to encourage innovation in the pharmaceutical sector by assuring international compensation for their intellectual property. Without such protection, industry claims it

could not recoup the high costs of developing new medicines.[1] Producers have unilaterally undertaken to reduce prices for certain HIV/AIDS medicines, but these efforts at differential pricing have not been systematic.[2] The United States has been forceful in defending the interest of the U.S. pharmaceutical industry in the negotiations. In December 2002, the United States blocked a compromise on the compulsory licensing issue to which all other nations had agreed; however, other countries with pharmaceutical industries such as the European Union, Switzerland, and Japan have also advanced positions consistent with the views of their pharmaceutical concerns.

Background

TRIPS is a component of Uruguay Round Agreements which created the WTO in 1995. It sets minimum standards of protection for patents, copyrights, trademarks and other forms of intellectual property based on three core commitments of the WTO: minimum standards, national treatment, and most-favored-nation treatment. Adherence to TRIPS is a prerequisite for membership of the WTO, and provisions of the agreement can be enforced through the WTO's Dispute Settlement Understanding mechanism.

The Doha Declaration. In agreeing to launch a new round of trade negotiations, trade ministers adopted a "Declaration on the TRIPS Agreement and Public Health" on November 14, 2001.[3] The Declaration sought to alleviate developing country dissatisfaction with the TRIPS regime. It delayed the implementation of patent system provisions for pharmaceutical products for least developed countries (LDC) until 2016. The declaration committed member states to interpret and implement the agreement to support public health and to promote access to medicines for all. It also affirmed the right of WTO members to use the flexibilities in the TRIPS agreement to promote these goals. The declaration reiterated that each member has the right to grant compulsory licenses and to determine the terms and circumstances in which they are issued. Each country also has the right to determine what constitutes a national emergency or circumstances of extreme urgency, defining these terms to include public health crises such as "HIV/AIDS, malaria, and tuberculosis and other epidemics."

Paragraph 6 of the Declaration directed the WTO's Council on TRIPS to formulate a solution to the use of compulsory licensing by countries with insufficient or inadequate manufacturing capability by December 2002. Compulsory licenses are issued by governments to authorize the use or production of a patented item by a domestic party other than a patent holder. They are authorized by Article 31 of TRIPS, which limits their issuance to cases in which the government has made efforts to obtain authorization on reasonable commercial terms or in a circumstance of extreme urgency or national emergency. In addition, the production or use of the invention covered by the patent is

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[1] Pharmaceutical Research and Manufacturers of America , Intellectual Property website, [http://www.phrma.org/issues/intprop].

[2] *Integrating Intellectual Property and Development Policy*, UK Commission on Intellectual Property (CIPR), September 2002, p. 41.

[3] Declaration on the TRIPS Agreement and Public Health, WTO Document WT/MIN(01)/DEC/2, November 14, 2001, available at [http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm].

limited in scope and duration to address the circumstances in which the license is authorized, the right holder is granted adequate remuneration for use of the patent, and such production is predominantly authorized for the domestic market. It is this last provision that was the focus of the Paragraph 6 negotiations because it conveys the right of compulsory licensing only to countries with the capability to manufacture a given product.

The Agreement

The Decision[4] reached on August 30, 2003 adopts the text drafted by a previous TRIPS Council Chairman Eduardo Perez Motta in 2002. That text previously was approved by all WTO members save the United States, which blocked its passage in December 2002 due to concerns of the U.S. pharmaceutical industry about potential abuse of the system. The Decision does not amend the Motta text, but adds a chairman's statement to clarify certain aspects of it . The Decision permits a waiver of Article 31(f) of the 1994 TRIPS agreement, which provides that compulsory licenses are to be used predominantly for the supply of the domestic market. The Decision waives 31(f) for exports of pharmaceutical products to least developed countries (LDC) and countries with insufficient manufacturing capacity. The accompanying Chairman's statement, which does not have the status of a binding legal document, reflects what it terms "several key shared understandings" of Members concerning the interpretation and implementation of the agreement. Disagreements persisted over how to permanently incorporate the Decision and the Chairman's statement into the TRIPS agreement until the eve of the Hong Kong Ministerial in December 2005. On December 6, WTO members agreed to incorporate the 2003 Decision as an amendment and an annex to TRIPS. The chairman's statement was reread, but it was not incorporated into the text of the agreement, which was seen as a concession by the United States.[5] The change will enter into force after being ratified by 2/3 of the member states; the waiver will continue in effect until then.

Disease Coverage. One key issue of the debate was disagreement on the language defining a grave public health threat. The Decision allows compulsory licensing for medicines based on the scope of the language in the Doha ministerial declaration: "HIV/AIDS, malaria, tuberculosis and other epidemics." During the December 2002 debate, developing countries accepted this wording as reflecting the intent of the Doha Ministerial declaration, although they had sought even less restrictive language. However, the U.S. considered this position too broad, and countered with more restrictive language: "HIV/AIDS, malaria, tuberculosis or other infectious epidemics of comparable gravity or scale, including those that may arise in the future."[6] This language was too restrictive for the developing countries, and debate over this language subsequently caused the United States to reject the Motta text. Developing countries were adamant

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[4] Council for TRIPS, "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," (IP/C/W/405), August 30, 2003, and accompanying Chairman's statement available at [http://www.wto.org/english/news_e/pres03_e/pr350_e.htm].

[5] "Proposal for a Decision on an Amendment to the TRIPS Agreement," (IP/C/41), December 6, 2005. [http://www.wto.org/english/news_e/news05_e/trips_decision_e.doc]

[6] "U.S. Sticks to Hard Line on TRIPS, as Supachai Tries to Broker Deal," *Inside U.S. Trade,* December 20, 2002.

that the language in the Ministerial Declaration on the scope of diseases should form the basis for the agreement, and during negotiations in the spring and summer of 2003, the U.S. position seemingly shifted from limiting the scope of diseases to restricting country eligibility.[7]

Eligible Countries. The scope of developing country eligibility to use the compulsory license mechanism has also proven controversial in the negotiations. The term 'developing country' in the WTO runs the gamut from the poorest, least developed countries to middle-income countries like South Korea and Brazil who have their own manufacturing capacity. As stated above, TRIPS grants each nation the ability to assign compulsory licenses to their domestic manufacturers. However, there is a broad range of technical sophistication among the pharmaceutical industries of the developing countries. A country that can make aspirin may not be able to reengineer or reformulate sophisticated drugs in order to utilize the existing compulsory license language of the agreement. The question became whether a country that has some manufacturing capability, but not necessarily a specialized expertise, would be able to use a Paragraph 6 mechanism to issue a compulsory license to a more sophisticated industry in another country to produce a medicine.

The Decision adopted on August 30 set out certain criteria for determining whether a country lacks domestic manufacturing capacity, but essentially countries would self-declare their eligibility by notification to the TRIPS council. It reflects the position of some developing countries to reject any restrictions on their ability to self-determine eligibility. It clarified that eligibility notification would include information on the manner in which a country determined it had no manufacturing capability. However, no formal reviewing mechanism to assess the self-determination of eligibility by developing countries, as the United States proposed, was incorporated into the statement.[8] The Chairman's statement also contained language that the system not be used as an instrument to pursue industrial or commercial policy objectives. This statement reflects industry concerns that the system could serve to aid the expansion of generic pharmaceutical industries in developing nations.

In addition, several groups also indicated they would not avail themselves of using the new compulsory license system. The Decision referred to 23 developed countries that would refrain from using the system as an importer. The chairman's statement reported that the 10 nations joining the European Union will also opt out of using the mechanism as importers from the date of their accession. Until that time, they pledge to use the mechanism only "in situations of national emergency or other circumstances of extreme urgency." In addition, several other nations announced that they would only use the system as importers under this same formulation including Hong Kong, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Taiwan, Turkey, and the United Arab

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[7] "U.S. Government, Industry Wrestle with New Approach to TRIPS and Health," *Inside U.S. Trade*, June 27, 2003.

[8] "U.S. Pushes for System to Review TRIPS Compulsory License Requests," *Inside U.S. Trade*, August 8, 2003.

Emirates. This list reflects U.S. efforts in the negotiations to seek to persuade more advanced developing countries to refrain using the waiver.[9]

Safeguards. Another concern was the issue of the use of safeguards to prevent diversion of these generically manufactured drugs from poor developed countries to developed country markets. The Decision calls for the drugs to be specially marketed or packaged with identifiable characteristics, such as distinguishable colors or shapes "provided that such distinction is feasible and does not have a significant impact on price."[10] It also declared that importing countries should take measures "within their means" to prevent trade diversion to prevent reexportation of products imported into their countries.[11]

The Chairman's statement reaffirmed the importance of protecting the system from diversion of pharmaceuticals to rich country markets. It clarified that specialized marking and characteristics should apply to active ingredients and final products, not just to formulated pharmaceuticals. It also adopted a U.S. suggestion explicitly to state that using special packaging or distinguishing characteristics is feasible and would not affect drug prices.[12] The statement listed several best practices for protecting against diversion in an annex. However, the statement did not incorporate a U.S. proposal to limit distribution of these generic drugs to humanitarian public health programs, either run by the government or by charitable organizations.[13]

Policy Implications

The issuance of compulsory licenses has been advanced as a way for developing countries without domestic manufacturing capability to obtain affordable medicines to treat their populations afflicted with HIV/AIDS and other epidemics. However, a system of compulsory licensing may have a relatively modest effect on the availability of medicines in the developing world. According to then-EU trade negotiator Pascal Lamy, "we have solved about 10% of the problem of access to medicines by developing countries," and cited other issues such as poor distribution systems for medicines in poor countries and the lack of trained personnel to administer the drugs may hinder the effectiveness of the new policy.[14]

Compulsory licenses have rarely been used by developing countries. This situation can be attributed to lack of patent protection in many countries. Developing countries were not required to enforce a TRIPS compliant patent system before 2005, and the

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[9] "WTO Chair Menon Pushes to Finalize Agreement on TRIPS- Essential Drugs," *International Trade Reporter*, August 21, 2003.

[10] Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Note from the Chairman, Paragraph 2(b)(ii), December 16, 2002.

[11] Ibid, Paragraph 4.

[12] *Inside U.S. Trade*, August 22, 2003.

[13] *Inside U.S. Trade*, August 1, 2003; "U.S. Sets New Condition for TRIPS Deal While Showing Flexibility," *Inside U.S. Trade*, August 22, 2003.

[14] "WTO Drug Pact Lifts Trade Talks," *Wall Street Journal*, September 2, 2003.

compliance date for LDCs was extended until 2016 by the Doha Ministerial Declaration. However, some developing countries do have patent regimes that cover some pharmaceuticals. In these countries, the threat of compulsory licensing can be used to negotiate better prices from developed world pharmaceutical manufacturers. Brazil, a country with a relatively sophisticated pharmaceutical industry with the ability to reverse engineer and innovate new drugs, has threatened to use compulsory licensing and manufacture generic HIV/AIDS drugs domestically to extract price concessions from patentholders and is currently in negotiations with several U.S. firms.[15]

Subsequent to the conclusion of the agreement, several nations have announced that they will utilize this mechanism. In Brazil, a Presidential decree issued September 5, 2003, granted the government the authority to import generic medicines without the consent of the patent holder in cases of national emergency or public interest. Mozambique, Zambia, Indonesia, and Malaysia have announced the granting of compulsory licenses for AIDS drugs.[16] In addition, several countries are considering legislation to provide patent waivers to allow their generic pharmaceutical companies to manufacture drugs for compulsory license under the WTO system. Canada, Norway and India have passed legislation amending their patent laws, while Switzerland, France, Korea, and the European Union have also proposed regulations or legislation to comply with the agreement.

There may be little economic incentive for a supplier to manufacture the product in the case of an LDC issuing a compulsory license. Under the system contemplated by the Decision of August 30, 2003, a developing country with no manufacturing capability may use a compulsory license to obtain a product for a generic manufacturer in another country. However, the generic manufacturer in the second country may have no incentive to do so, especially in limited quantities to poor countries. In addition, under many of the proposals the product would have to use special packaging or distinctive shapes to avoid diversion. Under such restrictions, it is not certain that a generic producer would undertake the development and formulation costs for such a limited market.[17] Thus, even though a compulsory license was issued, the drugs may never be manufactured.

According to some non-governmental organizations (NGOs) and AIDS activists, this is precisely the result being sought. One activist claimed that restrictions advocated by the U.S. create "a watertight system so that no generic drugs ever get through to the patients in developing countries who desperately need them."[18] U.S. officials maintain restrictions such as specialized packaging to prevent diversion serves the interest of recipient nations by providing additional safeguards that the medicines will be used by the intended recipients.[19]

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[15] "Brazil Steps Up Pressure on U.S. Companies Over AIDS Drug Prices," *FDA Week*, September 2, 2005.

[16] "Brazil to Issue Compulsory License on U.S. AIDS Drugs," *Inside U.S. Trade,* July 1, 2005.

[17] CIPR, pp. 45-46.

[18] *Medecins Sans Frontieres* News Release, August 25, 2003. available at [http://www.msf.org/content/page.cfm?articleid=E05CFA2B-B49D-4CED-8EA32C8A0588D147].

[19] Press Conference by Ambassador Peter Allgeier, Geneva, June 20, 2003.

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