USTR-2010-0003

UNITED STATES TRADE REPRESENTATIVE

IN THE MATTER OF

2010 SPECIAL 301 REVIEW:

IDENTIFICATION OF COUNTRIES UNDER SECTION 182 OF THE TRADE ACT OF 1974

SUBMISSION OF THE LAWYERS COLLECTIVE HIV/AIDS UNIT

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Anand Grover (Director)

Lawyers Collective HIV/AIDS Unit

62 Masjid Road

New Delhi India 110014

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SUMMARY

In India, and throughout rest of the developing world, the Special 301 reports have become synonymous with American foreign policy coercion in the area of intellectual property. In the past, USTR's has used Special 301, backed by America's economic power, to sanction countries that make use of flexibilities found in the Agreement on the Trade-Related Aspects of Intellectual Property Rights and also to promote TRIPs-plus measures.[1] The new administration has an opportunity to demonstrate its stated commitment to a fair and humane intellectual property foreign policy, one that will promote access to low cost, safe and efficacious medicines, and help save countless lives and promote the realization of the right to health of Indians and people in the developing world, by reconfiguring its approach to Section 301.[2]

India is the developing world's supplier of low cost, safe and efficacious medicines, providing nearly 67% of all essential medicines exported to developing countries.[3] Many national and international health public health programs purchase the medicines from India.[4] Restrictions on production and mechanisms that increase drug production costs in India have a disproportionate impact on access to affordable medicines around the world. The current

[1] Agreement on Trade Related Aspects of Intellectual Property Rights [hereinafter TRIPS], Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 8, Legal Instruments – Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994).

[2] Press Release, Barack Obama, Fighting HIV/AIDS Worldwide, *available at* http://www.barackobama.com/pdf/AIDSFactSheet.pdf. The Policy also indicates: "He also supports the adoption of humanitarian licensing policies that ensure medications developed with U.S. taxpayer dollars are available off-patent in developing countries."

[3] Médecins Sans Frontières,, "Untangling the Web of ARV Price Reductions", 11th edition (July 2008), at page 6, *available at* http://www.msfaccess.org/fileadmin/user_upload/diseases/hiv-aids/Untangling_the_Web/Untanglingtheweb_July2008_English.pdf.

[4] Nearly 80% of medicines distributed by the International Dispensary and about 50% of all drugs distributed by MSF in developing countries come from India.

situation, and substantial political pressure from the United States and EU, is untenable for the world's poor in need of life-saving medicines.

The American government has used many methods of coercion to manipulate domestic Indian patent law and policy. Examples of pressure from USTR, other parts of the government, and American industry as relates to India are numerous. Very recently, USTR and Pfizer held a meeting in India to re-evaluate Indian IPR policy. Additionally, US-India Business Council issued a report on Section 3(d) of the Indian Patent Act which was critical of this key component of Indian patent policy. All of these pressures, working in conjunction with the Section 301 listings, amount to serious threats to India's, and other developing countries, ability to fashion intellectual property laws that best serve their own needs.

This submission argues first that using Special 301 to apply pressure on foreign governments violates the United States obligations under the World Trade Organization and the Agreement on Trade-Related Aspects of Intellectual Property. After which it points out that America is required by the Doha Declaration to allow usage of TRIPS flexibilities.[5] Finally, by using Special 301 in the manner it does, the United States is likely in violation of the right to health as customary international law and infringes upon the rights of other States to fulfill their obligations under the International Covenant on Economic, Social, and Cultural Rights. We call upon USTR to cease practices inconsistent with the right to health and the Doha Declaration, conform them to its multilateral obligations under the WTO, and reform its administrative procedures regarding Section 301 to accommodate critical perspectives.

ARGUMENT

[5] World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001 WT/MIN(01)/DEC/2, 41 I.L.M. 755, para 4 (2002) [hereinafter Doha Declaration]

1. Using Special 301 to Apply Pressure On Foreign Governments Contrary To The United States Is In Violation of Its Multilateral Obligations Under the World Trade Organization and TRIPS

The Trade Act of 1974, as amended by Congress in 1988, includes what is known as "Special Section 301".[6] This section requires that the United States Trade Representative publish annually a list of countries that do not provide "adequate and effective protection of intellectual property," or ones that deny non-discriminatory market access to American companies.

a. The United States' Multilateral Obligations Under the WTO

This application of Section 301 does not comply with the United States multilateral obligations within the WTO. The United States and other WTO members are required to move forward with all trade-related disputes through the Dispute Settlement Mechanism to resolve conflicts arising under TRIPS.[7]

Section 301 originated in a pre-WTO, pre-TRIPS era to provide unilateral protection to American industry. Now that the Dispute Settlement Understanding and WTO-related multilateral mechanisms exist for addressing trade disputes, Section 301 is without purpose. Unilateral action is especially not justified in this period of multilateral framework governing trade. Just this point was addressed in 1999 in the US-EC Section 301 decision.

b. The 1999 EC-US Section 301 Decision

[6] Trade Act of 1974, 19 U.S.C. § 2242(a) (listing identification criteria); § 2242(e) (West 2010) (requiring Trade Representative to publish a list in the Federal Register).

[7] TRIPS art. 23.2. ("Members shall not make a determination to the effect that a violation has occurred, that benefits have been nullified or impaired or that the attainment of any objective of the covered agreements has been impeded, except through recourse to dispute settlement in accordance with the rules and procedures of this understanding.")

In 1999, the European Community challenged the United States use of Section 301 in the dispute settlement body of the WTO, the prescribed method of trade dispute settlement since the creation of the WTO.[8] The DSU found, in this case, that Section 301 did not violate the United States' obligations under Article 23.2(a) of the DSU.[9] However very significantly, the opinion included a caveat that if the United States repudiated or removed any of its undertakings in the Statement of Administrative Action (SAA), that section would be immediately found to be non-conforming.[10] Considering the radically different global public health situation, with degenerating global access to affordable medicines, the resultant proliferation of TRIPS flexibilities, and the Doha Declaration reaffirming flexibility use, the United States' subsequent aggressive use of Section 301, the 1999 US-EC decision is likely no longer valid, and the United States' undertakings may be effectively repudiated.

2. The Administration Should Ensure That The Use Of Section 301 Complies With The Doha Declaration and Allows for Full Use of Trips Flexibilities

Member States of the WTO are required to interpret their intellectual property standards not only in light of the flexibilities inherent in TRIPS, but also in light of the 2001 Doha Declaration on the TRIPS Agreement and Public Health. Doha makes clear that the right of WTO Members to

[8] Panel Report, *United States – Sections 301-310 of the Trade Act of 1974*, WT/DS152/R, adopted 27 January 2000, DSR 2000:II, 815 [hereinafter 301 Panel Report]

[9] Language from the WTO's summary of the case is as follows:

The Panel then concluded that Sec. 304 was "not inconsistent"
with US obligations under Art. 23.2(a) because, while the statutory language of Sec. 304 in itself constituted a serious threat that unilateral determinations contrary to DSU Art. 23.2(a) might be taken, the United States had (i) lawfully removed this threat by the "aggregate effect of the Statement of Administrative Action ('SAA')" and (ii) made a statement before the Panel that it would render determinations under Section 304 in conformity with its WTO obligations.

[10] 301 Panel Report supra note 8

use, to the full, the provisions in the TRIPS Agreement, which provide flexibility" to "promote access to medicines for all.[11]

a. TRIPS Negotiating History

The negotiating history of TRIPS and the subsequent Doha Declaration reinforce that TRIPS flexibilities were always intended to allow countries some discretion is intellectual property policy. Meanwhile, there has been continual pressure the on developing countries, such as the Philippines and Thailand, so resist/scale back their TRIPS flexibility use or pushing for TRIPS-plus provisions in their domestic intellectual property laws and policies. Some examples of this follow.

b. Compulsory Licensing

Article 31of TRIPS allows countries to grant what is known as a "compulsory license".[12] A compulsory license is a non-voluntary license that is granted without consent of the patent holder. As discussed, it has often been used to introduced generic competition and reduce drug prices. As reaffirmed by the Doha Declaration compulsory licensing is a TRIPS flexibility mechanism that Parties are well within their right to use at their discretion.

USTR has in many instances taken issue with countries granting compulsory licenses. The most notorious of these incidents involved a dispute in Thailand between the Thai government and American pharmaceutical manufacturers.[13] USTR, as reports indicate, was aggressively lobbied by the pharmaceutical industry to retaliate against Thailand for using this TRIPS

[11] Doha Declaration at 5
[12] TRIPS, Art. 31
[13] Knowledge Ecology International, Statement on USTR 301 list reference to Thailand, April 2007, available at http://www.keionline.org/content/view/44/1

flexibility, resulting in the decision to elevate the country to the "Priority Watch List".[14] The threat of sanctions was then enough for Thailand to back down from issuing many more compulsory licenses, which it was well within its rights to do. Though the case was eventually dropped this suggests great room for abuse of the 301 system.

c. Patentability Standards

India, while amending its patent law in 2005, introduced a key public health safeguard—section 3(d), which seeks to prevent the grant of frivolous patents and "evergreening". Section 3(d) of the Indian patent law disallows patents for a new form of a known substance, unless the new form exhibits significant increase in efficacy.[15] This prevents pharmaceutical companies from obtaining monopolies for minor modifications. This provision has been decisive in the denial of patents on crucial life-saving anti-HIV medicines, such as Nevirapine and Tenofovir in India, thus keeping them out of the monopoly regime of patents.

USTR has sought to push back against this provision of the Patent Act by seeking to undo Section 3(d). Minutes from meetings co-hosted by USTR and Pfizer, and the US-India business coalition suggest that both parties would like to see a rollback of Section 3(d).[16] It is inappropriate of USTR to advocate TRIPS-plus measures, when it is the express law and policy of India to limit patentability within the bounds afforded to it by TRIPS.

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[14] 2007 Section 301 Report

[15] Section 3(d) of the Patents Act, 1970, as it now stands, reads as follows: "The following are not inventions within the meaning of this Act,—…(d) *the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance* or *the mere discovery of any new property or new use for a known substance* or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.
Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substances, unless they differ significantly in properties with regard to efficacy." (emphasis supplied).

[16] Minutes taken from USTR/Pfizer meeting, Personal Communication, Lawyers Collective

d. Data Exclusivity

Data exclusivity, along with counterfeiting and enforcement concerns, has been amongst the most listed areas of concern on the 301 Watch List in recent years. Data exclusivity, though not required by TRIPS, is an intellectual property protection now being granted for test data related emerging from the drug approval process. It is submitted that the U.S. and EU wrongly argue that data exclusivity, in some form, can be found in Art. 39.3 of TRIPS.[17] On the contrary, the mandate of Art. 39.3 is against any form of data exclusivity**.**

India is currently being pushed regarding data exclusivity on many fronts. The EU is pursuing a free trade agreement with the nation in which data exclusivity has grown into a major point. And, as mentioned, the Special 301 Watch List has repeated called for greater data protections in India. Data exclusivity as it is now understood is an entirely U.S. and EU-based conception, one that is not required by TRIPS. The result of extending data protections is keeping generic drug competitors off market because they are unable to use test data, which would otherwise be available to the public without penalty.

e. Counterfeiting

The only reference to counterfeiting in TRIPS can be found in the trademarks section of the agreement. However, a new understanding of counterfeiting has emerge, one that relates it to spurious medicines. The 2007-2009 reports all bring up counterfeit drugs as a potential problem in India.[18]

[17] Art. 39.3 specifically states: Members, when requiring as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use.

[18] For example, the 2009 Report states:

Future USTR reports must make sure that true counterfeit drugs are clearly distinguished from legitimate generic drugs. The current reporting system distorts the difference and undermines the value of generic drugs, which offer a low-cost, high-quality alternative to branded medicines.

f. Patent Linkage

Patent linkage, a TRIPS-plus provision, is a system in which the drug regulator refuses to grant or delays marketing approval to a generic drug manufacturer to manufacture and sell generic version of a patented drug. This is known to be against public health interests as it delays the entry of cheaper, generic medicines into the market, thereby keeping medicines out of reach of those who need them. In India, as in most countries, the patent and drug regulatory systems are two independent legal systems with different objectives that function independently.

USTR has lobbied to extend patent linkage to India in a number of its recent Special 301 Watch Lists prompts.[19] This is even though in a very recent judgment the Delhi High Court held that, in India, there is no linkage between the patent process and the drug regulatory process.[20] Though the matter is on appeal, for the moment patent linkage is not the policy of the Indian government.

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> Piracy and counterfeiting, including of pharmaceuticals, remain a serious problem in India. India's criminal IPR enforcement regime remains weak. Police action against those engaged in manufacturing, distributing, or selling pirated and counterfeit goods, and expeditious judicial dispositions for IPR infringement and imposition of deterrent-level sentences, is needed.

[19] 301 Reports 2007 -2009

[20] Bayer Corporation v. Union of India and Others, Writ Petition No. 7833 of 2008. For further details, please refer to www.lawyerscollective.org .

The production of low cost, high quality medicines is essential to the treatment of millions of vulnerable persons around the world. The use of TRIPS flexibilities is now a proven method of introducing competition in medicines through generic competitors, reducing price and increasing accessibility.[21] Unilateral determinations on the part of the American government should not interfere with sovereign nation's usage of these flexibility mechanisms to which they are legally entitled. All of the actions detailed above increase pressure upon developing country governments, including the Indian government, to forego using TRIPS flexibilities and their legal rights under TRIPS.

3. Special 301 Violates the Right to Health Under Customary International Law and Infringes on India's Obligation, as State Party to the International Covenant on Economic, Social, and Cultural Rights, to Protect the Right to Health

The "Priority Watch List," "Watch List," and ability to unilaterally sanction TRIPS compliant countries who seek to make use of TRIPS flexibilities to promote access to affordable medicines violate the right to health. The right to health is articulated in the International Covenant on Economic, Social, and Cultural Rights as, "right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[22] State parties are obligation to protect, respect, and fulfill the right to health. Though some aspects of the right may require progressive realization, others may be immediately fulfilled.

Although the United States has not signed or ratified the ICESCR, the right to health has arguably ascended to customary international law, implying that the United States is required to

[21] South Centre and World Health Organization, The Use of TRIPS By Developing Countries: Can they Promote Access to Medicine? 65-67 (2006) (surveying countries).
[22] Article 12 of the *International Covenant on Economic, Social and Cultural Rights*, 993 UNTS 3 (1976).

respect this right. Denying the use of TRIPS flexibilities and pushing for TRIPS-plus provisions in domestic legislation through Special 301 is in direct conflict with this obligation.

Even if the United States is not required to protect the right to health through treaty obligations protect the right to health of its citizens and people in its territory, it is likely responsible to not interference with other nations who are State Parties to ICESCR. India has signed and ratified ICESCR and is therefore required to protect the right to health. American pressure upon India, and other parties to ICESCR, through Special 301 directly interferes with its ability to ensure the right to health. The Special Rapporteur on the Right to Health has termed this a "negative obligation" on the part of countries to do as little harm as possible, as it were, when drafting free trade agreements and other trade agreements.[23] The United States' unilateral enforcement through Section 301 violates the right to health in this regard. Moreover, as earlier mentioned, India is a major supplier of low cost, high quality drugs around the world and interfering with its ability to produce such medications has far-reaching health-related ramifications.

CONCLUSION/RECOMMENDATIONS

To truly advocate for lower cost medicines that will help save the lives of the global poor, USTR needs to deeply rethink Section 301. Under the current system, USTR is seen as an intellectual

[23] The Special Rapporteur, 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 (Mar. 31, 2009). The report finds that "[d]eveloped States also have a responsibility to take steps towards the full realization of the right to health through international assistance and cooperation," and admonished that "[f]rom a right to health perspective, developing countries and LDCs should be enabled to use TRIPS flexibilities." The report specifically states that all 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." Also, discussed in the Report is harmful impact of free trade agreements and TRIPS-plus provisions on the right to health.

property bully, in the pocket of large pharmaceutical companies, by much of the developing world. Fulfilling the country's obligations means it must shift from blocking the use of TRIPS flexibilities and advocating TRIP-plus provisions to just the opposite.

As a result of this analysis, we recommend the following actions:

1. Respect the sovereignty of India and its multinational obligations by stopping/restricting unilateral use of 301. Adopt guidelines preventing use of Special 301 to promote TRIPS-plus provisions.
2. Cease listing developing countries, which make necessary, legal use of TRIPS Flexibilities on the Special 301 "Watch List" or "Priority Watch List".
3. Make transparent the procedures governing Special 301. Allow for non-industry submission to counterbalance the currently industry dominated process.