

## Strategies for the Protection and Promotion of Public Health Arising Out of the WTO TRIPS Agreement Amendment Process

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The WTO TRIPS Agreement that entered into force on January 1, 1995, fundamentally altered the policy environment in which developing (and developed) countries operate with respect to producing and distributing pharmaceutical products needed to protect public health. The TRIPS Agreement's requirement to provide pharmaceutical product patent protection establishes the basis for market dominance (regarding newer products) by originator companies that are almost exclusively based in the OECD. Important policy space for developing countries was made available in the form of a transition period that extended until January 1, 2005. India and its generic producers took good advantage of that space, which has now largely been closed (although Least Developed Countries (LDCs) continue to benefit from a transition arrangement).

Compulsory (including government use) licensing is a critical tool for promoting effective price negotiations with patent holders, and for enabling local production, importation and distribution of patented medicines at affordable prices. However, a technical rule of the TRIPS Agreement threatened to make use of compulsory licensing extremely difficult for many developing countries after January 1, 2005, when availability of pharmaceutical patents would be required in all countries, except LDCs. This technical rule (Article 31(f)) limited use of compulsory licensing for the predominant supply of the domestic market of the country issuing the license. Countries without adequate production capacity, and without access to imports of off-patent medicines from other countries (such as from India), would be unable to effectively use compulsory licensing.

As part of negotiations regarding the Doha Declaration on the TRIPS Agreement and Public Health, developing countries sought a solution to the looming problem of effective use of compulsory licensing that would have been administratively straightforward and expeditious. In November 2001 at Doha, a programmatic formula was established that led to two years of further negotiations on a "waiver" (Decision of August 30, 2003) ("Waiver Decision"), followed by a proposed amendment (Article 31*bis*) of the TRIPS Agreement ("Amendment").

Members of the WTO are deciding whether to ratify and accept the Article 31*bis* Amendment to the TRIPS Agreement. The Amendment embodies a compromise among various stakeholders involved in researching and developing new medicines, manufacturing and distributing them, prescribing and delivering treatment, and those advocating on behalf of patients. The compromise involved government ministries seeking to promote the industrial policy interests of their nationally-based producers and government ministries concerned with protecting the public health of their citizens. The process of negotiation was long and difficult, and no stakeholder achieved all of its objectives. From whatever perspective one approaches the Amendment, it is imperfect.

There are no doubt significant impediments to expeditious use of the Amendment. Nonetheless, on the whole it would provide a “net benefit” in respect of access to medicines in developing (including LDC) countries. There are mechanisms that can be used to overcome certain of the administrative obstacles. In its adoption of an implementing regulation for the Decision and Amendment, the EU has in fact taken good advantage of the possibilities for encouraging effective use of the new system. Article 31 *bis* can be made functional, even if imperfectly, through a combination of political will, good lawyering, financial support for appropriate implementation efforts and collective action.

What matters most is that governments implement the Waiver Decision and/or Amendment in national law employing all options for maximum flexibility in its use. Developing country governments likewise should pursue programs of cooperation that will permit them to take advantage of economies of scale in purchasing, as well as in the production and distribution of pharmaceutical products.

The Waiver Decision and Amendment each expressly provide that they are without prejudice to other rights Members may have under the TRIPS Agreement. Article 30 remains a viable option for generic-producer exports of patented pharmaceuticals in circumstances that fall within the terms and context of that Article. The somewhat restrictive approach to interpretation of Article 30 by the panel in the *Canada-Generic Pharmaceuticals* case<sup>1</sup> was adopted prior to the Doha Declaration, which placed Article 30 in a new interpretative framework. The WTO Appellate Body has recognized the evolutionary nature of WTO and international law in its *Shrimp-Turtles* decision and elsewhere.<sup>2</sup>

OECD country governments consistently argue that higher standards of intellectual property protection will encourage “transfers of technology” to developing countries, which is essential for accelerated progress. But OECD governments suggest that technology transfer occurs through the operation of “free-market” forces. At least in the pharmaceutical sector, the evidence to support this thesis is not compelling. The major multinational pharmaceutical companies do not “out-license” newer products for manufacture and distribution by developing country enterprises; research and development is concentrated in the home countries of major producers; and manufacturing facilities are shuttered and relocated as a matter of economic convenience.

The evidence suggests that the wealthy OECD nations are little inclined to promote the development of world-class pharmaceutical producers in poor countries, which might eventually compete with the existing originators. The rhetoric of “transfer of technology” does not extend to the reality of investment in plant and equipment, upgrading systems for compliance with OECD GMP quality standards, or to the licensing of important pharmaceutical compounds. There is a great deal of pharmaceutical technology expertise available “for hire”, and pharmaceutical equipment manufacturers are willing sellers. The inhibitions on building up developing country pharmaceutical capacity are mainly

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<sup>1</sup> Canada—Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS114/R, 17 Mar. 2000.

<sup>2</sup> United States-Import Prohibition of Certain Shrimp and Shrimp Products, Report of the Appellate Body, AB-1998-4, WT/DS58/AB/R, 12 Oct. 1998.

financial, although intellectual property issues must and can be addressed if there is a will to do it.

We emphasize that measures such as pooling of essential medicines patents, the buying out of patent rights for developing country markets and/or the geographic (or other market, *e.g.*, public-private) segmentation of patent rights, may be very important tools for promoting pharmaceutical research and development, and for the establishment of production facilities, including for active pharmaceutical ingredients (APIs). We strongly encourage a more proactive role for OECD transfer of technology to the developing country pharmaceutical sector. At the very least, OECD governments should not stand in the way of South-South cooperation.

At the present time, originator pharmaceutical companies based in the OECD recover the bulk of their R&D expenditures in the more affluent OECD markets, and invest a small part of their R&D budgets on diseases of special relevance to developing countries. Consequently, the use by developing countries of compulsory licensing to ensure public access to affordable medicines is unlikely to have a material effect on the level of research currently undertaken in the OECD. If pharmaceutical companies, either in OECD countries or elsewhere, respond to TRIPS patent incentives by investing in R&D that pertains to poverty-related, tropical and neglected diseases of primary concern to developing countries, then resort to compulsory licensing may require a different calculus. Depending on the type of financing mechanism employed for research (*e.g.*, public or private), the originators may have to seek their returns on investment in the affected countries, and calculations regarding whether and how to use compulsory licensing should take account of the altered landscape.

The pressing need for more research and development on treatments for poverty-related, tropical and "neglected diseases" has lately captured the attention of governments. Today, much of the important work in this area is being done by Public-Private Partnerships (PPPs), with a substantial portion of the money coming from private foundation donors (such as the Gates Foundation). Creative new structures, such as the Drugs for Neglected Diseases initiative (DNDi) are up and running and it is essential that the scale of government contributions to these efforts be increased.

WIPO Substantive Patent Law Treaty negotiations could reduce patent flexibilities across the board for all countries, while the bilaterals and free trade agreements (FTAs) have significantly cut back on the ability of national governments to provide public goods that involve intellectual property inputs. The European Commission's decision to follow a more aggressive intellectual property strategy in the EPAs being negotiated with the ACP countries is particularly worrisome in this regard. Some observers, including one of the authors of this contribution, have gone on record to urge "a moratorium on further intellectual property standard setting exercises," in order to give the incipient transnational system of innovation, triggered by TRIPS, time to breathe and grow.<sup>3</sup>

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<sup>3</sup> Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 3-45 (K.E. Maskus & J. H. Reichman, eds., Cambridge U. Press, 2005).

At the heart of the intellectual property-access to medicines debate lies the fact that the world community seeks to address a "public goods" problem with a "private market" solution. The Doha Declaration recognizes a collective obligation to promote access to medicines "for all". We know that the private market can not meet that goal, and governmental measures are necessary to factor out the income curve when it comes to purchasing medicines necessary to sustain life. Failure to confront this truth results in an endless cycle of conflict, and leaves us with an unresolved collective action problem on a grand scale.