Submission to the U.S. Trade Representative

2014 Special 301 Review: Comments of Colombian Non Governmental Organizations

Docket number USTR-2013-0040

Bogotá, March 6th 2014
As Colombian NGO group seeking to enforce major public interests protection within Intellectual Property discourse, we believe that it is important to participate in this process and to evidence the many loopholes in the Special 301 review.

Karisma Foundation is a Colombian civil society organization that, during the last 3 years, has been involved in the public discussions on the Copyright reform driven by the FTA signed with the U.S. Additionally, Karisma have presented comments on its own name, on joint declarations with other world NGOs and through the American University’s PIJIP group (Program on Information Justice and Intellectual Property) during the Special 301 processes in 2011 and in 2013.¹

Ifarma is a Colombian civil society nonprofit organization, established according to colombian law within the Political Constitution framework and with a social objective. Ifarma meets its aim through a specialized research and political advocacy on issues related to policies' formulation and implementation; management, access, use and quality of medicines; and intellectual property with national and international reach.

Misión Salud is a Colombian civil society nonprofit organization whose objective, since its creation in 1998, is the promotion and advocacy of Colombians’ right to health and access to medicines. Misión Salud advocates in national and international settings seeking to promote that Governmental institutions prioritize public health before trade interests when formulating and implementing policies, trade agreements and regulations regarding intellectual property and pharmaceuticals.

As was mentioned by the PIJIP submission letter in 2013, 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 by all the U.S. trade partners as such.² We all endorse this year's comments by PIJIP that goes further into this argument.³

In addition to these specific concerns, the undersigned agree with other major general concerns raised by PIJIP in 2013 in relation to the 301 process and report:

• “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;”
• “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.”

It is evident that the Special 301 Program and list are unilateral instruments that should cease to exist. It “may ‘disrupt the very stability and equilibrium which multilateral dispute resolution was meant to foster’”, its use to threaten “trade sanctions for TRIPS and FTA compliant policies violates the WTO Accords” and it continues to be used as an illegitimate mechanism that pressures countries through a denouncing list.

Additionally, the WTO Dispute Settlement Understanding (DSU) article 23, when demanding to apply to the multilateral system of the WTO to solve differences, not only excludes the unilateral action but also impedes from applying to other forums for dispute settlement related to the WTO.

Colombia has been taking measures (and should take many more) that seek to enforce citizen fundamental rights, which are above individuals or countries' trade interests and can not be considered to harm an "adequate and effective intellectual property protection". Furthermore, high income countries are called to protect citizen fundamental rights’ enforcement in order to comply with the obligation of international cooperation in favor of humanity well-being, therefore they should not harm developing countries with trade provisions.

The above subscribers do not recognize the legitimacy of the 301 list, moreover, as it is explained below, we believe that Colombia is infringing no regulation or agreement that will justify a claim by US.

1. Intellectual Property and access to medicines

Within the “2014 Special 301 Review: Identification of countries under section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing” process we had access to the document submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA). The undersigned disagree with that position since it mistakenly presents

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4 Ibíd.
5 Ibíd.
7 Available from: http://keionline.org/ustr/special301
Colombia as a country that fails to complete its commitments, and as a country that doesn’t acknowledge international accords nor regulations.

A. Patent review mechanism

According to WTO there is no inconvenient if two organisms are involved on patents review\(^8\),\(^9\) and by no means it represents a TRIPS violation.\(^10\),\(^11\). Preliminary patent review mechanism does not violate the U.S. - Colombia Free Trade Agreement and Andean Law, since these instruments don’t prohibit such mechanism.

In addition, health experts participation in patent review is consistent with trade agreements that include intellectual property and it improves patents quality and avoids “evergreening”, both effects favoring public health and general well-being.

Finally, the right to establish a preliminary patent review mechanism comes from several TRIPS provisions, among which are:

- “Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice (TRIPS art. 1)’ which develops the national sovereignty principle”.\(^12\)
- “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development”\(^13\)
- “Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed 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.”\(^14\)
- “The prerogative to choose the most appropriate interpretation of patentability requirements - to be new, to involve an inventive step and to be capable of industrial application -, implied in TRIPS (art. 27.1)”\(^15\)
- “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health…” (TRIPS art. 27)”\(^16\)

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\(^8\) WT/DS114/R, 17\(^{th}\) March 2000.
\(^9\) WT/MIN(01)/DEC/W/2, 2001.
\(^10\) WT/TPR/M/212/Add.1, 30\(^{th}\) June 2009.
\(^12\) Holguín G. La guerra contra los genéricos - Un crimen silencioso [Book under printing process]. Bogotá. p. 193.
\(^14\) Ibid.
\(^16\) Ibid.
B. **Patent enforcement**

Colombia is complying with patent enforcement WTO regulations. In addition, with regards to the mechanism *linkage*, it is not present in WTO regulations, WHO has advised developing countries against its implementation, in most European countries it is not required and the U.S. - Colombia Free Trade Agreement states it, not as mandatory but as optional.\(^\text{17}\)

C. **Patentable subject matter**

Under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Colombia is not obliged to grant patents for second uses. TRIPS Article 27.1 refers specifically to product or processes not to uses.\(^\text{18}\)

In addition, during the U.S. - Colombia Free Trade Agreement negotiation, the USTR retracted the proposal on patents for second uses due to the fact that Colombia was not obliged to and because of the harm impact this IP provision would cause on Colombians health.

With regards to the Andean Community Commission, in the Decisión 486 de 2000 Article 21, states: "Products or processes that are already patented and included in the state of the art within the meaning of Article 16 of this Decision may not form the subject matter of a new patent owing to the fact of having a use ascribed to them different from that originally provided for in the first patent."\(^\text{19}\) Otherwise, novelty requirement would be unmet.

According to Decisión 486 de 2000 Article 16 “An invention shall be considered new when it is not included in the state of the art. The state of the art comprises everything that has been made available to the public by written or oral description, by use or marketing or by any other means prior to the filing date of the patent application or, where appropriate, the recognized priority date.”\(^\text{20}\)

D. **Biosimilars regulation**

Biosimilars regulation with regards to the marketing authorization refers to efficacy and safety of medicines, concepts that are by no means related to intellectual property rights, therefore its mention within a debate regarding IP rights is unacceptable.


\(^{18}\) Agreement on Trade-Related Aspects of intellectual Property Rights (WTO), art. 27.1.


Colombian proposed decree is in line with current United States biologics’ regulation system and process, since both nations aim at ensuring quality and competition in the market, while considering country specific conditions.

Finally, with regards to WHO guidelines, it refers to a recommendation which countries are free to adopt or not.

E. Price control regulations

Medicines prices’ overflow and its subsequent impact on health national systems’ stability have lead many countries to implement measures on different sectors in order of rationalizing expenditure and guaranteeing access and coverage,\(^{21}\) using different mechanisms, being international reference pricing one of them.

Medicines supply by health systems (specially to more vulnerable people) is a guarantee of equity and well-being. Its implementation requires the designing of clear negotiation policies and mechanisms, between health systems and medicines providers.\(^ {22}\) States shall guarantee health's right through universal coverage and the maximum effectiveness possible using available resources. In this vein, Colombia has the right to implement management, financial, negotiation and assistance models and control mechanisms to meet this purpose.\(^ {23}\) This does not mean violation of its trade agreements. Instead, it aims at ensuring balance among human rights and trade prerogatives, in line with the Constitution.

Reference countries were established according to trade integration criteria, geographic proximity with Colombia, similarity between their general economic intervention, OECD belonging and availability of information. It is out of proportion to argue that countries like Spain and Portugal are part of the reference countries, since both of them and despite their financial crisis, have maintained historically an overwhelmingly higher GNP than Colombia.\(^ {24},\)\(^ {25},\)\(^ {26},\)\(^ {27}\)

The regulatory decision implemented by Colombian Government is nothing different from using this sovereign right considering that free pricing of medicines, which ruled over the immediate past years, lead health system to go bankrupt and stopped scarce resources patients from having access to essential medicines for health and life.

\(^{21}\) World Health Organization. Available from: URL: http://apps.who.int/medicinedocs/es/d/Jh2958s/3.3.html

\(^ {22}\) World Health Organization. Available from: URL: http://apps.who.int/medicinedocs/es/d/Jh2958s/3.3.html

\(^ {23}\) Compilation of general comments and general recommendations adopted by Human Rights Treaty Bodies. Available from: URL: http://www.unhchr.ch/tbs/doc.nsf/898586b1dc7b4043c1256a4500044f331/3e4492f624f618b2c1256d500565fccc/$file/g0441305.pdf

\(^ {24}\) For further information: http://www.worldbank.org/

\(^ {25}\) For further information: http://www.datosmacro.com/pib/espana

\(^ {26}\) For further information: http://www.datosmacro.com/paises/colombia

\(^ {27}\) For further information: http://www.datosmacro.com/paises/portugal
2. **Copyright**

Colombia remains on the 2013 watch list, despite the many acknowledgments of the U.S. about the work of the Government of Colombia on behalf of rightsholders and international trade.

However, in 2013 the U.S. urged “Colombia to swiftly pass key pieces of currently pending IPR legislation in connection with the implementation of that agreement.” This comment ignores the fact that, in recent years, the Colombian government, policymakers and civil society has embarked on a sovereign and participatory policy-making process. In 2013, for instance, working tables were formed aiming at discussing various model of implementation with different stakeholders.\(^28\) Thus, the public debate is open. Pointing out the lack of FTA implementation as a reason to hold Colombia on the watch list is still, as it was in 2013, an undue external pressure to the country’s internal discussion.

It comes as a surprise for us that among the U.S. concerns in 2013 was the “lack of adequate resources and training for enforcement officials.” The Government of Colombia has implemented nearly 500 hours training on intellectual property in a total of 177 workshops that have taken place in more than 30 different locations throughout the country and have benefited more than 10,000 persons. Moreover, the trainings have included more than 200 judiciary officials. Not to mention the e-learning process that began in 2013, which substantially increases those figures.

If there are concerns on the Colombian copyright training, it should be that they are unbalanced. Colombia spends an important budget from taxpayer money in trainings that are mainly focused on the industry needs, leaving aside the importance of culture as a value and the need of a balanced legal framework where openness and users’ rights have a key place.

The USTR stated in the 2013 Special 301 Report that piracy over the Internet “is a growing problem in Colombia,” but such statement is not supported by concrete evidence. Certainly it cannot be the basis for a pressure that is meant to have important economic consequences. Moreover, the evidence shows there is no such problem in Colombia. The Colombian government’s written submission on the 2014 Special 301 review does not show even one process regarding this issue.\(^29\) Thus, how can this be a problem when allegedly affected rightsholders have not even begun none of the judicial processes available in the country?

If anything, Colombia has done the homework, so it should not be part of menacing blacklisted system, unless such index is one that emphasizes on weaknesses in the users’ rights protection and in the absence of support for more open copyright’s approaches in order to balance the law with other fundamental rights such as freedom of expression or access to knowledge (education, culture or science), certainly, where little has been done.

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\(^{28}\) More information on these activities is available at: [http://redpatodos.co/blog/mesas-de-trabajo-con-mincit-para-leyleras4-apuntese/](http://redpatodos.co/blog/mesas-de-trabajo-con-mincit-para-leyleras4-apuntese/).

\(^{29}\) The Colombian government’s submission letter on the 2014 Special 301 process can be consulted at [http://www.regulations.gov/#/documentDetail;D=USTR-2013-0040-0067](http://www.regulations.gov/#/documentDetail;D=USTR-2013-0040-0067)
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 found in U.S. law.”

The copyright reform that should take place in Colombia has to address not just rightsholders’ interests but also the Colombian society’s needs to develop a sound cultural ecosystem. This should be an important axe of the U.S. government concern.

The above subscribers do not recognize the legitimacy of the 301 list and find it against multilateral ruling regulation.

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30 As mentioned by several NGOs from around the world in a 2011 letter, which is available at http://infojustice.org/wp-content/uploads/2011/02/Joint-Policy-Statement-of-Ten-Civil-Society-Organizations-on-Special-301.pdf