

PATENTS AND PUBLIC HEALTH AT THE WORLD HEALTH ORGANIZATION

By Mark Schultz & Christopher Frericks*

Are patents bad for public health? Despite the vast number of fundamental public health challenges facing the world, the effect of the patent system on public health has emerged as a key focus of policy discussions at the international level. A coalition of NGOs and developing nations has raised objections to strong intellectual property protection in a number of international organizations. The issue of patents and access to essential medicines—particularly anti-retroviral drugs needed to combat the HIV virus—has been particularly contentious, spurring urgent calls for action to help the developing world. This article summarizes recent developments at the World Health Organization (WHO), which is currently examining the effect of patents on public health.

WHO AND THE INTERGOVERNMENTAL WORKING GROUP ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY

Developing nations and NGOs skeptical of intellectual property have recently shifted the focus of their efforts to restrict intellectual property rights in the name of public health to the World Health Organization (“WHO”). In many respects, this new focus appears to be an example of what Prof. Laurence Helfer describes as “regime shifting,” an attempt by policy proponents to move debate from one international forum to another, more sympathetic one. Responding to criticism of IP’s effect on public health, in 2004 WHO convened the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), which was charged with analyzing the relationships between IPRs, innovation and public health in the developing world. The CIPRH finished its work and issued a lengthy, detailed report in April, 2006. While not wholly skeptical of the benefits of IPRs, the CIPRH Report contended that there were serious deficiencies in the patent-driven model of public health research; it listed sixty recommendations.

Among the recommendations of the CIPRH there are several that are of particular interest to proponents of IPRs. The most notable of these include: pharmaceutical companies should use differential pricing and implement patenting and patent enforcement policies which benefit developing countries; WHO and WIPO, among others, should promote patent pooling; WHO and WIPO should establish a patent database; governments should legislate compulsory licensing in accordance with TRIPS to both improve access to, and promote research into, medications; governments should motivate researchers to contribute to “open source” methods of innovation; governments should impose patentability criteria that avoid barriers to “legitimate competition”; governments and the WTO should encourage transfers of technologies to developing countries; governments of developed countries should restrict parallel imports; and governments of developed

countries should not seek TRIPS-plus trade agreements that may reduce access to medicines.

A number of the CIPRH recommendations were controversial. Some of the members of the Commission appended partially dissenting statements. Critics of the CIPRH report are concerned that WHO is working from the wrong premises in an area outside of its expertise. Looking at drug patents in isolation from other factors that drive innovation (IPRs more generally, free markets, access to capital) and other factors that more directly affect public health (infrastructure, access to health care, worldwide shortfalls in trained doctors and nurses, public sanitation, availability of all medicines) could badly misconstrue the issues and lead to great mischief. Moreover, WHO brings considerable moral and actual authority to bear, despite its lack of a mandate with respect to intellectual property.

As recommended by the CIPRH Report, WHO established an intergovernmental working group (the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (“IGWG”)) to consider implementing the recommendations of the CIPRH report, as well as a secretariat to support its activities. The IGWG is charged with drawing up a “global strategy... to provide a medium-term framework based on the recommendations of the Commission.” This framework is intended to provide “enhanced and sustainable” incentives for need-based research and development into diseases which disproportionately affect the developing world. IGWG is currently working within a two-year time frame and is scheduled to report on its progress to the 60th World Health Assembly in spring 2007. A final strategy must be prepared a year later for the 2008 meeting of the 61st World Health Assembly.

IGWG ACTIVITIES THUS FAR

One of the IGWG’s first actions was to hold web-based “public hearings” between 1 and 15 November. In total, thirty-one groups or individuals contributed to the public hearing, representing a wide range of viewpoints, including: the International Federation of Pharmaceutical Manufacturers and Associations (“IFPMA”), the International Policy Network (“IPN”), Doctors Without Borders, Consumer Project on Technology (“CPTech”), as well as several individual health care professionals and academics. IFPMA observed that research and development of new medicines is both expensive and risky under current regulatory schemes, making the need for strong intellectual property protections a near necessity before initiating the process of innovation. The Doctors Without Borders submission announced their general agreement with the CIPRH report, but focused primarily on those recommendations concerning the delivery of medicines and medical treatment to those in need rather than the alleged defects of an intellectual property-funded research and development scheme. CPTech’s submission focused on encouraging research and development into diseases that disproportionately affect the developing world through the use of a prize fund. Other notable

* Mark Schultz is an Assistant Professor of Law at Southern Illinois University School of Law. Christopher Frericks is currently a law student at Southern Illinois University School of Law, J.D. expected, May 2007.

recommendations included separating the various functions of the pharmaceutical industry (such as research, marketing and manufacturing) and paying for each separately via government agencies,²⁷ increased use of public/private partnerships (PPPs),²⁸ and a universal acceptance of every recommendation made in the CIPIH report, perhaps embodied in an international R&D treaty.²⁹

Before the IGWG held its first official meetings in December, the United States government reportedly sent a demarche to several developing nations with which it has trade agreements, explaining that much of what is being proposed at the IGWG may not be in the long term best interest of developing countries.³⁰ The demarche observed that WHO had likely overstepped its expertise by attempting to influence international trade and intellectual property related agreements with the pending IGWG plan of action.³¹ Moreover, the demarche noted that other intergovernmental organizations, specifically the WTO and WIPO, have been established to deal with the subject matter of the IGWG and those issues should and would be taken up by those organizations.³²

In early December, the IGWG met to produce a plan for its work over the next two years.³³ The initial proposal was to organize work around the subjects addressed by the CIPIH report, including prioritizing health research and development needs; promoting drug research and development; building innovation capacity; improving delivery of and access to drugs; ensuring sustainable financing mechanisms for drug development, and establishing monitoring and reporting systems.³⁴

The main controversy at the meeting was whether the IGWG should also address the issues of intellectual property rights management and transfer of technology to developing nations. These issues had long been seen as the province of WIPO, and are currently being discussed as part of WIPO's Development Agenda discussions.³⁵ Representatives from WIPO, the IFPMA and several developed nations indicated that the IGWG was overstepping its area of technical expertise.³⁶ With regard to technology transfers, most countries agreed that such activity is helpful to both the transferor and transferee and should be encouraged.³⁷ However, the United States representative explained that transfers of technology could not be *forced* without undermining IPRs.³⁸ With regard to IPR management, most delegates of developed nations agreed that patent pooling might be an option, but several reserved final judgment on the idea until it could be shown practically viable, again without undermining IPR protections.³⁹

The final product of the IGWG's first meeting consisted of a progress report to the WHO executive board consisting of three annexes.⁴⁰ The first, the "final" draft of the "Elements of a Plan of Action," closely tracked the CIPIH Report. The IGWG intends to use these elements, now grouped into eight categories and including the two contentious IP-related topics, as a focus for continued discussions in various meetings throughout 2007. The second, "Elements of a Global Strategy," explains the mission of the IGWG and includes several strategies that the IGWG would like to implement in its plan of action. The third annex includes notes on the first two documents from individual

countries and groups of countries involved in the IGWG.

Some criticized the first meeting of the IGWG as unproductive, especially considering that it cost WHO a reported \$600,000.⁴¹ In most ways, however, it was typical of the beginning of such processes: The IGWG affirmed that it attempted to work toward its mandate to formulate a plan of action and strategy to improve research and development into diseases which disproportionately affect the developing world based on the recommendations of the CIPIH. It also reflected the fissures that have appeared at other recent intellectual property related meetings.⁴² Developed countries largely sought to defend the intellectual property system from fundamental change. Lesser developed countries with the greatest need, particularly the African Group, sought to obtain whatever technical assistance and technology transfer they could get. "Middle income" developing countries like Brazil and Thailand continue to demand radical changes that would benefit their domestic generic drug industries, alleviate public health budget strains, and provide them with leverage in trade talks at the WTO.

WHO EXECUTIVE BOARD MEETINGS

The WHO Executive Board met the week of January 22 and took up issues regarding the work of the IGWG Wednesday, January 24.⁴³ During the discussion, some countries, including Switzerland, Brazil, Kenya and Thailand, expressed their disappointment that the December meeting of the IGWG fell short of expectations.⁴⁴ Switzerland and Kenya proposed a resolution which would begin implementing some concepts discussed by the Working Group and possibly provide focus and muscle to the work of the IGWG.⁴⁵

The proposed resolution requested that the Director-General "promote, with other relevant organizations, patent pools of upstream technologies that may be useful to foster innovation which addresses diseases that affect developing countries."⁴⁶ Amendments proposed by Thailand (which had just broken certain Merck anti-retroviral patents) included requests "to promote competition of generic medicines and health products which would bring down prices and improve access;" "to continue to provide incentives to enterprises and institutions in their territories in accordance with Article 66.2 of the TRIPS Agreement," which concerns technology transfers; and "to strengthen, as appropriate, institutional and human capacity in the management of health-related intellectual property."⁴⁷

A number of countries, including the United States, expressed concerns regarding the proposed resolution.⁴⁸ The U.S. delegation was prepared to submit its own amendments which called for promoting research into diseases that disproportionately affect the developing world through incentives for their development, which would include "effective intellectual property protection" and "respecting international obligations."⁴⁹ The U.S. amendment was not submitted as support for the proposed resolution did not materialize.⁵⁰ When asked by Switzerland whether "there [were] delegations that would have a serious problem if there were no resolution," no country answered affirmatively.⁵¹ In

the end, Kenya requested to postpone the proposal because it became clear that discussion of the topic was, at that point, premature.⁵²

In February, member nations submitted comments on a report intended to guide the future progress of the IGWG.⁵³ The comments will be included in a working document which is slated to be released in July, 2007. The current version of the document states that the WHO director general and IGWG will “identify a pool of experts and concerned entities, ensuring a balanced representation between regions, developing and developed countries, and female and male experts.”⁵⁴ The document also stated that IGWG officers would “meet as necessary to consider other possible intersessional work and detailed arrangements for the second session.”⁵⁵ The second session of the IGWG is scheduled for October, 2007.⁵⁶ Two proposals were made to prepare for the October meeting: regional meetings, possibly with the aforementioned experts and another Internet-based public hearing.⁵⁷

The comments submitted displayed the now-familiar divisions in this debate. The United States advocated working to remove fundamental barriers to essential health care, like poor infrastructure. Other nations focused once again on patents as a barrier to access to health, advocating greater use of the so-called flexibilities in TRIPS to engage in compulsory licensing. As this article goes to press in spring 2007, the outcome of such debates remains unclear. The next steps to be taken at the upcoming World Health Assembly and further IGWG meetings remain to be seen.

WHAT WILL AND SHOULD RESULT FROM WHO'S EXAMINATION OF INTELLECTUAL PROPERTY RIGHTS?

The IGWG's final proposal will almost certainly not be radical. After all, the work product of international organizations is typically shaped by compromise. The developed world will not likely abandon the intellectual property system that has done so much to fuel innovation. Nor is it likely to abandon wholly the hard-won concessions of the last two decades tying trade liberalization to more effective enforcement of IPRS by trading partners. Alternative means of encouraging research into health issues that disproportionately affect developing countries will have to be compatible with current IPR practices to be accepted by the developed members of WHO.

Although radical change to the patent-driven system of innovation is unlikely (and arguably undesirable), there appears to be a consensus that something ought to be done about diseases that disproportionately affect developing countries. The IGWG process thus will inevitably produce some sort of substantive proposals. The question is what will and should be the nature of those proposals? Some of the diseases that afflict the developing world would indeed be greatly alleviated by new drugs, but also could be prevented by low-cost interventions. For example, a malaria vaccine is a long-sought dream, but in the meantime, mosquito netting, pest eradication, and other low-cost interventions would greatly alleviate the problem. Toward that end, countries should adhere to existing obligations like the Abuja Declaration on Roll Back Malaria, which calls for measures like malaria prevention education and reducing

taxes and tariffs on insecticides and repellents.⁵⁸ In addition, a large portion of the world's people lack clean water. Although providing clean water may seem less promising than high-profile R&D into silver bullet drugs, it is one of the world's most important public health priorities, as developing countries lose over three million lives each year to diarrheal diseases. The world has a long, long way to go before such low-cost interventions are exhausted. They ought to be a priority, as they could save millions of lives a year.

Nevertheless, new drug development could also do some good. There are some markets that are just too poor to attract research dollars for diseases uniquely associated with such markets, and some sort of public incentives might help. Toward that end, the IGWG might propose model legislation to facilitate development of drugs for “neglected” diseases—perhaps orphan drug legislation, tax incentives, or tradable patent extensions. Since problems are diverse and the potential solutions manifold, such programs ought to remain decentralized to allow for experimentation with respect to both problems and solutions. Encouraging new private/public partnerships between charities, NGOs, and governments would also be helpful, as such efforts tend to produce many flexible approaches. In the end, however, the IGWG would do well to avoid creating new supranational or transnational organizations; such efforts have proven to be fraught with politics and waste.⁵⁹

In addition, one ought to bear in mind that the very problems that make such markets unattractive to drug companies may interfere with the ability to deliver drugs to the people who need them most. Poverty, war, corruption, lack of infrastructure, health professional shortages, and other issues deter market solutions, but they are also great obstacles to successful charitable and aid efforts.⁶⁰ Such challenges do not mean that the developed world should not bother to try to help, but they should shape a more realistic response. Cutting-edge drug developing is important, but the developing world will benefit greatly in the long term with help on less glamorous tasks like fighting poverty, improving sanitation, and preventing disease. In the end, the developing world needs most of the institutions that have fostered prosperity in the developed world: private property rights, the rule of law, and free markets.

CONCLUSION

Health and development related issues will likely continue to dominate the activities of all intergovernmental organizations with a stake in public health and intellectual property. WIPO, which has done little but discuss a potential “development agenda” over the last few years, will continue to do so, taking into consideration the CIPIH report and the IGWG's activities. IP skeptics will certainly continue to raise issues at the WTO, the UN Human Rights Council, UNESCO, and any other organization that will entertain them.

Perhaps the most important immediate consequences of the IGWG's work will be continued distractions from the primary causes of misery in the developing world. Blaming IPRs for failing to engender development ignores the vast institutional failures that prevent IPRs and other market institutions from working in the developing world: The lack of clear property rights and enforceable contracts, confiscatory

taxes, stifling regulation, corruption, poorly functioning or non-existent capital markets, and the lack of physical security all greatly impede economic development. War, disorder, instability, predatory governments, and a lack of essential infrastructure and institutions also keep the developing world impoverished and thus keep IPRs from being an effective incentive for R&D into diseases that disproportionately affect impoverished countries.⁶¹ These same conditions, along with a fundamental failure in the public health systems of most developing countries, also cause great misery. Rather than spending time in Geneva arguing about the effect of IPRs, intergovernmental organizations and the nations of the world might better focus on fulfilling fundamental human needs and building secure, effective market institutions that empower people to lift themselves from poverty.

Endnotes

1 Challenges include world-wide shortages of trained health professionals, inability to obtain access to any health care or medicines (not just patented drugs), infrastructure problems impeding delivery of health care, lack of clean water, lack of obstetric and neo-natal care, corruption causing diversion of health funding, and other fundamental issues. See generally Laurie Garrett, *The Challenge of Global Health*, FOREIGN AFFAIRS (Jan/Feb 2007). Garrett notes that recent years have seen an extraordinary rise in public and private donations directed to alleviate public health problems in the developing world. Such donations have included patented drugs provided at reduced costs or for free. Unfortunately, the fundamental problems detailed by Garrett continue to impede progress. See *id.*

2 Brazil, Argentina, Kenya, and a number of countries have raised the issue of public health and patents at the World Trade Organization (“WTO”), the World Intellectual Property Organization (“WIPO”), and several other organizations. In particular, activity at WIPO the past two years has focused on the “Development Agenda,” which proposes to shift WIPO’s mandate from one that promotes intellectual property to one that promotes a more skeptical view of intellectual property rights in order to benefit developing nations. See Mark Schultz & David Walker, *How Intellectual Property Became Controversial: NGOs and the New International IP Agenda*, 6 ENGAGE 8.2 (2005) (available at <http://www.fed-soc.org/Publications/Engage/Oct%2005.pdf>). Thus far, the Development Agenda has met with limited success at WIPO, as it has engendered much talk but little action. See Mark Schultz, *Daily Reports from the 2006 Development Agenda Meetings*, <http://www.ngowatch.org/articles.php?id=320> (2006).

3 See Schultz & Walker, *supra* note 2.

4 See Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT’L L. 1 23-47 (2004).

5 REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY, INNOVATION AND PUBLIC HEALTH, WORLD HEALTH ORGANIZATION (Apr. 2006) available at <http://www.who.int/intellectualproperty/report/en/index.html> (last visited Jan. 16, 2007) (“CIPIH Report”).

6 *CIPIH Report*, *supra* note 5, at 115. “Differential pricing” is “[t]he practice of setting different prices for different markets, typically higher prices in richer markets and lower prices in poorer markets.” *Id.* at 192.

7 *Id.* at 122.

8 *Id.* at 53. “Patent pools” are defined as “[a]n agreement between two or more patent owners to license one or more of their patents to one another or third parties.” *Id.* at 194.

9 *Id.* at 122.

10 *Id.* at 120.

11 *Id.* at 55.

12 *Id.* at 91. “Open source” methods would be analogous to “computer program[s] in which the source code is available to the general public for use, and/or modification from its original design. Open source code is typically created as a collaborative effort in which programmers improve upon the code and share the changes within the community.” *Id.* at 194.

13 *Id.* at 134.

14 *Id.* at 123, 153.

15 *Id.* at 124. “Parallel imports” are patented goods purchased “from a lawful source in an exporting country” and “import[ed] without seeking the consent of the ‘parallel’ patent holder in the importing country.” *Id.* at 194.

16 *Id.* at 126, 130.

17 *Id.* at 187-188.

18 Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Toward a Global Strategy and Plan of Action, WHA Res. 59/24 (May 27, 2006) available at http://www.who.int/gb/ebwha/pdf_files/WHA59/A59_R24-en.pdf (last visited Jan. 16 2007).

19 *Id.*

20 *Id.* The IGWG is open to economic integration organizations to which WHO Member States have transferred the capacity to enter international legally binding regulations relevant to the subject matter of the resolution. Other organizations and individuals, including non-Member States and nongovernmental organizations with relations to WHO are allowed to observe meetings.

21 *Id.*

22 World Health Organization, *WHO to Hold Public Hearings on Public Health, Innovation and Intellectual Property*, Oct. 27, 2006, <http://www.who.int/mediacentre/news/notes/2006/np30/en/index.html>.

23 World Health Organization, *Contributions to Date*, http://www.who.int/public_hearing_phi/summary/en/index.html (visited Jan. 16 2007).

24 Eric Noehrenburg, *The R&D process for pharmaceutical products, diagnostics and vaccines*, http://www.who.int/public_hearing_phi/summary/14Nov06EricNoehrenberg.pdf (Nov. 15, 2006).

25 Ellen F. M. t’Hoen, *Towards a health needs driven framework for R&D and access to medicines*, http://www.who.int/public_hearing_phi/summary/15Nov06EllentHoenMSF.pdf (Nov. 15, 2006).

26 James Love, *Submission of CPTech to IGWG*, http://www.who.int/public_hearing_phi/summary/15Nov2006CPTech15nov06.pdf (Nov. 15, 2006).

27 Peter Mansfield, *Submission from Health Skepticism Inc.*, http://www.who.int/public_hearing_phi/summary/15Nov06MansfieldPeter.pdf (Nov. 15, 2006).

28 Trevor M. Jones, *WHO—Hearings on R&D into Drugs for Developing Countries*, http://www.who.int/public_hearing_phi/summary/13Nov06TrevorMJonesCBE.pdf (Nov. 13, 2006).

29 Health Action International Europe, *Submission to the World Health Organization Public Hearing on Public Health, Innovation and Intellectual Property*, http://www.who.int/public_hearing_phi/summary/14Nov06CollenDanielsHAL.pdf (Nov. 14, 2006).

30 Tove Iren S. Gerhardsen, *US Advises Developing Country FTA Partners Not To Follow WHO IP Plan*, <http://www.ip-watch.org/weblog/index.php?p=485&res=1024&print=0> (Dec. 11, 2006).

31 *Id.*

32 *Id.*

33 Tove Iren S. Gerhardsen, *Cautious Start For WHO IP Working Group As Members Feel Their Way*, <http://www.ip-watch.org/weblog/index.php?p=478&res=1024&print=0> (Dec. 5, 2006).

34 *Id.*

35 See *supra* note 2, and sources cited therein.

36 See *id.*

37 *Id.*

38 *Id.*

39 *Id.*

40 Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, *Elements of a global strategy and plan of action*, http://www.who.int/gb/phi/PDF/phi_igwg1_5-en.pdf (Dec. 8, 2006).

41 Tove Iren S. Gerhardsen, *WHO Group Lays Foundation For Global Neglected Diseases R&D Plan*, at <http://www.ip-watch.org/weblog/index.php?p=484&res=1024&print=0> (Dec. 11, 2006).

42 See *supra* note 2, and sources cited therein.

43 E-mail from Leonard Leo, Executive Vice President, Federalist Society, World Health Organization Daily Report, (Jan. 24, 2007) (on file with author).

44 *Id.*

45 Tove Iren S. Gerhardsen, *Immediate Action For Global Health Plan Called For At WHO Meeting*, at <http://www.ip-watch.org/weblog/index.php?p=512&res=1024&print=0> (Jan. 23, 2007).

46 E-mail from Leonard Leo, Executive Vice President, Federalist Society, World Health Organization Daily Report, (Jan. 24, 2007) (on file with author); see also Tove Iren S. Gerhardsen, *Immediate Action For Global Health Plan Called For At WHO Meeting*, <http://www.ip-watch.org/weblog/index.php?p=512&res=1024&print=0> (Jan. 23, 2007).

47 E-mail from Leonard Leo, Executive Vice President, Federalist Society, World Health Organization Daily Report, (Jan. 24, 2007) (on file with author).

48 *Id.*

49 *Id.*

50 *Id.*

51 *Id.*

52 Tove Iren S. Gerhardsen, *WHO Members Agree On Need to Improve IP and Public Health Process*, <http://www.ip-watch.org/weblog/index.php?p=517&res=1024&print=0> (Jan. 30, 2007).

53 Member States' Submissions to the IGWG Outcome Document, A/PHI/IGWG/1/5, <http://www.who.int/phi/submissions/memberstates/en/index.html>.

54 Intergovernmental Working Group on Public Health, Innovation and Intellectual Property [IGWG], Follow-up to the first session of the Intergovernmental Working Group: Report by the Secretariat, ¶ 3, WHO Doc. EB120/INF.DOC./5 (Jan. 27, 2007), available at http://www.who.int/gb/ebwha/pdf_files/EB120/B120_ID5-en.pdf (last visited Feb. 1, 2007).

55 *Id.* at ¶ 4.

56 *Id.* at ¶ 5.

57 Tove Iren S. Gerhardsen, *WHO Members Agree On Need to Improve IP and Public Health Process*, <http://www.ip-watch.org/weblog/index.php?p=517&res=1024&print=0> (Jan. 30, 2007).

58 Abuja Declaration, available at http://www.rbm.who.int/docs/abuja_declaration.pdf (last visited Feb. 18, 2007).

59 Recently, Dr. Richard Feachem, the executive director of the Global Fund to Fight AIDS, Tuberculosis and Malaria has been criticized for lavish misuse of Global Fund money, spending “hundreds of thousands of dollars on limousines, expensive meals, a boat cruise for Global Fund staff members and other expenses, according to an internal investigation” and other smaller personal expenses, including renting a wedding tuxedo. John Donnelly, *Director of Global AIDS Charity Used Funds for Private Purposes*, THE BOSTON GLOBE,

February 6, 2007, available at <http://www.iht.com/articles/2007/02/06/news/global.php>. Although it would be unfair to use one such incident to criticize all such efforts, stories of waste and fraud in international bureaucracies are legion. At best, large sums of money are spent honestly but wastefully on administrators, consultants, and other overhead expenses. See Garrett, *supra* note 1. Better then to focus on leaner, more direct efforts to help.

60 See *id.*

61 See Report of the Commission on Intellectual Property, Innovation and Public Health, World Health Organization,, Commentaries, 202 (Apr. 2006) available at http://www.who.int/intellectual_property/report/en/index.html (last visited Jan. 16, 2007).

