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

This contribution is derived from a Study prepared by the authors under commission from the International Trade Committee of the European Parliament (Access to Essential Medicines: Lessons Learned Since the Doha Declaration on the TRIPS Agreement and Public Health, and Policy Options for the European Union, June 2007, EXPO/B/INTA/2007/14, PE 381.392), a revised version of which will be published in Vol. 10, Issue 4 of the Journal of International Economic Law (Oxford) as Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, forthcoming 2007).

The entry into force of the WTO TRIPS Agreement in 1995 transformed the international intellectual property system. The harmonization of basic intellectual property standards has operated to protect investment in innovation, limiting risks from unjustified "free riding". Yet these same harmonized IP standards sharply curtailed the traditional capacity of suppliers of public goods, such as health care and nutrition, to address priority needs of less affluent members of society, particularly in (but not limited to) developing countries. In the Doha Declaration, the Waiver Decision of August 30, 2003 and the Article 31bis Protocol of Amendment, stakeholders concerned with re-opening policy space for the supply of newer pharmaceutical products pushed back against restrictive elements of the TRIPS Agreement.

Governments around the world are in the process of deciding whether to ratify and accept the Article 31bis Amendment. Based on their Study for the International Trade Committee of the European Parliament, the authors argue that acceptance of the Amendment will provide a "net benefit" for countries seeking to improve access to medicines. At the insistence of WTO delegations acting on behalf of the originator pharmaceutical industry lobby, Article 31bis regrettably is saddled with unnecessary administrative hurdles. Nonetheless, through skillful lawyering, political determination and coordinated planning, the system can be made to work. Among other options, expeditious back-to-back compulsory licensing linked with pooled procurement strategies may effectively achieve economies of scale in medicines production and distribution.

The authors doubt that the international political environment would support renegotiation of an "improved" solution. They express concern that failure to bring the Amendment into force will open the door to a campaign to undermine the Waiver Decision. Recent events in Brazil and Thailand illustrate both the opportunities and risks associated with implementing TRIPS exception mechanisms, and help to inform views on the negotiating environment. Specific proposals for regional cooperation in implementing the Amendment are laid out, and the authors emphasize the importance of pursuing concrete transfer of technology measures in support of developing country pharmaceutical manufacturing. Over-reliance on private market mechanisms for the supply of public health goods leaves the international community with an unresolved collective action problem on a large scale.