

ALLEGATION LETTER

UNITED NATIONS SPECIAL RAPPORTEUR ON THE RIGHT TO
HEALTH

IN THE MATTER OF
USE OF THE “SPECIAL 301” PROGRAM, SECTION 182 OF THE TRADE ACT OF 1974,
TO LIMIT ACCESS TO MEDICINES IN VIOLATION OF THE INTERNATIONAL RIGHT
TO HEALTH

Submission of

HEALTH GAP (Global Access Project); Agua Buena Human Rights Association; AIDS Access Foundation; Deli Network of People Living with HIV (DNP+); Drug Study Group Foundation for AIDS Rights (FAR); Foundation for Consumers; FTA Watch; Health and Development Foundation; International Treatment Preparedness Coalition; Kenya Legal and Ethical Issues Network on HIV & AIDS; **People’s Health Movement** - USA, Berkeley, CA; Positive Malaysian Treatment Access & Advocacy Group; Rural Pharmacist Foundation; Thai Network of People Living with HIV/AIDS; Thai NGOs Coalition on AIDS (TNCA); Thai Treatment Action Group; Professors Lateef Mtima and Steven D. Jamar, Institute of Intellectual Property and Social Justice, Howard University School of Law; Hala Essalmawi, Principal Attorney, The Library of Alexandria (Bibliotheca Alexandrina); Dr Vandana Shiva, Research Foundation for Science Technology and Ecology

Counsel of Record
Sean Fiil-Flynn
Program on Information Justice and Intellectual Property
American University Washington College of Law
4801 Massachusetts Ave NW
Washington DC 20016
(202)274-4157

1. In accordance with resolution 2002/31, we submit this allegation letter to request that the Special Rapporteur respond to the enclosed information documenting violations of the international right to health by the United States through the operation of its “Special 301” program and related trade policies.
2. The alleged victims in this matter are people in need of medicines in developing countries around the world. This allegation letter is submitted by Health GAP, 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. Health GAP is represented in this matter by Sean Flynn, Associate Director of the Program on Information Justice and Intellectual Property at American University Washington College of Law.
3. The United States has a long history of using Special 301, other trade negotiations, the Generalized System of Preferences, 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.

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

4. 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.¹ A primary reason for this avoidable carnage is the lack of access to affordable and effective treatments in poor countries. Of this 18 million,

¹ World Health Organization, *The World Health Report 2004*, Annex table 2 (2004).

2.1 million die per year in developing countries from untreated HIV infection. As of the end of 2008, only 4 million of the 14 million needing treatment under revised WHO Treatment Guidelines were receiving highly active antiretroviral therapy.

5. 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.² 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 Rights³ as well as Articles 22 and 25.1 of the Universal Declaration of Human Rights.⁴
6. 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.⁵
7. 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 rights to exclude competitors – in effect monopoly rights.
8. 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 and corporate rules prioritizing shareholder value provide legal justification to price needed medicines so high that only the richest sliver of populations can afford access.⁶ Even though this maximizes profits, the non-rich in most

² U.N. Comm. on Econ. Soc. & Cultural Rights [CESCR], *General Comment No. 14: The Right to the Highest Attainable Standard of Health*, ¶ 2, E/C.12/2000/4 (2000).

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

⁴ Universal Declaration of Human Rights, G.A. Res. 217A(III), at Arts. 22, 25, U.N. GAOR, 3d Sess., U.N. Doc. A/810 (Dec. 12, 1948) (protecting “the economic, social and cultural rights indispensable for his dignity” and “the right to a standard of living adequate for the health of himself and of his family, including . . . medical care”).

⁵ *Id.* at Arts. 22, 28 (requiring “national effort and international cooperation” and that “[e]veryone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized.”); 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”).

⁶ 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*

developing countries – the vast majority of the population – are prevented from purchasing (or the government purchasing on their behalf) much lower-cost generic medicines of assured quality. The ultimate cost of protecting profit-maximizing sales to the top 5% of the population is that 95% are left to suffer and die without access to life-saving or life-enhancing medicines.

9. 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.
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. These pressures threatened to doom AIDS treatment programs and stoked international outrage and an access to medicines popular movement.⁷
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 and that even then the international intellectual property

Pharmaceutical Drug Pricing: An Empirical Exercise (Ctr. for Econ. Analysis, Econ. Dep’t, Univ. of Colo. at Boulder, Working Paper No. 02-19, 2002).

⁷ 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 WIS. INT’L L.J. 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).

regime is ill-equipped to provide competitive and low-cost access to medicines to incentivize medical research on so-called neglected diseases primarily affecting poor people in developing countries.⁸

13. 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.”⁹
14. 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.¹⁰ Such reviews have included analysis of the

⁸ See Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health [hereinafter 2009 Special Rapporteur Report], ¶ 27, U.N. Doc. A/HRC/11/12 (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, ¶ 63, U.N. doc. A/63/263 (Aug. 11, 2008); Human Rights and Intellectual Property, U.N. Comm. on Econ., Soc. & Cultural Rts. [CESCR], 27th Sess., ¶ 12, U.N. Doc. E/C.12/2001/15 (2001); Report of the High Commissioner, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, ¶¶ 27, 28, E/CN.4/Sub.2/2001/13 (June 27, 2001).

⁹ See 2009 Special Rapporteur Report, *supra* note 8, at ¶ 27.

¹⁰ See UNHCR, Comm. on the Rights of the Child, *Concluding Observations: Thailand*, ¶ 58(f), CRC/C/THA/CO/2 (Mar. 17, 2006) (admonishing Thailand to “[e]nsure that regional and other free trade agreements do not have a negative impact on the enjoyment of the right to health”); UNHCR, Comm. on the Rights of the Child, *Concluding Observations: Peru*, ¶¶ 48-49, CRC/C/PER/CO/3 (Mar. 14, 2006); UNHCR, Comm. on the Rights of the Child, *Concluding Observations: Ecuador*, *Concluding Observations*, ¶ 21, CRC/C/15/Add.262 (Sept. 13, 2005); UNHCR, Comm. on the Rights of the Child, *Concluding Observations: Nicaragua*, ¶ 16, CRC/C/15/Add.265 (Sept. 21, 2005); UNHCR, Comm. on the Rights of the Child, *Concluding Observations: Philippines*, ¶ 59, CRC/C/15/Add.259 (June 3, 2005) (recommending that the State use “all the flexibilities reaffirmed by the Doha Declaration . . . to ensure access to affordable medicines”); UNHCR, Comm. on the Rights of the Child, *Concluding Observations: Chile*, ¶ 59, E/C.12/1/Add.105 (Nov. 26, 2004) (encouraging Chile “to provide greater access to generic medicine making use of the flexibility clauses permitted in [TRIPS]”); UNHCR, Comm. on the Rights of the Child, *Concluding Observations: Ecuador*, ¶ 55, E/C.12/1/Add.100 (June 7, 2004) (“strongly urges the State party . . . to make extensive use of the flexibility clauses permitted in [TRIPS] in order to ensure access to generic medicine”); UNHCR, Comm. on the Rights of the Child, *Concluding Observations: Botswana*, ¶ 20, CRC/C/15/Add.242 (Nov. 3, 2004); UNHCR, Comm. on the Rights of the Child, *Concluding Observations: El Salvador*, ¶¶ 47-48, CRC/C/15/Add.232 (June 30, 2004); UNHCR, Comm. on the Rights of the Child, *Concluding Observations: Uganda*, CCPR/CO/80/UGA (May 4, 2004).

duties of wealthy countries to promote the use of TRIPS flexibilities in poor countries.¹¹

15. 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.”¹²

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

16. Despite the Doha declaration, clear human rights duties and the demands of global health, the U.S. has used, and continues to use, its “Special 301” program to pressure developing countries to give up TRIPS flexibilities.
17. 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.”¹³ 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 in sub-Saharan Africa that “promotes access to HIV/AIDS pharmaceuticals or medical technologies” and complies with the minimum Standards of TRIPS.
18. The Bush Administration assented to the Doha Declaration in 2001, but ignored its intent through vigorous promotion of TRIPS-Plus standards on medicines,¹⁴ including in Sub Saharan Africa.¹⁵ The administration’s public position was that it could pressure developing countries to give up TRIPS flexibilities because “IP

¹¹ See Denmark, Summary Record, ¶ 7, E/C.12/2004/SR.37 (Nov. 16, 2004).

¹² General Assembly, ¶ 63, A/61/338 (Sept. 13, 2006).

¹³ OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, EXECUTIVE OFFICE OF THE PRESIDENT, 2000 SPECIAL 301 REPORT (2000), *available at* <http://keionline.org/ustr/special301>.

¹⁴ OXFAM, US BULLYING ON DRUG PATENTS: ONE YEAR AFTER DOHA (2002), *available at* http://www.oxfam.org.uk/resources/policy/health/downloads/bp33_bullying.pdf.

¹⁵ See Jonathan Berger and Achal Prabhala, *Assessing the Impact of Trips-Plus Patent Rules in the Proposed US-SACU Free Trade Agreement*, *available at* http://www.who.int/hiv/amds/capacity/tza2_oxfamreport_pricing_financing.pdf.

rights ultimately enhance public health.”¹⁶ 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.¹⁷

19. 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:¹⁸

- 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 special 301’s priority watch list and GSP benefits were revoked for passing a law authorizing TRIPS-compliant parallel importation;
- c. Up to and including the 2009 special 301 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 issuing compulsory licenses -- a move criticized by members of the U.S. Congress as sending “a troubling message . . . that the exercise

¹⁶ U.S. Government Accountability Office, *Report to Congressional Requesters: U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification*, Publication No. GAO-07-1198 at 28 (2007) [hereinafter GAO Access Report] (quoting administration officials).

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

¹⁸ See Sean Flynn, *Special 301 in the Obama Administration: The Assault on International Generic Medicines Continues*, available at <http://wcl.american.edu/pijip/go/flynn04132010>.

of recognized public health flexibilities in trade obligations is frowned on by the United States”¹⁹;

- 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.

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 were never patented 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.²⁰
21. 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.²¹
22. Since its inception in 1988, the United States Trade Representative’s “Special 301” adjudication of foreign intellectual property law standards has been used to promote policies restricting access to affordable medications around the world. President-elect Obama released a platform promising to “break the stranglehold

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

²⁰ Ellen R. Shaffer and Joseph E. Brenner, *A Trade Agreement’s Impact on Access To Generic Drugs*, Health Affairs, 28, no. 5 (2009): w957-w968 (Published online 25 August 2009), *available at* <http://content.healthaffairs.org>.

²¹ *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* (Essential Action, Working Paper), *available at* <http://www.essentialaction.org/access/uploads/tripsplusprovisions.doc>.

that a few big drug and insurance companies have on these life-saving drugs” and pledged support for “the rights of sovereign nations to access quality-assured, low-cost generic medication to meet their pressing public health needs.” The 2009 and 2010 Special 301 reports, however, indicate that the Obama Administration has not yet implemented this pledge. Although the 2010 Report shows some improvement, the Obama Administration continues using Special 301 to pressure developing countries to adopt escalating intellectual property rules that are not required by any international agreement and that will negatively impact access to medicines.

23. The 2009 and 2010 Special 301 Reports issued in the Obama Administration press developing countries to limit compulsory licenses, restrict freedom to define the scope of patentability, implement “linkage” between drug registration and assertions of patent protection, and adopt U.S. or EU-style “data exclusivity” rules that create drug monopolies independent of patents. In wealthier countries, the reports also promote extensions of patents beyond 20 years and the eradication of price controls on monopoly pharmaceutical providers.
24. There are strong arguments that the U.S.’s continued use of its Special 301 program to impose actual or threatened trade sanctions and trade pressures against WTO Member violates the multilateral dispute resolution mechanisms codified in the TRIPS Agreement.²²
25. Major US pharmaceutical companies and their trade association, PhRMA, also violate human rights norms when they pressure the USTR via their special 301 submissions to list countries that adopt and use TRIPS compliant measures to increase access to medicines for all. These multinational corporations have their own human rights obligations not to interfere with countries' ability to ensure the right to health, including access to essential medicines, nor to lobby the US government to do so.

CONCLUSION

26. The Special Rapporteur for the Right to Health should call on the U.S. halt its use of the Special 301 program and other elements of its foreign policy to encourage

²² Panel Report, *United States – Sections 301-310 of the Trade Act of 1974*, WT/DS152/R (Dec. 22, 1999).

and coerce developing countries to adopt intellectual property norms that restrict access to medicines, including access to antiretroviral medicines for people living with HIV/AIDS. The Special Rapporteur should encourage the U.S. to use its trade and foreign assistance programs to promote full use of TRIPS flexibilities and to otherwise revise its foreign policies to promote access to medicines. The Special Rapporteur should call on the U.S. to provide a procedure for the appeal of human rights issues within the Special 301 report, to reverse its unlawful unilateral threats of trade sanctions via Special 301, and to reconsider and reverse the many decisions it has made that violate the right to health of poor people around the world.