Submission to the Office of the United States Trade Representative

In the matter of
2019 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974
Docket No. USTR-2018-0037

Comments of Colombian Civil Society Organizations

Bogotá, February 7th 2019

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].

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 guarantee the human right to health and the access to treatment with equity to all who need them.

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.

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

[1] Fundación Karisma. Una vez más solicitamos que Colombia sea retirada del Informe Especial 301. [Online]. 2013 [Cited: 2019 Feb 5]. Available at: http://karisma.org.co/?p=2029 And Fundación Karisma, Colombia debería ser retirada de la lista 301. [Cited: 2019 Feb 5]. 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 [Cited: 2019 Feb 5]. 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/

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*"[6], and it should be assessed as such by all trading partners of the United States[7]. In this sense, we continue to support the other comments submitted in 2014 by the PIJIP[8], which delves into that argument.

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[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 2019 Feb 5]. 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 2019 Feb 5]. 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 2019 Feb 5]. Available at: https://www.mision-salud.org/nuestras_acciones/acuerdos-comerciales/2017-otra-vez-el-301/

[6] Infojustice.org. Flynn testifies in Special 301 Hearing. [Online] 2013. [Cited 2019 Feb 5]. Available at: http://infojustice.org/archives/28620

[7] 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 2019 Feb 5) 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 2019 Feb 5)

[8] Flynn S. Submission to the U. S. Trade Representative and Notice of Intent to Testify. [Online]. 2014 Feb 7 [Cited: 2019 Feb 5]. Available at: https://www.regulations.gov/document?D=USTR-2013-0040-0021

Articles 23.1 and 23.2 (a) of the Dispute Settlement Understanding (DSU) of the WTO 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.[9]

"[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".[10] 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

[9] 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: 2019 Feb 5] Available at SSRN:http://ssrn.com/abstract=2675990

[10] 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: 2019 Feb 5]

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[11], 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. 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.

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[12] for promoting

[11] Zhou, Suzanne. Op cit. Page 11. [Cited: 2019 Feb 5]
[12] Holguín, Germán. La guerra contra los medicamentos genéricos. Un crimen silencioso. 2014. Bogotá, Aguilar. p. 34.

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[13] [14] 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 2018 Special 301 Report

In the 2018 report Colombia was placed in the priority watch list. Moreover there was a call for a specific out-of-cycle *"focused on certain provisions of the United States-Colombia Trade Promotion Agreement (CTPA) and monitoring the implementation of Colombia's National Development Plan (NDP)"*.

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

Under section "Ongoing Challenges and Concerns" the USTR affirms the following: *"Finally, the United States continues to monitor Colombia's implementation of certain provisions of the NDP that could undermine innovation and IP systems, particularly those that would condition pharmaceutical regulatory approvals on factors other than safety or efficacy. In March 2018, Colombia issued Decree 433 to partially implement NDP Article 72, although questions remain as to whether the decree would condition regulatory approvals on factors other than safety and efficacy. The United States urges Colombia to take necessary steps to clarify such provisions and implement them in such a way as to ensure that they do not undermine innovation and IP systems."*

[13] 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: 2019 Feb 5] Available at http://www.unsgaccessmeds.org/final-report

[14] Moser, Petra. Patents and Innovation in Economic History (January 28, 2016). [Cited: 2019 Feb 5] Available at SSRN: http://ssrn.com/abstract=2712428

There are several clarifications to be made in order to understand 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[15], 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*

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

innovation and access to health technologies as a multi-dimensional and global problem that affects all countries"[16].

III. Furthermore, as recently reported by the WHO on its Technical Report "Pricing of cancer medicines and its impacts",[17] "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.

IV. With regards to the expression in the 2018 Special 301 Report that says "*The United States urges Colombia to take necessary steps to clarify such provisions and implement them in such a way as to ensure that they do not undermine innovation and IP systems",* there is not evidence to consider that new medicines price controls 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[18]. 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 approvals according to these current challenging circumstances.

Although Decree 433 partially implemented article 72, as noted in 2018 Special 301 Report, it is important to clarify that the regulation that was necessary to bring the benefits of article 72 to

[16] United Nations Secretary-General's High Level Panel on Access to Medicines. Op. Cit.
[17] https://apps.who.int/iris/bitstream/handle/10665/277190/9789241515115-eng.pdf?ua=1
[18] 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: 2019 Feb 5] 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

Colombians human right to health never came into light.[19] The regulation that is pending is the same regulation that the 2018 Special 301 Report classified as a matter of concern.

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 control of new medicines before they reach the market, to favor human right to health of its population.

2. Copyright

We have in Colombia, since July 12 of 2018 a new Copyright Law Reform that was promoted in the middle of a rushed legislative process that in the end did not favour civil society. This reform was approved on May 22, just after the United States government unilaterally decided to include Colombia within its "Priority Watch List".

This attitude of closure assumed by the Colombian government that excluded civil society from public debates and active and democratic participation, can be associated to the result of the pressures exerted from the United States government through this "black list", with other strategies such as to condition the entrance support to the OECD membership of Colombia until the reforms that were still pending to be carried out within the FTA framework between both countries, including those related to copyright, were carried out.

The Colombian government finally obtained United States entrance support to the OECD[20], but the law resulting from that undue pressure ironically to be part of an exclusive club of "good practices", is having today undesired effects that affects users communities, mainly because it's text given the urgency on its approval, only took into account the copyright holders views and needs, without any balance in favour of the public interest.

As a result of the hurry, there was no profound discussion about some important issues, such as the possibility to adopt a fair use system or a fair dealing provision on copyright, both valid options to replace the closed list of exceptions and limitations currently valid on our copyright reform. This absent will still being a problem to the development of Colombia because it does

19 https://www.elespectador.com/noticias/salud/la-gran-regulacion-de-precios-de-medicamentos-que-se-cayo-ultimo-minuto-articulo-805276

20 OECD official website available here: https://www.oecd.org/newsroom/oecd-countries-agree-to-invite-colombia-as-37th-member.htm

not guarantee a legal certainty context to new ventures and new uses that digital technology allows.

The current copyright law includes a sort of modifications that affects the community of users and in general, the enrichment of culture due the time increase of the protection given to published works by legal entities, from 50 to 70 years. This increase in 20 years that was established in the commercial agreement signed with the U.S, was introduced to the national legal framework without discussion or reflexion about the real impacts that will certainly reduce the public domain works for the next decades. The Colombian government thanks to the U.S. pressures, was just simply copying automatically the same provisions contained in the DMCA.

Since the goal of the U.S was to pressure Colombia to comply with pending obligations under the FTA, the new copyright law not only copied and pasted what this trade agreement establishes on the Technological Protection Measures TPM, but also hardened much more its content including aspects that were not even agreed by both countries.

With no time to allow public and democratic debates with civil society, the prior need for ratification by the Colombian Congress of the Marrakesh Agreement was lost, so that visual impaired people could benefit with the copyright reform beyond a simply inclusion that just one article of the current law made referring to this population, that in any case fails to meet the standards proposed by the mentioned Treaty.

Although the 301 report of 2018 was issued days before the approval of the new copyright law, it should have warned the Colombian government about the haste with which the legislative process was being carried out, which was satisfying nothing more than the interests of copyright holders without seeking a more just balance in order to strengthen access to knowledge, science and culture as a human right. Of course, the omission of this type of warnings by the United States, shows that this type of rights are not a priority for the commercial partner of Colombia in its follow-up of compliance with obligations, thus generating disproportionate results.

This biased view of the U.S. that pressed Colombia for the introduction of unbalanced legislative changes, highlights the lack of interest in the comprehensive protection of human rights that both countries seem to share in common.

We acknowledge that the 2018 report was not clearly mentioning specific copyright reforms. However, Colombian civil society is concerned that despite the fact that we have called to the attention of the USTR on the imbalance in the protection of human rights under current

Colombian copyright legislation, none of those concerns are included when the USTR asks the government to amend the law.

Considering that the Special 301 Report 2018 is unilateral and provide no data or proof for its complaints provides a poor understanding of the local situation. For instance, it mentions that piracy through mobile devices "continues to grow" but it offers no data and continues saying *"Colombian law enforcement authorities with relevant jurisdiction, including the National Police and the Attorney General, have yet to conduct meaningful and sustained investigations and prosecutions against the operators of significant large pirate websites and mobile applications based in Colombia"*. Again, no data, no concrete evidence that could support this statement.

The USTR 301 Report statements on online piracy and mentions to the San Andresito's situation as "major problems" without proofs can not be the basis to pressure Colombia or prove the existence of a scourge, especially if this can have important economic consequences.

In contrast, Colombia continue to develop a local and legal digital economy with a huge public investment that does not benefit from the stigmatization and piracy label that the 301 Report represents. Colombia is one of the countries in the Latin American region that has an important legal system to protect IPR and the rights holders interests. Once again we reiterate that Colombia should not be part of this menacing black list, unless that this index is one which emphasizes the shortcomings in the protection of the rights of users and the lack of support for more open approaches to the rights author law that balance it with other fundamental rights such as freedom of expression and access to knowledge (education, culture and science). Definitely a place where little has been done. If the USTR decides to make such an index will show that a focused market copyright, which gives priority only to holders in the equation, produces significant threats to human rights.

Therefore, the 2018 report should account for the impassivity of the Colombian government to fulfill the country's commitments to balance the copyright system to facilitate the exercise of the rights of visually impaired people and all those who have a disability that not allow them to read along.

Precisely, copyright has a number of mechanisms to balance the protection of authors and rights holders people with guarantees for the exercise of fundamental rights. The USTR should expressly recognize that such guarantees are commercially important because they are essential to the system of copyright, and that the fear of piracy doesn't justify any measure of enforcement of IPRs.

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[21] 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

Germán Holguín Zamorano
Misión Salud
direccion@mision-salud.org

Andrea Carolina Reyes Rojas
Misión Salud
subdireccion@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

[21] 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