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Public Citizen Hearing Testimony for the 2015 Special 301 Review

Re: Identification of Countries Under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing

Statement of Peter Maybarduk, Global Access to Medicines Program Director

February 6, 2015

Public Citizen is a national, 501(c)3 nonprofit consumer advocacy organization founded in 1971 to represent consumer interests in Congress, the executive branch and the courts. We have 300,000 members and supporters. Public Citizen's Global Access to Medicines Program works with partners worldwide to improve health outcomes through use of pharmaceutical cost-lowering measures including generic competition.

Our comments are drawn from our experience providing technical assistance to public agencies, particularly in developing countries, with regard to patent and other intellectual property (IP) rules. We begin with principles that we believe should inform any 301 review. In attachments, and in comments we will file subsequently, we will discuss several countries' use of flexibilities compliant with the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) to advance public interests.

Principles

Public Citizen takes note of commitments articulated in past Special 301 Reports that "the United States respects a trading partner's right to protect public health and, in particular, to promote access to medicines for all," and "the United States respects its trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement."¹ We support these commitments, which echo the WTO's unanimous 2001 Doha Declaration on the TRIPS Agreement and Public Health. The 2014 report further states, "The United States will work to ensure that the provisions of its bilateral and regional trade Agreements, as well as U.S. engagement in international organizations, including the United Nations and related institutions such as WIPO and the WHO, are consistent with U.S.

¹ See pages 24 and 25 of the 2014 Special 301 Report.

Government policies concerning IPR and health policy and do not impede its trading partners from taking measures necessary to protect public health.”

Nevertheless, past Special 301 Reports have frequently cited countries for exercising public health rights and other flexibilities enshrined in the TRIPS Agreement and Doha Declaration.

For example, past Special 301 Reports have frequently criticized countries for issuing TRIPS-compliant pharmaceutical compulsory licenses.² In some cases the criticism is direct. In others, the references are oblique or come in the form of pledges to monitor the situation. In each case, the mere reference is important—it is a form of sanction and an inappropriate warning against countries exercising established rights to promote public health. It is inconsistent with the Special 301 Report’s stated commitments and with United States commitments under WTO rules. American University law professor Sean Flynn has suggested that the Special 301 Report’s practice of threatening unilateral trade sanctions for practices which comply with trade rules is itself a violation of WTO rules.³

The Trade Act does not require an exercise akin to the Special 301 Report. Too frequently, the Special 301 is used to inappropriately assert influence, at the behest of private interests, to undermine public interests in developing countries. For these reasons, we believe the Special 301 Report should be discontinued in its entirety. Nevertheless, the balance of our comments addresses specific Special 301 practices that can and should be improved.

General commitments to principle made by the United States in the Special 301 Report are not necessarily meaningful unless borne out by the Report’s review of specific country practices. Public Citizen invites USTR and all agencies engaged in the Special 301 process to make meaningful U.S. commitments, including commitments to protect public health, by omitting express or implied references to countries’ practices that comply with international obligations.

We suggest the following principles to support this modest reform:

Special 301 should omit any reference, whether express or implied, to any country’s TRIPS-compliant policies to advance a public interest. USTR should not sanction such policies directly. Nor should it sanction such policies indirectly, for example, through imprecise references to failings in transparency or intellectual property protection or through otherwise unwarranted elevation in a country’s watch list status.

The Special 301 Report should not criticize countries for a lack of transparency or due process, unless such criticism clearly articulates the alleged violation of a TRIPS standard. The TRIPS Agreement provides not only substantive standards, but also standards

² See, e.g., Peter Maybarduk, “The U.S. Government’s ‘Watch List’ on Developing Countries’ Use of Health Rights,” Citizen Vox, May 2, 2013, *available at* <http://www.citizenvox.org/2013/05/02/us-governments-watch-list-on-developing-countries-use-of-health-rights>.

³ See Sean Flynn, “PIJIP Statement on the Release of the 2010 Special 301 Report,” American University Washington College of Law, April 30, 2010, *available at* <http://www.wcl.american.edu/pijip/go/pijip04302010>.

for transparency and due process. It is inappropriate to list (and thereby sanction) a country for an allegedly non-transparent practice, if the criteria for the listing is itself non-transparent and not articulated.

The Special 301 Report should treat public policy disagreement as a matter of clearly lower priority than criminal activity. If, in spite of the principles above, the Special 301 Report nevertheless cites countries for their TRIPS-compliant public policies, such country choices are clearly less objectionable than prevalence of criminal activity, such as alleged trade secret theft. The 301 Report should clearly reflect this ordering of priorities. Pharmaceutical or other public policy disagreements should never land a country on the Priority Watch List. The 301 Report should not conflate policy disagreement and allegedly criminal activity.

The Special 301 Report should only address intellectual property, not ancillary public policies. Past Special 301 Reports have criticized country policies that do not relate to the categories of intellectual property under the TRIPS Agreement. For example, pharmaceutical reimbursement, pricing, or procurement decisions are not intellectual property issues and are therefore outside of the scope of the Special 301 review.

The Special 301 Report should not list countries for not adopting U.S. policy preferences if those countries have no bilateral or international obligation to adopt the same. Even if the Special 301 Report continues to cite countries for TRIPS-compliant policies, Special 301 should not list a country for the absence of a policy that the country is not bound to uphold. For example, a country should not be criticized for not adopting a policy analogous to data exclusivity or patent linkage if that country does not have an agreement with the United States expressly and specifically requiring the same.

At a bare minimum, even if the Special 301 Report subjects wealthy countries to criticism for TRIPS-compliant public interest policies, developing countries should be given greater leeway. This too-modest criterion reflects our understanding of US trade policy today. We take note of the Special 301 Report's statement at page 7, "This [301] assessment is necessarily conducted on a case-by-case basis, taking into account diverse factors such as a trading partner's level of development (...)."

Criticism in the Special 301 Report should be accompanied by express and clearly articulated criteria. If a critique is too vague to be disproven, as we would argue has been the case in past Special 301 Reports, then it is manifestly unfair.

We appreciate this opportunity to comment. We are attaching documentation regarding several countries' specific TRIPS-compliant public interest policies.