A fair deal for the future: flexibilities under TRIPS

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When the Uruguay Rounds concluded in 1994, many countries signed on to the trade agreements creating the World Trade Organization (WTO) in hopes of benefiting from a system of trade rules "dedicated to open, fair and undistorted competition" (*1*). WTO members also undertook to implement the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Developing countries, major development agencies and civil society raised concerns over whether TRIPS might limit access to affordable, essential medicines. The Doha Declaration on the TRIPS Agreement and Public Health, adopted at the WTO ministerial conference in 2001, responded to these concerns: it emphasized that the TRIPS Agreement should not stand in the way of member governments acting to protect public health and affirmed governments' right to use the Agreement's flexibilities (*2*).

Oliveira et al. (pp. 815–821) provide insight into the flexibilities under TRIPS that provide public health safeguards and how they are coming under challenge despite the Doha Declaration. Their article on the implementation of TRIPS in Latin America and the Caribbean gives a snapshot of the key areas where TRIPS flexibilities important for public health must be reflected in a country's national legislation. Their work is particularly timely because negotiations for the Central American Free Trade Agreement (CAFTA) have been concluded (though the Agreement is not yet ratified), while efforts to move forward a United States free trade agreement (FTA) with Andean countries and the Free Trade Area of the Americas continue.

These FTAs have sought to curtail the flexibilities under TRIPS, such as compulsory licensing or parallel imports. Have they, though, placed at risk the potential role of generic competition or weakened public sector negotiating leverage? To highlight an area of growing concern, the United States has prioritized the creation or expansion of "exclusive rights" over pharmaceutical test data in FTA negotiations (*3*). Under Article 39.3 of the TRIPS Agreement, WTO members must protect test data, submitted to national drug regulatory authorities for pharmaceutical registration, against "unfair commercial use". While TRIPS does not specify how this is to be done, the United States has insisted in the FTA negotiations that countries provide at least five years of data exclusivity. Instead of generic competitors submitting bioequivalence data, they must repeat costly tests for marketing approval, which may deter generic entry. This may also raise ethical questions, as generic manufacturers would be forced to repeat human subject trials on drugs known to be bioequivalent.

Data exclusivity provisions apply whether or not a medicine is patented, but the most serious impact is likely to be on drugs that are not under patent. In such cases, data exclusivity will create a "patent-like" barrier that will prevent generic entry during the entire period of exclusivity (*4*). If a drug is patented, the government could issue a compulsory licence to overcome the patent barrier, but data exclusivity might prevent its market approval. This is the possible situation emerging under the CAFTA, where data exclusivity rules may delay generic competition effectively for up to ten years (*5*). Such FTAs are not only TRIPS-plus, but may also go beyond requirements under United States law.

As developing countries seek lower barriers to their agricultural exports and greater foreign direct investment, can TRIPS flexibilities be safeguarded? How can the playing field for negotiations be levelled? First, developing countries should refuse to accept TRIPS-plus provisions in FTAs. Barring this, they should avail themselves of what the United States practises under government use provisions through non-voluntary licences and what other countries do to prevent patent abuse (*6*). Secondly, developing country governments deserve fair access to independent, technical assistance and counsel of their own choosing in these negotiations. In recent Andean FTA negotiations, this basic principle of fairness was undermined when the United States delegation prevented the Colombian Government from seating an adviser at the negotiation table. Ministries of trade should also ensure representation of ministries of health in negotiations that will affect public health and access to medicines. Thirdly, the public health community should insist that evidence be provided and results tracked to document whether the promised gains or the potential public health risks from stronger IPR protection are realized. The reciprocal benefits of technology transfer should be as measurable as the United States monitoring of TRIPS compliance under the Section 301 "watch list".

Finally, regional economic blocs might consider collective approaches to applying the use of public health safeguards under TRIPS as they have for negotiating price reductions and procuring pharmaceuticals. Ten countries in Latin America banded together to reduce the price of antiretroviral drugs and HIV diagnostic tests with agreements from both originator and generic manufacturers (*7*). Such regional groups might benefit from exercising coordinated use of the public health safeguards under TRIPS (*8*).

The paper by Oliveira and her colleagues provides a useful starting framework for flexibilities under TRIPS, but a framework for fairness will require more. Only by taking into account the concerns of public health in trade agreements will we ensure that all countries have a fair deal for the future. ■

References

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1. *Understanding the WTO*. Geneva: World Trade Organization; 2003. p. 12. Available from: http://www.wto.int/english/thewto_e/whatis_e/tif_e/fact2_e.htm
2. Correa CM. *Implementation of the WTO General Council Decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*. Geneva: World Health Organization; 2004. Health Economics and Drugs Series, No. 16.
3. *Office of the United States Trade Representative 2004 Special 301 Report: Executive Summary*. Washington, DC: Office of the United States Trade Representative; 2004. Available from: http://www.ustr.gov/assets/Document_Library/Reports_Publications/2004/2004_Special_301/asset_upload_file963_5996.pdf
4. *Access to medicines at risk across the globe: what to watch out for in free trade agreements with the United States*. New York: Médecins Sans Frontières; 2004, pp. 4-5. Available from: http://www.accessmed-msf.org/documents/ftabriefingenglish.pdf
5. Weissman R. *Dying for drugs: how CAFTA will undermine access to essential medicines*. Washington, DC: Essential Information; March 2004. Available from: http://www.cptech.org/ip/health/trade/cafta/weissman032004.doc.
6. Reichman JH, Hasenzahl C. *Non-voluntary licensing of patented inventions: historical perspective, legal framework under TRIPS, and an overview of the practice in Canada and the United States of America*. Geneva: ICTSD; 2003. UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, Issue Paper No. 5. Available from: http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf
7. Fitzgerald J, Gomez B. An open competition model for regional price negotiations yields lowest ARV prices in the Americas. In: *International Proceedings of the 8th World STI/AIDS Congress, December 2003*. Bologna: Medimond Srl; 2003. p. 7-13.
8. Musungu SF, Villanueva S, Blasetti R. *Utilizing TRIPS flexibilities for public health protection through South-South regional frameworks*. Geneva: South Centre; 2004.