GRUPO DE TRABALHO SOBRE
PROPRIEDADE INTELECTUAL

rebrip
Rede Brasileira pela Integração dos Povos

GTPI's written comment on the 2010 USTR Special 301

Introduction

The Working Group of Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI[1]/REBRIP – acronym in Portuguese) coordinated by the Brazilian Interdisciplinary AIDS Association (ABIA – acronym in Portuguese) is comprised of several Brazilian civil society organizations that work to ensure the right to health, including organizations working with people living with HIV/AIDS, human rights and consumers rights. Created in 2003, the Group conducts studies and advocacy actions to overcome the negative impact of pharmaceutical patents and other monopolistic mechanisms on the access to essential medicines and the implementation of health policies in Brazil.

The Report on Special Section 301 - issued yearly by the Office of the United States Trade Representative - original goal, as stated in the US legislation [19 U.S.C. § 2242(a)(1)(A) & (B)], is of identifying countries that deny adequate and effective protection for intellectual property rights established under international agreements, or that deny fair and equitable market access for persons that rely on intellectual property protection. In addition, USTR has created a "Priority Watch List" and "Watch List" to assist the Administration in pursuing the goals of the Special 301 provisions. Placement of a trading partner on the Priority Watch List or Watch List indicates that particular problems exist in that country with respect to IPR protection, enforcement, or market access for persons relying on intellectual property. Trading partners placed on the Priority Watch List are the focus of increased bilateral attention concerning the

[1] The GTPI is comprised of several Brazilian civil society groups and two international organizations, in addition to a number of activists and researchers. Nationals: ABIA, GIV, GAPA-SP, GAPA-RS, GESTOS, GRAB, Pela Vidda-SP, Idec, Conectas Direitos Humanos, RNP+ Maranhão, Federação Nacional dos Farmacêuticos. Internationals: Oxfam, Doctors Without Borders (MSF).

Av. Presidente Vargas, 446 / 13° andar - Centro . 20071 907 . Rio de Janeiro/RJ . Brasil

Phone.: +55 21 2223 1040 . Fax: +55 21 2253 8495

E-mail: abia@abiaids.org.br . Site: www.abiaids.org.br

problem areas. Therefore its main focus is clearly not to denounce irregularities related to international agreements or internal practices or legislations that are not fair and equitable.

The Report on Special Section 301 was created during an era marked by unilateralism/bilateralism in trade relations. But in the last decades it was created multilateral forums that possess dispute settlements mechanisms that are able to solve trade issues between countries. Since the US, and the majority of its trade partners, are signatories of such agreements it should seek these multilateral forums to deal with any infringements to international legislation they may consider to be performed by any country.

Actually, this report is used as a tool for pressing governments to abandon their sovereign rights of deciding which national legislation best serve its interests and to adopt those that are aligned with the interests of the US. It is an obvious right to every nation to create the norms of trade within its borders as long as they do not contradict any international obligation the country has agreed upon.

The USTR trade policy regarding the Special 301 list has been marked by allowing only for bias inputs primarily from the Pharmaceutical Research and Manufacturers of America (PhRMA), which focuses its analyses on IPR related to pharmaceuticals, and the International Intellectual Property Alliance (IIPA), that represents publishers and copyright owners. Therefore, the Special 301 list published by USTR has been historically known to reflect only the main concerns of those groups. Therefore, in comparison, the USTR's actions of receiving written comments and holding public hearings on the 2010 Special 301 represents a step forward in broadening the discussion about its trade policy by getting new evidences from other stakeholders.

Av. Presidente Vargas, 446 / 13° andar - Centro . 20071 907 . Rio de Janeiro/RJ . Brasil

Phone.: +55 21 2223 1040 . Fax: +55 21 2253 8495

E-mail: abia@abiaids.org.br . Site: www.abiaids.org.br

Although this new possibility is an improvement, we consider that the nature of this report is not helpful to foster positive and free trade between the US and their trade partners; on the contrary, it is more harmful to US foreign relations then a stimulus to innovation and worldwide access to newly developed products. It does worsen the US image abroad as a unilateralist nation that tries to impose their legislation to their commercial partners instead of holding cooperative and constructive negotiations.

Actually, Brazil grants more intellectual property protection to pharmaceutical products then the minimum required by the TRIPS agreement under provisions such as the pipeline patents.

Having stated that, we are going to proceed to the counter argumentation of the points related to pharmaceutical intellectual property rights mentioned in the previous report of 2009 presenting the legal basis both nationally and internationally of the mechanisms that allegedly infringes multilateral agreements signed by Brazil, including the agreement on TRIPS.

ANVISA'prior consent

"Concerns remain regarding patent protection for pharmaceuticals and medical devices, including with respect to: (…) the role of Brazil's health authority, ANVISA, in the patent application process."

ANVISA's prior consent refers to the participation of Ministry of Health officials in the processes of analyzing pharmaceutical patent applications. According to Brazilian legislation on industrial property (Law nº. 9.279/1996, Article 229-C), applications for pharmaceutical patents must obtain the prior consent of ANVISA (Brazilian Health Surveillance Authority) in order to be granted. Prior approval is

required in virtue of the importance of medicines to public health. The TRIPS Agreement, in its Article 8, allows its Members to adopt all the necessary measures to protect public health. Given the impact of patents in the public health system and access to medicine in developing countries, it its important that only products that really fulfill all the patentability requirements be protect by patents. Therefore, the Brazilian legislators decided to give the best technical analyses possible to patents filled in the pharmaceutical sector. Such legislation allows ANVISA to work in partnership with INPI (Brazilian Patent Office). Being a specialized agency in the health sector, ANVISA has specific knowledge and technical proficiency in the field, which facilitates that public health is taken into consideration in the analysis of pharmaceutical patent applications. Many times, ANVISA's activity is crucial to detect and prevent evergreening methods by the patent's applicants (as in 'me too' drugs or 'patent clusters', *etc*), which are especially harmful to public health. WHO identified the participation of public health authorities in the analyzes of pharmaceutical patent applications as being a positive measure to protect public health since it helps to prevent concession of frivolous patents[2]. .

It is a TRIPS Agreement flexibility, established in its Article 8, and reinforced by the Doha Declaration. WTO already manifested that State members are allowed to adopt different processes of analyzing patent applications in specific fields and that does not constitute a violation of the non-discrimination principle[3]. Therefore, ANVISA's prior consent is a legitimate measure adopted by the Brazilian legislation to protect the public health.

[2] Final report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health, CIPIH/2006/1, p. 76.
[3] WT/DS114/R, March, 17th, 2000, paragraph 7.92.

Polymorphs and second-use inventions

"Concerns remain regarding patent protection for pharmaceuticals and medical devices, including with respect to: the decision against granting patents for polymorphs and second-use inventions…"

Polymorphism is an intrinsic property of matter in its solid state, that is to say, they may exist in different physical forms, which may have different properties more or less pharmaceutically significant. Since polymorphism is a natural property, polymorphs cannot be considered an invention; they are discovered normally as part of routine experimentation. Therefore, they are not patentable under the Brazilian Law. Furthermore, the discovery of a polymorph that presents a better solubility and bioavailability is obvious for a person skilled in the art and the method, because such is already described in prior art. Therefore, there is no inventive step but, at most, a discovery. And, as already put before, discovers are not patentable under Brazilian Law, because it lacks an inventive step.

The decision of granting patent protection for both use claims and polymorphs is related to the definition of the patentability standards, which each country has the possibility, under the TRIPS Agreement, to interpret in its own way. The definition of such criteria constitutes a key aspect of patent policy, with implications in other areas, such as industrial and public health policies. The patentability standards – novelty, inventive step and industrial application – may be interpreted in different ways, and countries and specialists do not necessarily adopt the same interpretation. Especially regarding use claims and polymorphs, the *WHO Guidelines for the examination of pharmaceutical patents*[4] recommends that countries should not grant patent

[4] Carlos CORREA, 2007. Guidelines for the examination of pharmaceutical patents: developing a public health perspective. Available at: http://ictsd.net/downloads/2008/06/correa_patentability20guidelines.pdf.

protection for use claims and polymorphs. Therefore, Brazil has the right to adopt whichever interpretation of the patentability requirements it believes is best to protect its population and the country development, as allowed by article 8 of the TRIPS Agreement, and all other countries must respect that right and not threaten with illegitimate commercial retaliations.

Patent protection for use claims allows the grant of protection for a new use of a product that is already known. Use claims in the pharmaceutical field consists, basically, of the pharmaceutical use of an already known composition that was not previously used for treatment purposes, or a new pharmaceutical use for a composition that is already known and is already therapeutically used. In both cases it is a new use for a known product, therefore, there is no new invention, but only a new use for an already existing invention. Firstly, they do not meet the novelty patentability standard (article 27, TRIPS and article 8º, Law nº. 9.279/1996). Secondly, new uses are mere discoveries of a new effect of a known substance, since nothing has been changed in the previously used product. It is important to reiterate that discoveries are not patentable under Brazilian Industrial Property Law (article 10, Law nº. 9.279/1996). Therefore, use claims do not meet the patentability requirements set by Brazilian law's.

Finally, it is important to mention that even in USA the Federal Trade Commission has drawn attention to the problem of the quality of patents that are being granted because the patentability standards are becoming too low, negatively affecting the public domain and bringing negative effects access and to innovation[5].

5 ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT. *Patents and innovation: trends and policy challenges.* Paris, 2004, p. 28.

Intellectual Property and Health Policy

The United States will work to ensure that the provisions of our bilateral and regional trade agreements are consistent with these views, and do not impede the taking of measures necessary to protect public health. In addition, USTR will continue its close cooperation with the Department of Health and Human Services, which contributed to the negotiation of the recently adopted Global Strategy on Public Health, Innovation and Intellectual Property and the agreed parts of its Plan of Action at the World Health Organization, to ensure that public health challenges are addressed and the patent system is supported as a mechanism to promote research and innovation."

As stated in the section "*Intellectual Property and Health Policy*" of the 2009 Special Section 301, the US government is committed to ensure that provisions in bilateral and regional trade agreements "do not impede the taking of measures to protect public health". Also, US recognized the recent adopted *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property* (WHA 61.21) (hereafter GSPA) as a way to ensure that public health challenges are addressed.

In the Element 5 of the GSPA, related to the "application and management of intellectual property to contribute to innovation and promote public health", it is explicitly clear the right of WTO and WHO Members States to adapt its national legislation in order to maximize the use of TRIPS flexibilities to protect public health:

> *(5.2) (a) consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003*

> *(b) take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States*

Public health TRIPS flexibilities are not only those that ensures the generic competition to achieve more affordable prices during the patent term, such as compulsory license, but also the establishment of means to avoid the granting of undue patents, such as those that aim the *evergreening* strategy to extend the monopoly of know products.

In this spirit, the Brazilian decision to adopt the Anvisa's role in the analysis of pharmaceutical patent applications, as well as to not accept the granting of patent for polymorphs and second use are absolutely in consonance not only with TRIPS, but also with the GSPA, in which the US government is supportive.

It is important to note that the *evergreening* strategy goes against the promotion of innovation, as the patent system is used as mean for extending the monopoly of known products, instead of the just rewarding of genuine inventions.

Undisclosed test data protection

> *"In addition, the United States continues to urge Brazil to provide effective protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products."*

In Brazil, the protection against unfair commercial use of undisclosed test and other data generated to obtain marketing approval for pharmaceutical products is

effective. Such protection is established in Article 195; item XIV of the Brazilian Industrial Property Law (Law nº. 9.279/96), *in verbis*:

> *Art. 195; item XIV - divulges, exploits, or utilizes, without authorization, results of tests or other undisclosed data whose preparation involves considerable effort and that were submitted to government agencies as a condition for obtaining approval to commercialize products.*
> *Penalty--imprisonment, for 3 (three) months to 1 (one) year, or a fine.*

Therefore, this regulation is complaint with international obligations made in the Article 39. 1 of the TRIPS Agreement that limits the protection of undisclosed information "against unfair competition as provided in Article 10*bis* of the Paris Convention".

Such protection stipulated in TRIPS and the Brazilian Industrial Property Law requires, remedial action against "dishonest" commercial practices, but does not give rise to exclusive rights. This position established in TRIPS of not establishing exclusive rights for undisclosed information is also grounded on the pro-competitive effects of low entry barriers for pharmaceutical products. Since, the early entry of generic competition is likely to increase the affordability of medicines at the lowest possible price.

Conclusion

As was detailed in this document, all the arguments related to pharmaceutical intellectual property rights and related regulations, in the case of Brazil, are entirely in accordance with all international agreements Brazil is part of and in no case promote unfair or inequitable market access for any national or foreign citizen or company.

Indeed all the critics made to Brazil regarding pharmaceutical I.P. rights in all the Special 301 lists have never been taken to a panel at the WTO by the US, as an indication that the US are aware that they hurt only their national interests and not Brazil's international obligations.

We, from the Civil Society Organizations, support and defend the sovereignty of Brazil to adopt regulations and laws, in accord with international agreements, which aim to mitigate the impact of pharmaceutical patents and intellectual property rules on the access to medicines.

Veriano de Souza Terto Jr
General Coordinator
ABIA

Renata Reis
Lawyer and Project Coordinator
ABIA

Francisco Viegas Neves da Silva
Lawyer and Project Assistant
ABIA

Oscar Vilhena Vieira
Juridical Director
CONECTAS Human Rights

Marcela Fogaça Vieira
Lawyer
CONECTAS Human Rights

Sérgio Souza Costa
Project Assistant
GESTOS

Alessandra Nilo
Executive Coordinator
GESTOS