THE WHO & INTELLECTUAL PROPERTY IN BILATERAL FREE TRADE AGREEMENTS

Over the past ten years, the World Health Organization (WHO) has actively engaged in the discussion on TRIPS and Public Health. The WHO's work in analyzing the TRIPS Agreement has been helpful in the efforts to ensure that intellectual property and trade policy at the WTO take into account the aim of better health outcomes.[1] Pharmaceuticals and their associated technologies and treatment regimes are at the core of all public health delivery systems; policies that affect their availability and affordability directly impact on public health outcomes. It is thus clearly within the WHO's mandate to intervene in policy discussions and debates which implicate its core public health mission.

November 14th, 2006, was the 5th anniversary of the Doha Declaration on TRIPS and Public Health. The declaration established that "the TRIPS Agreement should not prevent members from taking measures to protect public health [… and] 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."[2] The broad spirit of the declaration was a significant achievement that spurred continued action in other fora such as the World Intellectual Property Organization. At the WTO, paragraph six of the Declaration[3] was incorporated as an amendment to TRIPS in December 2005, one of the first major amendments in the history of the agreement.

The moderate success achieved in the Doha Declaration, however, is in danger of being reversed. Policy is being made in bilateral and regional free trade agreements (FTAs) that directly affects the ability of countries and individuals to access medicines at low cost and to utilize the flexibilities and policy space available under TRIPS. The past five years since the Doha Declaration have seen a significant increase in the number of FTAs with extensive intellectual property provisions. The vast majority of these FTAs are between major industrialized economies and less well-resourced developing countries. The US has concluded FTAs with 10 partners[4] and has entered negotiations with 8 further countries.[5] The EU has concluded FTAs with Chile, Mexico and South Africa and has ongoing negotiations with Mercosur, with the six nation Gulf Cooperation Council and future negotiations with Central American and Andean Community countries. Also of serious concern is the fact that the EU is negotiating reciprocal

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[1] See e.g. Health Economics - The Uruguay Round and Drugs (WHO/DAP, WHO/TFHE; 1997; 40 pages)
Globalization, TRIPS and Access to Pharmaceuticals - WHO Policy Perspectives on Medicines, No. 3, 2001
Implications of the Doha Declaration on the TRIPS agreement and public health (WHO/EDM/PAR/2002.3) [pdf 159kb]
Implications of the Doha Declaration on the Trips Agreement and Public Health (WHO; 2002; 56 pages)
Globalization and Access to Drugs: Perspectives on the WTO TRIPS Agreement, EDM Series No. 7 [pdf 289kb] (2005)

[2] Doha Declaration on TRIPS and Public Health, para 4

[3] The paragraph called for allowing countries with insufficient manufacturing capacity to import pharmaceuticals from other countries under compulsory license.

[4] Australia, Bahrain, Central America and Dominican Republic, Chile, Colombia, Lao People's Democratic Republic, Morocco, Oman, Peru and Singapore.

[5] Ecuador, Panama, Malaysia; Republic of Korea, Southern African Customs Union (SACU), Thailand and United Arab Emirates (UAE).

trade agreements with regional groups of the African, Caribbean and Pacific (ACP) group of countries, many of whom are least developed economies.

For the industrialized countries, the IP provisions of these agreements are clearly aimed at gaining greater concessions on intellectual property protection than they were able to achieve during the TRIPS negotiations. In particular, the industrialized countries have pushed for stronger and more extensive patent protection for pharmaceutical products and processes, as well as biotechnological products and animals. The developing countries are, for the most part, negotiating, not to increase their market access, but simply to maintain the market access that they already have under existing preference schemes that are either expiring or being phased out.

Several analyses and reports have already highlighted the IP provisions in FTAs that go beyond the requirements of TRIPS.[6] The US FTAs, for example, have provisions directly aimed at limiting the scope and application of the Doha Declaration on Public Health and other flexibilities. These include restrictions on the application of compulsory licensing, bans on parallel importation, longer patent terms, and exclusivity of test data. Perhaps the most disturbing aspect of the push for greater protection of pharmaceuticals is that as the number of countries that sign up to such provisions grows, the number of countries able to export pharmaceuticals to developing countries under the 2005 Amendment to TRIPS will shrink. Each additional country that signs up to such provisions, significantly undercuts the value of the amendment. It may only take a few middle income countries with pharmaceutical manufacturing capacity[7] to sign up, and the entirety of the 2005 Amendment will be rendered worthless.

The WHO must bring to bear its considerable research and analytical resources to examine the domestic and global public health impacts of such IP provisions in FTAs. Yet, the WHO is already hearing calls to refrain from making statements or involving itself in FTAs.[8] Some argue that FTAs are outside the expertise of the WHO and that it should defer to other institutions such as the WTO. While this may be true in some areas, the WHO remains the pre-eminent international public health organization responsible for developing health and regulatory standards that govern the approval, selection and use of pharmaceuticals and other treatment of diseases. It is only proper and appropriate that it should examine and evaluate the pharmaceutical regulatory standards (including intellectual property) established by FTAs and their impact on public health. Rather than being excluded from discussions of the effect of such FTA provisions on public health, the WHO should be closely and extensively consulted before such provisions are adopted and applied.

It is especially imperative that the WHO be involved in the evaluation and analysis of the public health impacts of IP provisions in FTAs, if the recommendations of the WHO Commission on

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[6] See e.g. Musungu and Oh, "The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines?" (WHO/South Centre 2006) (available at http://www.southcentre.org/publications/flexibilities/FlexibilitiesStudy.pdf)

[7] For example Brazil, India, China, and South Africa.

[8] See e.g. US Seeks Review Of WHO Publication Policy After Report On US Trade Deals (IP Watch 28/09/2006, available at http://www.ip-watch.org/weblog/index.php?p=409&res=1024_ff&print=0), reporting on US objections to a joint WHO/South Centre Research Paper on "The use of flexibilities in TRIPS by developing countries: Can they promote access to medicines?" written for the CIPIH and commenting on the public health implications of US bilateral free trade agreements.

Intellectual Property Innovation and Public Health (CIPIH) are to be fully implemented by WHO member States. The recommendations of the CIPIH are a significant step forward in international intellectual property, trade and public health policy-making. Further, several of the CIPIH recommendations require the exercise of all the available policy space under TRIPS.[9]

Intellectual property provisions on pharmaceuticals lie at the core of the WHO's public health mission. It has taken action at the multilateral level in establishing the Intergovernmental Working Group on Intellectual Property, Innovation and Public Health. Progress at the multilateral level, however, will be lost if developments at the bilateral level are ignored. The WHO must work to ensure that better health outcomes are a core part of the aim of all IP provisions in FTAs.

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CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW

The Center for International Environmental Law (CIEL) is a nonprofit organization working to use international law and institutions to protect the environment, promote human health, and ensure a just and sustainable society. CIEL's Intellectual Property and Sustainable Development Project works with developing country governments and non-governmental organizations to include sustainable development concerns in current multilateral and bilateral rules on intellectual property. CIEL has offices in Geneva and Washington D.C.

[9] This would include, for example, recommendation 4.13 on the Doha Declaration, as well as recommendation 4.14 on compulsory licensing, recommendation 4.15 on the August 2003 Decision on importation under a compulsory license, recommendation 4. 18 on transfer of technology, recommendation, 4.19 on parallel importation, recommendation 4.20 on test data protection, recommendation 4.23 on competition, and recommendation 4.26 on bilateral free trade agreements.