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# International Health Law

LAUREL R. HYLE, AFIA K. ASAMOAH, AND RAYMOND T. RUFER\*

## I. Introduction

International health issues continued to make headlines in 2008, particularly with respect to unsafe products from China. Less headline-grabbing but equally important legal developments occurred in the fields of women's health, the implementation of the World Health Organization's International Health Regulations (IHR), and the adoption of new laws and policies on the use of health information technologies by many countries. The European Union (EU) continued work on harmonizing its patent regime and there were some interesting legal developments in Brazil with respect to its patent regime. Finally, this article summarizes developments with respect to the interpretation and application of the Agreement on Trade Related Aspects of Intellectual Property, a World Trade Organization (WTO) agreement, and developments at the World Intellectual Property Organization (WIPO), that have implications for international health issues.

## II. Women's Health

There continues to be a significant relationship between the health of women and children and the lack of legal protection pertaining to violence against women. Research demonstrates a "high prevalence and wide-range of health consequences" from domestic violence,<sup>1</sup> and the United Nations (U.N.) Secretary General's report in 2006 on violence against women also provides significant data regarding the scope and depth of this problem.<sup>2</sup> For instance, the report highlights the fact that only about half of U.N. member states had enacted legislation to address domestic violence. As a result of this report, the

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1. See, e.g., Manuela Colombini et al., *Health-Sector Responses to Intimate Partner Violence in Low-and Middle-Income Settings: A Review of Current Models, Challenges and Opportunities*, WORLD HEALTH ORGANIZATION [WHO] (Aug. 2008), available at <http://www.who.int/bulletin/volumes/86/8/07-045906/en/>.

2. The Secretary-General, *In-Depth Study on All Forms of Violence Against Women, delivered to the General Assembly*, U.N. Doc. A/61/122/Add.1 (July 6, 2006).

United Nations resolved to intensify efforts to remedy this global problem and in February 2008, it launched a campaign to address violence against women and girls.<sup>3</sup>

The United Nations organized a meeting of experts in 2008 to discuss this issue and issued a report entitled, *Good Practices in Legislation on Violence Against Women*.<sup>4</sup> This report indicates that U.N. member states are obligated to have laws that protect the safety of women and girls and that such legislation is not merely a discretionary matter. The report also provides specific, detailed guidance for developing legislation on violence against women. This includes guidance for drafting and implementing legislation as well as guidance for those involved in prevention, intervention, investigation, and prosecutorial efforts. Notably, the report endorses a gender-sensitive, rather than gender-neutral, approach to such legislation.<sup>5</sup> Additionally, on November 6, 2008, the Third Committee of the U.N. General Assembly adopted a resolution to intensify efforts to eliminate violence against women.<sup>6</sup>

### III. International Law, Trade, and Public Health

The year 2008 saw a number of concerns related to international law, trade, and public health. Perhaps most notable was the case involving China. In November 2008, the U.S. Food and Drug Administration (FDA) issued an import alert detaining milk products from China over a concern that such products might be unsafe due to melamine contamination.<sup>7</sup> The FDA's action was accompanied by reports that over 50,000 Chinese infants had become sick due to melamine-contaminated milk, and four had died.<sup>8</sup> During 2008, the FDA also issued import alerts pertaining to certain categories of Chinese bean curd, rice, melon seeds, garlic, and seafood.<sup>9</sup> Also, there were concerns about contamination of Heparin, a blood-thinning drug imported into the United States from China.<sup>10</sup> These alerts followed not far behind previous health concerns raised over other products from China, for instance, toothpaste, painted children's toys, and pet food.

Although there was significant media focus on China, it is certainly not the only country struggling to maintain safe, profitable products for export. For instance, there has been significant concern raised about the safety of pharmaceutical imports in a number of global locales and a recent New York Times article pointed out that:

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3. Press Release, United Nations Department of Public Information, United Nations Report Offers Guidelines for Legislation on Violence Against Women, U.N. Doc. WOM/1704 (Nov. 11, 2008).

4. U.N. Division for the Advancement of Women, U.N. Office on Drugs and Crime, Expert Group Meeting, May 26-28, 2008, *Good Practices in Legislation on Violence Against Women*, available at [http://www.un.org/womenwatch/daw/egm/vaw\\_legislation\\_2008/Report%20EGMGPLVAW%20\(final%2011.11.08\).pdf](http://www.un.org/womenwatch/daw/egm/vaw_legislation_2008/Report%20EGMGPLVAW%20(final%2011.11.08).pdf).

5. See *id.*

6. Intensification of Efforts to Eliminate All Forms of Violence Against Women, G.A. Res. 63/155, U.N. Doc. A/RES/63/155 (Jan. 30, 2009).

7. U.S. Food and Drug Administration, Import Alert IA 9930, Nov. 12, 2008, available at [http://www.fda.gov/ora/fiars/ora\\_import\\_ia9930.html](http://www.fda.gov/ora/fiars/ora_import_ia9930.html).

8. Gardiner Harris & Andrew Martin, *F.D.A. Detains Chinese Imports for Testing*, N.Y. TIMES, Nov. 13, 2008, at A18.

9. U.S. Food and Drug Administration, FIARS Report Page, available at [http://www.fda.gov/ora/fiars/ora\\_import\\_40cn.html](http://www.fda.gov/ora/fiars/ora_import_40cn.html).

10. Walt Bogdanich, *Tainted Blood Drug to Face Import Tests*, N.Y. TIMES, Mar. 15, 2008, available at <http://www.nytimes.com/2008/03/15/health/policy/15fda.html>.

Generic drug makers in the United States, where price competition is fierce, were the first to seek cheaper drug ingredients in China. Last year, generic drug applications to the F.D.A. listed 1,154 plants providing active pharmaceutical ingredients: 43 percent of them were in China, and another 39 percent were in India. Only 13 percent were in the United States. Branded drug makers, with their fatter profit margins, resisted buying ingredients from China for years, but with their businesses now suffering, even major pharmaceutical companies like AstraZeneca, Bayer, Baxter[,] and Pfizer have announced deals to outsource manufacturing to China.<sup>11</sup>

And in 2008, the FDA banned the importation of more than thirty generic drugs, including antiretrovirals, due to concern that the drugs were manufactured in India by Ranbaxy in a manner that could result in impotent or sub-standard drugs.<sup>12</sup> This was of particular concern because antiretrovirals manufactured by Ranbaxy had been used to treat thousands of HIV-positive patients in Africa.<sup>13</sup>

Some have argued that in response to such concerns countries should pursue legal action through the World Trade Organization (WTO) and Article XX(b) of the General Agreement on Tariffs and Trade in order to ban potentially dangerous imports until the safety of such goods can be effectively established.<sup>14</sup> Others argue that greater transparency can help resolve such issues without resort to such stringent measures.<sup>15</sup> In almost all such arguments posited by government and regulatory bodies as well as individuals there is an undeniable tension between political-economic concerns and public health concerns. Also, it is not uncommon for litigation to be filed if such products produce harmful results, which could provide a disincentive for open disclosure.

#### IV. Implementation of the International Health Regulations

The International Health Regulations, promulgated by the World Health Organization (WHO) in 2005 and implemented in 2007, bind 194 states.<sup>16</sup> In 2008, WHO issued its report on the implementation of IHR.<sup>17</sup> Under the regulations, each state that is a party to the regulations is obligated to assess the ability of national structures and resources to meet the minimum requirements of the regulations.<sup>18</sup> Also, as a complement to the regulations and as a means to facilitate implementation, WHO supports additional educational materials, including guidance on the use of the model international certificate on vaccina-

11. See Gardiner Harris, *The Safety Gap*, N.Y. TIMES, Nov. 2, 2008 at MM46.

12. Kaiser Daily HIV/AIDS Report, Citing Safety Concerns, FDA Bans Imports of Ranbaxy Drugs Made in Two Indian Plants, Including Antiretrovirals, KaiserNetwork.org (Sept. 17, 2008), [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=1&DR\\_ID=54503](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=54503).

13. Kaiser Daily HIV/AIDS Report, U.S. Investigating Indian Pharmaceutical Company Ranbaxy over Generic Drugs, Including Antiretrovirals Used in PEPFAR, KaiserNetwork.org (July 15, 2008), [http://www.kaisernetwork.org/daily\\_reports/rep\\_index.cfm?hint=1&DR\\_ID=53288](http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=53288).

14. Elvira Cortez, *Total Recall on Chinese Imports: Pursuing an End to Unsafe Health and Safety Standards Through Article XX of GATT*, 23 AM. U. INT'L L. REV. 915, 918 (2008).

15. Ljiljana Biukovic, *Selective Adaptation of WTO Transparency Norms and Local Practices in China and Japan*, 11 J. INT'L ECON. L. 803, 803 (2008).

16. WHO, Sixty-first World Health Assembly, Report by the Secretariat, *Implementation of the International Health Regulations (2005)*, ¶ 3, U.N. Doc. A61/7 (Apr. 3, 2008).

17. See *id.* at 1.

18. See *id.* ¶ 10.

tion and guides to hygiene and sanitation for ships and aircraft, which are intended to help assess risks associated with international travel and transportation.<sup>19</sup> WHO has also implemented an event management site for member states to report public health events and to facilitate communication about the same. As part of WHO's monitoring of member states' response to public health events in the context of the IHR, it has identified a need to help countries establish the infrastructure necessary to implement national pandemic response plans.<sup>20</sup> Also, WHO is in the process of establishing specific indicators for core competency readiness, which it hopes will help to better gauge member states' preparedness to respond to a public health emergency.

## V. Adoption of Health Information Technology

In 2008, several countries passed legislation or introduced new policies relating to health care technology, namely in the areas of electronic health records systems, electronic prescribing, and telemedicine initiatives. The WHO also highlighted the use of information and communication technologies to improve access, quality, and efficiency of primary care services. Security and privacy of personal information remain issues associated with the adoption of these systems.

In the United Kingdom, the agency in charge of the National Health Service (NHS) National Programme for IT (NPFIT), Connecting for Health (CfH), announced a change in policy regarding the use of medical information contained in an electronic health record. Rather than requiring patients to indicate in advance that information in their electronic health record should be kept confidential, CfH will now require clinicians and other health care workers to secure patient permission prior to accessing a patient's electronic record.<sup>21</sup> Due in part to concerns about the privacy implications of the previous model, under the new plan patients will have the right to refuse to allow their electronic health records to be uploaded to the national health records system, to request that their permission be sought each time the electronic health record is viewed, or to permit the health record always be available to NHS staff with access rights.

Other countries sought to pass legislation that supports the implementation of electronic health records while protecting the confidentiality of patient information. In May 2008, British Columbia became the first Canadian province to create a legislative framework governing the collection, use, and disclosure of personal health information in electronic health records. The E-Health (Personal Health Information Access and Protection of Privacy) Act (EHR) will create an electronic health record for every British Columbian.<sup>22</sup> Among other things, the legislation prohibits disclosure of health information for market research, establishes monetary penalties for privacy and security breaches associated with the electronic health record, and allows patients to exercise control over the disclosure of their personal information by blocking access to the information. Implementation of the EHR will begin next year. In Australia, however, a plan by the National

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19. See *id.* ¶ 11.

20. See *id.* ¶ 12.

21. *Patient Record Consent Plan Changes*, KABLE, Sept. 18, 2008, <http://www.kablenet.com/kd.nsf/Frontpage/4BE07545CDACD413802574C8003C9DFE?OpenDocument>.

22. E-Health (Personal Health Information Access and Protection of Privacy) Act, 2008 S.B.C., ch. 38 (Bill 24) (Can.), available at [http://www.leg.bc.ca/38th4th/3rd\\_read/gov24-3.htm](http://www.leg.bc.ca/38th4th/3rd_read/gov24-3.htm) (last visited Nov. 30, 2008).

E-Health Transition Authority<sup>23</sup> to set up a national scheme to govern the exchange of electronic health records across state borders has not yet been approved by the Council of Australian Governments (COAG). The failure to secure approval from the COAG has further delayed the implementation of a national electronic health records system.<sup>24</sup>

United States lawmakers also proposed bills to support the adoption of electronic medical records.<sup>25</sup> None of the bills were enacted, and some lawmakers and advocacy groups continue to express concerns over the security of patient information contained in electronic health records. President Bush issued an executive order in 2004 that called for the development and nationwide implementation of an interoperable health information technology infrastructure by 2014 to improve the quality and efficiency of health care.<sup>26</sup> Bush's executive order created the position of National Health Information Technology Coordinator within the Department of Health and Human Services to lead the effort. It is now believed that health information technology legislation will not be addressed by the Congress until mid-2009 and the goal of a nationwide electronic medical records system by 2014 will not be fully realized.

Progress toward the goal of a nationwide electronic health records system in the United States, however, was made this year. In June 2008, the Centers for Medicare and Medicaid Services (CMS) announced that twelve sites would participate in a five-year demonstration project. The CMS Electronic Health Record Demonstration Project will provide incentives to physicians for using electronic health records to improve patient care.<sup>27</sup> And on August 10, 2008, the State of Massachusetts passed a health care bill that, among other things, seeks to disseminate health care technology across the State, which includes implementing electronic health records in all health care provider settings in the State by 2015. The law establishes a health information technology council to lead that effort.<sup>28</sup>

In addition to attempts to implement electronic health records systems outlined above, some countries sought to implement other forms of health information technology to improve health care services. For example, in November 2008, after extensive consultation with the EU member states, health professionals, patient associations, and industry representatives, the European Commission announced an initiative to increase the scope of telemedicine services for EU citizens and healthcare professionals across Europe.<sup>29</sup>

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23. The National E-Health Transition Authority, a not-for-profit company created by the Council of Australian Governments, was established to set the standards and infrastructure requirements for secure, interoperable electronic health information systems. All state, territorial, and national governments jointly fund it.

24. Ben Woodhead, *Patient Records Off Agenda*, MIS FINANCIAL REVIEW, Oct. 6, 2008, available at <http://www.misaustralia.com/viewer.aspx?EDP://20081006000030389252>.

25. The Protecting Records, Optimizing Treatment, and Easing Communication Through Health Care Technology Act of 2008, H.R. 6357, 110th Cong. (2008); Wired for Health Care Quality Act, S. 1693, 110th Cong., S. 1693 (2007).

26. Exec. Order No. 13,335, 67 Fed. Reg. 24,059 (Apr. 27, 2004).

27. Press Release, U.S. Department of Health and Human Services, HHS Secretary Announces 12 Communities Selected to Advance Use of Electronic Health Records in First Ever National Demonstration (June 10, 2008) available at <http://www.hhs.gov/news/press/2008pres/06/20080610a.html>.

28. MASS. GEN. LAWS ch. 40J, § 6D (2008).

29. *European Commission Adopted a Communication to Support and Improve Access to Telemedicine*, eHEALTHNEWS.EU, Nov. 5, 2008, available at <http://www.ehealthnews.eu/content/view/1387/27/>; see also *Telemedicine for the Benefit of Patient, Healthcare Systems and Society*, Europe's Information Society, [http://ec.europa.eu/information\\_society/activities/health/policy/telemedicine/index\\_en.htm](http://ec.europa.eu/information_society/activities/health/policy/telemedicine/index_en.htm) (last visited Nov. 30, 2008).

Telemedicine is viewed as a tool to improve quality of care and increase access to health-care services.<sup>30</sup> The European Commission initiative includes clarifying existing EU legislation applicable to telemedicine services. That same month in the United States, the CMS implemented an initiative to encourage the use of electronic prescribing, another tool to improve health care quality and efficiency. The CMS passed a regulation that provides physicians with monetary incentives<sup>31</sup> to use a qualified electronic prescribing system<sup>32</sup> to transmit prescriptions to pharmacies when prescribing drugs for patients with Medicare.<sup>33</sup>

The annual report of WHO noted the benefits of using information and communication technologies to improve access to and quality of health care services.<sup>34</sup> For example, the report highlights the use of health information technology in Chile to immediately transmit electrocardiograms of patients suspected of having a heart attack to specialists who confirm the diagnosis by email and fax. A village in Kenya has drastically reduced clerical labor and errors and improved follow-up care through the use of electronic health records integrated with laboratory systems, drug procurement systems, and reporting systems. In Cape Town, South Africa, patients with tuberculosis are sent personalized SMS messages reminding them to take their medicine. In May 2005, the World Health Assembly adopted Resolution WHA 58.28 which established a health information technology strategy for WHO and urged member states to develop and implement appropriate health information technologies in their countries.

## VI. Patent and Regulatory Developments

In late 2007 and through 2008, the EU continued efforts to harmonize existing divisions regarding a new EU patent scheme but had generally limited results.<sup>35</sup> Of concern have been divisions in member state preferences as to the priority of creating an EU-wide patent system as well as a standardized system for resolution of patent disputes. While the EU has sought to control patent administrative costs by limiting the patent regime to a specific number of languages,<sup>36</sup> no agreement has been reached on this matter or on choice of jurisdiction for resolving patent disputes as of 2008. Notwithstanding the EU's

30. Telemedicine is the delivery of health care services using information and communication technologies where individuals (e.g., two health care professionals or a health care professional and patient) are not in the same location.

31. During 2009 and 2010, physicians who use electronic prescribing systems will receive an incentive payment of two percent of their total Medicare allowed charges. The incentive amount will be reduced to one percent for 2011 and 2012 and will be half of a percent in 2013. Beginning in 2012, payments to Medicare eligible providers will be reduced if they do not adopt e-prescribing.

32. A qualified electronic prescribing system must be able to: (1) communicate with the patient's pharmacy; (2) help the physician identify appropriate drugs and provide information on lower cost alternatives for the patient; (3) provide information on formulary and tiered formulary medications; and (5) generate alerts about possible adverse events, such as improper dosing, drug-to-drug interactions, and allergy concerns.

33. E-Prescribing Exemption for Computer-Generated Facsimile Transmissions, 73 Fed. Reg. 69726, 69783-88 (Nov. 19, 2008).

34. WHO, THE WORLD HEALTH REPORT 2008: PRIMARY HEALTH CARE NOW MORE THAN EVER 51.

35. See e.g., Joe Kirwin, *EU Members Fall Short of Breakthrough in Long Effort to Consolidate Patent Regimes*, 75 Pat., Trademark & Copyright J. (BNA) 121 (Nov. 30, 2007).

36. *Id.* The proposed plan to use only German, English, and French has been unpopular with certain EU member states (e.g., Spain and Italy) as a potential dilution of use of their home languages in other areas.

difficulties in standardizing a patent regime, regulatory authorities and drug makers have generally agreed upon the need for a single European patent office, patent law, and patentability standards.<sup>37</sup>

In 2008, multiple public comments expressed an ongoing concern with the use of patents as a mechanism to impede global access to medications and diagnostics on a wide-scale. An interim report of the European Commission states that EU pharmaceutical firms use certain tactics to delay market entry for generic drug products.<sup>38</sup> Such tactics include “patent clustering,<sup>39</sup> multiple litigations involving prospective producers of generic equivalents, and settlements of patent disputes under which a generic producer may voluntarily agree to delay market entry in exchange for royalty payments derived from sales of the patented products or other compensation.<sup>40</sup> The Commission’s report is a prelude to focused enforcement strategies, but the Commission did note that having “found the scent” of potential market restraints, the Commission would “not hesitate to take antitrust action when required.”<sup>41</sup>

Echoing the concerns of the European Commission, but with respect to biotechnology, at least one trade group issued a criticism of patent regimes, noting that the progression of technological advances and the provision of new drug therapies to global consumers may be restricted if patent regimes are not restructured to promote collaboration over hyper-protection.<sup>42</sup> The trade group’s 2008 report notes that overemphasis on patents and research controlled by private interested parties has generated litigation potentially paralyzing consumer interests, along with limitations and market entry roadblocks preventing consumer access to critical therapeutics and diagnostic tests. Of note are recommendations that academic entities and universities should: clarify and codify guidelines on generation, use, and dissemination of intellectual property; focus technology transfer benchmarks on social effect rather than on number of patents filed and owned; and promote inter-institutional collaborations, particularly between developed and developing countries.<sup>43</sup>

Specific patent issues addressed in 2008 included a European ruling that EU patent law does not recognize the patentability of human stem cell cultures prepared as a consequence of the destruction of human embryos.<sup>44</sup> The ruling, made by the European Patent

37. See e.g., Joe Kirwin, *Commission Accuses Drug Companies of Impeding Market Entry of Generics*, 77 Pat., Trademark & Copyright J. (BNA) 132 (Dec. 5, 2008).

38. See Competition DG, EUROPEAN COMMISSION, PHARMACEUTICAL SECTOR INQUIRY: PRELIMINARY REPORT (2008), available at [http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/exec\\_summary\\_en.pdf](http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/exec_summary_en.pdf).

39. Patent clustering describes the filing and maintenance of a web of patents covering and claiming a drug product, methods of manufacture and use of the drug product, etc. See *infra* note 37, at 132-33.

40. See *id.*

41. *Id.* (citing Competition Commissioner Neelie Kroes).

42. See *Outmoded IP System Must Give Way to Collaborative One, Biotech Group Says*, 76 Pat. Trademark & Copyright J. (BNA) 759 (Oct. 3, 2008) (citing INT’L EXPERT GROUP ON BIOTECHNOLOGY, INNOVATION AND INTELL. PROP., TOWARD A NEW ERA OF INTELLECTUAL PROPERTY: FROM CONFRONTATION TO NEGOTIATION (2008) [hereinafter NEW ERA OF INTELL. PROP.], available at [http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP\\_Report\\_E.pdf](http://www.theinnovationpartnership.org/data/ieg/documents/report/TIP_Report_E.pdf)).

43. See *id.*

44. *In re Wisconsin Alumni Research Foundation*, [2008] EWHC (Pat.), No. G 0002/06, 2008, (Eng.) [hereinafter *In re WARF*], available at [http://documents.epo.org/projects/babylon/eponet.nsf/0/428862B3DA9649A9C125750E002E8E94/\\$FILE/G0002\\_06\\_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/428862B3DA9649A9C125750E002E8E94/$FILE/G0002_06_en.pdf).

Office's Enlarged Board of Appeal, followed a 2006 request for clarification of the patentability of an application by the Wisconsin Alumni Research Foundation (WARF) claiming a method for obtaining primate embryonic stem cell cultures under EU law.<sup>45</sup> The Board acknowledged that the claimed human stem cell cultures cannot be produced but for the destruction of human embryos, and thus are unpatentable under the European Patent Convention's applicable provisions which prohibit patenting "inventions whose commercial exploitation would be contrary to public order or morality."<sup>46</sup> It is critical to note that the Board expressly reserved any comment or opinion on the question of whether human stem cells can be patented under any circumstances, and in declining to so opine, invited comment from the industry regarding the effect of its decision:

In reaching its decision, the Enlarged Board of Appeals emphasized the fact that[when] . . . the priority patent application was filed (in 1995), the only method of obtaining hESCs [human embryonic stem cells], as described in the application, required the use of a human embryo. In contrast, following . . . [the discovery claimed by the 1995 application], many [human embryonic stem cell] lines became widely available through stem cell banks, obviating the need for researchers to culture the cells from embryonic material. Therefore, this decision should not affect patent applications for later-developed [human embryonic stem cell] technologies, including technologies . . . to enable scalable manufacture of [human embryonic stem cells] for therapeutic and drug discovery applications, and their differentiation into a range of functional cell types. . . .<sup>47</sup>

Similarly, WARF noted that there should be little to no effect under U.S. patent law because the Board's ruling 'was based on European patent rules that are peculiar to Europe.'<sup>48</sup>

Brazil established what has been regarded as a precedent in its attempts to revisit the validity of patents issued claiming non-Brazilian pharmaceutical products.<sup>49</sup> Before the 1996 enactment of Brazil's intellectual property law, Brazil did not grant patents for pharmaceutical products, but a certain provision of the 1996 enactment automatically grants such products Brazilian patent protection if patented elsewhere in the world without examination by Brazilian patent authorities.<sup>50</sup> In the precedent setting case, Brazilian pharmaceutical company Libbs Farmaceutica sought to overturn Bayer Schering's patent on the birth control pill Yasmin, claiming that Yasmin is identical to another Schering prod-

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45. John T. Aquino, *EPO Rejects Stem Cell Patent Application from WARF Because Embryos Destroyed*, 77 Pat. Trademark & Copyright J. (BNA) 130 (Dec. 5, 2008) [hereinafter *EPO Rejects WARF*].

46. *Id.* (citing Article 53(a) EPC and the EU Biotechnology Directive (98/44/EC)). The Board's ruling explicitly rejected the WARF argument that the prohibition only applied to claims covering human embryos, noting that human stem cells could not be used without having been made, and could not have been made without destruction of human embryos. See *In re WARF*, No. G 0002/06 at §§ X.15, 22, 23.

47. *EPO Rejects WARF*, *supra* note 45, at 130 (quoting the Nov. 27, 2008 statement of Geron Corporation).

48. *Id.* (quoting WARF News, European Patent Office Decision on WARF Appeal for Stem Cell Patent, Statement From Wisconsin Alumni Research Foundation, (Nov. 27, 2008) [http://www.warf.org/news/news.jsp?news\\_id=236](http://www.warf.org/news/news.jsp?news_id=236)).

49. Ed Taylor, *Brazilian Court Sets Precedent in Revoking Patent Issued for Birth Control Pill Yasmin*, 76 Pat. Trademark & Copyright J. (BNA) 740, 740 (Sept. 26, 2008).

50. *Id.* This provision has been known as the "pipeline" clause, and resulted in valid Brazilian patents extending to the limit of patent protection under non-Brazilian laws.

uct whose patent protection had expired.<sup>51</sup> The Brazilian government intervened with an opinion that Yasmin was not patentable due to lack of “inventiveness,” which Brazilian law requires.<sup>52</sup> Although Schering of Brazil has specified its intent to appeal the decision to Brazil’s Supreme Court, the Brazilian government appears to have indicated its willingness to pursue such challenges in the future.<sup>53</sup>

## VII. World Trade Organization and United States Trade Representative

In 2008, Jordan became the eighteenth World Trade Organization member to ratify the 2005 amendments to the WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>54</sup> The protocol, incorporating an August 2003 agreement, provides a waiver of section 31(f) of TRIPS and permits pharmaceutical products manufactured under compulsory licenses to be exported to countries without production capacity.<sup>55</sup> In late 2007, Rwanda became the first country to notify the WTO that it plans to import generic pharmaceutical products (specifically Apo-triAvir) under these provisions<sup>56</sup> and Canada agreed to provide the drug to Rwanda as a first venture under Canada’s plans to export drugs under the TRIPS compulsory licensing regime.<sup>57</sup>

From late 2007 through 2008, the United States raised repeated objections to the WTO as to what it sees as certain member countries’ failure to provide appropriate intellectual property protections. In late 2007, the WTO addressed continuing concerns of China’s restriction on the sale and distribution of audiovisual and music downloads from the United States and other countries, ultimately creating a dispute panel under the authority of its Dispute Settlement Body.<sup>58</sup> The United States alleged that China permits only state-run companies to import a variety of entertainment media,<sup>59</sup> effectively favoring Chinese domestic distributors of audiovisual entertainment over foreign distributors. Additionally, the United States argued that Chinese rules require “content review” before the distributing of any music in which rights are held by foreign entities, although China responded that such requirements actually protect intellectual property rights “by ensuring dependable market channels for duly-authorized cultural products.”<sup>60</sup>

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51. *Id.* at 741.

52. *Id.*

53. *See id.* (quoting statement of Mauro Maia, chief prosecutor of the Brazilian patent office; *see also id.* (noting that the Brazilian patent office has already applied the lack of inventiveness standard to reject a patent application for Gilead Sciences’ antiretroviral drug Tenofovir)).

54. *See* Daniel Pruzin, *Jordan Ratifies WTO TRIPS Amendments on Access to Essential Medicines*, 76 Pat. Trademark & Copyright J. (BNA) 559 (Aug. 15, 2008). The amendments will become effective only upon ratification by two-thirds of the 151 WTO members. The current deadline is December 31, 2009. *See id.*

55. *See id.*

56. *See Rwanda Notifies WTO of Plans to Import Medicines Under New TRIPS Rules*, 74 Pat. Trademark & Copyright J. (BNA) 412 (Aug. 3, 2007). Apo-triAvir is a fixed-dose combination of Zidovudine, Lamivudine, and Nevirapine, manufactured by generic pharmaceutical manufacturer Apotex, Inc.

57. *See* Daniel Pruzin, *China Ratifies WTO TRIPS Amendments on Essential Medicines for Poor Nations*, 75 Pat. Trademark & Copyright J. (BNA) 145 (Dec. 7, 2007).

58. Daniel Pruzin, *WTO Sets up Dispute Panel to Rule on Chinese Audiovisual Restrictions*, 75 Pat. Trademark & Copyright J. (BNA) 123 (Nov. 30, 2007). The panel was established after a second request by the United States, the first of which was blocked by China. *See id.*

59. *See id.* at 123-124. Such media include DVDs, books, movies, journals, and other publications.

60. *Id.* at 124.

Additionally, the United States reiterated concerns with Thailand's policies regarding intellectual property protection and such policies' contribution to declining U.S. investment in Thailand.<sup>61</sup> Specifically, the U.S. Ambassador to the WTO noted 'a significant overall decline in enforcement actions and an increase in piracy levels' since the WTO's trade policy report on Thailand in 2003.<sup>62</sup> Thailand responded that while it remains committed to enhanced enforcement of intellectual property rights and has made substantial efforts to combat piracy and counterfeiting, intellectual property rights violations will be difficult to eliminate altogether given the lower cost of pirated or counterfeit goods.<sup>63</sup> Additionally, the United States Trade Representative (USTR) reaffirmed Thailand's status as "one of the nine worst countries for the protection of intellectual property rights" in the USTR's annual Special 301 Report, reportedly due to Thailand's continuing interest in the compulsory licensure of drug products.<sup>64</sup>

In 2008, Thailand again emphasized that it is willing to require compulsory licensure of several U.S. drug products to treat cancer and cardiovascular disease, drawing strong criticism from some members of the U.S. Congress.<sup>65</sup> These critics noted that although TRIPS may be utilized to address critical public health needs, its rules should not be construed to grant the right to 'allow compulsory licenses as a matter of standard governmental policy, especially without any meaningful prior consultation with the patent holders.'<sup>66</sup> The February 2008 report issued by the Thai Ministry of Public Health and National Health Security Office stated that, with respect to four oncology therapies, generic equivalents can be produced at significantly lower prices.<sup>67</sup> But it also notes that the Thai government had considered only seven drugs for compulsory licensing and that compulsory licensing will be utilized only in cases where such licensing is 'truly necessary.'<sup>68</sup>

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61. Daniel Pruzin, *U.S. Cites Backsliding by Thailand on IP Protection, Weakening Investment*, 75 Pat. Trademark & Copyright J. (BNA) 123 (Nov. 30, 2007).

62. *Id.* (quoting Press Release, Ambassador Peter F. Allgeier (USTR), US Mission to the WTO (Nov. 26, 2007) available at <http://geneva.usmission.gov/Press2007/1126ThailandTPR.html>).

63. *See id.*

64. Philip Snashall, *Thai Government Lashes out at U.S. Decision to Keep Country on IPR Priority Watch List*, 76 Pat. Trademark & Copyright J. (BNA) 95 (May 16, 2008) (citing U.S. TRADE REPRESENTATIVE, 2008 SPECIAL 301 REPORT (2008), available at [http://www.ustr.gov/assets/Document\\_Library/Reports\\_Publications/2008/2008\\_Special\\_301\\_Report/asset\\_upload\\_file553\\_14869.pdf](http://www.ustr.gov/assets/Document_Library/Reports_Publications/2008/2008_Special_301_Report/asset_upload_file553_14869.pdf)).

65. *See* Amy Tsui, *Lawmakers Write to USTR Protesting Thailand's Compulsory Licensing of Drugs*, 76 Pat. Trademark & Copyright J. (BNA) 559 (Aug. 15, 2008).

66. *Id.* (quoting letter from 52 members of U.S. Congress, to Susan Schwab, U.S. Trade Representative (July 31, 2008) available at [http://www.chi.org/uploadedFiles/News/News\\_Items/Thailand%20CL%20Letter%20-%20Schwab%20-%207-31-08.pdf](http://www.chi.org/uploadedFiles/News/News_Items/Thailand%20CL%20Letter%20-%20Schwab%20-%207-31-08.pdf)).

67. *See id.* The drug products, their brands, and their respective indications included Docetaxel (Taxotere, for the treatment of lung cancer), Letrozole (Femara, for the treatment of breast cancer), Erlotinib (Tarceva, for the treatment of chronic myeloid leukemia), and Imatinib (Gleevec, for the treatment gastrointestinal stromal tumors).

68. *Id.* (quoting THE MINISTRY OF PUBLIC HEALTH & THE NATIONAL HEALTH SECURITY OFFICE THAILAND, THE 10 BURNING QUESTIONS REGARDING THE GOVERNMENT USE OF PATENTS ON THE FOUR ANTI-CANCER DRUGS IN THAILAND, 13 (2008) available at [http://unitcost.fda.moph.go.th/cl/document\\_file/document\\_20080611111245-1.pdf](http://unitcost.fda.moph.go.th/cl/document_file/document_20080611111245-1.pdf)).

### VIII. World Intellectual Property Organization

The World Intellectual Property Organization (WIPO) appointed a new director-general, Francis Gurry, on October 1, 2008, completing a process initiated in late 2007 with the announcement by former director-general, Kamil Idris, that he planned to leave office prior to expiration of his term on November 30, 2009.<sup>69</sup> In his acceptance speech to the WIPO General Assembly on September 22, 2008, Gurry identified several challenges to global intellectual property protection and enforcement consistent with WIPO's areas of ongoing focus, including trademark and industrial design protection issues.<sup>70</sup> For example, on November 12-16, 2007, WIPO's Standing Committee on the Law of Trademarks, Industrial Designs and Geographic Indications met to continue investigation of how to standardize practices, including: (a) the protection of new types of marks, including three-dimensional, holographic and sound marks;<sup>71</sup> (b) opposition procedures, including extent of examination of opposition procedures, length of opposition and settlement negotiations, (c) industrial design registration formalities, and (d) international non-proprietary names for pharmaceutical substances under current WHO programs and resolutions.<sup>72</sup> Furthermore, in 2008 WIPO noted an 18 percent increase in internet domain name disputes raised before the Organization in 2006—a result of sustained growth in domain name registrations, as well as an increase in “questionable practices,” including “domain name ‘tasting,’” and the use of privacy and/or proxy registration services to disguise or cover the identity of the domain name holder.<sup>73</sup> Such automated practices potentially thwart the efforts of the rights holder in effectively proceeding with complaints against violators as well as compromising the integrity of the international domain registration system, according to Deputy Director-General Gurry:

The potentially useful purpose of any new domains would be frustrated if these get filled predominantly with automated pay-per-click content. . . . This is not just an issue of protecting rights of trademark holders, but also an issue of the reliability of the addressing system of the Internet in matching interested parties with authentic subjects.<sup>74</sup>

In an attempt to address potential solutions, WIPO proposed obligating registration services to provide reasonable information on registrants in response to claims of trademark abuse, as well as the possibility of requiring an upfront fee for registration, thereby discouraging registrants from engaging in domain tasting.<sup>75</sup>

69. See Daniel Pruzin, *IP Organization Unveils Proceedings to Nominate Replacement Director-General*, 75 Pat. Trademark & Copyright J. (BNA) 117 (Nov. 30, 2007).

70. See Daniel Pruzin, *WIPO to Focus on Trademark Issues, Areas of Convergence*, 75 Pat. Trademark & Copyright J. (BNA) 120 (Nov. 30, 2007).

71. *Id.*

72. See *id.* The WHO has resolved that generic designations for pharmaceuticals should not be registered as trademarks, although approximately 7,000 international non-proprietary names have been published by WIPO since 1950. *Id.*

73. Daniel Pruzin, *WIPO Notes Jump in Domain Name Disputes, Threat From ‘Tasting,’ Proxy Registrations*, 75 Pat. Trademark & Copyright J. (BNA) 605 (Apr. 4, 2008). Domain tasting involves registration of domain names during a five-day no-fee grace period to take advantage of pay-per-click revenue generation on the registered site.

74. *Id.*

75. *Id.*

Finally, with respect to patent matters before the WIPO in 2008, the WIPO General Assembly agreed to a decrease in the Patent Cooperation Treaty (PCT) international filing fee from 1400 Swiss francs to 1330 francs,<sup>76</sup> and agreed to increase the discount on the PCT filing fee for applicants from developing countries from 75 percent to 90 percent.<sup>77</sup>

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76. Daniel Pruzin, *WIPO Members Approve Patent Fee Cuts, Agree on Budget*, 75 Pat. Trademark & Copyright J. (BNA) 604 (Apr. 4, 2008). The reduced filing fee became effective on July 1, 2008.

77. See *id.* (Qualifying developing countries are those with annual per capita income less than \$3,000.).