Submission to the Office of the United States Trade Representative

In the matter of
2020 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974
Docket No. USTR-2019-0023-0001

Comments of Colombian Civil Society Organizations

Bogotá, February 6th 2020

I. Introduction

As a group of Colombian non-governmental organizations seeking to defend and protect important public interests and fundamental human rights within the discourse of Intellectual Property, we want to participate again this year commenting on the many gaps present in the Special 301 Process and Report.

The Karisma Foundation is an organization of Colombian civil society which, since 2011, has participated in the public debate on the reform of copyright driven by Colombia FTA signed with the US. In addition, the first time Karisma submitted observations was in a joint statements with other NGOs through the group Program on Information Justice and Intellectual Property (PIJIP, for its acronym in English) of the American University Washington College of Law, during the proceedings of the Special Report 301 in 2011 and 2013[1].

Misión Salud is a Colombian non-profit civil society organization whose goal since its foundation in 1998, is to promote and defend the right of Colombians to health and access to medicines. Misión Salud advocates in national and international scenarios to promote that governmental institutions prioritize public health over commercial interests when formulating and implementing policies, trade agreements and regulations related to intellectual property and pharmaceuticals.

IFARMA Foundation is a Colombian non-profit, civil society organization, that develops research, consulting and activism activities, focused on the issues of access, use and quality of medicines. The main objective of IFARMA Foundation is to positively influence public health and drug policies in Colombia, as well as regionally in the Americas and globally, with the ultimate goal of guaranteeing the human right to health and the access to treatment with equity to all who need them.

The Center for Internet and Society of Rosario University –ISUR in Spanish– is an academic research center that works from a public interest and human rights perspective on pressing issues regarding digital technologies and society. Through high quality research, ISUR informs and influences colombian and regional debates around these issues.

In this sense, we, Karisma Foundation, Misión Salud, IFARMA Foundation and ISUR, presented our comments on the 2014[2], 2015[3], 2016[4], 2017[5] and 2019[6] Special 301 Reports

---

[1] Fundación Karisma. Una vez más solicitamos que Colombia sea retirada del Informe Especial 301. [Online]. 2013. Available at: http://karisma.org.co/?p=2029 And Fundación Karisma, Colombia debería ser retirada de la lista 301. Available at: http://karisma.org.co/?p=611

[2] Misión Salud, Fundación Karisma, Fundación IFARMA. Submission to the U.S. Trade Representative
2014 Special 301 Review: Comments of Colombian Non Governmental Organizations. Docket number USTR-2013-0040. [Online]. Bogotá, March 6th 2014. Available at: http://www.mision-salud.org/2014/02/21/la-propuesta-del-ustr-para-el-capitulo-de-propiedad-intelectual-del-acuerdo-de-asociacion-transpacifico-tpp-arriesga-el-acceso-a-los-medicamentos-para-todos/

along with other organizations of Colombian civil society. The substantive comments regarding the Special 301 process and report we have presented collectively since 2014 remain applicable, so this submission re-articulates many of the considerations presented in the past in the light of the 2019 Special 301 Process.

II. The unilateral adjudication of trade disputes through the Special 301, with respect to the agreements signed within the WTO, violates the Dispute Settlement Understanding of the WTO

As we did in previous years, we must insist that "*the current use and operation of the program as a set of increasingly serious 'watch lists' ending in a priority foreign country listing with a specific trade sanction process violates the World Trade Organization's ban on unilateral adjudication of trade disputes*"[7], and it should be assessed as such by all trading partners of the United States[8]. In this sense, we continue to support the other comments submitted in 2014 by the PIJIP[9], which delves into that argument.

Articles 23.1 and 23.2 (a) of the Dispute Settlement Understanding (DSU) of the WTO

---

[3] Misión Salud, Fundación Karisma, Fundación IFARMA. Submission to the U.S. Trade Representative 2015 Special 301 Review: Comments of Colombian Non Governmental Organizations. Docket number USTR-2014-0025 (Online) Bogotá, February 6th 2015. [Cited 2020 Feb 6]. Available at: http://www.mision-salud.org/2014/02/21/la-propuesta-del-ustr-para-el-capitulo-de-propiedad-intelectual-del-acuerdo-de-asociacion-transpacifico-tpp-arriesga-el-acceso-a-los-medicamentos-para-todos/

[4] Misión Salud, Fundación Karisma, Fundación IFARMA. Submission to the Office of the United States Trade Representative. In the matter of 2016 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974. Docket number USTR-2015-0022. Comments of Colombian Civil Society Organizations. [Online]. Bogotá, February 5th 2016. [Cited 2020 Feb 6]. Available at: http://www.mision-salud.org/2016/02/08/proceso-special-301-en-2016-concluida-primera-fase-de-este-tradicional-instrumento-de-presion/

[5] Misión Salud, Fundación Karisma, Fundación IFARMA. Submission to the Office of the United States Trade Representative In the matter of 2017 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974. Docket No. USTR-2016-0026. Comments of Colombian Civil Society Organizations. [Online]. Bogotá, February 9th 2017. [Cited 2020 Feb 6]. Available at: https://www.mision-salud.org/nuestras_acciones/acuerdos-comerciales/2017-otra-vez-el-301/

[6] Available at http://blogs.eltiempo.com/medicamentos-sin-barreras/2019/03/06/special-301-enviamos-comentarios-al-ustr-en-su-consulta-para-reporte-2019/

[7] Infojustice.org. Flynn testifies in Special 301 Hearing. [Online] 2013. [Cited 2020 Feb 6]. Available at: http://infojustice.org/archives/28620

[8] Similar approaches have already been addressed by countries like Canada in 2007 (http://www.ourcommons.ca/DocumentViewer/en/39-1/SECU/meeting-35/evidence#T1150 - Cited 2020 Feb 6) and Chile in 2013 (https://www.emol.com/noticias/nacional/2013/05/01/596379/chile-no-reconoce-la-validez-de-la-lista-negra-de-pirateria-de-eeuu.html - Cited 2020 Feb 6)

[9] Flynn S. Submission to the U. S. Trade Representative and Notice of Intent to Testify. [Online]. 2014 Feb 7 [Cited: 2020 Feb 6]. Available at: https://www.regulations.gov/document?D=USTR-2013-0040-0021

establish:

1. *When Members seek the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, and abide by, the rules and procedures of this Understanding.*
2. *In such cases, Members shall:*

(a) 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, and shall make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under this Understanding;

Thus, Article 23 of the DSU of the WTO, by requiring the application of WTO multilateral system for resolving trade disputes, not only excludes unilateral action for the determination of "violations", but also prevents the implementation of other forums or unilateral mechanisms for the resolution of disputes concerning WTO.[10]

"[Special 301] promotes an environment where different approaches to TRIPS implementation are framed as 'rule of law' problems, rather than deliberate legislative choices, and therefore undermines those choices".[11] It is to avoid such effects that Article 23 of the DSU takes special sense, and therefore all Member States of the WTO should both respect it and enforce it.

III. Other general concerns regarding the Special 301

The undersigned agree with other important general concerns raised by the PIJIP in 2013, and we denounce:

- "that the 301 process and report fails to implement stated U.S policy promoting balanced intellectual property policy on major public interest issues, including on policies affecting access to affordable medications in poor countries and promotion of users' rights in copyright policy;" Precisely, Special 301 process and report are used to apply pressure against the use of human rights safeguards by middle-- and low--income countries[12], blocking the exercise of rights under international law (TRIPS Agreement and Doha Declaration, for example) in favor of nations. It is important to emphasize that these are not mere exceptions or faculties but rights.

[10] Zhou, Suzanne. Challenging the Use of the US Special 301 Procedures against Developing Country Access to Medicines Policies -- Indian Pharmaceutical Patents and the WTO (September 1, 2015). Pages 13 and 20. [Cited: 2020 Feb 6] Available at SSRN:http://ssrn.com/abstract=2675990

[11] Susan Sell, 'TRIPS and the Access to Medicines Campaign' (2002) 20 Wisconsin International Law Journal 481 , 500--504. Cited by Zhou, Suzanne. Op cit. Footnote 106. [Cited: 2020 Feb 6]

[12] Zhou, Suzanne. Op cit. Page 11.

With the difference that, because they are directly related to human rights, they are of higher category than commercial interests.

- "that the definition of what is ‘adequate and effective intellectual property protection’ cannot follow a one size fits all model where every country in the world is expected to have the same rules and interpretations as possessed by the United States– such a norm ignores the painful fact of gross income disparity in developing countries which incentivizes monopoly holders to price the great majority populations (at least 90%) out of the market;”
- "the process for considering public submissions is inadequate and leads to arbitrary and capricious outcomes in the report.”

Clearly, the Special Program 301 and its list are unilateral instruments that should cease to exist: (1) They "may ‘disrupt the very stability and equilibrium which multilateral dispute resolution was meant to foster" (2) Its use to threaten to "trade sanctions for TRIPS and FTA compliant policies violates the WTO Accord," and (3) it continues to be used as an illegitimate mechanism for pressuring countries through a denouncing list.

Furthermore, there has to be said that the Special 301 Report does not respect the international norms about sovereignty. According to the article 4 of the Montevideo Convention, States are juridically equal, and, for that reason, have autonomy to legislate over their own matters. The Special 301 Report violates that disposition because it imposes mandates directed to modify the internal laws of other sovereign countries. In that sense, the U.S. government is not entitled to monitor nor modify the laws that regulate intellectual property rights in other States.

Accordingly, not only the U.S. government is not entitled to qualify others State’s regulation on intellectual property, but also, the standards applied by the USTR are against international instruments about Human Rights, such as the International Covenant on Economic, Social and Cultural Rights of which Colombia is part.

The article 15.1.b of the Covenant clearly establishes that everyone has the right to enjoy the benefits of scientific progress, which is not possible under the requirements of the USTR, considering the circumstances of public health and education in Colombia. If the Colombian government compromised itself with the USTR agenda without considering the circumstances of its citizens, the burden imposed by intellectual property rights on Colombian people would make them extremely vulnerable both in the education and public health fields.

The standards that the USTR is forcing other States to apply fail to recognize the right under the article 15.1.b of the International Covenant on Economic, Social and Cultural Rights, and also violate the article 27 of the Universal Declaration of Human Rights: “*Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits*”.

Because of these reasons, first, that the U.S. government has no right to monitor, qualify and force legislation about intellectual property in foreign States, second, the standards proposed

by the USTR represent a violation to the International Covenant on Economic, Social and Cultural Rights and the Universal Declaration of Human Rights, the standards of the Special 301 Report should not be taken into account for Colombian internal public policy and legislation.

IV. Colombia's measures to ensure the fulfillment of citizens' fundamental rights can not be considered to harm an "adequate and effective intellectual property protection"

Colombia has been taking measures (and must take many more) to ensure the fulfillment of citizen's fundamental rights, which are above individuals' or countries trade' interests, and it can not be legitimately considered that such fulfillment harms an "adequate and effective intellectual property protection".

Furthermore, high-income countries are called upon to protect the fulfillment of citizens' fundamental rights in order to comply with international cooperation obligations[13] for promoting the welfare of mankind, therefore, they should not harm developing countries with trade provisions.

Moreover, since the intellectual property rights' model has failed as a mechanism to encourage innovation and access to its fruits for all[14,15] trading partners of the United States should make considerable efforts towards finding other models that effectively encourage the development of accessible and affordable solutions to social challenges of the world, before acting in response to this unilateral program and its list.

V. Colombia and the 2020 Special 301 Report

The undersigned **do not recognize the legitimacy of the list 301. In addition, as it is discussed below, we believe that Colombia is not infringing any regulation or agreement that would justify a claim by the United States.**

1. US claims affecting negatively Colombians human right to health

In the previous Special 301 Report Colombia was placed on the Watch List. It says "*With respect to Article 72 of the NDP, Colombia issued Decree 422 in March 2018, as amended*

[13] Holguín, Germán. La guerra contra los medicamentos genéricos. Un crimen silencioso. 2014. Bogotá, Aguilar. p. 34.
[14] United Nations Secretary-General's High Level Panel on Access to Medicines. The United Nations Secretary-General's High Level Panel on Access to Medicines Report. 14th September 2016. [Cited: 2020 Feb 6] Available at http://www.unsgaccessmeds.org/final-report
[15] Moser, Petra. Patents and Innovation in Economic History (January 28, 2016). [Cited: 2020 Feb 6] Available at SSRN: http://ssrn.com/abstract=2712428

by Decree 710 of April 2018, to clarify that Colombia would not condition regulatory approvals on factors other than the safety and efficacy of the underlying compound."

Considering that statement made in the previous 301 review, it would be convenient to describe why the Colombian legislative initiative under article 72 was and still is necessary from a public interest perspective and why such initiative is worth replicating:

I. Article 72 of the National Development Plan 2014 - 2018 was intended to address new medicines high prices before they enter into the market. The proposed mechanism consisted on a governmental assessment of the price of each new drug based on its therapeutic added value, as a way to ensure the sustainability of the health system, to guarantee Colombians Right to Health and to clarify which new medicines indeed add therapeutic value.

   A. An example to explain the importance of this regulation is Juxtapid®, a medication to treat a genetic metabolic disorder. Juxtapid® entered into the market in 2016 at a price of approximately US$1160 per tablet (20mg). In 2017, the price of each tablet was nearly US$1400. Due to those price variations, in a single year the health system paid more than US$6 million dollars for only this new medication. It is worth noting that the salary for millions of Colombian families is around US$268.
   B. The Manager of the resources of the General System of Social Security in Health in Colombia (ADRES, from its initials in Spanish) has several cases like Juxtapid® to address, because there has not been a mechanism to prevent from happening abusive prices in new medicines. ADRES reported in 2018 that medicines not covered by the benefit plan of the health system corresponded to 84.72% of the payments made with additional resources.

II. The impact of new medicines high prices on national or individual's budgets is no longer a burden only for low or middle-income countries once high income countries are being affected. A sign of the pressure that high income countries are facing on this matter is the presentation at the beginning of 2019 of the following 3 bills by a group of Senators and Representatives for US Congress approval: The Prescription Drug Price Relief Act[16], The Medicare Drug Price Negotiation Act and the Affordable and Safe Prescription Drug Importation Act.

    In the same direction, it is worth citing the expression of the United Nations Secretary General's High Level Panel on Access to Medicines Report: *"the High-Level Panel views innovation and access to health technologies as a multi-dimensional and global problem that affects all countries"*[17].

---

16 https://www.sanders.senate.gov/download/final_-prescription-drug-price-relief-act-of-2019?id=8E25C2B3-6DFF-4183-BB2E-7787AE070C34&download=1&inline=file

17 United Nations Secretary-General's High Level Panel on Access to Medicines. Op. Cit.

III. Furthermore, as recently reported by the WHO on its Technical Report "Pricing of cancer medicines and its impacts",[18] "pharmaceutical companies set prices according to their commercial goals, with a focus on extracting the maximum amount that a buyer is willing to pay for a medicine". Hence, it is more than reasonable that a middle income country such as Colombia puts a special effort on controlling the price of new medicines before they reach the market and considering its therapeutic added value, as some South American countries are progress on.

IV. With regards to the expression in the previous Special 301 Report that says *"Finally, the United States continues to engage Colombia on patent-related matters and encourages it to incentivize innovation through strong IP systems",* there is not evidence to consider that new medicines price regulation would undermine innovation and IP systems. All the opposite, as suggested in the aforementioned WHO Technical Report "..lowering current prices might in fact be conducive to long-term innovation."

V. Finally, there is no justifiable reason why pharmaceutical regulatory approvals of new drugs could not be conditioned on factors other than safety or efficacy, like price. New medicines continue being too expensive for Government and people's budget; and medicines price controls that apply after the drug has been for long time in the market cannot be efficient enough to protect budgets from a financial catastrophes due to highly priced new medicines[19]. Being the Government responsible for respecting, protecting and fulfilling the human right to health of its population (considering that 98% of Colombians are covered by the Health System), it is necessary that the Colombian Government updates pharmaceutical regulatory approval according to these current challenging circumstances.

How valuable would be for the undersigned organizations and for Colombians in general to find that the USTR encourages Colombian Government to exercise its right-obligation of putting in place all mechanisms available, including price **regulation** of new medicines before they reach the market, to favor human right to health of its population.

2. Copyright

2019 Special 301 report once again keeps sustaining a narrative that demands the Colombian government on one hand, to harden its laws and regulatory framework on intellectual property and copyright, on the other, to assume new measures that allows to prosecute and punish online piracy among others. The novelty this time, is that the US government stated in its last Special 301 report that Colombia is "actively engaging with the

[18] https://apps.who.int/iris/bitstream/handle/10665/277190/9789241515115-eng.pdf?ua=1

[19] ADRES. ADRES pagó $3.13 billones por servicios no incluidos en el plan de beneficios en salud en 2018 [ADRES paid $ 3.13 trillion for services not included in the health benefit plan in 2018]. [Cited: 2020 Feb 6] Available at: https://www.adres.gov.co/Inicio/Noticias/Post/6150/ADRES-pag%C3%B3-3-13-billones-por-servicios-no-incluidos-en-el-plan-de-beneficios-en-salud-en-2018

United States on implementing notice-and-take-down and safe harbor provisions for Internet service providers".

Unilateral documents such as the Special 301 report issued year after year by the US government through the USTR, puts an undue pressure under a sovereign nation such as Colombia requesting it to bring forward expeditious legislative reforms that do not fit with internal democratic values. The USTR should demand to its commercial partner instead, that those processes derived from CTPA agreements should comply with national laws and social participation guarantees, stating the need to avoid rush and not agreed legal reforms as that one that took place in 2018 that introduced a reform on copyright framework.

2019 Special 301 report sustained that there is currently an actively engaging process between Colombia and United States on implementing notice-and-take-down and safe harbor provisions for Internet Service Providers, which should address intellectual property related commitments under the CTPA. That process needs to guarantee a broad, open, participative and democratic discussion that allows Colombian government to adjust those commitments to its internal reality and regulatory framework.

We the organizations endorsing this document have criticized with strong emphasis the results of this type of undue pressures put under states as Colombia by the USTR. Colombia's national legislative agenda has been modified in the past by this type of pressures that has derived in legal proposals that does not take into account the need for balances or expectancies of all parties at stake what affects in the end the protection of public interest, the access to culture, knowledge.

Until now there has not been released any information about what type of "actively engaging process" are currently developing both Colombia and the US government to provide a "safe harbor" to ISP and what it will mean in terms of regulatory modifications. A year later of the issuance of the Special 301 report announcing this process that may probably derive into a legal reform that implements notice-and-take-down provisions, civil society organizations and other stakeholders still ignore how this process has evolved, what actions or steps have already been taken, if there is or not a draft law and what its content is.

This scenario shows once again, that transparency is the exception instead of a common practice, even more when there is a pressure resulting from an unilateral document as the Special 301 is. That report should instead insist the Colombian government to attend commercial commitments adjusting its internal regulations attending democratic and participative processes.

2019 Special 301 report is also worrying as it keeps sustaining a narrative of "incentive" and "promotion" of innovation through the strengthening of IP provisions. This vision emphasizes and encourages the protection of authors and right holders ignoring that there is an actual need for balance but also that creation is a process specially designed to increase and enrich culture and public interest in favor of the rights to culture, knowledge, freedom of expression, health, science, education among others.

VI. Final comments

Once again, the Special 301 Report should not be used "to pressure countries to adopt intellectual property protection that exceeds the level required by the TRIPS Agreement" or "to pressure countries to adopt intellectual property protection that exceeds the level of protection that is in the law of the United States." Otherwise, it is a neo colonial tool. The declaration from the Chilean government[20] regarding this 301 special report 2015 is clear when stating "that it does not reflect our reality, nor it reflects the advancements of our country", such words can be used by Colombia as well. According to the Chilean government it is a unilateral document produced by the United States, it has no clear criteria to determine the status of the different countries, but overall it "reflects the interest of the North American industry to selectively enforce their intellectual property standards to other countries".

Due to all what we have stated throughout this document, the undersigned do not recognize the legitimacy of the list exposed in the Special 301 Report and we find it against multilateral regulation

Carolina Botero Cabrera
Karisma Foundation
contacto@karisma.org.co

Angela Acosta Santamaría
Misión Salud
angela.acosta@mision-salud.org

Andrea Carolina Reyes Rojas
Misión Salud
direccciongeneral@mision-salud.org

Francisco Rossi Buenaventura
IFARMA Foundation
ifarma@ifarma.org

Claudia Marcela Vargas Peláez
IFARMA Foundation
cvargas@ifarma.org

Julio Gaitán
Centro de Internet y Sociedad
Universidad el Rosario
julio.gaitan@urosario.edu.co

[20] The Declaration can be found here http://www.direcon.gob.cl/2015/04/declaracion-oficial-con-respecto-a-la-publicacion-del-reporte-especial-301-de-eeuu-senalamos-lo-siguiente/?lang=es