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The WTO and Access to Essential Medicines: Recent Agreements, New Assignments

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In November 2001, the World Trade Organization's (WTO) fourth ministerial conference in Doha, Qatar, temporarily weakened intellectual property rules to allow the poorest nations to compulsorily license patented drugs in public health emergencies. Although the main reasons for lack of access to essential medicines are poverty and a lack of health infrastructure, this temporary declaration and its recent signing into full WTO law mean that the WTO can now work on more important factors restricting access to essential medicines. The most obvious obstacle is high tariffs that poor countries impose on medicines and medical devices. These should be removed. The benefits of increased access are considerable and well-accepted, and the revenue lost to poor nations if the tariffs are removed is relatively small.

Perhaps the most divisive topic of discussion prior to the World Trade Organization's fourth ministerial conference was the issue of access to essential medicines in developing countries and the potential harm that WTO intellectual property agreements played in undermining access.

It was therefore a welcome breakthrough for all delegates when trade ministers in an unprecedented yet unanimously agreed-upon action adopted the *Doha Ministerial Declaration on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and Public Health*.[1]

The November 2001 declaration affirmed the flexibility and willingness of TRIPS member states to set aside intellectual property rights for allegedly better access to essential medicines.

WTO Debates, 2001–2005

According to the World Health Organization (WHO), approximately one-third of the world's population lacks access to essential medicines and proper medical treatment.[2] Although this figure—which represents between 1.3 and 2.1 billion people—is a serious cause for concern, access to medicines has actually increased in recent years. In 1975, less than half of the world's population had access to medicines, and although the overall number of people without access to them has remained constant, the proportion of the world's population without access has fallen. Rising incomes and increased prosperity in many developing countries, particularly those in Southeast Asia, contribute to the improvement.[3]

Access to medicines is lowest in poor countries, which also have the lowest life expectancy, high disease burdens, and relatively high tariffs.[4] The reasons for inadequate access to medicines and medical care are numerous and varied. Although the Doha conference identified drug patents as a prime cause, in reality, they have very little to do with it.[5]

In his opening remarks at the 2001 Doha Conference, Pascal Lamy, then the EU commissioner for trade and now newly elected director general of the WTO, emphasized the importance of fostering a harmonious balance between TRIPS and

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public health, stating, "[W]e must also find the right mix of trade and other policies—consider the passion surrounding our debate of TRIPS and access to medicines, which has risen so dramatically to become a clearly defining issue for us this week, and rightly so."[6] Of course, part of the reason for his eagerness to debate the TRIPS issue was his desire to divert attention from poor countries clamoring for removal of indefensible European agricultural subsidies.

A quick tour of the seven-paragraph agreement that emerged from the conference reveals that while recognizing the role of intellectual property protection "for the development of new medicines," the WTO specifically acknowledges concerns about the effect of patents on prices and urges its members to interpret and implement the said provisions under the agreement, in a manner supportive of public health, and in particular "to promote access to medicines for all."[7] As a result, the least developed countries were given until January 1, 2016, to implement sections 5 (patents) and 7 (protection of undisclosed information) of part II of the TRIPS Agreement. The agreement establishes in paragraph 5, sub paragraph (b): "Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which licences are granted." Furthermore, subtext (c) of the same paragraph states, "Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."[8]

Paragraph 6 revisits the problems inherent in article 31(f) of the preexisting TRIPS Agreement (established under the Uruguay Round), which stipulates that a compulsory license must be issued predominantly for the supply of the domestic market of the member state granting the license. For developing countries that have neither the manufacturing capabilities nor the infrastructure to take full advantage of the compulsory licensing provisions, this stipulation poses a problem. Consequently, paragraph 6 of the Doha Declaration instructed the Council for TRIPS to find a solution and report to the General Council by the end of 2002. However, it was not until August 30, 2003—shortly before the Cancún Ministerial Conference—that consensus was reached.

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The General Council consensus that emerged from the August 30 decision granted rights to developing countries to waive provisions of article 31(f), subject to certain conditions. Generally, it enabled countries with production capability to export drugs made under compulsory license to countries that could not manufacture them. The waiver was intended to be temporary, pending the permanent amendment of the TRIPS Agreement. The General Council chairperson's remarks on the August 30 decision specifically noted that the "[d]ecision should be used in good faith to protect public health and . . . should not be an instrument to pursue industrial or commercial policy objectives."[9]

On December 6, 2005, WTO members approved changes to the intellectual property agreement, making permanent the August 2003 decision. The TRIPS Amendment will be effective December 1, 2007, but until then, the current waiver stands and has the distinction of being the first time a core WTO agreement has been amended. The TRIPS Amendment agreement has three parts—article 31 "bis" (i.e., an additional article after Article 31), an annex, and an appendix to the annex. Briefly, Article 31 "bis" establishes that developing countries without a significant pharmaceutical capacity or sector in the event of a public-health crisis can access alternative supplies of medicines. The annex sets out specific circumstances under which export compulsory licenses can be used and provides safeguards against parallel importing. The appendix deals with assessing lack of manufacturing capability in the importing country.[10]

Commentary from Interested Parties

Following the release of the WTO TRIPS Amendment on December 6, U.S. trade representative Rob Portman expressed enthusiastic support, stating, "This is a landmark achievement that we hope will help developing countries devastated by HIV/AIDS and other public health crises."[11] Echoing the sentiments of his American colleague, the UK's trade secretary Alan Johnson said, "This announcement should be an important step in making drugs available in poor countries." The European Union's trade commissioner Peter Mandelson also added, "The EU has worked hard for this outcome and welcomes that others have moved to make this possible."[12] No

doubt all political negotiators were relieved to get the issue off the table, especially African governments that had urged members to act quickly to reach a deal before the Hong Kong ministerial meeting. As one African delegate involved in the discussions noted, "This is an African issue, people are dying of HIV/AIDS. . . . There is a need for us to have a solution."[13] To this effect, South Africa, Egypt, and Kenya—on behalf of the African Group—had moved swiftly to endorse the proposal on December 2, 2005, four days before the formal agreement was approved.

Meanwhile, Doctors Without Borders (Médecins Sans Frontières, MSF), a prominent, international humanitarian aid organization, did not share this optimism. Indeed, MSF expressed alarm at the WTO's decision. MSF believes that despite the provisions made under the August 30 decision three years ago, "there is no experience [to date] using the mechanism—not one patient has benefited from its use." MSF asserts the situation is graver still, claiming that it is already being confronted with steep price increases for its drugs, paying as much as five to thirty times more for second-line AIDS medicines to treat patients who need newer drugs.[14] Evidently, part of the reason more patients are requiring second-line treatment is because of resistance to first-line therapy, which is likely to have been exacerbated by the use of nonbioequivalent copycat drugs. Ironically, nonbioequivalent copycat drugs were promoted by MSF in order to lower drug prices.

MSF joined forces with twenty-two other nongovernmental organizations (NGOs)—including Oxfam International, ACT Up-Paris, Consumers International, the European AIDS Treatment Group, and Third World Network—calling on WTO members to suspend any new bilateral and regional trade agreements that include provisions on intellectual property rights involving medicines. The coalition claimed that such trade agreements "restrict the grounds for compulsory licensing and parallel trade and bring in data exclusivity rules" to the detriment of developing countries.[15]

There is reason to temper enthusiasm over the 2005 deal with skepticism. At issue is the difference between the letter and spirit of the agreement. As discussed in our recent *Health Policy Outlook* on Brazil's AIDS treatment program, that country's comportment in recent years regarding its AIDS program has proven that more developed countries manipulate all too easily the declaration to suit their own needs; in this respect, Brazil's declared intention has often been to procure antiretroviral drugs (ARVs) at prices far closer to nonprofit prices than those more appropriate to the wealth of the country.[16] As MSF correctly argues, the declaration has not so far been used—and for good reason. Undermining companies' patents damages relations between countries and companies, thus reducing incentives for future research. The closest any nation has gotten to undermining corporate patents is Brazil, which has threatened to issue a compulsory license, but has not yet acted. It remains to be seen whether the December 6 agreement will embolden any nation to actually go beyond Brazil's action.

Developing countries are often desperate for revenue, but imposing tariffs on drug imports and then taxing these lifesaving products is an odd way to raise revenue.

Despite these uncertainties, it is possible that the era of conflict between TRIPS and public health is gradually coming to an end. The 2005 breakthrough should encourage the WTO to move ahead on other critical issues.

Alan Johnson called the lack of access to essential medicines one of the gravest injustices in the world. Pascal Lamy, stressing the importance of improving access to medicines for developing countries, referred to the issue as a deal breaker of the new round. If Johnson and Lamy are correct—and serious—about improving access to medicines, they should use the WTO to find methods to help developing countries remove tariffs. Developing countries are often desperate for revenue, but imposing tariffs on drug imports and then taxing these lifesaving products is an odd way to raise revenue. Perhaps the WTO could discuss this in the next two years and reach an agreement to remove tariffs before the end of the Doha round.

How Tariff Removal Can Help

Every day, thousands of people in poor countries die from preventable and curable diseases. In our analysis of fifty-three low-income countries, import tariffs for completed medicines and essential medical products—like bandages and the raw materials for drug production—range from zero in Brunei to 9.6 percent in Brazil, 16 percent in India, and as much as 20 percent in Nigeria. When all the duties and taxes are combined, the average

TABLE 1
AVERAGE TARIFF AND TAX RATES IN SELECTED COUNTRIES

Country	Access to Essential Medicines in 1999 (%)	Tariff (%)	Value Added Tax (%)	Combined Tariff (%)
Kenya	36	22[1]	16	38[1]
Morocco	66	18.5	19	37.5
Tanzania	66	16.2	20	36.2
Uganda (East African Community Customs Union)	70	10	21	31
Peru (Andean Community)	60	10	19	29
Nigeria	10	20	8	28
Brazil	40	9.6	18	27.6
Bolivia (Andean Community)	70	12	13	25
Zimbabwe	70	7.5	15	22.5
Congo	ND	8.8	13	21.8
India	35	16	4	20

SOURCE: Roger Bate, Richard Tren, and Jasson Urbach, "Taxed to Death," (working paper, AEI-Brookings Joint Center, Washington, D.C., 2005), available at http://aei-brookings.org/publications/abstract.php?pid=930.
NOTES: ND = No data available. 1. Over the past year, Kenya has removed its 10 percent tariff rate.

cost of medicines and medical equipment is routinely inflated by around 30 percent.[17]

Undeniably, it is the sovereign right of any nation to raise revenue as it sees fit. Our statistical analysis, however, finds a negative association between access to essential medicines, as measured by the United Nations, and the degree to which countries inflate the price of medicines. If the relationship is as causal as we suspect, this means that for countries with high tariff rates such as Nigeria (20 percent), Uganda (10 percent), Kenya (10 percent), Tanzania (10 percent), Congo (8.8 percent), and Zimbabwe (7.5 percent), many tens of millions more people could afford access to valuable medicines if all tariffs were removed (see table 1).

Although India is often hailed as a purveyor of cheap generic drugs abroad, high tariffs at home limit patient access to critical drugs made by foreign manufacturers. In fact, only 35 percent of Indians have access to essential medicines and far less have access to domestically produced copycat ARVs for HIV. This is worrisome given that the Global Fund recently said as many as 8.5 million Indians could be HIV positive.[18]

While the leaders of the poorest countries are happy to lobby for more aid and demand that pharmaceutical companies offer their drugs at reasonable costs, they routinely tax medicines until they are unaffordable. Our statistical analysis indicates that sales taxes are less harmful than tariffs in denying access, although the impact is definitely negative. However, removing internal taxes is not an issue for the WTO and consequently not relevant to this discussion.

High import tariffs are often levied to protect domestic industries as much as to raise revenue (as is the case in India and Brazil). As a result, foreign drug manufacturers are less likely to sell to those markets in the first place. Adding insult to injury, countries like India (until recently) and Brazil are also much less likely to respect foreign patents, further decreasing their populations' access to essential medicines produced abroad.

Attacking patents and keeping high import tariffs hurt the sickest and poorest citizens in poor nations. Over the past thirty years, deregulation and free trade have been embraced by the West as tools for economic growth. And as the various indices of economic freedom attest, wealth generation is associated with better health care.[19]

Poor countries have yet to benefit from this discovery. State-imposed price hikes, along with numerous and very burdensome bureaucratic barriers, strangle the developing world's access to medicines. Drug manufacturers must often jump through numerous bureaucratic hoops before they can sell their products, even if they have already complied with drug safety standards in the U.S., the

EU, and Japan. There is little value in maintaining these barriers—except to the bureaucratic elite in poor countries, whose budgets depend on the perpetuation of onerous rules and regulations.

Western governments, NGOs, and pharmaceutical companies are trying to improve the level of research and development on health problems afflicting developing nations. Yet for many diseases that kill millions—such as influenza, malaria, and gastrointestinal ailments—vaccines and drugs exist, and they should be made available to the world's poor today.

The pleas for a greater Western commitment to tackle problems in developing countries ring hollow when the governments of poor countries maintain taxes, tariffs, and bureaucracies that frustrate decent health care for their own populations and ensure that their own citizens die needlessly. This is an issue that the WTO should take up with a passion. The WHO recently published a paper agreeing with this position: "It is vital that policy makers, both at a national and international level, address the issue of tariffs on medicines and recognize the regressive nature of these duties, which ultimately tax the sick without regard for their economic status or ability to afford these medicines. Pharmaceutical tariffs could be eliminated without adverse revenue or industrial policy impacts."[20]

The revenue lost to developing countries from tariff abandonment is generally small, and revenue can be raised in far less regressive ways, such as through domestic income taxes or sales taxes on nonessential goods. Herein lies a real win for the WTO, as opposed to the Doha Declaration, which although much lauded is more a mirage than a constructive measure.

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Notes

1. World Trade Organization, *Doha Ministerial Declaration on the TRIPS Agreement and Public Health* (Geneva: World Trade Organization, November 14, 2001), available at http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed December 22, 2005).

2. World Health Organization, *The World Medicines Situation* (Geneva: World Health Organization, 2004), 63.

3. For instance, between 1960 and 2000 in Malaysia and Thailand, per-capita GDP rose from $974 to $4,796 and $464 to $2,804, respectively (1995 U.S. dollars). US-ASEAN Business Council, "ASEAN Finance and Macroeconomic Surveillance Unit Database," http://www.us-asean.org/aftatariffs.asp (accessed December 18, 2005).

4. In 2003, low-income countries had an average life expectancy of 58.3 years compared to high-income countries that had an average life expectancy of 78.3 years. World Bank, *World Bank Development Data, 2005* (Washington, D.C.: World Bank, 2005), available at http://devdata.worldbank.org/external/CPProfile.asp?PTYPE=CP&CCODE=LIC and http://devdata.worldbank.org/external/CPProfile.asp?PTYPE=CP&CCODE=HIC.

5. Amir Attaran, "How Do Patents and Economic Policy Affect Access to Essential Medicines in Developing Countries?" *Health Affairs* 23, no. 3 (2004): 155–66.

6. Pascal Lamy, European commissioner for trade (plenary speech to the fourth ministerial meeting, Doha, Qatar, November 10, 2001), available at http://europa.eu.int/rapid/pressReleasesAction.do?reference=SPEECH/01/512&format=HTML&aged=0&language=EN&guiLanguage=en (accessed December 20, 2005).

7. World Trade Organization, "Doha Declaration on TRIPS and Public Health," paragraphs 1–3, World Trade Organization, http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (accessed December 20, 2005).

8. Ibid., paragraphs 5b and 5c.

9. World Trade Organization, "The General Council Chairperson's Statement," *WTO News,* August 30, 2003, available at http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm (accessed December 23, 2005).

10. World Trade Organization, *Proposal for a Decision on an Amendment to the TRIPS Agreement* (Geneva: World Trade Organization, December 6, 2005), available at http://www.wto.org/English/news_e/news05_e/trips_decision_e.doc (accessed December 18, 2005).

11. "WTO Upholds Cheaper Drugs Waiver," BBC News, December 12, 2005, available at http://news.bbc.co.uk/2/hi/business/4504922.stm (accessed December 19, 2005).

12. Ibid.

13. Tove Iren S. Gerhardsen, "Chances Diminish for Solution on TRIPS and Public Health before Hong Kong," *Health Now*, November 23, 2005, available at http://www.health-now.org/site/printfriendly.php?articleId=518&menuId (accessed December 23, 2005).

14. Doctors Without Borders/Médecins Sans Frontières, "Amendment to WTO TRIPS Agreement Makes Access to Affordable Medicines Even More Bleak: MSF Concerned That Patients the World over Will Have to Pay the Price," news release, December 6, 2005, available at http://www.

doctorswithoutborders.org/pr/2005/12-06-2005_1.cfm (accessed December 19, 2005).

15. International Federation of Pharmaceutical Manufacturers & Associations, "WTO to Tackle Trade Deals That Affect Access to Medicines," *SCRIP World Pharmaceutical News*, December 21, 2005, available at http://www.ifpma.org/PressReviewEmail/PressReviewDetail.aspx?nID=4032&SD=15EeoWgH%2f0lqyZJvfgT8mA%3d%3d (accessed December 19, 2005).

16. Roger Bate and Richard Tren, "Brazil's AIDS Program: A Costly Success," *Health Policy Outlook* 1 (2006).

17. Roger Bate, Richard Tren, and Jasson Urbach, "Taxed to Death," (working paper, AEI-Brookings Joint Center, Washington, D.C., 2005), available at http://aei-brookings.org/publications/abstract.php?pid=930.

18. UNAIDS, *2004 Report on the Global AIDS Epidemic*, (Geneva: UNAIDS, 2004), available at http://www.unaids.org/bangkok2004/report.html (accessed December 19, 2005).

19. Brett D. Schaefer and Ariel Cohen, "The Keys to an African Economic Renaissance," (backgrounder #1369, Heritage Foundation, Washington, D.C., May 10, 2000) available at http://www.heritage.org/Research/Africa/bg1369.cfm (accessed December 20, 2005).

20. Muge Olcay and Richard Laing, "Pharmaceutical Tariffs: What Is Their Effect on Prices, Protection of Local Industry and Revenue Generation?" (study, Commission on Intellectual Property Rights, Innovation and Public Health, World Health Organization, Geneva, May 2005), available at http://www.who.int/intellectualproperty/studies/tariffs/en/ (accessed December 18, 2005).