



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

Bogotá, February 5th 2016

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 2013¹, and since 2014 we do it with other organizations of Colombian civil society.

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 and 2015² 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

¹ Fundación Karisma. Una vez más solicitamos que Colombia sea retirada del Informe Especial 301. [Online]. 2013 [Cited: 2016 Feb 5]. Available at: <http://karisma.org.co/?p=2029>. And Fundación Karisma, Colombia debería ser retirada de la lista 301. [Cited: 2016 Feb 5]. 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: 2016 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/>

many of the considerations presented in the past in the light of the 2015 Special 301 Report.

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 mentioned in the comments submitted by the PIJIP in 2013 regarding the process of the Special 301 process, we also believe 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 States³. In this sense, we support the other comments submitted in 2014 by the PIJIP⁴, 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:

(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

³ 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: 2016 Feb 5]. Available at:

<http://www.lanacion.cl/noticias/economia/comercio/chile-es-incluido-en-lista-negra-de-pirateria-pero-gobierno-desconoce-legitimidad/2013-05-01/160857.html>

⁴ Flynn S. Submission to the U. S. Trade Representative and Notice of Intent to Testify. [Online]. 2014 Feb 7 [Cited: 2016 Feb 5]. Available at:

<http://www.regulations.gov/#!documentDetail;D=USTR-2013-0040-0021>

determination of "violations", but also prevents the implementation of other forums or unilateral mechanisms for the resolution of disputes concerning WTO.⁵

"[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 delegitimises those choices".⁶ 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 countries⁷, blocking the exercise of rights under international law (TRIPS Agreement and Doha Declaration, for example) in favor of countries. 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."

⁵ 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: 2016 Feb 5] Available at SSRN:<http://ssrn.com/abstract=2675990>

⁶ 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: 2016 Feb 5]

⁷Zhou, Suzanne. Op cit. Page 11. [Cited: 2016 Feb 5]

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,^{8 9} 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 the world, before acting in response to this unilateral program and its 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. Access to medicines

A. Local Production of Medicines

The 2015 Special 301 Report states "In Colombia and Ecuador, proposals 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

⁸ Moser, Petra. Patents and Innovation in Economic History (January 28, 2016). Available at SSRN: <http://ssrn.com/abstract=2712428>

⁹ <http://www.statnews.com/pharmalot/2016/01/11/nih-drug-costs-patents/>

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 as well as for the effect that competition has on lowering prices in the market, with its consequent access to medicines' increase. This was acknowledged by members of US Congress at the hearing "Developments in the prescription drug market: insight", convened by the House Oversight and Government Reform Committee for February 4th, 2016, who highlighted the importance of increasing competition.¹⁰

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, not the fact that it is adopting measures to strengthen local production of medicines.

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 of granting compulsory licenses to favor human right to health, which is above trade interests.

B. Patent Term Adjustment for unreasonable patent office delays

The 2015 Special 301 Report says that "in 2014, the Government of Colombia made progress on implementing the United States-Colombia Trade Promotion Agreement (CTPA), including by establishing patent term adjustment for unreasonable patent office delays". Through the Amending Protocol (art. 16.9.6.a) of the US-CTPA this provision was eliminated from the Agreement, so Colombia is not obliged to grant this adjustment in the term of the patent. It is alarming to know that Colombian Government has decided to sacrifice public good to provide to few individuals intellectual property privileges that are beyond the country's commitments. Such decision, far from deserving recognitions, should be object of protests as it delays even more the entrance into the market of affordable life-saving medicines, constituting a violation of the fundamental right to health.

¹⁰ <http://www.c-span.org/video/?404183-1/hearing-prescription-drug-market>

C. Review Patent Mechanism

The 2015 Special 301 Report states "Colombia also reduced patent application backlogs and continued to train judges and law enforcement officials on IPR." This recognition supports the concerns of civil society with respect to the decisions made by the Patent Office of Colombia which tend to give priority to the interests of holders of rights rather than the public interest.

As civil society organizations, we urge the Government 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" 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:

- "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).

2. Copyright

Colombia remains on the watch list in 2015, although the report mentions the efforts made by the Government to implement the Free Trade Agreement and the provisions thereof, the country has remained here as we reiterate reviews in other years.¹¹ However, this consideration of the USTR about the FTA does not pose in the acknowledgment that makes the concerns of civil society by the imbalance in the protection of human rights under the right of Colombian author.

The Special 301 Report 2015 again reiterated the problem of San Andresitos stating that *“despite dedicating more resources toward enforcement in 2014, the government has also not been able to reduce significantly the large number of pirate and counterfeit hard goods being sold at Bogota’s San Andresitos markets, on the street, and at other distribution hubs around the country.”* for this report, the USTR provides only one example – that it's not enough - of piracy of physical goods.

Furthermore, in relation to online piracy, the report points out that it needs to be greater compliance with agreements on copyright protection contained in the FTA, particularly when it has to do with the challenges of the digital era. The document notes that *“Online piracy, particularly via mobile devices, has grown significantly in Colombia in the last few years; Columbia is currently the third biggest smartphone market in Latin America, with over one-third of Colombians owning one, and more than two-thirds of Colombians having access to the Internet. Colombian law enforcement authorities with relevant jurisdiction, including the National Police and the specialized national-level IPR unit in the Attorney General’s Office, have yet to engage in meaningful and sustained investigations and prosecutions against the operators of significant large pirate websites and mobile applications based in Colombia”*

In that context, the 2015 report calls on the national authorities *“to engage in meaningful and sustained investigations and prosecutions against the operators of significant large pirate websites and mobile applications based in Colombia”*. Any concrete evidence support this statement. The single USTR statement on online piracy as a major problem in the country can not be the basis to pressure Colombia or prove the existence of a scourge without any evidence, in particular whether this can have significant economic consequences. In contrast, Colombia has developed a local digital

¹¹ En el informe de 2014, los EE.UU. declaró que *“el progreso realizado sobre la legislación de propiedad intelectual se perdió en 2013, cuando la Corte Constitucional de Colombia invalidó, por razones de procedimiento, la Ley que reconocía compromisos relacionados con los DPI derivados del Tratado de Libre Comercio entre Estados Unidos y Colombia (TLC). Colombia aún no ha establece las disposiciones contenidas en la ley invalidada”*. Por lo tanto, la falta de implementación del TLC es otra vez una razón para mantener a Colombia en la lista de 2014, tal y como se describió en anteriores informes. De esta forma una vez más esta declaración se convierte en una indebida presión externa a la discusión legislativa interna del país.

agenda, which has become a regional reference and a millionaire budget is invested in content creation and local "apps", which focuses on the development of a proper and legal digital economy. The country cannot continue to be stigmatized with a label of piracy that does not match the investments that are being developed.

We insist once again that Colombia has made the task of protecting IPRs and the interests of rights holders. We reiterate that the country should not be part of the system 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.

For example, the action of the Colombian state has 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.

Therefore, the 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 it has been almost three years and the Treaty has not been submitted yet 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."¹² 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

¹² *Informe de la Relatora Especial sobre los derechos culturales, Farida Shaheed. Políticas sobre los derechos de autor y el derecho a la ciencia y la cultura. A/HRC/28/57. Consejo de Derechos Humanos, ONU (2014). Disponible en http://www.ohchr.org/EN/HRBodies/HRC/RegularSessions/Session28/Documents/A_HRC_28_57_SPA.doc*

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 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

Due to all 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

Francisco Rossi Buenaventura
IFARMA Foundation
ifarma@ifarma.org

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