



# Time for a Collective Response to the United States Special 301 Report on Intellectual Property

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## Introduction

On 25 April 2019, the Office of the United States Trade Representative (USTR) released the annual Special 301 report for 2019. This report is a unilateral review and characterization of selected countries' intellectual property (IP) laws and practices on IP protection and enforcement. The report lacks empirical evidence and objective

analysis. It reflects the strong influence of domestic industry actors on the foreign IP and trade policy of the United States of America (US). The report is a means to pressure countries bilaterally to increase IP protection and enforcement measures beyond existing international standards with disregard to public interest considerations. The threat of trade sanctions by the US is used to trigger legal and policy change in third countries.

## Abstract

This policy brief discusses the annual Special 301 report issued by the Office of the United States Trade Representative (USTR). The report is a unilateral tool of the US to pursue its foreign intellectual property (IP) policy by exerting pressure on countries to reform their IP laws and practices. Developing countries are particularly susceptible to this threat. The report identifies countries that are considered by the US as not providing adequate and effective protection of IP of rights holders from the US. The selection of countries is biased to the concerns raised by segments of the US industry. The report targets balanced provisions in countries' legislations to ensure that IP rights do not hinder the ability of the government to adopt measures for promoting development priorities, particularly in the area of public health. A uniform and collective international response by the affected countries is long overdue. The way forward is to continue dialogue in appropriate multilateral fora, recognizing the need for all countries to maintain policy space to use IP as a domestic policy tool.

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La présente note de synthèse porte sur le rapport annuel spécial 301 publié par le Bureau du représentant américain au commerce (USTR). Ce rapport est un outil de politique étrangère utilisé par les États-Unis de manière unilatérale qui vise à faire pression sur les autres pays afin qu'ils réforment leurs lois et pratiques en matière de propriété intellectuelle. Les pays en développement sont particulièrement vulnérables à cette menace. Le rapport recense les pays qui sont considérés par les États-Unis comme n'assurant pas une protection adéquate et efficace des droits des titulaires d'un brevet américain. Le choix des pays est biaisé et repose uniquement sur les préoccupations soulevées par certains segments de l'industrie américaine. Le rapport cible les dispositions contenues dans les législations des autres pays qui garantissent un équilibre et font en sorte que les droits de propriété intellectuelle n'entravent pas la capacité des autorités gouvernementales à adopter des mesures destinées à favoriser la réalisation des priorités en matière de développement, en particulier dans le domaine de la santé publique. Une réponse uniforme et collective des pays concernés est attendue depuis longtemps. La poursuite, dans les instances multilatérales compétentes, d'un dialogue qui reconnaisse la nécessité pour chaque pays de conserver une marge d'action en matière de propriété intellectuelle afin qu'elle demeure un instrument de politique intérieure est essentielle pour y parvenir.

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Este informe de políticas analiza el informe anual especial 301 emitido por la Oficina del Representante de Comercio de los Estados Unidos (USTR, por sus siglas en inglés). El informe es una herramienta unilateral de los Estados Unidos para proseguir su política de propiedad intelectual (PI) exterior ejerciendo presión sobre países para reformar sus leyes y prácticas de PI. Los países en desarrollo son especialmente vulnerables ante esta amenaza. El informe señala que países son los que los Estados Unidos consideran que no proporcionan una protección adecuada y efectiva a la PI de los titulares de derechos de los Estados Unidos. La selección de países está sesgada por la preocupación que han manifestado sectores de la industria de los Estados Unidos. El informe se centra en disposiciones equilibradas en la legislación de los países para garantizar que los derechos de PI no afecten a la capacidad del Gobierno para adoptar medidas destinadas a promover las prioridades de desarrollo, en particular en el ámbito de la salud pública. Hace ya mucho tiempo que se espera una respuesta internacional uniforme y colectiva por parte de los países afectados. El camino para progresar pasa por continuar el diálogo en los foros multilaterales pertinentes y reconocer la necesidad de que todos los países mantengan un espacio de políticas para utilizar la PI como una herramienta de política nacional.

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## **I. The impact of the Special 301 Report**

The Special 301 Report is an annual report by the United States Trade Representative (USTR) under the Trade Act of 1974, which identifies countries that are considered by the US as not providing adequate and effective protection of intellectual property rights (IPRs) or fair and equitable market access to IP rights holders from the US. The report has been issued every year since 1989. The Special 301 report designates countries as “priority foreign country”, “priority watch country”, and “watch list country”. Designation as a priority foreign country initiates an investigation and possible application of sanctions on the foreign country, while designation in a Priority Watchlist suggests serious IPRs deficiencies that require greater US attention. Other countries that are considered to have serious IPRs deficiencies but are not designated for greater US attention are placed in a Watchlist.

The referred to Report includes both developed and developing countries, though the latter are more at risk of persuasion through the trade pressures to take on the reforms required to address the problems identified in the report, even if in detriment to their national interests. Among the developing countries, the 2019 Special 301 Report has designated Argentina, China, Chile, India, Indonesia, Kuwait, Saudi Arabia, and Venezuela as countries in the Priority Watchlist. This means that these countries will receive greater pressure from the USTR to address the concerns mentioned in the report with respect to their IP laws and policies.

The targeting of countries in the Section 301 Report is arbitrary. The report lacks empirical evidence and objective analysis, and is biased to the concerns raised by segments of the industry of the US with regards to the protection and enforcement of IP rights abroad. A careful analysis of the legislations in the targeted countries under the Special 301 report for 2019 reveals that these include balanced provisions to ensure that IP rights do not hinder the ability of the government to adopt measures for promoting development priorities, particularly in the area of public health. These legislations and their implementation are fully in line with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and reaffirmed by the Declaration adopted at the WTO Ministerial Conference in Doha on the TRIPS Agreement and Public Health.<sup>1</sup>

The continued use of threat of unilateral sanctions by the US against countries listed in the Special 301 Report is against the spirit of the landmark WTO Doha Ministerial Declaration on TRIPS and Public Health. Developing and least developed countries have the right to use the flexibilities in the TRIPS Agreement to the fullest extent for advancing public health needs and other development priorities. The Report provides no evidence suggesting that the legal and regulatory measures that have been used by the developing countries for protecting public health are inconsistent with

the WTO TRIPS Agreement. The continued threat of unilateral trade sanctions by the US to developing countries through the Special 301 review undermines the legitimacy of the WTO, particularly the TRIPS Agreement and the WTO’s dispute settlement system.

The US threat of unilateral sanctions to the countries in the Section 301 report is against the spirit of multilateralism and the existing multilateral rules. Any country may be designated in a “Priority Watchlist” under the “Special 301” provisions of the US Trade Act of 1974. The mere threat of potential sanctions by placing a country in any specific category in the US watch list would appear to violate the WTO Dispute Settlement Understanding. A WTO panel noted, in a dispute brought in 1999 by the European Union (EU) against Section 301 of the US law, that “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.”<sup>2</sup>

## **II. Legitimate pro - public health measures under attack**

The 2019 Special 301 Report has raised concerns about a number of measures in national laws of the designated countries, that effectively seek to make use of the flexibilities under the TRIPS Agreement for promotion of the public interest. This is particularly evident with respect to the use of TRIPS flexibilities to promote public health objectives.

The Special 301 Report has raised specific concerns about measures denying the possibility of submission of supplementary data during patent examination, lack of data exclusivity for test data, no patent term extension or linkage of marketing approvals for generic medicines to the existence of patent/s in force, the application of strict patentability criteria, and compulsory licensing provisions.

The following specific objections can be raised in response to the concerns identified in the USTR 2019 Special 301 Report:

First, national patent offices or the judiciary are not obliged to rely on supplementary information provided by a patent applicant in making a determination concerning a patent application. Hence, non-admissibility of such information in any particular country is within the scope of the reasonable discretion which any administrative or judicial authority may exercise, and it is fully consistent with the provisions of the TRIPS Agreement.

Second, with regard to protection of test data, the only obligation under Art.39.3 of the TRIPS Agreement for a WTO member is to protect such data against unfair commercial use. There is no obligation under the TRIPS Agreement to grant exclusive rights over such data. More-

over, it is fully consistent with the TRIPS Agreement to limit the scope of test data protection to medicines that contain chemical entities that have not been the object of marketing authorization previously in the country concerned.

Third, there is no obligation for any WTO member under the TRIPS Agreement to grant extension of the term of a patent for delays in obtaining regulatory approval for marketing a drug or for other reasons. Imposing such requirements in the national laws of developing countries through unilateral coercive mechanisms such as the Special 301 designation would have detrimental consequences by deterring early generic availability of affordable medicines.

Fourth, the establishment by the government of rigorous and robust criteria to examine patent applications, the right to issue compulsory licenses, and the use of patent pre-grant and post-grant opposition proceedings are, among others, important flexibilities that serve to protect public health, consistent with the TRIPS Agreement. None of the recent decisions in developing countries to reject patents on known medicines or to issue compulsory licenses on patented medicines have been challenged before the WTO dispute settlement mechanism. In fact, the United States is the country that uses compulsory licensing the most. Many developing countries have issued compulsory licenses for ensuring access to affordable medicines to meet their public health needs, including Brazil, Ecuador, Eritrea, Ghana, India, Indonesia, Malaysia, Mozambique, Thailand and Zambia. Such licenses have also been recently granted in Russia and Germany.

Fifth, there is no obligation under the TRIPS Agreement for any country to deny the marketing approval of a medicine on the basis of the existence of a patent right. There is also no obligation on any country under the TRIPS Agreement to provide information to patent right holders on whether marketing approval has been granted to a generic manufacturer where a patent exists. It is for the right holder to exercise due diligence and remain vigilant in ensuring that the patent right is not infringed in the event, and it is not the obligation of the drug regulatory authority to provide or act on the basis of such information.

### **III. The USTR 2019 Special 301 Report demands on enforcement and copyright protection**

The Special 301 Report alleges that the listed countries failed to take decisive action to curb counterfeit goods or bad faith registration of trademarks. This stance is untenable because the onus of taking decisive action against such acts falls on the right holder. The fundamental question is whether the procedures available to right holders to initiate such enforcement action are effective. No empirical evidence or objective analysis is provided to make that assertion with regards to the listed countries.

The TRIPS Agreement requires WTO members to provide right holders with effective procedures and mechanisms for enforcing their IP rights, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. However, the specific nature of these procedures and remedies are not specified. Indeed, WTO members have no obligation to create special regimes for enforcement of IP that is separate from the general law enforcement regime they have. Moreover, the primary obligation for enforcing IP rights is on the right holder and not the State.

On copyright, the 2019 Special 301 report also fails to provide empirical evidence and objective analysis of the listed countries' legislations. Rather than highlighting alleged shortcomings in copyright protection and enforcement, the US could contribute through multilateral discussions on how to advance limitations and exceptions to copyright protection, based on the experience of the US with its fair use exception that allows for usage rights that are broader than those available in many of the countries listed in the report.

### **Conclusion**

The USTR 2019 Special 301 Report, as in previous years, is a unilateral tool of the US to pursue its foreign IP policy by exerting pressure on countries to reform their IP laws and practices. Developing countries are particularly susceptible to this threat.

A uniform and collective international response by the affected countries is long overdue. The US administration must be required to act in accordance with its obligations under the WTO and World Intellectual Property Organization (WIPO)-administered agreements, and not take unilateral actions in violation of multilateral rules. The way forward is to continue dialogue in appropriate multilateral fora, recognizing the need for all countries to maintain policy space to use IP as a domestic policy tool. This requires continuous fine tuning of national IP regimes to set the adequate balance between protection and access to the outcomes of innovation in order to advance national development and the implementation of the 2030 Agenda for Sustainable Development.

Countries should continue to make full use of the TRIPS flexibilities for public health and in the public interest, consistent with their rights and obligations under WTO rules.

### **Endnotes:**

<sup>1</sup> [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)

<sup>2</sup> Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies (September 2016). Available from <https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/57d9c6ebf5e231b2f02cd3d4/1473890031320/UNSG+HLP+Report+FINAL+12+Sept+2016.pdf>.

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