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PROGRAM ON INFORMATION JUSTICE AND INTELLECTUAL PROPERTY

Submission to the U.S. Trade Representative for the 2012 Special 301 Review

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1. Threatening Trade Sanctions through Special 301 Violates the WTO Dispute Settlement Understanding

Enacted at a time when there was no international minimum standard for intellectual property and no effective multilateral dispute mechanism, the Special 301 statute authorizes a program through which USTR issues unilateral findings and threats of trade sanctions not authorized by any international agreement. As such the program violates WTO dictates that trade disputes be settled through its multilateral dispute settlement process.[1]

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

Special 301's criticism of pharmaceutical reimbursement programs[2] 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." Foreign health regulations that restrain the prices firms charge, but not their market entry as such, do not reasonably fall into the category of

[1] Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, art. 23.2, Legal Instruments – Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) ("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."); Panel Report, United States – Sections 301-310 of the Trade Act of 1974, ¶ 7.89, WT/DS152/R (Dec. 22, 1999) ("Members faced with a threat of unilateral action, especially when it emanates from an economically powerful Member, may in effect be forced to give in to the demands imposed by the Member exerting the threat... To put it differently, merely carrying a big stick is, in many cases, as effective a means to having one's way as actually using the stick. The threat alone of conduct prohibited by the WTO would enable the Member concerned to exert undue leverage on other Members. It would disrupt the very stability and equilibrium which multilateral dispute resolution was meant to foster and consequently establish, namely equal protection of both large and small, powerful and less powerful Members through the consistent application of a set of rules and procedures."). Operation of the program also violated GATT rules. *See* Jagdish Bhagwati and Hugh T. Patrick (eds.), Aggressive Unilateralism: America's 301 Trade Policy and the World Trading System, pp. 113-14 (University of Michigan 1993).

[2] 2011 Special 301 Report, page 14.

"market access" issues that Special 301 reaches. This would certainly not be the interpretation that would follow from one seeking to promote the Doha Declaration on TRIPS and Public Health or internationally recognized human rights principles.

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. state governments – especially state Medicaid programs – follow the same basic policies and principles of foreign countries that Special 301 criticizes.

3. Submission on Best practices

We recommend the following best practices in public policy:

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.[3]
- Promote open ended, flexible exceptions that can adapt to technology and use changes.[4]
- Encourage countries that penalize anti-circumvention to offer flexible and open ended limitations and exceptions to liability.[5]
- Protect free expression by promoting exceptions to copyright for non-commercial user-generated content.[6]
- Promote exceptions to copyright for temporary reproductions for technological purposes (e.g. cache and RAM copies on internet).[7]
- Encourage protections for cross border sharing of copyrighted works created under an exception for visually impaired.[8]

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[3] 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").

[4] 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").

[5] 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.

[6] 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.

[7] 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."

b. Remedies and Enforcement

- Protect and promote commercial thresholds for the imposition of statutory damages.[9]
- Promote restrictions on damages to ensure proportionality to harm to right owner.[10]
- Promote safeguards on internet enforcement policies to avoid threats to free expression, business innovation and free trade.[11]

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).[12]

d. Research and Development

- Promote incorporation of WHA Global Strategy and Plan of Action into research and development policies.[13]

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[8] 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)

[9] 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."

[10] 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."

[11] 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.").

[12] 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).

[13] 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").

- Promote public benefits from publicly funded research, including by promoting accessibility, availability, affordability and access to data and information from government funded research.[14]

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.[15]
- Promote exemptions from data exclusivity requirements. [16]

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."[17]
- Promote and affirm Trips Art. 30 solutions to enable supply of needed medicines to countries with insufficient manufacturing capacity.[18]

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[14] 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)).

[15] 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.")

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

[17] India Patent Act Sec. 3(d).

[18] 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.")