

**Oral Statement of
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To the

**UNITED NATIONS SPECIAL RAPPORTEUR ON THE RIGHT TO
HEALTH**

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

On the occasion of the 2010 International AIDS Conference in Vienna, Austria, eighteen international public health and public interest organizations filed a complaint with the Special Rapporteur on the Right to Health documenting violations of the international right to health by the United States through the operation of its “Special 301” program and related trade policies. I am acting as counsel for the group of complainants in that matter. I submit this testimony to give further background into the complaint and am here to answer any questions about it or the more general issue of regarding TRIPS-plus trade pressures and their impact on access to medicine in developing countries.

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The Special 301 program was put in place by Congress in 1988. It actually traces its genesis back four years early to the 1984 amendments to Section 301 of the Trade Act of 1974. Those amendments authorized the USTR to use unilateral imposition of trade sanctions on foreign countries for a failure to enact intellectual property laws or policies that the US desired. Such sanctions were authorized without regard to whether the policies in question were required by any binding international agreement. The 1988 amendments put in place the current system

which, in addition to the possibility of sanctions, includes an annual process for creating “watch lists” of countries that the US considers the worst intellectual property offenders.

The Special 301 program has been a prime means through which the U.S. has promoted the international exportation of US-style patent and other intellectual property laws to developing countries. And pharmaceuticals has always been a key focus.

The first country sanctioned under Section 301 for an intellectual property issue was Brazil in 1988. That sanction was for Brazil’s then practice of exempting pharmaceuticals from the full scope of its patent law, a practice that was common in many countries at the time. The sanctions worked. Against its own interests, Brazil amended its patent law to cover pharmaceutical products long before such extensions were required by TRIPS.

Indeed, Special 301 was a key tool of coercion used to bully developing countries into signing TRIPS. The US placed five of the ten “hardliners” opposing TRIPS in the first Special 301 Report in 1989—Brazil, India, Argentina, Yugoslavia, and Egypt. Two years later, India, China, and Thailand became the first Priority Foreign Countries, triggering Section 301 investigations. Brazil lost its GSP benefits in 1988; Thailand in 1989; and India in 1992—all on matters related to pharmaceutical patents.

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. Indeed, the High Commissioner for Human Rights determined that exercise of these flexibilities is necessary to square TRIPS with human rights concerns.¹

Many developing countries expected the 301 program to end with the 1994 passage of the TRIPS agreement as part of the WTO. But instead the program was amended to make clear that

¹ See 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). See also 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).

compliance with TRIPS did not render a country immune from unilateral listing and sanction through Special 301.

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What we see in the post-WTO years is that the use of Special 301 to actually sanction countries has decreased to essentially zero. But Special 301 continues to be used to make unilateral findings of TRIPS violations and to pressure countries to adopt new pharmaceutical-restricting policies nowhere contained in TRIPS.

To name a few key examples:

- Special 301 was used to pressure South Africa to give in to complaint filed against Nelson Mandela in 1998 and to get rid of TRIPS-permissible authority to use parallel imports and compulsory licenses to improve access to AIDS medications.
- Special 301 has been used against Thailand to pressure that country to get rid of its policy promoting compulsory licenses of needed medicines for its health system.
- Special 301 has been used against India to pressure that country – the world’s largest supplier of affordable medicines – to grant more patents on a wider range of uses than TRIPS requires.
- Brazil has been pressured to get rid of its innovative processes for including the expertise of health officials in patent rights determinations.
- Ecuador has been put on notice for issuing an order declaring certain medicine patents to be of public interest, a first stage toward licensing in that country.
- Dozens of countries every year are placed on watch lists for lacking data exclusivity – a new form of monopoly right not required by TRIPS that prohibits generics from registering in a country for a period of time even absent any valid patent.
- The US also lists countries for failing to extend patents beyond 20 years and for failing to make drug registration officials enforce patent rights through registration denials.

These policies have largely continued in the Obama administration.

In short, Special 301 is being used to push a number of policies that increase the scope of patent rights in poor countries and thereby restrict access to medicines.

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The reason ever-greater scope of patent rights restrict access to medicines in poor countries is because of the income inequality in poor countries. In countries where there are a small number of very rich people and a great number of very poor people, the profit maximizing approach is to price to the top income earners. You make more money by selling one unit at \$1,000 than 500 at \$1.

So what we have in Special 301 is a unilateral program to pressure countries under threat of sanction to adopt policies that will predictable lead to shortages in access to medicines by those who need them most. It is done with insufficient participation by the subjects of the pressure in an adjudication that lacks objectivity or international standards. This process, we content, violates the right to health.

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

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

States are bound to promote public participation in policies that impact the right to health, particularly participation by those affected by the policy and by people who are traditionally marginalized in decision making processes.

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”).

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.”⁶

We submit that the use of Special 301 to pressure developing countries to adopt TRIPS-plus standards for pharmaceuticals violates these human rights duties.

We have arranged for testimony from representatives of those affected by Special 301 before you today. We also invited the US government to attend, but numerous invitations were rebuffed.

Our ask is this:

The Special Rapporteur for the Right to Health should call on the U.S. halt its use of the Special 301 program to coerce developing counties to adopt intellectual property norms that restrict access to medicines.

The Special Rapporteur should call on the U.S. to instead use its trade and foreign assistance programs to promote full use of TRIPS flexibilities.

⁶ General Assembly, ¶ 63, A/61/338 (Sept. 13, 2006).