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2024 Special 301 Review Post-Hearing Comment

February 28, 2024

During the 2024 Special 301 Review public hearing, agency representatives asked three questions about our comments. We answer those questions in greater detail here.

Question: In your submission, you make several arguments as to why the Special 301 Report should not identify country policies or practices that are compliant with the TRIPS Agreement. Congress has told USTR that a country, "may be determined to deny adequate and effective protection of intellectual properties, notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the TRIPS Agreement", (19 U.S.C. section 2242). How do your arguments align with this statement?

The principles laid out in our comment state that countries should not be listed in the Special 301 Report for TRIPS-compliant policies or for using TRIPS flexibilities to safeguard public health and access to medicines.[1] Our comment also includes a slate of principles to improve on the Special 301 status quo if a broad TRIPS compliance standard is not feasible at this time.

While the statute states that a country "may" be determined to deny adequate and effective protection of IP rights notwithstanding TRIPS compliance, it does not instruct the review committee to cite countries for TRIPS-compliant practices, or to apply any particular standard. The committee has the discretion not to cite countries for TRIPS-compliant practices, and we believe this is particularly important as regards practices that support health. The U.S. should not pressure countries to adopt TRIPS-plus measures harmful to development and access to medicines in developing countries. A statement reflecting this principle – that the Special 301 respects TRIPS-compliant policy choices that support health – would be quite helpful.

Further, the statutory basis for the identification of countries in the Special 301 Report does not include concrete criteria to determine which countries deny "adequate and effective" protection of IP. One such determinative norm should be the practices of the United States itself, such as President Biden's announcement of price as a basis for marching-in on government funded inventions and licensing to other manufacturers to produce more affordable alternatives. Therefore, at a minimum, the Special 301 Report should continue to not critique the compulsory licensing practices of other countries for vital medicines where that avenue is also being pursued domestically.

The interagency committee gives deference to Executive Order 13155 during its review process.[2] That EO defines adequate and effective IP protection as that which is consistent with TRIPS. There is nothing in the existing statute inhibiting the application of this standard to other developing countries in the

[1] Public Citizen Comment re: 2024 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974, (Jan. 30, 2024), https://www.citizen.org/wp-content/uploads/Public_Citizen_2024-Special-301_Review_Comment.pdf

[2] Executive Order 13155—Access to HIV/AIDS Pharmaceuticals and Medical Technologies, (May 10, 2000), https://www.govinfo.gov/content/pkg/WCPD-2000-05-15/pdf/WCPD-2000-05-15-Pg1058-2.pdf

interest of supporting access to medicines while ensuring adequate and effective IP protection in line with the TRIPS Agreement.

If the Report continues citing countries for TRIPS-compliant policies, still it should not list a country for the absence of a policy that the country is not bound to uphold by bilateral or international treaty obligations. For example, a country that has no U.S. trade agreement binding it to particular standards of data exclusivity, patent linkage or patentability standards should not be listed for applying its own TRIPS-compliant standards instead.

The Special 301 Report also should make a clear distinction between public policy disagreements (e.g., pharmaceutical data exclusivity) and proliferation of criminal activity (willful, commercial-scale trademark counterfeiting and copyright piracy). The absence of such a clear distinction places undue pressure on foreign governments working in support of the public interest, while tainting Special 301's appropriate goals of law enforcement.

Question: The State Department Office of Intellectual Property Enforcement is charged with compiling and coordinating the TRIPS Article 66.2 report annually. In your submission, you mention a lack of implementation of TRIPS Article 66.2 and a lack of clarity on how developed country members should provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfers to lesser developed or least developed country members. What changes do you recommend that the United States make to its TRIPS Article 66.2 programs or reporting? Do you have any suggestions as to how WTO members could improve or add clarity around how TRIPS Article 66.2 is implemented?

During the TRIPS negotiations, technology transfer was considered part of the "grand bargain" between developed and developing countries: in exchange for increased IP protections, developing countries would be offered new technologies. In our view, more must be done to deliver on this promise. Special 301 upsets the intended balance of IP protection and technology transfer where it supports TRIPS-plus measures keeping new technologies or information out of the public domain.

The "objectives" introduced by TRIPS Article 7 state that the protection and enforcement of intellectual property "should contribute to the promotion of technological innovation and to the transfer of and dissemination of technology." Article 66.2 provides a specific obligation for developed country members to provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfers to least-developed country (LDC) members to enable them to create a sound and viable technological base in their respective economies. Though developed countries are obligated to submit reports to the TRIPS Council on Article 66.2 implementation, ambiguities remain in how to measure and define incentives and even technology transfer itself.[3]

The U.S. has extraordinary capabilities to support technology transfer, and authority under existing law to do so. The U.S. government supports many of the world's leading research programs, and can make information, trainings and technology available, to the betterment of the world.

[3] Suerie Moon, "Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs? An Analysis of Country Submissions to the TRIPS Council (1999-2007)", ICTSD, Policy brief Number 2, (Dec. 2008) https://unctad.org/system/files/official-document/iprs_pb20092_en.pdf

For example, U.S. scientists and agencies have supported the mRNA Technology Transfer Program backed by the World Health Organization (WHO).[4] That initiative aims to equip scientists at fifteen sites across the Americas, Asia and Africa with advanced mRNA techniques. The Program operates on a share-and-share-alike model for technology and scientific knowledge that will help screen new vaccine candidates, advance science against key global disease targets, and ultimately manufacture new vaccines. The U.S. National Institutes of Health (NIH) have provided technical support for lipid production through the Vaccine Research Centre. The Biomedical Advanced Research and Development Authority has provided trainings for program scientists at its Texas manufacturing facility. NIH scientists have provided technical assistance and guidance. The U.S. can do much more, including licensing NIH vaccine candidates and technologies for non-exclusive use by the program (and encouraging vaccine manufacturers to do the same). The U.S. also should include conditions in its funding agreements with manufacturers that facilitate technology transfer to WHO partners such as the mRNA Technology Transfer Program and the Medicines Patent Pool.

The U.S. also should support technology transfer provisions in the proposed WHO pandemic agreement. In a recent comment to HHS, we detail various provisions in the proposed agreement that the U.S. can and should be supportive of, as well as various incentives and mechanisms for implementing these provisions.[5]

Past and future U.S. support for these initiatives that promote sharing of technology and knowledge for the benefit of all, including LDCs, should be documented in the 66.2 report.

Question: Your submission states that 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". What transparency and due process standards from the TRIPS Agreement should be considered when assessing other countries' practices? Is there any value in considering best practices from U.S. government processes as well?

Articles of the TRIPS Agreement provide not only substantive standards for particular areas of law, but also standards for transparency and due process. For example, TRIPS Article 31 details the steps that must be taken by members considering a compulsory license. These include, under particular circumstances, efforts to obtain authorization by the right holder, notification of the right holder, adequate remuneration and judicial review, among others. These procedural safeguards were carefully negotiated. It would be appropriate for the Special 301 Report to clearly articulate an alleged breach of these standards. It would not be appropriate to create additional procedural requirements, or to allege a process problem without reference to one of these Article 31 conditions.

Additionally, TRIPS Part III establishes a number of standards for legal process (fair and equitable procedures, evidence), transparency (decisions in writing, right of information) and remedies (injunctions).

Complaints in the Special 301 Report regarding transparency and due process should cite the relevant TRIPS article and detail the requirements that USTR believes have not been met.

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[4] World Health Organization, The mRNA vaccine technology transfer hub initiative, https://www.who.int/initiatives/the-mrna-vaccine-technology-transfer-hub

[5] Public Citizen Comment re: Implications of Access and Benefit Sharing (ABS) Commitments/Regimes and Other Proposed Commitments in the WHO Pandemic Agreement, (Jan 31, 2024), https://www.citizen.org/wp-content/uploads/Public_Citizen_Comment-Re_WHO_Pandemic_Instrument.pdf

In cases where USTR deems it necessary to go beyond the standards in the TRIPS Agreement, it should clearly articulate the issue. Governments or public interest groups cannot offer an adequate reply to the complaints in the Special 301 Report unless the complaint and its basis are fully detailed. 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.