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

Bogotá, February 9th 2017

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, Karisma has submitted observations on his own behalf and on 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], and since 2014 we do it with other organizations of Colombian civil society every year.

IFARMA is a Colombian non--- profit organization, established in accordance with the law, within the Constitution and with a social objective. IFARMA fulfills its purpose through specialized research and political advocacy on issues related to policies' formulation and implementation; management, access, use and quality of medicines; and issues related to intellectual property and access to medicines with national and international reach.

Misión Salud is a Colombian nonprofit civil society organization whose goal since its inception in 1998, is to promote and defend the right of Colombians to health and access to medicines. Misión Salud advocates in national and international arenas to promote that government institutions prioritize public health over commercial interests in the formulation and implementation of policies, trade agreements and regulations related to intellectual property and pharmaceuticals. In this sense, we presented our comments on the 2014, 2015[2] and 2016[3]

[1] Fundación Karisma. Una vez más solicitamos que Colombia sea retirada del Informe Especial 301. [Online]. 2013 [Cited: 2017 Feb 9]. Available at: http://karisma.org.co/?p=2029 And Fundación Karisma, Colombia debería ser retirada de la lista 301. [Cited: 2017 Feb 9]. Available at: http://karisma.org.co/?p=611

[2] Misión Salud. Organizaciones de la Sociedad Civil Colombiana cuestionan la legitimidad del Informe Especial 301. [Online]. 2014 y 2015. [Cited: 2017 Feb 8]. Available at: http://www.mision-salud.org/2014/02/21/la-propuesta-del-ustr-para-el-capitulo-de-propiedad-

Special 301 Reports 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 2017 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 last year, 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*", and it should be assessed as such by all trading partners of the United States[4]. In this sense, we continue to support the other comments submitted in 2014 by the PIJIP[5], which delves into that argument.

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:*

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intelectual-del-acuerdo-de-asociacion-transpacifico-tpp-arriesga-el-acceso-a-los-medicamentos-para-todos/

[3] Misión Salud. Proceso "Special 301" en 2016. [Online]. 2016. [Cited 2017 Feb 8]. Available at: http://www.mision-salud.org/2016/02/08/proceso-special-301-en-2016-concluida-primera-fase-de-este-tradicional-instrumento-de-presion/

[4] Similar approaches had already been addressed by countries like Chile: EFE. Chile es incluido en "Lista Negra" de Piratería, pero Gobierno desconoce legitimidad. [Online]. Nación.cl. 2013 May 1 [Cited: 2017 Feb 9]. Available at: http://www.lanacion.cl/chile-es-incluido-en-lista-negra-de-pirateria-pero-gobierno-desconoce-legitimidad/noticias/2013-05-01/160857.html

[5] Flynn S. Submission to the U. S. Trade Representative and Notice of Intent to Testify. [Online]. 2014 Feb 7 [Cited: 2017 Feb 9]. Available at the cache link: http://webcache.googleusercontent.com/search?q=cache:dTxrdD4IwTMJ:infojustice.org/wp-content/uploads/2014/02/Flynn-2014-Special-301-Submission.doc+&cd=1&hl=es&ct=clnk&gl=co

(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.[6]

"[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 delegitimizes those choices".[7] 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[8], 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

[6] 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: 2017 Feb 9] Available at SSRN:http://ssrn.com/abstract=2675990

[7] 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: 2017 Feb 9]

[8] Zhou, Suzanne. Op cit. Page 11. [Cited: 2016 Feb 5]

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 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,[9] [10] trading partners of the United States should make considerable efforts towards finding other models that effectively encourage the development of

[9] 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: 2017 Feb 9] Available at http://www.unsgaccessmeds.org/final-report

[10] Moser, Petra. Patents and Innovation in Economic History (January 28, 2016). [Cited: 2017 Feb 9] Available at SSRN: http://ssrn.com/abstract=2712428

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 2016 Special 301 Report

In the 2016 report Colombia remains in the watch list. Moreover there was a call for specific out-of-cycle reports that will assess *"Colombia's commitments to the IP provisions of the United States- Colombia Trade Promotion Agreement and to monitor the implementation of Colombia's National Development Plan"*. The 301 Special Report in 2016 still recognizes efforts from the Colombian Government to implement the Free Trade Agreement and the provisions thereof, but the country remains in the watch list.

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. Intellectual Property and Health

As a starting point, 2016 Special 301 Report states "IPR protection plays an important role in providing the incentives necessary for the development and marketing of new medicines. An effective, transparent, and predictable IPR system is necessary for both manufacturers of innovative medicines and manufacturers of generic medicines." Nonetheless "discussions at WHO on how to address failures of the current monopoly-based R&D system have been ongoing for over a decade"[11] and, with the aim of proposing solutions for addressing the incoherencies between international human rights, trade, intellectual property rights and public health objectives, the The UN Secretary-General established back in 2015 the High-Level Panel on Access to Medicines, which released its report on September 2016.

An updated view from all stakeholders, including the United States, of the current global health challenges and how they are enhanced by IPR model, is needed in order to address the "significant gaps in health technology innovation and access that persist"[12], not only in low and middle income countries but all around the world. We highly encourage the USTR to incorporate in its framework the recommendations contained in the United Nations Secretary-General's High Level Panel on Access to Medicines Report in order to "stimulate public debate over ways

[11] Barber, M, Gotham, D, Montaña J, Balasubramaniam, T, et al. Open letter to the candidates for Director-General of WHO: will you support a patient-centred R&D agreement?. The Lancet Global Health. 9th December 2016. [Cited: 2017 Feb 9] Available at: http://www.thelancet.com/journals/langlo/article/PIIS2214-109X(16)30353-9/fulltext

[12] United Nations Secretary-General's High Level Panel on Access to Medicines. Op cit.

of reforming the research-and-development system to better serve the global public interest"[13] In this context we also urge the USTR to refrain from impeding the negotiation for a binding R&D Global Convention that identifies a system of incentives for innovation that delink the expectation of patents and high drug prices.

We continue presenting our considerations with regards to specific aspects that refer to Colombia and access to medicines.

A. Granting of compulsory licenses

Whereas the 2016 Special 301 Report states that "the United States respects its trading partners' rights to grant compulsory licenses in a manner consistent with the provisions of the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and the Public Health", along the process to declare the access to imatinib under competition conditions of public interest U.S. officials may have discouraged Colombian government officials from issuing the compulsory license.[14]These interventions have harmed this local process, by trying to block the public interest declaration and issuance of the compulsory license, and clearly oppose to the duty of the Government of United States to respect Colombia's right to grant compulsory licenses.

Considering this situation, what is evident as a censurable conduct of Colombian Government is the fact of not exercising its right, conferred by international law (TRIPS and Doha Declaration), of using as much as possible public health safeguards, among which compulsory licenses stand out for its efficacy.

It is unjustifiable that while Colombian Government grants pharmaceutical patents continuously, abided by TRIPS, since 1994 it has not granted not even one compulsory license, which is the mechanism provided by the same agreement to encourage competition under national emergency or public interest circumstances.

How valuable would be for the undersigned organizations and for civil society in general to find that the USTR encourages Colombian Government to exercise its right-obligation of granting compulsory licenses to favor human right to health, which is above trade interests.

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[13] Moon, S. Powerful Ideas for Global Access to Medicines. The New England Journal of Medicine. January 18th 2017. [Cited: 2017 Feb 9] Available at: http://www.nejm.org/doi/full/10.1056/NEJMp1613861

[14] Letter addressed to the Honorable Michael Froman by 17 members of the House of Representatives. May 25th 2016. [Cited: 2017 Feb 9] Available at: https://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/VS/MET/Pronunciamiento-congreso-estados-unidos.pdf

B. Local Production of Medicines

The 2016 Special 301 Report states “Proposals in Colombia and Ecuador designed to enhance domestic manufacturing capacity for pharmaceuticals could adversely affect market entry and investment and, in effect, limit access by consumers to the latest generation of medicines." The purpose of strengthening local production of medicines’ capacity is a legitimate national development objective in any country (for example United States or Colombia), from an economic perspective but specially because building local pharmaceutical production capacity is part of the strategies to increase access to affordable medicines[15], due to the effect that competition has on lowering medicines’ prices in the market.

By no means it is understandable that enhancing domestic manufacturing capacity for pharmaceuticals be considered a censurable matter while, from a human rights’ perspective, it should be received by Colombia’s trading partners as an achievement towards increasing the fulfillment of right to health of its citizens.

Furthermore, the importance of increasing competition was highlighted by members of US Congress at the hearing "Developments in the prescription drug market: oversight”, convened by the House Oversight and Government Reform Committee for February 4th, 2016[16]

C. Establishing a role for the health ministry in the examination of pharmaceutical patent applications

The 2016 Special 301 Report states “However, other National Development Plan (NDP) provisions, depending on how they are interpreted and implemented, may undermine innovation and IP systems (e.g. establishing a role for the health ministry in the examination of pharmaceutical patent applications)”. As civil society organizations, we urge the Government of Colombia to promote the participation of health experts in reviewing of patent applications, which is consistent with the trade agreements that include intellectual property, improve patent quality and prevents "evergreening", therefore promoting public health and general welfare. The right to form a preliminary patent review mechanism comes from various provisions of the TRIPS, among which stand:

[15] United Nations Conference on Trade and Development. Program on local pharmaceutical production and access to medicines. 2006. [Cited: 2017 Feb 9] Available at: http://unctad.org/en/Pages/DIAE/Intellectual%20Property/Building-local-pharmaceutical-production--supply-capacity.aspx

[16] The official website of the hearing is https://oversight.house.gov/hearing/developments-in-the-prescription-drug-market-oversight/

- "Members will be able to determine freely the appropriate method of implementing the provisions of this Agreement within their own legal system and practice" (TRIPS Art. 1), which implements the principle of national sovereignty.
- “Members, in formulating or amending their laws and regulations, may adopt measures necessary to protect public health and nutrition of the population, or to promote the public interest in sectors of vital importance to their socio-economic and technological development"
- “It may be necessary to implement appropriate measures, provided that they are compatible with the provisions of this Agreement, to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."
- "The prerogative to choose appropriate performance requirements for patentability --- novelty, inventive step and industrial applicability --- implicit in TRIPS (Article 27.1.)"
- "Members may exclude from patentability inventions whose commercial exploitation within their territory must be prevented to protect public order or morality, including to protect the health or life of people or animals ... " (TRIPS art.27).

Based on the grounds listed above, the 2017 Special 301 Report should encourage Colombia to speed the implementation of a role for the health ministry in the examination of pharmaceutical patent application in order to generate the desirable outcomes in terms of patents quality and promotion of public health.

2. Copyright

We acknowledge that the 2016 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 2016 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.

During 2016 the government accepted the need to discuss the possible copyright reforms with others but still the actions of the Colombian government is focused primarily on providing training in copyright. Such training, though all taxpayers' persons fund it, has focused primarily on the needs of the industry and has left relegated the importance of culture as a value and the need for a balanced legal framework where the opening and rights of users people have an important place. The courses offered by the National Copyright Office (such as copyright in the music industry, copyright in the publishing industry, copyright in the software industry, copyright in the audiovisual industry and even the course copyright for children) demonstrate precisely this approach in which guarantees for the exercise of fundamental rights have no role or are not even mentioned. Something similar happens with the social networks where only copyright holder's interests are mentioned.

Therefore, the 2016 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. Since 2013, Colombia signed the Treaty of Marrakesh proposed by the OMPI, but another year went through and the Treaty has not been submitted for ratification by the Congress. USTR position to choose to account only what it considers are violations of the state with the holders of the copyrights forget that the Colombian state also has a *"positive obligation to establish a robust and flexible system of exceptions and limitations to the copyright to fulfill its obligations on human rights."*[17] Precisely, copyright has a number of mechanisms to balance the

[17] Report of the Special Rapporteur on Cultural Rights, Farida Shaheed. A/HRC/28/57. UN (2014). That can be read at

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[18] 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".

The reform of copyright to be carried out in Colombia needs to address not only the interests of right holders but also the needs of Colombian society to develop a balanced cultural ecosystem. This should be an important focus of the US government as a whole.

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

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http://www.ohchr.org/EN/HRBodies/HRC/RegularSessions/Session28/Documents/A_HRC_28_57_SPA.doc

[18] 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