

**UNITED STATES**  
**JOINT SUBMISSION TO THE UN UNIVERSAL PERIODIC REVIEW**  
**NINTH SESSION OF THE HRC UPR WORKING GROUP**  
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American University Washington College of Law's Program on Information Justice and Intellectual Property (PIJIP) and Health Global Access Project (Health GAP), European Community Advisory Board (ECAB)  
Sean Flynn, Associate Director, PIJIP

1. This submission requests that the Committee review U.S. compliance with human rights duties to promote access to medicines in developing countries through its trade policies. The United States has a long history of using trade agreements, foreign aid, technical assistance and diplomatic pressure to promote intellectual property and pharmaceutical regulations that restrict access to affordable medications in developing countries. These policies are continuing in the present administration, and cause grave and needless suffering around the world. UN Human Rights officials have frequently affirmed that promoting access to medicines in poor countries is a human rights duty of all countries, including of donors and trade partners, and have reviewed country compliance with these mandates in human rights review proceedings such as this one.
2. PIJIP is a program of American University Washington College of Law that promotes public interests in U.S. and international intellectual property policy. Health GAP is an organization of U.S.-based AIDS and human rights activists, people living with HIV/AIDS, public health experts, fair trade advocates and concerned individuals who campaign against policies that deny treatment for HIV. ECAB is a volunteer, community-based structure, collaborating actively with national Community Advisory Boards in Europe and other groups to broaden access to HIV treatment.

**HUMAN RIGHTS OBLIGATE COUNTRIES TO PROMOTE ACCESS TO MEDICINES  
IN TRADE POLICY**

3. The World Health Organization estimates that the deaths of about 18 million people, one third of all human deaths, are caused by medical conditions that we could treat or cure.<sup>1</sup> A primary reason for this avoidable carnage is the lack of access to affordable and effective treatments in poor countries.
4. Promoting access to affordable medicines for the poor is a widely recognized human rights duty, emanating from the recognition of civil and political as well as social and economic rights that bind the United States.<sup>2</sup> Health and social policies which increase mortality and morbidity implicate the right to life in Article 6(1) of the International Covenant on Civil and Political Rights<sup>3</sup> as well as Articles 22 and 25.1 of the Universal Declaration of Human Rights.<sup>4</sup>
5. States are bound to promote and protect the rights to life and health not only of their own citizens, but also of the citizens of other countries affected by their foreign policy, trade and assistance programs.<sup>5</sup>
6. Intellectual property is a prime determinate of access to needed medicines because it is a form of social regulation that, by design, raises prices through monopoly rights.
7. The negative social impact of intellectual property on access to medicines in developing countries can be particularly severe. In countries with high income inequality, which

defines most poor countries, intellectual property monopolies provide economic incentives to price needed medicines so high that only the richest sliver of populations can afford access.<sup>6</sup> Thus, in the late 1990s, it was common (and rational) for patent holding companies to charge over \$10,000 a year for AIDS treatments in rich and poor countries alike, even though generic versions can now be obtained for less than \$100 a year (an indication of the true cost of competitive production).

8. In recognition of the foreseeable impact of monopolies on needed medicines, particularly in developing countries, the globalization of intellectual property for pharmaceutical products through the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) included a full range of permissible limitations and exceptions.
9. As described by the Special Rapporteur on the Right to Health, to promote access to medicines and the right to health while complying with the minimum standards of the TRIPS agreement, developing countries “should incorporate the flexibility to: (a) Make full use of the transition periods; (b) Define the criteria of patentability; (c) Issue compulsory licences and provide for government use; (d) Adopt the international exhaustion principle, to facilitate parallel importation; (e) Create limited exceptions to patent rights; (f) Allow for opposition and revocation procedures. In addition, countries need to have strong pro-competitive measures to limit abuse of the patent system.”<sup>7</sup>
10. After passage of the TRIPS agreement, the U.S. pressed many countries to give up their rights to use many of these pro-access policies, including to issue compulsory licenses (i.e. authorization to use a patent in return for compensation) and to “parallel import” less expensive versions of patented drugs from other countries. Two particular cases – pressure on South Africa to give up parallel importation and pressure on Brazil to give up compulsory licenses – threatened to doom AIDS treatment programs and stoked international outrage and an access to medicines popular movement.<sup>8</sup>
11. The World Trade Organization’s 2001 Doha Declaration on TRIPS and Public Health was passed in direct response to U.S. pressure and sought to clarify the ability of countries to use exceptions and limitations to intellectual property rights to promote public health. The agreement affirmed “the right of WTO Members to use, *to the full*, the provisions in the TRIPS Agreement, which provide flexibility [to promote access to medicines for all].”
12. UN human rights officials and bodies have repeatedly found that the globalization of intellectual property rights can only be squared with human rights if countries are permitted and encouraged to utilize the full scope of intellectual property exceptions and limitations provided for in the TRIPS agreement to promote access to medicines.<sup>9</sup>
13. Examining the human rights duties of states to take advantage of TRIPS flexibilities to promote access to medicines has been a frequent subject of human rights treaty monitoring bodies.<sup>10</sup> Such reviews have included analysis of the duties of wealthy countries to promote the use of TRIPS flexibilities in poor countries.<sup>11</sup>
14. This body of human rights law was summarized by Special Rapporteur Paul Hunt as meaning that “that no rich State should encourage a developing country to accept intellectual property standards that do not take into account the safeguards and flexibilities included under the TRIPS Agreement. In other words, developed States should not encourage a developing country to accept ‘TRIPS-plus’ standards.”<sup>12</sup>

## **THE U.S. PRESSES COUNTRIES TO RESTRICT ACCESS TO MEDICINES THROUGH “TRIPS-PLUS” TRADE PRESSURE**

15. Despite the Doha declaration, clear human rights duties and the demands of global health, the U.S. has continued to pressure developing countries to give up TRIPS flexibilities.
16. During a brief period at the end of the Clinton Administration, U.S. trade policy was altered to reduce TRIPS-plus pressure on access to medicines. The USTR announced a new policy that “should a government determine to avail itself of the flexibility the TRIPS Agreement” to address a public health need, “the United States will raise no objection.”<sup>13</sup> President Clinton’s Executive order 13155 ordered that “the United States shall not seek, through negotiation or otherwise,” alteration of any intellectual property or pharmaceutical regulation that “promotes access to HIV/AIDS pharmaceuticals or medical technologies” and complies with the minimum Standards of TRIPS.
17. The Bush Administration assented to the Doha Declaration in 2001, but ignored its intent through vigorous promotion of TRIPS-Plus standards on medicines,<sup>14</sup> including in Sub Saharan Africa.<sup>15</sup> The administration’s public position was that it could pressure developing countries to give up TRIPS flexibilities because “IP rights ultimately enhance public health.”<sup>16</sup> This position has been frequently countered by the World Health Organization, which has constantly emphasized the public health need for developing countries to take full advantage of intellectual property flexibilities to promote access to medicines.<sup>17</sup>
18. One of the central tools used by the U.S. to promote “TRIPS-plus” policies on access to medicines has been the “Special 301” program. The program requires USTR to publish a list of countries that deny “adequate and effective protection of intellectual property” and permits the unilateral imposition of trade sanctions against such countries, even in the absence of violation of any trade agreement. There are many notable examples of the use of the Special 301 program to sanction countries for access to medicines policies that do not violate international trade commitments:<sup>18</sup>
  - a. Before TRIPS was enacted, Brazil, Thailand and India were sanctioned through GSP benefit withdrawals for not granting product patents for pharmaceuticals (a policy of Switzerland, Japan and other developed countries well into the 1970s);
  - b. In 1998, South Africa was listed on 301’s watch lists and GSP benefits were revoked for passing a law authorizing TRIPS-compliant parallel importation;
  - c. Up to and including the 2009 report, Brazil, India, Thailand and other countries were threatened with sanctions under Special 301 for taking advantage of TRIPS flexibilities, including utilizing transition periods and compulsory licenses -- a move criticized by members of the U.S. Congress as sending “a troubling message . . . that the exercise of recognized public health flexibilities in trade obligations is frowned on the by the United States”<sup>19</sup>;
  - d. In 2003, the report announced that the U.S. would interpret TRIPS to require an additional form of “data exclusivity” monopoly protection for pharmaceuticals, even though such a provision was explicitly amended out of the TRIPS agreement in the negotiation.

19. Free trade agreements signed with developing countries after the Doha declaration pressed those countries to adopt numerous TRIPS-plus intellectual property standards that threaten access to medicines.<sup>20</sup>
20. The United States has a long history of using pressuring countries to adopt special marketing monopolies called “data exclusivity.” Data exclusivity prevents the registration of generic products for a period of time, even if the brand name company does not have or cannot obtain a patent. Research by the Center for Policy Analysis on Trade and Health (CPATH) has shown that TRIPS-plus data exclusivity provisions advanced by the US have granted marketing monopolies for products that were already on the market as generics in Guatemala (leading to withdraws of supplies), including for medicines that never filed for a patent in the region and are off patent in the U.S. To comply with U.S.-promoted policies, the Guatemalan public sector now faces higher prices – up to 846 percent higher – for important drugs to fight diseases such as diabetes and HIV/AIDS.<sup>21</sup>
21. TRIPS-plus trade pressures are continuing under the current administration. The 2009 Special 301 Report, the first issued in the Obama Administration, presses developing countries to limit grounds for compulsory licenses, restrict freedom to define the scope of patentability, prohibit parallel importation, extend patents beyond 20 years, implement “linkage” between drug registration and assertions of patent protection, adopt U.S. or EU-style “data exclusivity” rules that create drug monopolies independent of patents, and do away with evidence-based formularies and other price and competition restrictions on pharmaceutical monopoly power.<sup>22</sup> The administration also co-hosted a meeting in India with Pfizer in which it advocated for the adoption of TRIPS-plus rules, including data exclusivity and patent linkages, in that country.

## CONCLUSION

22. The Committee should call on the U.S. to account for its foreign policy that encourages developing countries to adopt intellectual property norms that restrict access to medicines. The Committee should encourage the U.S. to use its trade and foreign assistance programs to promote full use of TRIPS flexibilities to promote access to medicines.

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<sup>1</sup> World Health Organization, *The World Health Report 2004* Annex table 2 (2004).

<sup>2</sup> CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health, E/C.12/2000/4 para 2 (2000).

<sup>3</sup> See *The Right to Life*, U.N. GAOR Human Rights Comm., 37th Sess., Supp. No. 40, at Gen. Comment No. 6, ¶ 5, U.N. Doc. A/37/40 (1982); Concluding Observations of the Human Rights Committee: Peru, ¶¶ 13, 15, U.N. Doc. CCPR/C/79/Add.72 (1996).

<sup>4</sup> Art. 22 protects “the economic, social and cultural rights indispensable for his dignity”; Art. 25 protects “the right to a standard of living adequate for the health of himself and of his family, including . . . medical care.”

<sup>5</sup> Universal Declaration of Human Rights, Art. 22 (requiring “national effort and international cooperation”); Art. 28 (“Everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized.”); 166 U.N. CHARTER arts. 55-56 (calling on members to take “joint and several action” to promote “a higher standard of living,” “solutions of international economic, social health and related problems,” and “universal respect for, and observance of, human rights”).

<sup>6</sup> Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. Med. & Ethics 184 (2009); Eina V. Wong, *Inequality and Pharmaceutical Drug Pricing: An Empirical Exercise*, Ctr. for Econ. Analysis, Econ. Dep’t, Univ. of Colo. at Boulder, Working Paper No. 02-19 (2002).

<sup>7</sup> See Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, U.N. doc. A/HRC/11/12 para 27 (Mar. 31, 2009).

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<sup>8</sup> See ELLEN F. M. ‘T HOEN, *THE GLOBAL POLITICS OF PHARMACEUTICAL MONOPOLY POWER DRUG PATENTS, ACCESS, INNOVATION AND THE APPLICATION OF THE WTO DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH* (2009); Susan Sell, *TRIPS and the Access to Medicines Campaign*, 20 *Wisconsin International Law Journal* 2 (2002); Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 *U. PA. J. INT’L ECON. L.* 1069 (1996).

<sup>9</sup> See Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, U.N. doc. A/HRC/11/12 para. 27 (Mar. 31, 2009); Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, U.N. doc. A/63/263 para. 63 (11 August 2008); Human Rights and Intellectual Property, U.N. Comm. on Econ., Soc. & Cultural Rts., 27th Sess., ¶ 12, U.N. Doc. E/C.12/2001/15 para 12 (2001); “The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights,” Report of the High Commissioner, E/CN.4/Sub.2/2001/13 para 27-28 (27 June 2001).

<sup>10</sup> See Thailand, Concluding Observations, CRC/C/THA/CO/2, para 58 (27 January 2006); Peru, Concluding Observations, CRC/C/PER/CO/3, para 48-49 (27 January 2006); Ecuador, Concluding Observations, CRC/C/15/Add.262, para 21 (13 September 2005); Nicaragua, Concluding Observations, CRC/C/15/Add.265, para 16 (21 September 2005); Philippines, Concluding Observations, CRC/C/15/Add.259, para 59 (3 June 2005); Chile, Concluding Observations, E/C.12/1/Add.105, para 59 (26 November 2004); Ecuador, Concluding Observations, E/C.12/1/Add.100, para 55 (7 June 2004); Botswana, Concluding Observations, CRC/C/15/Add.242, para 20 (3 November 2004); El Salvador, Concluding Observations, CRC/C/15/Add.232, para 47-48 (30 June 2004); Uganda, Concluding Observations CCPR/CO/80/UGA, (4 May 2004).

<sup>11</sup> See Denmark, Summary Record, E/C.12/2004/SR.37, para 7 (16 November 2004).

<sup>12</sup> General Assembly A/61/338 para 63 (13 September 2006).

<sup>13</sup> USTR, 2000 Special 301 Report, <http://keionline.org/ustr/special301>

<sup>14</sup> Oxfam, *US Bullying on Drug Patents: One Year after Doha*, [http://www.oxfam.org.uk/resources/policy/health/downloads/bp33\\_bullying.pdf](http://www.oxfam.org.uk/resources/policy/health/downloads/bp33_bullying.pdf)

<sup>15</sup> See Jonathan Berger and Achal Prabhala, *Assessing the Impact of Trips-Plus Patent Rules in the Proposed US-Sacú Free Trade Agreement*, [http://www.who.int/hiv/amds/capacity/tza2\\_oxfamreport\\_pricing\\_financing.pdf](http://www.who.int/hiv/amds/capacity/tza2_oxfamreport_pricing_financing.pdf)

<sup>16</sup> GAO, Rep. to Congressional Requesters, *U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification*, GAO-07-1198 (2007) at 28.

<sup>17</sup> See Report of the Commission on Intellectual Property Rights, Innovation and Public Health (Apr. 2006) at 126; World Health Organization, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property of the Sixty-first World Health Assembly*, 24 May 2008, WHA61.21, element 5.2.c; WHO, *Globalization, TRIPS and Access to Pharmaceuticals*, WHO Doc WHO/EDM/2001.2 (Mar. 2001) at 4-5.

<sup>18</sup> See Sean Flynn, *Special 301 in the Obama Administration: The Assault on International Generic Medicines Continues*, [wcl.american.edu/pjijip/go/flynn04132010](http://wcl.american.edu/pjijip/go/flynn04132010)

<sup>19</sup> Letter from Rep. Henry Waxman, United States House of Representatives, et. al. to The Honorable Susan Schwab, United States Trade Representative (Jun. 20, 2007), available at <http://waxman.house.gov/News/DocumentSingle.aspx?DocumentID=153595>.

<sup>20</sup> See United States House of Representatives, Committee On Government Reform – Minority Staff, Special Investigations Division, *Trade Agreements and Access To Medications Under The Bush Administration*, Prepared For Rep. Henry A. Waxman (June 2005); Robert Weissman, *TRIPS-Plus Provisions in Trade Agreements: Consequences for Public Health*, Working Paper <http://www.essentialaction.org/access/uploads/tripsplusprovisions.doc>.

<sup>21</sup> Shaffer, Ellen R. and Brenner, Joseph E., *A Trade Agreement’s Impact On Access To Generic Drugs*, *Health Affairs*, 28, no. 5 (2009): w957-w968 (Published online 25 August 2009).

<sup>22</sup> See Sean Flynn, *Special 301 in the Obama Administration*, supra.