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

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

Summary

In August 2003, the World Trade Organization (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 Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement 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. Producers have unilaterally undertaken to reduce prices for certain HIV/AIDS medicines, but these efforts at differential pricing have not been systematic. 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, it was also the first nation to ratify the December 2005 amendment.

In the 109th Congress, legislation was introduced (S. 3175, Leahy) to establish procedures to grant compulsory licenses for exporting patented pharmaceutical products to certain countries under the WTO Decision. This legislation was not acted upon in the 109th Congress, but it may be reintroduced in the 110th Congress.

The system of compulsory licensing may have a relatively modest effect on the availability of medicines in the developing world. Compulsory licenses have rarely been used by developing countries because many patent regimes did not protect pharmaceuticals before 2006. Countries providing patent protection to pharmaceuticals have used the threat of compulsory licensing as a method to negotiate lower drug prices. Although some countries have amended their national laws to allow compulsory licensing for pharmaceutical exports, there may be little economic incentive for a supplier to manufacture the product in the case of an LDC issuing a compulsory license. To date, only Rwanda has notified the WTO of its intention to use the WTO notification process to import HIV/AIDS medication from Canada.

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Introduction

In August 2003, the World Trade Organization (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 Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement 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, it was also the first nation to ratify the December 2005 amendment. In the 109th Congress, legislation was introduced (S. 3175) to establish procedures to grant compulsory licenses for exporting patented pharmaceutical products under the WTO Decision. This legislation was not acted upon in the 109th Congress, but it may be reintroduced in the 110th.

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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.

Background

TRIPS is one of the Uruguay Round Agreements, which also 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.[3]

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.[4] 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 (LDCs) 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."

Compulsory Licenses. 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 generally 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, Article 31 limits the scope and duration of a compulsory license to address the circumstances for which the license is authorized, grants the rights-holder adequate remuneration for use of the patent covered by compulsory license, and restricts production authorized by compulsory license predominantly to the domestic market. It is this last provision that was the focus of the Paragraph 6 negotiations because it, in effect, conveys the right of compulsory licensing only to countries with the capability to manufacture a given product.

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[3] The text and a summary of the TRIPS Agreement are available at the WTO website, [http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm].

[4] Declaration on the TRIPS Agreement and Public Health, (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].

The Agreement

The Decision[5] reached on August 30, 2003, adopted 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 did not amend the Motta text, but added a chairman's statement to clarify certain aspects of it. The Decision provided for a waiver of Article 31(f) of the 1994 TRIPS agreement, the language which stipulates that compulsory licenses are to be used predominantly for the supply of the domestic market. The Decision waived 31(f) for exports of pharmaceutical products to least developed countries (LDCs) and countries with insufficient manufacturing capacity. The accompanying Chairman's statement, which did 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.[6] The change would enter into force after being ratified by two-thirds of the member states; the waiver will continue in effect until the ratification period terminates on December 31, 2009.[7] As of November 2007, the protocol has been ratified by the United States, Switzerland, El Salvador, South Korea, Norway, India, the Phillippines, Israel, Japan, Australia, and Singapore. Canada, China, India, Korea, Norway, and the European Union have incorporated into their domestic or community law, although Canada and China have not ratified the agreement. The European Parliament approved the amendments on October 24, 2007, and if approved by the European Council of Ministers, the amendments can be ratified by the EU member states.[8]

Disease Coverage. One key issue of the debate was disagreement on the language defining a grave public health threat. The Decision allowed 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

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[5] 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].

[6] "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]

[7] The ratification period initially was to expire on December 1, 2007, but was extended at a meeting of the TRIPs Council on October 23, 2007.

[8] "WTO Members Extend Deadline for Ratification of Trips Amendments on Essential Medicines," *International Trade Reporter*, November 1, 2007.

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."[9] 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 that the language in the Ministerial Declaration on the scope of diseases should form the basis for the agreement, and this position eventually prevailed. 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.[10]

Eligible Countries. The scope of developing country eligibility to use the compulsory license mechanism also proved 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 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. This position reflected the rejection by developing countries of any restrictions on their ability to self-determine eligibility. The Decision 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.[11] 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.

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

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

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

In addition, several groups also indicated they would not avail themselves of 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 in 2004 would also opt out of using the mechanism as importers from the date of their accession. Until that time, they pledged 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 Emirates. This list reflected U.S. efforts in the negotiations to seek to persuade more advanced developing countries to refrain from using the waiver.[12]

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 called 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."[13] It also declared that importing countries should take measures "within their means" to prevent trade diversion.[14]

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.[15] 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.[16]

Notifications. The Decision also set forth certain notification requirements. An eligible importing member, other than a least developed member, must notify the WTO that it intends to use the system to import medicines under compulsory license. For each instance, the importing country must disclose the name and expected quantities of the medicine sought, affirm that it has insufficient manufacturing capability to produce the medicine itself, and provide confirmation that it has granted a compulsory license to obtain the medicine from a third-country manufacturer.

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

[13] 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.

[14] Ibid., Paragraph 4.

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

[16] *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.

Conversely, an exporting country must provide information on the conditions attached to the compulsory license it approves, the name and address of the licensee, the products involved, the quantities produced, the designated import countries, and the duration of the license. The WTO has set up a website in order to track notifications of the system's use. To date, only Rwanda has notified the WTO of its intention to use the system to import the drug TriAvir from Canada.[17]

U.S. Legislation

In the 109th Congress, the Life-Savings Medicines Export Act of 2006 (Leahy, S. 3175) was introduced to establish procedures to grant compulsory licenses for exporting patented pharmaceutical products to certain countries under the WTO Decision. This legislation was not acted upon in the 109th Congress, but it may be reintroduced in the 110th Congress.

The legislation would have authorized the Director of the U.S. Patent and Trademark Office (PTO) to issue compulsory licenses for the export of generic pharmaceuticals to least developed countries and other developing countries without sufficient manufacturing capability. The legislation explicitly would have permitted using non-governmental organizations to assist in distributing the medicines to the eligible country. It stipulated the content for license applications, established an office within PTO to assist applicants in filing applications, and placed certain conditions on the granted license. Among the latter, the legislation specified that the licensed product be distinguishable from product manufactured by the patent holder in terms of size, shape, color, packaging or other distinguishing characteristics to prevent reexportation of the product.

The normal term for the compulsory license under the bill was set at seven years, and the bill provided for renewal under certain conditions. The Director would have determined the royalty payment by using a formula provided by the bill and by taking into account certain enumerated considerations. The legislation provided for expedited approval of license applications for emergency situations. It also would have established a national advisory board to provide advice and guidance on the implementation of the compulsory licensing program and authorized appropriations for this entity.

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" by the WTO's action. He cited other issues such as inadequate distribution systems for medicines in poor countries and the lack of

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[17] "TRIPS and Public Health: Dedicated Webpage for Notifications," [http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm]

trained personnel to administer the drugs as factors that could hinder the effectiveness of the new policy.[18]

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 compliance date for LDCs was extended until 2016 for pharmaceutical patents 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 to manufacture generic HIV/AIDS drugs domestically to extract price concessions from patent-holders, which it did most recently in 2005.[19]

Subsequent to the Decision, several nations announced that they will use 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 announced the granting of compulsory licenses for AIDS drugs; however, they did not do so under the aegis of the WTO notification system.[20]

In December 2006 and January 2007, Thailand issued compulsory licenses for the production of generic version of two HIV/AIDS medicines (Efavirenz and Kaletra) and the heart disease medication Plavix in India. Thailand's public health minister maintained they undertook this action to provide this medication at an affordable price for its universal health-care system.[21] Despite not issuing the license to a domestic firm, Thailand did not avail itself of the WTO notification system. In its 2007 Special 301 report, USTR placed Thailand on its Priority Watch List, in part, because of a "weakening respect for patents" as a result of the Thailand's compulsory licensing. While USTR acknowledged a country's right to issue compulsory licenses, it criticized what it considered "the lack of transparency and due process exhibited in Thailand."[22] In a June 20, 2007 letter, House Oversight Committee chairman Henry Waxman criticized USTR's action and sought to have Thailand removed from the Priority Watch list and to "abandon any further retaliation for

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

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

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

[21] "Thailand Authorizes Generic Production of Two More Patented Drugs," Bridges Weekly Trade News Digest, January 31, 2007. (www.ictsd.org/weekly/07-01-31).

[22] United States Trade Representative, 2007 Special 301 Report, p. 27.

Thailand's public health efforts."[23] Meanwhile, the Senate approved language in the Food and Drug Administration Revitalization Act (S. 1082) that expressed concern that "certain countries have engaged in unfair price manipulation and abuse of compulsory licensing" and called on USTR to use all tools at its disposal to address IPR concerns and violations (Sec. 516). This language did not appear in the final version of the bill passed into law (P.L. 110-85).

On the export side, 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. As noted earlier, Canada, China, India, Korea, Norway, have enacted legislation amending their patent laws and the European Union has adopted regulations to this effect in June 2006. Switzerland and France 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 Decision, 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.[24] Thus, even though a compulsory license may be issued, the drugs may never be manufactured.

According to some non-governmental organizations and AIDS activists, this is precisely the result being sought by patent-holders. One activist claimed that restrictions, such as special packaging and notification requirements, create "a watertight system so that no generic drugs ever get through to the patients in developing countries who desperately need them."[25] However, U.S. officials have contended that these restrictions preventing diversion serve the interest of recipient nations by providing additional safeguards that the medicines will be used by the intended recipients.[26]

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[23] Letter from Rep. Waxman to USTR Schwab, June 20, 2007, [http://www.henrywaxman.house.gov/pdfs/thailand%20letter%20to%20ustr%2006-20-07.pdf].

[24] CIPR, pp. 45-46.

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

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