

**Submission to the U.S. Trade Representative and Notice of Intent to
Testify**

2014 Special 301 Review: Identification of Countries Under Section 182 of the
Trade Act of 1974: Request for Public Comment and Announcement of Public
Hearing

<http://www.regulations.gov>

Docket number USTR-2013-0040.

Sean Flynn
Associate Director
Program on Information Justice and Intellectual Property
February 7, 2014

THE RECENT IMPLEMENTATION OF SPECIAL 301 HAS BEEN IN VIOLATION OF U.S. AND INTERNATIONAL LAW

There is an acute need to review the legality of the current operation of the Special 301 Program and change it to comply with international law as well as with the enabling statute. Specifically, the continued use of 301 to threaten GSP benefit reductions or other trade sanctions for policies not adjudicated to violate TRIPS or any other binding international agreement violates the World Trade Organization accords. The inclusion of criticism of pharmaceutical reimbursement policies and the promotion of (selective and biased) “best practices” lack statutory authority.

1. Threatening Trade Sanctions for TRIPS and FTA Compliant Policies Violates the World Trade Organization Accords

The continued use of the Special 301 Report to threaten GSP benefit reductions or other trade sanctions for failure to adhere to policy demands not required by TRIPS or any other binding international agreement violates the WTO’s Most Favored Nation Clause, GSP Enabling Clause and its Dispute Settlement Understanding.

The WTO’s Most Favoured Nation (MFN) clause requires that tariff treatment provided to one member of the WTO be provided to all, subject to limited exceptions. The use of Special 301 to threaten altering GSP or other benefits to countries subject to its investigation must comply with one of these exceptions. The applicable exceptions to MFN are for:

- issues adjudicated to violate the WTO,
- preferences negotiated through a free trade area agreement and,
- through the GSP enabling clause, for trade preferences based on criteria that are “generalized, non-reciprocal and non discriminatory” and “addressed to a particular development, financial or trade need” of developing countries.¹

The statutory language authorizing 301 for “TRIPS-plus” investigations² must be implemented in light of these binding international rules.

The WTO Appellate Body ruled in the *EC Tariffs* case on the permissible bounds of GSP programs, and struck down an EU program that, like Special 301, was justified by domestic

¹ General Agreement on Tariffs and Trade, October 30, 1947, art. 1, T.I.A.S. 1700, 55 U.N.T.S. 194 and associated appendices; WTO, Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries, L/4903 (28 November 1979).

² 19 U.S.C. § 2242(d)(4).

economic interests rather than the “non-reciprocal” development interests of other countries. In that case, the Appellate Body stressed that GSP criteria must be tailored to the needs of *developing countries*, and held that such needs may not be “based merely on an assertion to that effect by . . . a preference-granting country.” Rather, the basis for GSP criteria must be an “objective . . . [b]road-based recognition of a particular need,” such as those “set out in the WTO Agreement or in multilateral instruments adopted by international organizations.”³

A WTO panel also ruled that Section 301 – of which Special 301 is a part – cannot be used to unilaterally adjudicate alleged violations of the WTO. The WTO panel in the *Section 301* case found that the continuation of the 301 statute after the WTO accords were enacted created a “presumptive violation” of the WTO Dispute Settlement Understanding’s requirement that “Members shall not make a determination to the effect that a violation has occurred . . . except through recourse to . . . this understanding.”⁴ The panel upheld Section 301 only because of the existence of a “Statement of Administrative Action” in which the United States pledged to use the DSU to determine any alleged WTO violation.⁵ Notably, the panel held that its reasoning applied as well to threats of sanction, which is, of course, the main substance of the 301 Report. The panel admonished: “a threat of unilateral action, especially when it emanates from an economically powerful Member,” may “disrupt the very stability and equilibrium which multilateral dispute resolution was meant to foster.”⁶

Reading *EC Tariffs* and the *Section 301* case together, it impossible to justify continued threats of sanctions under Special 301 for issues not litigated in the WTO or under a regional free trade agreement. Such TRIPS-plus demands are insufficiently “objective” and “broad-based” to meet the test for GSP benefit criteria because they are not based on the norms of a binding multilateral treaty. And reducing GSP benefits for alleged, but non-litigated, TRIPS violations is unilateral adjudication prohibited by the DSU.

³ Appellate Body Report, *European Communities--Conditions for the Granting of Tariff Preferences to Developing Countries*, WT/DS246/AB/R, ¶ 163 (Apr. 20, 2004)

⁴ Dispute Settlement Understanding, art. 23.2.

⁵ Panel Report, *United States—Sections 301–310 of the Trade Act of 1974*, WT/DS152/R (December 22, 1999).

The Statement of Administrative Action states in relevant part that in cases involving alleged WTO violations the Trade Representative will:

- invoke DSU dispute settlement procedures, as required under current law;
- base any section 301 determination that there has been a violation or denial of U.S. rights under the relevant agreement on the panel or Appellate Body findings adopted by the DSB;
- following adoption of a favourable panel or Appellate Body report, allow the defending party a reasonable period of time to implement the report's recommendations; and
- if the matter cannot be resolved during that period, seek authority from the DSB to retaliate.

⁶ Panel Report, *United States—Sections 301–310*: para ¶ 7.89.

2. Non-IP Health Policies that Do Not Discriminate Against IP Owners Are Outside the Scope of the Special 301 Report

Special 301's recent addition of criticism of pharmaceutical reimbursement programs⁷ is not authorized by statute. To include countries in the 301 process, USTR must make a factual finding that the alleged conduct will "deny adequate and effective protection of intellectual property rights, or deny fair and equitable market access to United States persons that rely upon intellectual property protection." 19 USC 2242(a)(1). The statute defines the denial of "fair and equitable market access" narrowly. To list a country on this ground, the practice must either violate the provisions of an international agreement or "constitute discriminatory nontariff barriers." 19 USC 2242(d)(3).

Health programs that restrain the prices firms charge, but do not discriminate against market entry, do not reasonably fall into the category of "discriminatory nontariff barriers" that the Special 301 statute reaches. PhRMA's submissions do not attempt to make a case for discrimination. Their position is extreme – that the lowering of profits on their patented products by regulating monopoly rents through pooled purchasing and reimbursement "devalues" their property. There are no international restrictions on such practices, and absent a claim of discrimination – such practices are clearly outside the scope of the 301 statute.

The criticism of foreign reimbursement programs is incredibly unwise at a time when the U.S. is struggling to find ways to restrain its own health costs. And it is hypocritical because U.S. federal and state governments – especially state Medicaid programs, the 340B program, Veterans Affairs and DoD hospitals and programs and GSA purchasing formularies – follow the same basic policies and principles of foreign countries that Special 301 criticizes.

This recurring section in the report should be eliminated.

3. India's recent compulsory license and patent reform law is TRIPS compliant and should be excluded from the 301 report

Under separate cover, two other law professors and I have submitted a note explaining why India's recent patent reform under Section 3(d) and its compulsory license – including on local working grounds – do not violate TRIPS. Most relevant to this submission – neither of them have been adjudicated to violate TRIPS or any other binding international agreement and therefore any use of them to threaten India with trade sanctions of GSP benefit withdrawals is illegal for the reasons discussed above.

As time permits, I will be happy to address India's compulsory license and local working requirements in my oral testimony or in meetings with agency personnel.

⁷ 2011 Special 301 Report, page 14.

4. USTR should eliminate its unbalanced, selective and biased “best practices” section

In recent years, USTR has asked commentators to opine on best practices in IP policy making or implementation around the world. But it has ignored the submissions of consumers, academics and competitive entrants on this issue – only endorsing ideas in its report that come from the branded pharmaceutical industry or major content industries. There is nothing in the enabling statute that requires or permits this section of the report. Especially given that USTR is prone to implement it in an unbalanced manner that ignores the submissions of some while accepting the recommendations of other, the section should be eliminated.

At minimum – USTR should follow its own advice it is pushing for in the Trans Pacific Partnership and other trade agreements in various healthcare “transparency” annexes and divulge, in writing, the principles and methodologies it uses to acknowledge some submissions while ignoring others.

In the past – the public interest and innovative business sectors has identified many best practices in domestic and international law that would warrant inclusion in an unbiased account of the field. These include:

a. Copyright in the Digital Environment

- Promote “notice and notice” systems for limiting ISP liability that do not rely on censorship of online material without a court order.⁸
- Promote open ended, flexible exceptions that can adapt to technology and use changes.⁹
- Encourage countries that penalize anti-circumvention to offer flexible and open ended limitations and exceptions to liability.¹⁰
- Protect free expression by promoting exceptions to copyright for non-commercial user-generated content.¹¹

⁸ See Copyright Modernization Act, [Bill C-11](#), 41st Parliament § 47 (60 Elizabeth II, 2011) (Canada) [hereinafter Canada Bill C-11] (introducing § 41.25) (provides protections against liability where “[a] person described in paragraph 41.25(1)(a) or (b) who receives a notice of claimed infringement that complies with subsection 41.25(2) shall, on being paid any fee that the person has lawfully charged for doing so, (a) without delay forward the notice electronically to the person to whom the electronic location identified by the location data specified in the notice belongs and inform the claimant of its forwarding or, if applicable, of the reason why it was not possible to forward it”).

⁹ See [Washington Declaration](#) (calling for “efforts to defend and expand as appropriate the operation of limitations and exceptions in the years to come,” including “efforts to assure that international law is interpreted in ways that give States the greatest possible flexibility in adopting limitations and exceptions”).

¹⁰ E.g. E.g. Canada [C-11 sec. 41.21\(a\)](#) permits the government to prescribe “additional circumstances in which” TPM paragraph 41.1(1)(a) does not apply.

¹¹ E.g. Canada Bill [C-11 §22 creating 29.21](#), providing that it is “not an infringement of copyright for an individual to use an existing work . . . in the creation of a new work . . . or to authorize an intermediary to disseminate it, if . . . the use of, or the authorization to disseminate, the new work or other subject-matter is done solely for non-commercial purposes” and other factors, such as attribution, are met.

- Promote exceptions to copyright for temporary reproductions for technological purposes (e.g. cache and RAM copies on internet).¹²
- Encourage protections for cross border sharing of copyrighted works created under an exception for visually impaired.¹³

b. Remedies and Enforcement

- Protect and promote commercial thresholds for the imposition of statutory damages.¹⁴
- Promote restrictions on damages to ensure proportionality to harm to right owner.¹⁵
- Promote safeguards on internet enforcement policies to avoid threats to free expression, business innovation and free trade.¹⁶

c. Promotion and protection of Human Rights

- USTR should refrain from TRIPS+ demands for intellectual property norms that may restrain internationally recognized rights (such as to freedom of expression and health).¹⁷

¹² E.g. Canada [Bill C-11 § 32](#), creating a new § 30.71, providing that it “is not an infringement of copyright to make a reproduction of a work or other subject-matter if (a) the reproduction forms an essential part of a technological process; (b) the reproduction’s only purpose is to facilitate a use that is not an infringement of copyright; and (c) the reproduction exists only for the duration of the technological process.”

¹³ E.g. World Blind Union, [Proposed] WIPO Treaty for Improved Access for Blind, Visually Impaired and other Reading Disabled Persons (Oct. 23, 2008), available online at http://www.keionline.org/misc-docs/tvi/tvi_en.html (Articles 4 & 8)

¹⁴ E.g. Canada [Bill C-11 § 46\(1\)](#), introducing a new § 38.1(1), limiting statutory damages to “a sum of not less than \$100 and not more than \$5,000 that the court considers just, with respect to all infringements involved in the proceedings for all works or other subject-matter, if the infringements are for non-commercial purposes.”

¹⁵ E.g. the [Washington Declaration](#) calls for “proportional approaches to enforcement that avoid excessively punitive approaches to enforcement, such as disproportionate statutory damages; undue expansion of criminal and third party liability; and dramatic increases in authority to enjoin, seize and destroy goods without adequate procedural safeguards.”

¹⁶ See e.g. [White House statement](#), Victoria Espinel, Aneesh Chopra, and Howard Schmidt, Combating Online Piracy while Protecting an Open and Innovative Internet, WE THE PEOPLE (Jan. 14, 2012) (calling for “any enforcement of copyright on the internet must be narrowly targeted to cover activity clearly prohibited under existing laws, provide strong due process and be focused on criminal activity,” “any provision covering Internet intermediaries such as online advertising networks, payment processors, or search engines must be transparent and designed to prevent overly broad private rights of action that could encourage unjustified litigation that could discourage startup businesses and innovative firms from growing,” laws to “not tamper with the technical architecture of the Internet through manipulation of the Domain Name System (DNS), a foundation of Internet security.”).

¹⁷ See [Report](#) of the Special Rapporteur on the Right to Health, Anand Grover, The Right to Health and Access to Medicines (2009); [Report](#) of the Special Rapporteur on the promotion and protection of the right to freedom of opinion and expression, Frank La Rue (2011).

d. Research and Development

- Promote incorporation of WHA Global Strategy and Plan of Action into research and development policies.¹⁸
- Promote public benefits from publicly funded research, including by promoting accessibility, availability, affordability and access to data and information from government funded research.¹⁹

e. Protection of Test Data

- Permit countries the full range of avenues to meet TRIPS Art. 39.3 data protection requirements, including cost sharing mechanisms.²⁰
- Promote exemptions from data exclusivity requirements.²¹

f. Doha Declaration and TRIPS Flexibility

- Incorporate language from the high level UN meeting on non-communicable diseases, affirming US understanding that Doha Declaration principles and flexibilities are not restricted to communicable diseases.
- Affirm Doha Declaration Para 4 right to use TRIPS flexibilities “to the full.”
- Promote the Doha Declaration in all interpretations of TRIPS or other international intellectual property policy standards.
- Acknowledge that domestic flexibility to define patentability standards leaves countries free to define an invention so as to exclude “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.”²²

¹⁸ Sixty-First World Health Assembly, [Global strategy and plan of action on public health, innovation and intellectual property](#) (“Each country shall explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the cost of research and development and the price of health products.”); Free Trade Agreement between Colombia, Peru, and the European Union (25 March 2011) (“The Parties also recognise the importance of promoting the implementation of Resolution WHA 61.21 Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, adopted by the World Health Assembly on 24 of May 2008”).

¹⁹ See <http://www.federalregister.gov/articles/2010/09/20/2010-23395/request-for-comments-on-incentivizing-humanitarian-technologies-and-licensing-through-the>; March-in requirements of the Bayh-Dole legislation (for a failure to make the product “available to the public on reasonable terms,” 35 U.S.C. § 201(f) (defining “practical application”) or to “alleviate health or safety needs.” 35 U.S.C. § 203(a)(2)).

²⁰ E.g. Agreement Between the EFTA States and the Republic of Korea, Annex XIII (Article 3), E.F.T.A.- S. Kor., Dec. 15, 2005 (“Any Party may instead allow in their national legislation applicants to rely on such data if the first applicant is adequately compensated.”)

²¹ [Peru-EU FTA](#), Chapter 3 §6 Art 231 (parties may adopt exceptions for reasons of public interest)

²² India Patent Act Sec. 3(d).

- Promote and affirm Trips Art. 30 solutions to enable supply of needed medicines to countries with insufficient manufacturing capacity.²³

²³ E.g. [letter from the U.S. to Canada](#) on July 16, 2004 (agreeing that NAFTA permits: “Where a compulsory license is granted by a Party in accordance with such terms, the Parties agree that, as between themselves, adequate remuneration pursuant to Article 1709(10)(h) of the NAFTA will be paid in the exporting Party taking into account the economic value to the importing country of the use that has been authorized in the exporting Party.”)

BIBLIOGRAPHY

Submission of Civil Society Groups, *In the Matter of 2013 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974* (2013), available at <http://infojustice.org/wp-content/uploads/2013/02/2013-Joint-Civil-Society-Submission.pdf>.

Sean Flynn, Oral Submission to the U.S. Trade Representative for the 2012 Special 301 Review (Feb. 23, 2012), available at <http://infojustice.org/wp-content/uploads/2012/02/Flynn-Special-301-Submission-Oral-2012.pdf>.

Submission of Global Health Organizations, *In the Matter of the 2010 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974* (Feb. 16, 2010), available at <http://www.pijip-impact.org/wp-content/uploads/2013/02/2010-Joint-NGO-Submission.pdf>.

Submission of Ten Civil Society Groups, *Joint Policy Statement on the Special 301 Report Review* (2011), available at <http://www.pijip-impact.org/wp-content/uploads/2013/02/2011-Joint-Policy-Statement-of-10-Civil-Society-Groups.pdf>.

Submission of U.S. State Health Organizations, *In the Matter of the 2010 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974* (Feb. 15, 2011), available at <http://www.pijip-impact.org/wp-content/uploads/2013/02/2011-Joint-submission-by-NLARx-and-FDT.pdf>.

Submission of Global Health Organizations, *In the Matter of the 2011 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974* (Feb. 15, 2011), available at <http://www.pijip-impact.org/wp-content/uploads/2013/02/2011-Joint-Statement-of-Nine-Health-NGOs.pdf>.

U.S. Civil Society Platform on Trade-Related Intellectual Property and Access to Medicines Issues INFOJUSTICE.ORG (2009), available at <http://infojustice.org/wp-content/uploads/2011/04/Coalition-Platform-on-Trade-and-Access-to-Medicines-may-2009.pdf>.

Sean Flynn, *How Listing Ukraine as a Priority Foreign Country in Special 301 Violates the World Trade Organization Agreements*, INFOJUSTICE.ORG (May 13, 2013), available at <http://infojustice.org/archives/29556>.

Sean Flynn, *Special 301 and Access to Medicines under the Obama Administration*, INFOJUSTICE.ORG (May 21, 2013), available at <http://infojustice.org/archives/29472>.

Michael Palmedo, *USTR Special 301 Attacks Indian Novartis Ruling – WTO Director General Defends It*, INFOJUSTICE.ORG (May 1, 2013), available at <http://infojustice.org/archives/29456>.

Sean Flynn, *What is Special 301? A Historical Primer*, INFOJUSTICE.ORG (May 1, 2013), available at <http://infojustice.org/archives/29465>.

Michael Palmedo, *Notes on Industry and Civil Society Testimony at the 2013 Special 301 Hearing*, INFOJUSTICE.ORG (Feb. 21, 2013), available at <http://infojustice.org/archives/28628>.

Michael Palmedo, *Notes on Government Testimony at the 2013 Special 301 Hearing*, INFOJUSTICE.ORG (Feb. 20, 2013), available at <http://infojustice.org/archives/28622>.

Sean Flynn, *USTR 2012 Special 301 Report Ignores Legal Criticism*, INFOJUSTICE.ORG (May 2, 2012), available at <http://infojustice.org/archives/18703>.

Michael Palmedo, *Notes from the Special 301 Hearing*, INFOJUSTICE.ORG (Feb. 22, 2012), available at <http://infojustice.org/archives/8412>.

Michael Palmedo, *Special 301, Access to Medicine, and Various U.S.G. Pledges to Respect the Doha Declaration*, INFOJUSTICE.ORG (Feb. 22, 2012), available at <http://infojustice.org/archives/8361>.

Michael Palmedo, *Some of the Regular "Asks" of USTR During Special 301 Reviews*, INFOJUSTICE.ORG (Feb. 22, 2012), available at <http://infojustice.org/archives/8351>.

Sean Flynn, *Initial Reaction to the 2011 Special 301 Report*, INFOJUSTICE.ORG (May 3, 2011), available at <http://infojustice.org/archives/3345>.

Michael Palmedo, *USTR Publishes the 2011 Special 301 Report*, INFOJUSTICE.ORG (May 5, 2011), available at <http://infojustice.org/archives/3320>.

Michael Palmedo, *Notes on the 2011 Special 301 Hearing*, INFOJUSTICE.ORG (Mar. 3, 2011), available at <http://infojustice.org/archives/1656>.