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In response to the request for public comment and announcement of public hearing concerning the **2011 SPECIAL 301 REVIEW**, issued by the Office of the United States Trade Representative and published on the Federal Register on 12.30.2010, the **Overmundo Institute** and **GTPI** (Intellectual Property Working Group) of Rebrip (The Brazilian Network for the Integration of Peoples) hereby present their joint submission.

The **Overmundo Institute (Instituto Sociocultural Overmundo)** is a nonprofit organization dedicated to promoting access to knowledge and cultural diversity in Brazil. Created in 2006 and headquartered in Rio de Janeiro, the Institute is concerned with the establishment of new channels and opportunities for the dissemination of cultural production throughout Brazil; the development of studies and strategies of new possibilities for creation, sharing, and circulation of culture and knowledge generated by the Internet and digital technologies; and the encouragement of innovative models for the management of intellectual property and business in the areas of culture and communication. The Institute coordinated the team of researchers responsible for the chapter on Brazil of the Social Science Research Council report *Media Piracy in Emerging Countries*.

The **GTPI (Intellectual Property Working Group)** of **Rebrip (The Brazilian Network for the Integration of Peoples)** is a group of civil society organizations (of public interest), researchers and students whose mission is to fight to guarantee the right to health, specifically the right to pharmaceutical assistance by monitoring and struggling against the impacts of intellectual property rules on access to essential goods and knowledge. GTPI members are: ABIA—Brazilian Interdisciplinary AIDS Association; CONECTAS Human Rights; FASE—Solidarity and Education; FENAFAR - National Federation of Pharmaceuticals; GAPA/RS—Support Group for AIDS Prevention in Rio Grande do Sul; GAPA/SP—Support Group for Prevention of AIDS in Sao Paulo; GESTOS—Seropositivity, Communication & Gender; GIV—Incentive Life Group; GRAB—Asa Branca Resistance Group; Group Pela Vidda, Rio de Janeiro; Group Pela Vidda, São Paulo; IDEC – Brazilian Institute for Consumers Protection; INESC - Institute for Socioeconomic Studies; MSF - Doctors Without Borders, Projeto Esperança de São Miguel Paulista; RNP+/MA—Network of People Living with HIV/AIDS, Maranhão.

1. Introductory Remarks

The Overmundo Institute and GTPI fully subscribe to the criticism directed at the Special 301 process by the international access to medicines and access to knowledge communities.

Special 301 was established to unilaterally serve the interests of IP rightsholders in ways that are abusive and unbalanced toward broader public interests. It has been used, year after year, to pressure foreign states into adopting IPR standards and enforcement practices that are well above the minimum levels required by TRIPS, while undermining these states' sovereignty in implementing legislation that makes use of the flexibilities contained in the agreement. Substantially, therefore, the Special 301 Report has consistently sidestepped US commitments under the *Doha Declaration on*

TRIPS and Public Health and *WIPO's Development Agenda*.

Recommendation 45 of the Development Agenda, in particular, bears transcription:

> *To approach intellectual property enforcement in the context of broader societal interests and especially development-oriented concerns, with a view that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations", in accordance with Article 7 of the TRIPS Agreement.*

Article 7 of TRIPS, in turn, establishes that:

> *The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.*

Both Recommendation 45 of WIPO's Development Agenda and article 7 of TRIPS call for a balance in IP enforcement that has been entirely absent in past Special 301 reports. Not only the reports are inspired by a clearly maximalist IP agenda—with little concern to developing countries' particular needs or the welfare of IP users—but the entire 301 process is driven by industry demands and informed by data provided by industry. We at Overmundo and GTPI expect that the recent increase in public interest NGO participation in the 301 process motivates the USTR to take a more nuanced view of the enforcement debate.

Threats of unilateral economic sanctions are always looming in the background when the Special 301 lists are published, even though authorization by WTO's DSB would be necessary for sanctions to ever be applied. Special 301 should not be used by the US to pressure other countries to implement TRIPS-plus standards; it should not be used to bypass WTO procedures; and it should steer away from its origins as a tool for aggressive unilateralism.

Furthermore, the evidentiary standards under which a country is evaluated by the USTR for inclusion in the Special 301 lists are notoriously low. The *Media Piracy in Emerging Economies* report, which SSRC is publishing in the first quarter of 2011,[1] highlights a number of problems on research carried out or commissioned by the copyright industries, used by the IIPA to determine rates of piracy and the value of losses attributed to piracy. The numbers presented by the IIPA in its yearly reports should be put under rigorous evaluation before they are considered as basis for a country's placement in any of the Special 301 lists.

Proposals presented by the Brazilian and Pakistani governments during the 5th meeting of WIPO's Advisory Committee on Enforcement[2] both highlight the need for research on media piracy that is more rigorous from an academic standpoint, less driven by the agenda of industry groups, and better able to serve as analytical tools for an enforcement debate effectively framed by Recommendation 45 of WIPO's Development Agenda. The proposals also emphasize the need to consider that different countries have different social and economic contexts, which demand equally differentiated responses.

Skepticism regarding methodology and adequacy of industry-sponsored research is now so common and widespread that its main audience, the USTR, should catch up with the criticism. The April 2010 GAO report *Intellectual Property: Observations on Efforts to Quantify the Economic Effects of Counterfeit and Pirated Goods*[3], and SSRC's *Media Piracy in Emerging Economies* should put a definitive end to the era of unaccountability of industry sponsored research. From now on, the

1 To be made available at: http://piracy.ssrc.org
2 Available as annexes to the Conclusions of the Chair, downloadable at: http://www.wipo.int/meetings/en/details.jsp?meeting_id=17445
3 http://www.gao.gov/products/GAO-10-423

USTR should make a better effort to transparently base its decisions on research that is empirically grounded, methodologically sound, and correctly weighed against bias.

The same is true when taking into consideration IIPA's qualitative accounts of piracy in the countries covered in the organization's Special 301 reports. USTR's history of compliance with industry requests is usually translated into short descriptions of countries' supposed lack of respect for American IP that are vague and generic, with little concern for matters of balance and individual countries' specific social and economic contexts, following a "one-size-fits-all" approach that is in stark contrast with WIPO's Development Agenda. USTR should thoroughly fact check and analyze industry's qualitative reporting, and give equal voice to the submissions of other governments and public interest NGOs.

The government of Brazil, as reflected by Note to Press 205, from 05.01.2007, has made it clear that "the maintenance of [Brazil] in any 'Special 301' list does not correspond to the intellectual property protection standards present in [its] national legislation, fully compatible with the compromises taken by Brazil in multilateral fora such as the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO)."[4]

Overmundo and GTPI would like to stress that both organizations agree with the Brazilian government, and that the analysis provided in this submission is strictly for the purpose of highlighting the flaws of previous 301 reports. The WIPO and the WTO are the proper fora to continue this conversation, not Special 301. ACTA, in addition, is viewed by most developing countries and their respective civil society organizations as an initiative that lacks transparency and proper consideration to development issues. It is an obvious attempt at forum shopping that should not be allowed to prosper, given that appropriate multilateral fora already exist.

4 http://www.itamaraty.gov.br/sala-de-imprensa/notas-a-imprensa/2007/01/reclassificacao-do-brasil-nas-listas-da-special/?searchterm=special%20301

2. Piracy and Counterfeiting

In the 2010 Special 301 report, the USTR commends Brazil for continued "commitment to fighting counterfeiting and piracy and to strengthening its enforcement efforts," but still complains about "significant levels of piracy and counterfeiting." Despite what is described as an optimistic scenario in terms of cooperation by government and law enforcement authorities, the USTR presents a number of concerns that would justify the maintenance of Brazil on the Watch List. The optimism, in part, derives from the creation of the National Council on Combating Piracy and Intellectual Property Crimes in 2004. The Council was created after strong pressure was delivered in the form of a GSP review by the US— petitioned by the IIPA in 2000, initiated by the USTR in 2001, concluded in 2006—and the inclusion of Brazil on the Priority Watch List in 2002. The Council's public-private composition ensured that some of industry's demands were efficiently channeled into the government, and that greater coordination among law enforcement agencies was achieved at the federal level. It also resulted in industry antipiracy/anticounterfeiting discourse being uncritically adopted by Brazilian government at the domestic level.

Overmundo is highly critical of both the National Council on Combating Piracy and its National Plan on Combating Piracy. Both go farther than they what is acceptable in terms of enforcement policy based on public resources, especially if we are to consider Article 7 of TRIPS and Recommendation 45 of WIPO's Development Agenda. Brazil's strong, pro-development positions in international fora have not been translated into a balanced enforcement debate domestically, and Brazil has arguably done more than it was supposed to do by actively complying with industry demands. Still, according to the 2010 Special 301 report, "concerns remain over border enforcement and the lack of expeditious and deterrent sentences," as well as book piracy and Internet piracy.

Brazil is also criticized for not signing into the WIPO Internet Treaties. In fact, these treaties have much narrower adoption, if compared to other WIPO sponsored treaties, such as the Berne Convention. WCT was signed by 88 countries and WPPT was signed by 87 countries. The Brazilian government has given clear signs that it does not intend to sign into the Internet treaties, and this

reflects a sovereign decision by the Brazilian state that should never be used as a criterion for Special 301 listing.

Hard goods piracy and counterfeiting

Brazil is operating at full capacity to combat hard goods piracy and counterfeiting, burning away resources that would be better spent in the prevention of crimes that are considerably more serious than copyright or trademark infringement. Civil, not criminal enforcement of IPR should be emphasized. It is irresponsible to request for intellectual property crimes to be met with criminal prosecution and imprisonment when the nature of the offenses does not justify it; criminal prosecution should be reserved for offenses that are actually serious, such as murder, robbery and rape. Infrastructure problems, additionally, make it sure that Brazilian prisons and courts will never be able to the meet demand established by an all-criminalizing approach. Brazil's prisons are overcrowded,[5] and the Brazilian judicial system is operating over its capacities.[6]

If, as the IIPA claimed in its 2010 Special 301 report regarding Brazil, a "reform of the judiciary" is needed to effectively solve IP enforcement issues, it is important to stress that TRIPS does not require any signatory country to establish a judicial system for IP enforcement that is different from that for the enforcement of law in general, nor obligates signatory countries to distribute enforcement resources differently between IP crimes and crimes in general. This is what the language of TRIPS 41.5 determines:

> *It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of*

5 According to official data, in December 2009, Brazil had a total prison population of 473626 prisoners (all imprisonment regimes included), for a system designed for 294684. See: http://portal.mj.gov.br/etica/data/Pages/MJD574E9CEITEMIDC37B2AE94C6840068B1624D28407509CPTBRNN.htm

6 Brazilian state courts of appeal had an average workload of 2180 cases per judge in 2009 (Conselho Nacional de Justiça, "Justiça em Números 2009: Indicadores do Poder Judiciário, Justiça Estadual," p. 133). At the lower level, state courts had an average workload of 2931 cases per judge (ibid., p. 228).

> *Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.*

It also bears repeating that criminal law has been a fundamentally inadequate tool to deal with piracy and counterfeiting. The pricing and access issues that SSRC's *Media Piracy in Emerging Economies* report describes in detail should not be met with a criminal response, but with creative, consumer-friendly business models. A criminalizing approach necessarily leads to operational deficits in the criminal justice system, and these will be impossible to solve in developing countries, if we are follow industry demands. Industry and the USTR should take into consideration developing and least developed countries' social and economic contexts, and operate within Article 7 of TRIPS. The use of the criminal justice system should be parsimonious; a few industry-sponsored bill currently in Brazilian Congress are not cause for celebration, but concern, procedurally and substantially. Bills 2079/2003, 1807/2007, 5057/2009, 5535/2009, 5908/2009, and, more recently 8052/11[7], represent significant problems both in terms of their fundamental inadequacy, and for introducing flaws into Brazilian procedural law, to the point of compromising due process in IP-related cases.

Internet and book piracy

The context in Brazil is considerably more complex for book and Internet piracy than it is for hard goods piracy and counterfeiting, and involves policy related to public education and the access to communications and knowledge. To frame the broad set of issues that relate to book and Internet piracy simply in terms of IP enforcement is to miss a wide range of policy controversies. These debates should not be strictly subsumed to the enforcement agenda. They demand an all-inclusive, democratic, transparent conversation, and an approach that is as far distant as possible from sending police forces into Brazilian universities, which is how the ABDR, the Brazilian Reprographic Rights Association, has been dealing with the issue. This type of action should not be tolerated in any country with an

7 http://www.camara.gov.br/internet/sileg/Prop_Detalhe.asp?id=148171

educational deficit such as Brazil, much more so when the alternative business models so far proposed tend to follow blatantly anti-consumer lines, and are unable to meet Brazil's development needs.

Numbers for losses for the US publishing industry, additionally, have been stuck at a suspicious US$ 18 million since 2004, which is a sign that not a lot of research is going on—if, to begin with, there ever was any reliable research. For Brazilian losses, despite much noise made by ABDR, interviews carried out for the *Media Piracy in Emerging Economies* report revealed that no new research has been conducted since 2002, and even with regards to the 2002 study, ABDR will not disclose detailed methodology or raw data. As we conclude in the SSRC report, concerning publishing industry research in Brazil, "The published data is inadequate to understanding the scope and significance of book copying in Brazil and should not be credited in discussions of either enforcement or the publishing industry's numerous business-model problems in Brazil."

Internet piracy is an entirely different matter. There is little hope that Brazil will ever adopt a graduated response system to deal with file sharing over the Internet. This is clear from an attempt by Deputy Bispo Gê to introduce legislation similar to France's HADOPI in 2009, which failed due to massive public outcry. The ISP Working Group—initiated in 2008 under the authority of the Ministry of Culture, as part of a National Council on Combating Piracy initiative—has discussed the possibility of three strikes measures based on the contracts users sign with their ISPs. This proposal has been shrouded in language that proposes “cooperation” between ISPs and rightsholders, in ways that clearly point toward a graduated response system. Trying to implement graduated response through contractual law may prove harder than expected, mainly because of a number of provisions in Brazil's Consumer Rights Code. It would also be completely at odds with the current Internet policy debate in Brazil.

Brazil is at the moment working on its National Broadband Plan, as well as the results of a public consultation process for an Internet regulation bill, the Marco Civil. The Marco Civil was wrapped in May 2010, and will be sent to Congress in 2011. Marco Civil is driven by a user-rights perspective, while at the same time providing for strong architectural protection for the Internet as an environment that enables access to information and culture. The policy considerations here are much

broader than that of the enforcement agenda, and industry will have to provide good arguments pro or against the provisions of Marco Civil in Brazilian Congress, as opposed to insist on the image of Brazil as a digital pirate nation. Special 301 unfortunately remains oblivious of the rich Internet regulation debate in Brazil, and frames an universe of extremely broad issues through the narrow lens of IP enforcement.

3. Intellectual Property and Health Policy

Some of the comments made by the USTR regarding Brazil's patent and health policy deserve direct response. Bolded text refers to USTR's 2010 Special 301 Report.

"**Patent concerns remain, including about the scope of patentability [...]" (p. 29)**

In line with the TRIPS Agreement, the Brazilian Industrial Property Law allows patents to be granted for inventions, whether products or processes, in all fields of technology, provided that technical requirements are observed (novelty, inventive step and industrial application). The Brazilian legislator went even further by creating some TRIPS plus measures such as the *pipeline* patents, with deep impact on the public health and access to medicines in the country.

Nonetheless, IP rights were subordinated to political and social interests by the Brazilian Constitution of 1988 (Article 5, XXIX). Such condition totally agrees with the TRIPS Agreement, which allows its Members to "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" (Article 8), such as the pharmaceutical one. This right was reassured by *WTO's Doha Declaration on the TRIPS Agreement and Public Health*. TRIPS also allows countries to exclude from patentability inventions in order to preserve human life and health (Art. 27.2).

Taking that into consideration, the Interministerial Group on Intellectual Property (GIPI), which was established under the Brazilian Ministry of Development, Industry and Foreign Trade with the

purpose of reconciling the positions of the Executive's organs on IP issues, decided that patent applications for polymorphs and second-use inventions should be rejected, considering their disagreement with public and economic development interests of the Brazilian government[8]. Besides GIPI's decision there are other relevant arguments to deny patent applications in such cases.

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. For this reason, 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.[9] recommends that countries should not grant patent 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

8 http://www.mdic.gov.br/arquivos/dwnl_1229696044.pdf

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

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 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 the Brazilian law.

"**Patent concerns remain, including (…) the uncertain role of ANVISA, Brazil's sanitary regulatory agency, in examination of certain patent applications." (p. 29)**

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,[10] *the grant of patents to pharmaceutical products and processes* ***will depend*** *on the previous approval of the National Health Surveillance Agency - ANVISA."* (highlighted). This requirement is due to the importance of medicines to the realization of the human right to health and the implementation of public health policies.

Given the impact of patents in the public health system and access to medicines in developing countries, it its important that only products that really fulfill all the patentability requirements be protected by patents. Therefore, the Brazilian legislators decided to give the best technical analyses possible to patents filled in the pharmaceutical sector, what is materialized by an expected partnership between ANVISA and INPI (Brazilian Patent Office). This mechanism 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.[11]

10 Law nº. 9.279/1996, Article 229-C. Available in English at INPI's website: http://www.inpi.gov.br/menu-esquerdo/patente/pasta_legislacao/legislacao-outros-idiomas/lei_9279_ingles_html/

11 WT/DS114/R, March, 17th, 2000, paragraph 7.92.

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. In many occasions, 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.

An important study developed by ANVISA analyzes qualitatively the decisions taken in the context of prior consent from 2001 to 2009[12] and brings some evidence to be observed. These numbers demonstrate the importance of ANVISA's prior consent in the process of granting patents in the pharmaceutical area, once it avoided improper granting of patents. In that period, ANVISA analyzed 1,346 patent applications, out of which 988 were given prior consent, 119 were not given prior consent, 90 were denied by INPI after ANVISA's participation in the process and 149 are in other situations (such as waiting for ANVISA's analyzes or waiting for the applicant to answer requirements made by the agency).

The main reasons for ANVISA's denial of prior consent are shown in the table below:

Main reason for denial of ANVISA's prior consent	*n.*	*%*
Lack of novelty (total or partial)	57	47.9%
Lack of inventive step	27	22.7%
Lack of sufficient description	19	16%
Product of nature	7	5,9%
Object not defined	6	5%
Late modifications on the application	2	1,7%
Application file outside the time limit	1	0,8%
Total	119	100%

12 ANVISA, Coordination of Intellectual Property – COOPI/GGMED/ANVISA. Technical note on problems related to pharmaceutical patent claims.

It is important to stress that ANVISA's analysis occurs only after the patent application was already analyzed and approved by INPI. According to the mentioned study ANVISA's participation on the analyzes of pharmaceutical patent applications, in addition to preventing the granting of numerous undeserved patents, also corrected dozens of inaccuracies in applications that in INPI's view would be ready for approval. In those cases, the granting of the patents could have caused a great harm to the public programs of distribution of the medicine and to consumers in general, since the patent could be used to stifle competition in the supply of this product.

For that reason, 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.[13]

"**Brazil also does not provide for the adequate protection against unfair commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval for pharmaceutical products." (p. 29)**

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 compliant with international obligations made in the Article 39.1 of the TRIPS Agreement that limits the protection of undisclosed information "*against unfair competition*

13 Final report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health, CIPIH/2006/1, p. 76.

as provided in Article 10bis 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. It considers that early entry of generic competition is likely to increase the affordability of medicines at the lowest possible price.

"**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. Accordingly, USTR will continue its close cooperation with the Department of Health and Human Services to ensure that public health challenges are addressed and the patent system is supported as a mechanism to promote research and innovation." (p. 13)**

As stated in the section "Intellectual Property and Health Policy" of the 2010 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." Last year, the US recognized the 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 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 Member States to adapt their national legislations 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 known products.

In that spirit, Brazilian legislators decided to include ANVISA in the processes of analyzing pharmaceutical patent applications in order to offer the best technical analyses possible for patent applications in the area and to mitigate the impact of patents on the public health system and access to medicines.

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

4. Conclusion

Overmundo, GTPI and the increasingly more active and alert Brazilian public interest civil society will keep close watch on legislative, judicial and administrative developments in Brazil to ensure that they do not sidestep the Brazilian Constitution and the international agreements signed by Brazil. Our submission to this year's Special 301, we expect, is a first step in a conversation that will prove to be

democratic, open to different points-of-view, more grounded on reliable empirical research, and acknowledging of the proper international, multilateral fora for IP controversies: the WIPO and the WTO.

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