



## **Submission to the U.S. Trade Representative**

2015 Special 301 Review: Comments of Colombian Non Governmental  
Organizations

Docket number USTR-2014-0025

Bogotá, February 6<sup>th</sup> 2015

As Colombian NGO group seeking to enforce major public interests protection within Intellectual Property discourse, we want to participate again this year with comments to evidence the many loopholes in the Special 301 review.

Karisma Foundation is a Colombian civil society organization that, since 2011, has been involved in the public discussions on the Copyright reform driven by the FTA signed by Colombia with the U.S. Additionally, Karisma has presented comments on its own name, on joint declarations with other NGOs and through the American University's PIJIP group (Program on Information Justice and Intellectual Property) during the Special 301 processes in 2011 and 2013.<sup>1</sup> During 2014, we delivered comments along with other Colombian civil society organizations.

Ifarma is a Colombian nonprofit civil society 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 nonprofit civil society 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. In this vein, we submitted our comments on the Special 301 review in 2014 along with other Colombian civil society organizations.

The Doctoral Program in Law at the University of Rosario, through the Legal Pluralism research line, has addressed the challenges posed by new forms of production and circulation of knowledge, and its production centers. In turn, it has also studied the dynamics of cognitive capitalism as the strengthening of intellectual property rights, and its impact on access to information, access to knowledge and the exercise of other human rights. From this framework, the PhD program has promoted the realization of academic events on intellectual property, access to medicines, human rights in the digital era, among others.

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<sup>1</sup> Fundación Karisma. Una vez más solicitamos que Colombia sea retirada del Informe Especial 301. [Online]. 2013 [Cited 2014 Feb 26]. Available from: URL:<http://karisma.org.co/?p=2029>. And Fundación Karisma, Colombia debería ser retirada de la lista 301. [Cited 2014 Feb 26]. Available from:<http://karisma.org.co/?p=611>

## Background

There has been no substantial change since we presented our comments in 2014, therefore, we will keep substantially the same background comments as in our former document. As was mentioned by the PIJIP submission letter in 2013 with regards to 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 by all the U.S. trade partners as such.<sup>2</sup> We all endorse last year's comments by PIJIP that goes further into this argument.<sup>3</sup>

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;”<sup>4</sup> its use to threaten “trade sanctions for TRIPS and FTA compliant policies violates the WTO Accords”<sup>5</sup> and it continues to be used as an illegitimate mechanism that pressures countries through a denouncing list.

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<sup>2</sup> 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 2014 Feb 26]. Available from: URL:<http://www.lanacion.cl/noticias/economia/comercio/chile-es-incluido-en-lista-negra-de-pirateria-pero-gobierno-desconoce-legitimidad/2013-05-01/160857.html>

<sup>3</sup> Flynn S. Submission to the U. S. Trade Representative and Notice of Intent to Testify. [Online]. 2014 Feb 7 [Cited 2014 Mar 4]. Available from: URL:<http://www.regulations.gov/#!documentDetail;D=USTR-2013-0040-0021>

<sup>4</sup> *Ibíd.*

<sup>5</sup> *Ibíd.*

Additionally, article 23 of the WTO Dispute Settlement Understanding (DSU), when demanding to apply to WTO multilateral system to solve differences, not only excludes the unilateral action but also impedes from applying to other forums for dispute settlement related to the WTO<sup>6</sup>.

Colombia has been taking measures (and should take many more) that seek to enforce citizens' fundamental rights, which are above individuals or countries' trade interests and it 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 international cooperation obligations for the advancement of well-being of humankind, therefore, they should not harm developing countries with trade provisions.

The undersigned do not recognize the legitimacy of the 301 list, moreover, as it is explained below, we believe that Colombia is not infringing any regulation or agreement that will justify a US claim.

## **1. Intellectual Property and access to medicines**

### **A. Patentable subject matter**

The 2014 Special 301 states that "Colombia's limitations on the patentability of certain pharmaceuticals... are areas of concern". As we explained in last year's submission, 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 use<sup>7</sup>

In addition, during the US-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" 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*

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<sup>6</sup> Dispute Settlement Understanding 1996 (WTO), art 23. Available from:  
URL:[http://www.wto.org/spanish/tratop\\_s/dispu\\_s/dispu\\_s.htm](http://www.wto.org/spanish/tratop_s/dispu_s/dispu_s.htm)

<sup>7</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights (WTO), art. 27.1.

*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.”<sup>8</sup> Otherwise, novelty requirement would be unmet.*

According to Article 16 of the “Decisión 486 de 2000”: *“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.”<sup>9</sup>*

## **B. Patent Review Mechanism**

2014 Special 301 acknowledges that “Colombia has made tangible progress in the areas of internal coordination of enforcement agencies, reducing patent application backlogs, and training judges and law enforcement officials on IPR issues.” Such recognition supports civil society concerns with regards to the decisions made by the Colombian Patent Office which tend to prioritize rights holders interest before public interest.

As civil society organizations we urge the Government to promote health experts participation in patent review, which is consistent with trade agreements that include intellectual property and it improves patent quality and avoids “evergreening,” both effects favoring public health and general well-being.

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”.<sup>10</sup>
- ◆ “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

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<sup>8</sup> Decision No. 486 of 2000 - Common Regime on Industrial Property (CAN), art. 21. Available from: URL:[http://www.wipo.int/wipolex/es/text.jsp?file\\_id=223717](http://www.wipo.int/wipolex/es/text.jsp?file_id=223717)

<sup>9</sup> Decision No. 486 of 2000 - Common Regime on Industrial Property (CAN), art. 16. Available from: URL:[http://www.wipo.int/wipolex/es/text.jsp?file\\_id=223717](http://www.wipo.int/wipolex/es/text.jsp?file_id=223717)

<sup>10</sup> Holguín G. La guerra contra los genéricos - Un crimen silencioso. Bogotá: Aguilar. 2014. p. 193.

technological development”<sup>11</sup>

- ◆ “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.”<sup>12</sup>
- ◆ “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)”<sup>13</sup>
- ◆ “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *order public* or morality, including to protect human, animal or plant life or health...’ (TRIPS art. 27).”<sup>14</sup>

### C. Patent enforcement

Colombia is complying with WTO patent enforcement regulations. Furthermore, as civil society organizations we urge that enforcement attention be oriented safeguarding public interest from intellectual property right’s abuse. For instance, we prevent Colombian Government from implementing the TRIPS plus mechanism *linkage*, which in the US-Colombia Free Trade Agreement is optional not mandatory;<sup>15</sup> its adoption would impact negatively access to lifesaving medicines.<sup>16</sup> This mechanism is not present in WTO regulations, while WHO has advised developing countries against its implementation and in most European countries it is not required.<sup>17</sup>

Article 39.3 of the TRIPS Agreement does not require linkage application.<sup>18</sup> A provision on patent-registration linkages, would prevent approval of new medicines by national drug regulatory authorities if they could potentially infringe existing patents. With such provisions, national regulatory authorities will be discouraged

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<sup>11</sup> Agreement on Trade-Related Aspects of intellectual Property Rights (WTO), art. 8. Available from: URL:[http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf)

<sup>12</sup> *Ibíd.*

<sup>13</sup> Holguín G. Op. cit. p. 193.

<sup>14</sup> *Ibíd.*

<sup>15</sup> Holguín G. Op. cit. p. 202.

<sup>16</sup> [http://www.citizen.org/documents/Access\\_Briefing\\_TPP\\_ENG\\_2013.pdf](http://www.citizen.org/documents/Access_Briefing_TPP_ENG_2013.pdf)

<sup>17</sup> *Ibíd.*

<sup>18</sup> Data exclusivity prohibits drug regulatory authorities from accepting applications from generic producers that refer to the existence of data of the originators on file with the authorities and claim bioequivalence. This prevents the registration of generics in a market regardless of patent status.

from registering new medicines and may be forced to invalidate medicines' registration, even when there is no proof that a patent has actually been violated.<sup>19</sup> There is growing evidence that this trend exerts a negative impact on public health.<sup>20</sup>

#### **D. Biotherapeutic products regulation**

As we expressed last year, biologics regulation with regards to marketing authorization refers to efficacy and safety of medicines. These concepts are by no means related to intellectual property rights, therefore, its mention within an IP rights debate is unacceptable and aims at blocking competition and favouring commercial interests before people's right to health.

Colombian biotherapeutics' decree on marketing authorization issued on September 2014 (Decree 1782 of 2014)<sup>21</sup> is based on a progressive approach that defends three clear principles:

- i. Ensuring quality, safety and efficacy of biotherapeutics.
- ii. Not establishing unnecessary barriers to competition.
- iii. Reducing the financial burden that these medicines represent to public health programs.<sup>22</sup>

In addition, the Decree follows the World Health Assembly request to increase access to biotherapeutic products ensuring their quality, safety and efficacy<sup>23</sup> and requests compliance with Good Manufacturing Practices regulations. Furthermore it considers local capacities and needs and complies with the International Covenant on Economic, Social and Cultural Rights (ICESCR). Besides, during its consultation process, the WTO was notified according to the Agreement on Technical Barriers to Trade and the Decree does not affect Colombian commitments under the US-

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<sup>19</sup> The potential impact of Free Trade Agreements on Public Health UNDP, UNAIDS Issue Brief 2012 [http://www.unaids.org/sites/default/files/media\\_asset/JC2349\\_Issue\\_Brief\\_Free-Trade-Agreements\\_en\\_0.pdf](http://www.unaids.org/sites/default/files/media_asset/JC2349_Issue_Brief_Free-Trade-Agreements_en_0.pdf)

<sup>20</sup> A recent study in Thailand projected that if a 10 year patent extension was granted as proposed under the Thai-US FTA, the following negative consequence will accrue over the next 20 years: a 32% increase in the price index for medicines; spending on medicines would increase from baseline to approximately USD 11,191 million; the domestic industry would lose USD 3,370 million. See Kessomboon N. Limpananont J. Kulsomboon V. Maleewong U. Eksaengsri A. and Paothong P. Impact on Access to Medicines from TRIPS-Plus: A Case Study of Thai-US FTA. *Southeast Asian Journal of Tropical Medicines and Public Health*, 2010, 41(3): 667-677, at 637-638.

<sup>21</sup> <http://www.minsalud.gov.co/sites/rid/Lists/BibliotecaDigital/RIDE/DE/DIJ/decreto-1782%20de%202014.pdf>

<sup>22</sup> <http://infojustice.org/archives/33187>

<sup>23</sup> [http://apps.who.int/gb/ebwha/pdf\\_files/WHA67/A67\\_R21-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R21-en.pdf)

Colombia Free Trade Agreement. It is worth noting that guidelines on evaluation of similar biotherapeutic products issued by international organizations, for example WHO, are recommendations which countries are free to adopt or not and by no means they are a mandatory norm or standard.

The Decree establishes clearly all requirements that need to be fulfilled with own studies by ALL biotherapeutic products that aim approval by Colombian National Medicines Regulatory Authority, which are: detailed description of the process and production site, expression system, biological identity test, evaluation of potency, physicochemical properties, evaluation of biological activity, evaluation of purity, immunogenicity test and risk management plan. Currently both immunogenicity and stability guidelines are under development. The former ones will define pre and clinical information that would be necessary to submit according to the characterization and complexity of the active pharmaceutical ingredient, among other product characteristics. Stating that biotherapeutics approved under this decree could be unsafe or ineffective lacks of complete support.

In addition, the Decree also describes when the third pathway would be suitable for application: besides complying with own studies all requirements described above, the active pharmaceutical ingredient is to be enough characterized, safety/efficacy profile is highly documented and there should be wide clinical experience and robust pharmacovigilance information. These specific conditions aim at protecting patients safety while technological advances, the regulatory expertise and the clinical experience on biotherapeutics are used in benefit of general public by increasing access.

Finally, the undersigned reaffirm our reject to any allusion to this Decree as a matter related to an IP rights debate.

## **E. Price control regulations**

Price control regulations along 2014 kept the public health interest as in 2013, therefore our considerations on this issue do not have substantial changes. Medicines prices' overflow and its subsequent impact on the stability of health national systems' stability have lead many countries to implement measures on different sectors in order of rationalizing expenditure and guaranteeing access and

coverage,<sup>24</sup> 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.<sup>25</sup> States shall guarantee health 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.<sup>26</sup> 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.<sup>27, 28, 29,30</sup>

The regulatory decision implemented by the 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.

## **2. Copyright**

Colombia remains on the 2014 watch list, despite the fact that the report itself acknowledges the work of the Colombian Government on behalf of rightsholders and

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<sup>24</sup> World Health Organization. Available from:

URL:<http://apps.who.int/medicinedocs/es/d/Jh2958s/3.3.html>

<sup>25</sup> World Health Organization. Available from:

URL:<http://apps.who.int/medicinedocs/es/d/Jh2958s/3.3.html>

<sup>26</sup> Compilation of general comments and general recommendations adopted by Human Rights Treaty Bodies. Available from:

URL:[http://www.unhchr.ch/tbs/doc.nsf/898586b1dc7b4043c1256a450044f331/3e4492f624f618b2c1256d5000565fcc/\\$file/g0441305.pdf](http://www.unhchr.ch/tbs/doc.nsf/898586b1dc7b4043c1256a450044f331/3e4492f624f618b2c1256d5000565fcc/$file/g0441305.pdf)

<sup>27</sup> For further information: <http://www.worldbank.org/>

<sup>28</sup> For further information: <http://www.datosmacro.com/pib/espana>

<sup>29</sup> For further information: <http://www.datosmacro.com/paises/colombia>

<sup>30</sup> For further information: <http://www.datosmacro.com/paises/portugal>

international trade by stating *"The Government of Colombia has made tangible progress in the areas of internal coordination of enforcement agencies, reducing patent application backlogs, and training judges and law enforcement officials on IPR issues."* Under this compliment, the USTR failed to acknowledge the civil society concerns on the Colombian unbalanced copyright framework. For instance, the copyright training, funded by the taxpayer and focused on the industry needs, leaves 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.

However, the recognition of the work that Colombia has done to enforce IPR was not enough to keep Colombia from being part of this black list. In the 2014 report, the US stated that *"earlier progress on IPR legislation was reversed in 2013 when the Colombian Constitutional Court invalidated on procedural grounds the law enacting many IPR-related commitments made under the United States-Colombia Trade Promotion Agreement (CTPA). Colombia has not yet re established the provisions contained in the earlier invalidated law."* Thus, the lack of FTA implementation is also a reason to hold Colombia on the 2014 watch list, as it was in former reports, turning once again this statement into an undue external pressure to the country's internal legislative discussion.

The comment ignores that the Colombian Government, policymakers and civil society have embarked since 2011 on a sovereign and participatory policy-making process. In 2014, the Government was engaged in the national elections, and was debating and analyzing internally the various comments that emerged from the working tables that, as part of the FTA implementation, were opened to listen at different stakeholders during 2013.<sup>31</sup> The Colombian Government seems to understand that instead of a fast track legislation, the issue deserves a solid discussion and a thorough legislative process. On the other hand, civil society in the hands of the collective that opposes the 2011 draft law to implement the "notice and takedown system", RedPaTodos, also worked on possible bridges to a new draft. During 2014, RedPaTodos published some recommendations<sup>32</sup> that can ease the path to a consensus draft on an issue that has not even been mentioned in the Special 301. The US should be supporting these democratic values, instead of promoting fast track procedures that harm fundamental rights discussions.

The USTR stated in the 2014 Special 301 Report that *"persistently high levels of both hard goods and Internet piracy continue to plague the country in spite of periodic, laudable*

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<sup>31</sup> More information on these activities is available at: <http://redpatodos.co/blog/mesas-de-trabajo-con-mincit-para-leylleras4-apuntese>

<sup>32</sup> You can see the recomendations for a Human Rights perspective in a law on Intermediaries liability and the discussion process here [redpatodos.co/blog/queremos-construir-junto-a-ustedes-las-recomendaciones-para-leylleras/](http://redpatodos.co/blog/queremos-construir-junto-a-ustedes-las-recomendaciones-para-leylleras/).

*enforcement efforts. For example, Colombia's San Andresitos markets remain rife with counterfeit and pirated products and were again named in USTR's Notorious Markets List in 2013.*" For this report, the USTR offers a single example -which it is not enough- of hard goods piracy and, even worse, on online piracy. Such statement is not supported by any concrete evidence. The USTR declaration on piracy as a major problem in the country cannot be the basis to put pressure upon Colombia, in particular due to important economic consequences it may have.

As in 2014, we believe that Colombia has done the homework to protect IPR and the rightholders' interests. We strongly believe that the country 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.

If the USTR decides to do such an index will show that a market focused Copyright approach that prioritizes only rightholders in the equation produces important human rights threats. For example, the Constitutional Court in Colombia during 2013 confronts three lawsuits seeking to declare unconstitutional the Law 1680 of 2013. This statute seeks to guarantee an autonomous and independent access to information, communication, knowledge and ICT for blind and visually impaired people by including an exception to the IPR regulation. Such law, in comparison to the US legal provisions in favor of this population, can be considered "light." However, while waiting for the ratification and implementation of the Marrakesh Treaty on these matters, Law 1680 has meant a breakthrough in the recognition of the exercise of the rights of persons with visual disabilities. But, the lawsuits do not recognize this, on the contrary, petitioners request the total unenforceability of this act, i.e., calling for "repealing the law." Among the arguments, the petitioners claim that the guarantee for visually impaired persons unknown the constitutional duty of the State to protect intellectual property, therefore, rightholders will become victims of piracy. The USTR position backs up this arguments when is not clear to recognize that copyright protection is not absolute. The USTR should state clearly that the copyright system provides mechanisms intended to balance the protection of authors and rights-holders with safeguards for the exercise of fundamental rights, that those safeguards are important to commerce because are essential to the copyright system, and that the fear to piracy does not justify any IPR enforcement.

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.*<sup>33</sup> Otherwise, it is a neocolonial tool. 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 US Government concern.

**Due to all what we stated throughout this document, the undersigned do not recognize the legitimacy of the 301 list and find it against multilateral regulation.**

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<sup>33</sup> 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>