

**Submission to the Office of the United States Trade Representative**

In the matter of  
2021 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974.  
USTR-2020-0041

Comments of Colombian Civil Society Organizations

Bogotá, February 4th 2021

## **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 comment 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 statement 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.

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 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, 2015, 2016, 2017, 2019 and 2020 Special 301 Reports along with other organizations of Colombian civil society.

## **II. Colombia and the 2020 Special 301 Report**

In the last Special 301 Report, Colombia was placed on the Watch List. The Report identifies Colombia as a trading partner that do not adequately or effectively protect and enforce intellectual property (IP) rights, or otherwise deny market access to U.S. innovators and creators that rely on protection of their IP rights.

The undersigned do not recognize the legitimacy of the Special 301 report. 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.

### III. Flexibility Due To Health Emergency

The following statement becomes an urgent claim for the US government during this pandemic situation:

**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”. Due to all what we have stated for more than five years, the undersigned do not recognize the legitimacy of the list exposed in the Special 301 Report and we find it against multilateral regulation.**

Below we present substantive comments regarding the last Special 301 Report, published in April 2020. The undersigned agree to recognize President Biden's current administration as an opportunity to promote equitable and inclusive policies that achieve fair trade and affordable health interventions for Latin-American countries.

In the Special Report in 2020, the United States continues to engage Colombia on patent-related matters and encourages it to incentivize innovation through strong IP systems. In that sense, USTR should not enter into, maintain or enforce any agreements on damages for infringement that exceed the standards set out in the TRIPS agreement.

In the framework of the health emergency, we request flexibility in terms of the application of Intellectual property measures. For Example, the governments of India and South Africa, co-sponsored by Kenya and Eswatini, signed a letter to the WTO. This document made a proposal that calls for the suspension of implementation, application and compliance with certain obligations of the TRIPS Agreement for the treatment, prevention and vaccines for COVID-19.

This request is made considering Articles IX 3 and 4 of the Marrakesh Agreement by which, in exceptional circumstances (which in this case would be the Sanitary emergency of COVID-19), the WTO may grant an exemption from certain obligations under treaties such as TRIPS<sup>1</sup>. This proposal was debated in the TRIPS Council of the WTO held on 15 and 16 October. The request was supported by more than 400 civil society groups around the world, other actors included governments of developing countries.

The petition did not have the support of several of the highest-income countries, including those with strong pharmaceutical industries such as the United States and the European Union. Other countries that rejected the deal were Switzerland, Norway, Australia, Canada, Japan, the United Kingdom and Brazil, which is concerning as most of the development of vaccines and drugs is taking

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<sup>1</sup> Médicos Sin Fronteras. India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies Briefing Document 8 - October 2020.

place in high-resource countries. These corporations will be responsible for the production and distribution of COVID-19 vaccines, so it is detrimental not to have their support.

#### **IV. The New Government.**

Taking advantage of the new administration of the Biden government. Since the Special 301 list was first published in 1989, the world has changed, so the USTR should consider new policies, regulations that could be necessary to advance equity in agency actions and programs.

- **Promotes access to pharmaceuticals, medical technologies:**

Patents seek to stimulate innovation in the research field, but in practice, laboratories have focused on the accumulation of capital, causing pioneers to have a high cost that makes it difficult for populations to access and provide health services by insurers. It is considered that it is time to introduce structural modifications to the TRIPS system both on the global and national stages, starting with the exclusion of patent protection for essential medicines.

It is necessary to explore scenarios other than the model based on "business diseases" and a disproportionate pricing that is far from the real costs of research and development. It requires abandoning the patent monopoly system and affordable and fair pricing for essential medicines. We must focus on generating medicines that actually cure diseases and not only mild palliative or mere harmless medicines that keep the patient in disease or do not cure the disease in order to increase the benefits of pharmaceutical patent holders.

Health is not a business; it is a human right. The ownership of the innovation must be open to society as they are global public goods, but the particular benefits of the same must fall on the creator, researcher or scientist and not necessarily on the one who finances, regardless of whether it is public or private or mixed financing.

- **Seek a balance between public interest and intellectual property rights:**

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, blocking the exercise of rights under international law 12 (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.

- **Consider abolishing the watch list**

Some actors consider this to be a unilateral measure by the United States to exert pressure, while others consider it to be a measure to monitor that IPRs are rigorously enforced<sup>2</sup>. Several governments are making efforts to place their countries within the global collaboration led by

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<sup>2</sup> Holguín G. La guerra contra los medicamentos genéricos. Un crimen silencioso. Aguilar; 2014. 53–54 p

the World Health Organization WHO to accelerate development, production and equitable access to diagnostic tests, treatments and vaccines against COVID-19, under criteria of protection and defense of health and life of People, of favoring the national interest, and speed in the reestablishment of full social activity and economic. There is a call not for the review of TRIPS compliance in the countries, but for solidarity. The existence of the 301 list in the context that is being lived is not reasonable.

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.

- **Respect for local regulations on intellectual property**

Special Report 301 imposes mandates aimed at modifying the internal laws of other sovereign countries. In that sense, the United States government should not monitor or modify the laws that regulate intellectual property rights in other states. Consequently, not only does the US government not have the right to qualify the regulation of other states on intellectual property, but also, the standards applied by the USTR are against international instruments on human rights, such as the International Covenant on Economic, Social and Cultural Rights, of which Colombia is a party. Remembering the article 4 of the Montevideo Convention, States are juridically equal, and, for that reason, have autonomy to legislate over their own matters.

- **The right to enjoy the benefits of scientific progress and its applications**

As stated, the global crisis generated by the COVID 19 virus has increased the need of digital tools in every aspect of daily life. This is important because, not only the high burden of Intellectual Property regulation required by the USTR will affect citizen's human right to health, but also, because the strong restrictions proposed in the Special 301 Report have the potential to deter children and adults' access to education, work and culture, which are only available online due to the mandatory quarantine mechanisms of prevention.

There is no doubt that the world will not be the same again, and that the rapid growth of online services and goods we are experiencing in this pandemic will determine our future relationships with the education, labor and health systems. Considering that the online environment will expand in enormous proportions, it is clear that intellectual property rights cannot be an obstacle to the development of online citizenship that will be mandatory for all the people in the world.

In April of the last year, the Committee on Economic, Social and Cultural Rights of the UN published the General Comment No. 25, which underlines the importance of the right to enjoy

the benefits of scientific progress and its applications. According to the document, this right has a cultural dimension that obligates States to: “adopt the measures necessary to eliminate conditions and combat attitudes that perpetuate inequality and discrimination in order to enable all individuals and groups to enjoy this right without discrimination”.

- In that sense, according to the stated in this document, the Special 301 Report fails to comply with the human right’s standard adopted by the international community in regard with the technological advance. If the Colombian State were to adopt the measures suggested by the Report, it will violate the content of the article 15 of the International Covenant on Economic, Social and Cultural Rights, because of the discrimination that such measures impose between high income and low income nationals. High burdens on intellectual property regulation have proven to increase in unfair proportions the access of citizens to technology. In countries such as Colombia, and in the chaotic context we are facing, it is not possible to comply with the requirements of the Report, Colombians need with urgency their right to enjoy the benefits of scientific progress.

## **V. Copyright.**

The Special 301 report maintains, as is customary, its hardening narrative with a punitive and restrictive approach, with which it pressures the Colombian State to adjust its legislation and public policy on intellectual property. Since 2018 and until now, Colombia has remained on the watch list because, according to the 2020 report, the country has barely made modest adjustments to its legislation that meet the demands of its trading partner.

We call attention again, due to the undue pressure that constitutes the Special 301 report that leads Colombia to reform its intellectual property legislation to the detriment of democratic guarantees of citizen participation, as well as possible balanced approaches favorable to other rights such as access to knowledge, culture, health and access to medicines, among others.

As indicated in the 2020 report, Colombia and the United States have started a bilateral discussion process for the design of a bill on intermediary liability that includes notice-and-takedown and safe harbor mechanisms for Internet Service Providers. If this is the case, we are concerned that to date none of these discussions have been public, the public has not been invited to participate. The current status and content of this drafted bill is unknown. We hope that this situation does not materialize in an expedited and abbreviated legislative process.

In the 2020 report, the United States once again “incentivized” Colombia to tighten its legislation on patents and intellectual property. The pandemic afflicting humanity right now shows precisely the opposite. We cannot continue to close the intellectual property system, flexibilities are needed worldwide in patents but also in the copyright system.

Quarantines and social isolation are the best strategy we have to prevent Covid-19. At the same time, these are strategies that impact human communication, affecting the functioning of activities related to education and work, especially in countries with a significant digital divide as Colombia.

Even though covid-19 has boosted significant digital acceleration our countries were not prepared for a crisis like this and neither were the intellectual property systems. In the United States, fair use made it possible to react and facilitate that some activities were transferred to virtuality, while in countries like Colombia, exceptions to copyright which are scarce for digital spaces has proved to be insufficient.

The access to knowledge must also be protected in cases of health emergencies or events that result in the affectation of vulnerable populations. Access to knowledge and various tools of culture and entertainment is also an issue of great importance to contribute to the mental health care of society.

While in this report the United States pressures Colombia to impose an even more restrictive regulation than the current one on copyright, different civil society organizations that advocate for a balanced approach to copyright have put in mind the need to have a regulation with a broad view on exceptions. This view is capable of allowing without obstacle or limitation, formal and non-formal education activities through the Internet, as well as visits to museums, libraries, bookstores, film exhibition events and others carried out in houses of culture that take place now on the internet.

The European network “Communia”, which promotes policies that expand the public domain and increase access and reuse of content that enrich culture and knowledge, raised the following limits that must be considered in a pandemic situation such as the current one and that serve as guide for the Colombian discussion on the subject.

Firstly, copyright flexibilities should support education, research, and other activities of public interest that, in times of emergency, take place remotely.

Secondly, Congress must find a balance between copyright and the fundamental rights of users. In emergencies, this balance should favor the rights to freedom of information, science and education over the rights of the author or owner, which prevent the use of their work.

Thirdly, the exercise of fundamental rights must be guaranteed to allow modifications or derogations of exclusive rights of copyright holders in order to protect activities that educational institutions, research organizations and cultural heritage institutions normally do in physical spaces and that, in crisis like this one the world is living, are seen forced to close.

If this balance between the rights of users and authors or owners were taken into account by Colombia without external pressures such as those posed by the Special 301 Report, the exceptions could be extended so that they benefit teachers, libraries, archives, museums and other cultural institutions that decide to make their resources available to the public online, without having to face

the uncertainty of legal actions that could criminalize their dissemination, lending and access to content by their users.

The reality is that many of these practices are carried out daily by institutions, organizations and individuals from the educational, research and cultural communities. However, for the most part, they are made with the constant uncertainty of having to face possible copyright infringements.

For example, those who make use of different platforms including social networks to support the dissemination of this type of content, in many cases are blocked, censored or see their content removed for possible copyright violation. Pressuring Colombia to increase restrictions on intellectual property and copyright online and offline, ignores the reality and needs of Colombians while marginalizing the wealth of activities that disseminate and promote culture and knowledge. This is especially true in times of pandemic like today.

Likewise, the USTR should think about the effects of notice-and-take down systems, which are easily instrumentalized in maximalist visions of protection. For example, during the quarantines we have seen that the broadcasts of cinema clubs that took place on YouTube or Facebook, among other social networks were frequently suspended, even in meetings that were organized around material on public domain, unlicensed or with the consent and authorization of copyright holders.

The Special 301 Report discourages Colombia from taking a step closer to open and favorable approaches to exceptions of this type that not only consider the public interest but are also in line with international regulations. This disincentive is justified in relation to pending obligations of the CTPA signed between both Colombia and the United States, ignoring the need and convenience of having a balanced copyright system.

The United States through its USTR must cease its effort to pressure Colombia in the sense that it provides its own legislation on intellectual property. The pandemic has brought to the fore the urgency for Colombia to adopt an autonomous and contextual view of its own norms as they impact people in the exercise of the most vital rights.

The Special 301 also, in its most recent version, reproaches Colombia for its high levels of digital piracy that persist year after year, as well as draws attention to the absence of efforts to reduce the retransmission of paid Internet television services to large groups of people without subscription. It also adds that it is necessary to expand the jurisdiction of the police authorities to prosecute online piracy, the trade of illegal goods, among others.

However, these assertions are made without having data or evidence that provides support based on the evidence, and they do pressure Colombia to direct its efforts towards tasks whose normative, economic and rights impact has not yet been estimated. Debates on the scope of the powers of the police authorities correspond to the citizenry, not to the States that attend to pending commercial



obligations and that pressure so that the Internet -among others- becomes a terrain for police surveillance.

## 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. We insist on the declaration from the Chilean government<sup>3</sup> regarding the Special 301 report from 2015, 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 the 301 special report 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

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<sup>3</sup> 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>