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Incentives for Global Public Health: Patent Law and Access to Essential Medicines

Edited by

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"This portrait of the global debate over patent law and access to essential medicines focuses on public health concerns about HIV/AIDS, malaria, tuberculosis, the SARS virus, influenza, and diseases of poverty. The essays explore the diplomatic negotiations and disputes in key international fora, such as the World Trade Organization, the World Health Organization and the World Intellectual Property Organization. Drawing upon international trade law, innovation policy, intellectual property law, health law, human rights and philosophy, the authors seek to canvass policy solutions which encourage and reward worthwhile pharmaceutical innovation while ensuring affordable access to advanced medicines. A number of creative policy options are critically assessed, including the development of a Health Impact Fund, prizes for medical innovation, the use of patent pools, open-source drug development and forms of 'creative capitalism'" --Provided by publisher

... (pp. 3-4)

2. Connecting public and international law

This volume is the second in a new series bringing public and international lawyers and public and international policymakers together to examine key issues in the twenty-first century. This series broadens both public and international laws' understanding of how these two areas intersect and is unique in consciously bringing together public and international lawyers to consider and engage in each other's scholarship. What can public lawyers bring to international law and what can international lawyers bring to public law? What are the common interests? What tensions become apparent when we consider public and international law together?

This second volume focuses on these questions in the context of the contemporary debate over access to essential medicines...

... (pp. 7; 21)

... Given the enormous magnitude of the access to medicines problem, it is fairly obvious that this problem cannot be overcome through the various global health initiatives of recent years, even though these have indeed been impressive. As stated in the recent *WHO Global Strategy*:

Member States, the pharmaceutical industry, charitable foundations and nongovernmental organizations have taken initiatives in recent years to develop new products against diseases affecting developing countries and to increase access to existing health products and medical devices. However, these initiatives are not sufficient to surmount the challenges of meeting the goal of ensuring access and innovation for needed health products and medical devices.

In addition to these initiatives, substantial progress calls for an integrated solution that combines public law and international law elements to form an effective reform package: ‘Proposals should be developed for health-needs driven research and development that include exploring a range of incentive mechanisms, including where appropriate, addressing the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries...

... (p.10)

There have been dramatic battles over patent law and access to medicines under the shadow of the TRIPS Agreement. These conflicts have involved international law, constitutional law, intellectual property law, competition law and trade law.

... After a number of high-profile conflicts over access to essential medicines in South Africa and Brazil, and a panic over bioterrorism in North America, the WTO issued the Declaration on the TRIPS Agreement and Public Health (‘Doha Declaration’) at the fourth WTO Ministerial Conference in Doha in 2001...

... (pp. 11-12)

... In August 2003, the World Trade Organization developed a decision on the export of pharmaceutical drugs to address the need for the export of pharmaceutical drugs to countries lacking local manufacturing capacity (‘WTO General Council Decision of 30 August 2003’). **The decision emphasized that a WTO member country could export pharmaceutical products made under compulsory licenses, subject to a number of substantive and procedural terms.** In 2005, at the Hong Kong meeting, the WTO proposed that the WTO General Council Decision of 30 August 2003 should be incorporated into the formal text of the TRIPS Agreement 1994 (‘TRIPS Waiver’). As of February 2009, only twenty countries and the members of the European Union have supported the TRIPS Waiver. Adoption of the measure requires support from two-thirds of the members of the WTO. The deadline to accept the TRIPS Waiver was extended until December 2009.

The international regime for the export of pharmaceutical drugs under compulsory license has been criticized as ineffectual – which may explain the lack of enthusiasm for the TRIPS Waiver. Only a select number of countries have implemented domestic legislation to allow for such exports. Significant manufacturers of pharmaceutical drugs – such as the US, Japan, Switzerland and Australia – have not established schemes.

...Furthermore, there have also been concerns that the United States Trade Representative has negotiated TRIPS-Plus bilateral and regional trade agreements that undermine the intent and impact of the Doha Declaration and the WTO General Council Decision of the 30 August 2003.

(p. 13)

The Doha Declaration and the WTO General Council Decision of 30 August 2003 have not ended the acrimonious disputes over patent law and access to essential medicines. Antony Taubman has observed that compulsory licenses remain contentious: ‘Bilateral trade representations continue over compulsory licensing, even though TRIPS itself, the Doha Declaration and subsequent waiver and amendment marked significant progress in articulating and clarifying multilateral standards in this domain.⁵² In 2007, Novartis was unsuccessful in its arguments to the High Court of Judicature at Madras that Indian patent laws were invalid under the TRIPS Agreement and contrary to the Indian Constitution. In Thailand, the government issuance of a number of compulsory licenses earned the ire of brand-name pharmaceutical companies, especially Abbott Laboratories, which threatened to stop registering drugs in that country.

There has been controversy over the willingness of the Government of Brazil to engage in compulsory licensing. 55...

52 Antony Taubman, ‘Rethinking TRIPS: “Adequate Remuneration” for Non-Voluntary Patent Licensing’ (2008) 11(4) *Journal of International Economic Law* 927-70.

55 Brazil disputes over compulsory licensing of essential medicines: www.cptech.org/ip/health/c/brazil/; and Lawrence A. Kogan, ‘Brazil’s IP Opportunism Threatens U.S. Private Property Rights’ (2007) 38 *University of Miami Inter-American Law Review* 1.

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