

DEPARTMENT OF TRADE AND INDUSTRY  
NATIONAL INTELLECTUAL PROPERTY POLICY, 2013

SUBMISSION BY

GTPI/Rebrip  
(Working Group on Intellectual Property from the Brazilian Network for the Integration of  
Peoples)

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## 1. Introduction

The Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/REBRIP, acronym in Portuguese), coordinated by the Brazilian Interdisciplinary AIDS Association (ABIA, acronym in Portuguese), is comprised of several Brazilian civil society organizations<sup>1</sup> 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 and on Global South.

We welcome the public consultation opened by the South Africa government related to draft an intellectual property policy. We expect that this important step represent a continuous commitment with transparency and open dialogue, which can certainly inspire other countries to become more accountable as regards to decisions relating to IP policies. Below, we address some of the main issues opened for discussions during the consultation process.

We also would like to acknowledge and congratulate the efforts made by South Africa Civil Society groups on the “Fix the Patents laws” campaign, which certainly was key to pave the way for such an important public consultation.

Recently in Brazil, the National Congress launched a high level study entitled “Brazil’s patent reform: Innovation towards national competitiveness” (available for download at: [http://bd.camara.gov.br/bd/bitstream/handle/bdcamara/14797/brazils\\_patent\\_reform.pdf?sequence=2](http://bd.camara.gov.br/bd/bitstream/handle/bdcamara/14797/brazils_patent_reform.pdf?sequence=2)), calling for a reform in our national patent in order to promote the public interest. The introduction chapter of this study contains references to the “Fix the patent laws” campaign in South Africa as an “evidence that we have a chance to build international momentum and re-address the patent policies in developing countries in order to better serve their local needs of access to medicines, technological innovation, and capacity-building”

This submission is aimed at strengthening this international momentum. We hope that the long-term experience of civil society groups and the experience in using TRIPS flexibilities in Brazil can be instructive to improve some of the elements present in the draft IP policy in South Africa.

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<sup>1</sup> Associação Brasileira Interdisciplinar de AIDS – ABIA; Conectas Direitos Humanos; Federação Nacional dos Farmacêuticos – FENAFAR; Grupo de Incentivo a Vida – GIV; Grupo de Apoio à Prevenção à AIDS-SP – GAPA-SP; Grupo de Apoio à Prevenção à AIDS-RS – GAPA-RS; GESTOS – Soropositividade, Comunicação & Gênero; Grupo de Resistência Asa Branca – GRAB; Grupo Pela Vida-SP; Grupo Pela Vida-RJ; Instituto Brasileiro de Defesa do Consumidor (IDEC); Projeto Esperança São Miguel Paulista – PROJESP; Rede Nacional de Pessoas Vivendo com HIV+ - Núcleo Maranhão.

## **2. The negative impact of pharmaceutical patents on the implementation of health related public policies and measures protective of the public interest**

As widely recognized by multinational agencies, the enforcement of intellectual property (IP) rules has had a negative impact on public health policies and access to essential medicines. Many medicines are just too expensive for patients or even governments to afford. One reason for this is the market monopoly granted to the originator company by a patent, which has hampered competition and scaled-up prices of life-saving medicines.

As a mean to minimize the negative impact of the patent system on access and development, countries have the right to adopt some measures protective of the public interest. The World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), the most relevant international treaty on intellectual property rules for pharmaceutical products, included a full range of permissible exceptions and protective measures, known as flexibilities. Especially in its article 8, in which its principles are established, the TRIPS Agreement defines:

1. 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, provided that such measures are consistent with the provisions of this Agreement.

In 2001, WTO member countries, including Brazil and South Africa, approved the Doha Declaration on the TRIPS Agreement and Public Health, which reinforces the right of countries to adopt measures to protect public health, in the following terms:

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

United Nations human rights officials and bodies<sup>2</sup> have repeatedly found that the globalization of intellectual property rights can only be squared with human rights if countries are permitted

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<sup>2</sup> See, for example, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, A/HRC/11/12, Paragraph 27, (2009); Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, A/63/263, Paragraph 63, (2008); Human Rights and Intellectual Property, Committee on Economic, Social and Cultural Rights [CESCR], E/C.12/2001/15, Paragraph 12, (2001); Report of the High Commissioner, The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, E/CN.4/Sub.2/2001/13, Paragraphs 27 and 28, (2001).

and encouraged to utilize the full scope of intellectual property protective measures provided for in the TRIPS Agreement to protect public health and promote access to medicines. Therefore, the UN recognized not only the right **but also the duty** of States to make full use of the TRIPS flexibilities to promote public health.

4. Recognizes that the Doha Ministerial Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health confirms that the Agreement does not and should not prevent States Members of the World Trade Organization from taking measures to protect public health and that the Declaration, while reiterating the commitment to the Agreement, affirms that it can and should be interpreted and implemented in a manner supportive of the rights of States Members of the World Trade Organization to protect public health and, in particular, to promote access to medicines for all; and further recognizes, in this connection, the right of States Members of the World Trade Organization to use, to the full, the provisions of the above-mentioned Agreement, which provide flexibility for this purpose; [UNITED NATIONS. A/HRC/RES/12/24. Paragraph 4. 2009]

At the time of its signature, the TRIPS Agreement was surrounded by promises of investments, technology transfers and greater innovation, none of which has been satisfactorily fulfilled in developing countries to date. Therefore, a growing number of countries are taking the view that the recognition of patents in the pharmaceutical industry was based on promises that have yet to be delivered. In reality, there is growing evidence that the patent system has strayed from its original purpose, and instead of driving genuine innovation it has served as an incentive for offensive patenting strategies that focus on trivial innovations used to stifle competition and raise the profits of patent-holding companies, based in developed countries. In this regard, a review of the patent law is inevitable in any country that takes the public interest seriously.

As discussions around how the patent law can be reformed to avoid over patenting of medicines and undeserved monopoly extension are improving, collaborations between countries need to be explored. By reforming its patent laws and making use of improved provisions, developing countries can send a very strong signal to each other on how to expand the policy space which is essential for access to medicines. Also, for all countries that have been struggling since the passage of the Doha Declaration on TRIPS and Public Health in 2001 to affirm their right to implement public health safeguards in their national laws, favourable conditions can be created as collaboration between patent law reform initiatives improve.

The WTO TRIPS Agreement brings standards of patent protection that has to be granted by all countries. However, it also leaves considerable room for each country to adopt a patent law according to their own reality and social and economic needs and current stage of technological development.

The World Health Organization (WHO) has urged its member countries “(2) to 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 (TRIPS)” (WORLD HEALTH ASSEMBLY. Intellectual property rights, innovation and public health. WHA56.27. Paragraph 2. 2003).

The UN Special Rapporteur on the right to health has addressed this subject in his report presented to the UN Human Rights Council in June 2009, in which is recommended that developing countries should include in their national legislation all of TRIPS flexibilities to promote access to medicines and remove all TRIPS-plus measures that hinder access. And specified what countries should do to enable the use of TRIPS flexibilities from a right to health perspective:

27. From a right to health perspective, developing countries and LDCs should be enabled to use TRIPS flexibilities. More particularly, their national laws should incorporate the flexibility to:

- (a) Make full use of the transition periods;
- (b) Define the criteria of patentability; (highlighted)
- (c) Issue compulsory licences and provide for government use;
- (d) Adopt the international exhaustion principle, to facilitate parallel importation;
- (e) Create limited exceptions to patent rights;
- (f) Allow for opposition and revocation procedures.

[Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover. A/HRC/11/12. 2009].

There is a wide range of measures compliant with the WTO TRIPS Agreement that can be used to improve public interest. By reviewing South Africa’s draft policy, we could notice that some of these measures were considered in the text. Nowadays, almost 20 years after the signature of the TRIPS Agreement, a country willing to reform its patent law can benefit from several analysis and debates developed at the multilateral level, as well as learn from other countries experiences what are the best practices when it comes to implementation and use of flexibilities. In this regard there is a general understanding that flexibilities used before a patent is granted can be much more cost-effective than those flexibilities used after a patent has been granted.

Type	Examples
<p><b>Preventative:</b></p> <p>Ensure that patents do not hinder access. Easier, faster, less politically sensitive</p>	<ul style="list-style-type: none"> <li>• <b>Exclusion from Patentability:</b> new use of known substances, methods, processes (Articles 27.2 and 27.3)</li> <li>• <b>Patentability Criteria:</b> Mitigate frivolous patents and “evergreening” opportunities. (Articles 1 and 27.1).</li> <li>• <b>Patent Opposition:</b> Pre-grant and post-grant</li> <li>• <b>Waiver for LDCs:</b> until 1 January 2016</li> </ul>
<p><b>Remedial:</b></p> <p>Preventative flexibilities cannot always be used</p>	<ul style="list-style-type: none"> <li>• <b>Compulsory Licences and Government Use Orders</b> (Article 31 (a) – (j))</li> <li>• <b>Compulsory Licences for Export</b> - WTO 30 August, 2003 Decision.</li> <li>• <b>Parallel Import</b> (Article 6)</li> <li>• <b>Exceptions:</b> Bolar, research and experiments, individual use (Article 30)</li> <li>• <b>National Competition Laws</b> to prevent IPR abuse and provide remedies (Articles 8.2, 31(k) and 40)</li> </ul>
<p><b>Enforcement:</b></p> <p>Part III TRIPS sets <b>minimum standards</b> for IPR enforcement.</p>	<ul style="list-style-type: none"> <li>• <b>No border measures</b> for suspected patent infringement (Article 51)</li> <li>• <b>No criminalization</b> of patent infringement (Part III, Section 5)</li> </ul>

Source: UNDP

Below, we will share some experiences in Brazil related to the use of some of those measures and the best way we believe they could be adopted by South African patent law, especially related to:

- substantive examination system and the participation of the health sector on the analyses of pharmaceutical patent application;
- patentability criteria;
- patent oppositions;
- compulsory license and government use.

### 3. Brazilian Patent Law and lessons learned on the use of TRIPS flexibilities in Brazil

Until 1996, intellectual property legislation in Brazil did not grant patents for pharmaceutical products and processes. Brazil could have used the transition period established by the TRIPS Agreement and have changed its patent law in the pharmaceutical sector only in 2005, but the new patent law was adopted in 1996. The new legislation had a great impact in the Brazilian public health system, overhauling the existing legal regime that permitted medicines to be produced locally at affordable prices. The new IP law put at risk the sustainability of national health policies. In 2005, the Brazilian Ministry of Health issued a report showing that the great increase on the prices of new antiretroviral drugs, under patent protection, was putting at risk the continuation of the public policy of universal access to ARV adopted in 1996.

The Brazilian Patent Law (LPI)<sup>3</sup> included some of the flexibilities of the TRIPS Agreement that are in the interest of public health. Other measures could also be adopted to improve the Brazilian patent law to better protect the public interest. That is the current debate around the Brazilian patent law reform mentioned above.

Below we will highlight some of the flexibilities already adopted in Brazil, some good results achieved through them and finally we will highlight some of the improvements in these provisions that have been discussed in Brazil in the scope of a patent law reform.

#### a) Bolar exception and experimental use

**Experimental Use** allows researchers to use patented inventions in their research for the purpose to better understand the invention. It is designed to encourage domestic technological development through utilizing disclosed information about the patent. Reverse engineering depends upon experimental use. Experimental use is permitted in Brazil by Article 43, II of the patent law. It represents one of the ways of striking a balance between the interests of the patent holder and national interests, as that it allows patented information to be used to promote domestic scientific and technological development. Scientific experimentation can be conducted by any research laboratory, either public or private.

**Bolar Exception** allows manufacturers of generic drugs to use a patented invention to obtain marketing approval—e.g. from public health authorities—without the permission of the patent owner and prior to patent expiration. The use of this flexibility has a twofold advantage for the country: in addition to promoting quicker entry of generic drugs into the market, it also facilitates research through the dissemination of information on the invention. Bolar exception was incorporated into the Brazilian patent law in 2001 through an amendment integrating item VII to Article 43.

Both provisions should be incorporated into South Africa's patent law in order to allow for a greater use of patented knowledge from a public interest perspective.

#### b) Patentability Criteria

One of the most important measures to protect public health is the possibility for countries to interpret the requirements for the grant of a patent in accordance with criteria established at national. The WTO TRIPS Agreement provides that an invention is patentable if it is new, has an inventive step and industrial application (art. 27.1). However, TRIPS does not establish the criteria for interpretation of these requirements, which are set by each country. From a public health perspective, the analysis criteria must be strict to prevent the granting of low quality patents, which only adds to restrict competition and access to health goods.

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<sup>3</sup> Available in English at the Brazilian patent office website: [http://www.inpi.gov.br/menusquerdo/patente/pasta\\_legislacao/legislacaooutros-idiomas/lei\\_9279\\_ingles.html/](http://www.inpi.gov.br/menusquerdo/patente/pasta_legislacao/legislacaooutros-idiomas/lei_9279_ingles.html/)

The TRIPS Agreement also allows exceptions to patentability, even if the patentability requirements are met (art. 27.2 and 27.3, TRIPS). Brazilian patent law establishes some cases that are not considered invention, and therefore are not patentable (art. 10) and also provides cases that can not be patented even though they are inventions (art. 18). The exceptions most relevant to public health are: (a) mere discoveries and therapeutic methods (art. 10, I and VIII) and (b) that which is contrary to public health (art. 18, I).

The interpretation that a country decides to give to patentability requirements is not only a technical decision, but a political decision. A broad interpretation can lead to a greater number of patents granted, while stricter criteria analysis can reduce this number. Considering the negative impact that the granting of a patent has on access to health goods, it is important to ensure that only genuine inventions are granted a patent.

The discussion around new uses and new forms of known products fall under this topic. Brazilian patent law does not allow some forms of patenting, as mere discoveries and therapeutic methods. The patents for new uses and new forms of already known substances could be classified into these categories and be rejected. However, the current examination guidelines adopted by Brazilian patent office, for example, enables the granting of such patents. The possibility of protecting new uses and new forms of known products facilitates the practice known as evergreening to the detriment of protection for real pharmaceutical innovations. Such patents can be classified as undeserved and abusive practices can be overcome by the means of strict patentability requirements, including the clarification of claims that cannot be granted a patent.

This issue is also being addressed by the current patent law reform debate happening in Brazil. Brazilian legislators understood that the law must clearly define that new uses and new forms of known products cannot be patented in Brazil. Some of the bills that are under analysis by the National Congress address this issue. Inspired by India law, one of the bill provides a list of claims that cannot be considered as innovations: salts, esters, polymorphs, metabolites, pure forms, the size of particles, isomers, mixture of isomers, complexes, combinations and other derivatives from a known substance. In GTPI's opinion, new forms of known substances should never be granted a patent, even if there is enhancement of efficacy, since it is impossible to analyze the effectiveness of the product in a patent application.

Therefore, we believe it is important for South Africa's patent law to be very clear on this issue to prevent the patenting of new uses and new forms of known substances.

Finally, patent offices guidelines must be aligned with the patentability criteria as outlined in the law and national policies. For this reason, it is important to ensure that patent offices act transparently and be always at the service of the national interest.

#### c) Public health sector analyses of pharmaceutical patent applications

In Brazil, the grant of a patent in the pharmaceutical area depends by law on the prior consent of ANVISA - National Agency for Sanitary Vigilance (Brazilian drug regulatory authority).



ANVISA's prior consent refers to the participation of Ministry of Health officials in the processes of analyzing pharmaceutical patent applications. According to Brazilian patent law (article 229-C), "the grant of patents to pharmaceutical products and processes will depend on the previous approval of the National Health Surveillance Agency -ANVISA".

ANVISA's prior consent is required in virtue of 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 medicine in developing countries, it is important that only products that really fulfill all the patentability requirements be granted. Therefore, Brazilian legislators decided to give the most accurate technical analyses possible to patents filled in the pharmaceutical sector. Such legislation allows ANVISA to work in partnership with INPI – National Institute of Industrial Property (Brazilian patent office).

A close collaboration between health regulatory authorities and patent offices in the examination of pharmaceutical patent applications has been identified by WHO and United Nations Conference on Trade and Development (UNCTAD) as a measure to enhance the examination of pharmaceutical patents from a public health perspective<sup>4</sup>.

Public health protective measures 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. Therefore, ANVISA's prior consent is a legitimate measure adopted by the Brazilian legislation to protect the public health since 2001 – twelve years ago. Many times, ANVISA's activity has been 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 and brings some evidence to be observed. It is important to remind that till 2012, ANVISA's analysis occurred only after the patent application was already analyzed by INPI and was ready for approval. 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:

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<sup>4</sup> *Guidelines for the examination of pharmaceutical patents: Developing a public health perspective, WHO-ICTSD-UNCTAD*, by Carlos Correa, Professor, University of Buenos Aires, January 2007, page 25.

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%

It is important to highlight that out of the 988 applications that received ANVISA's prior consent, about 40% only received ANVISA's approval after fulfilling some requests made by the agency. According to the study, most of these demands reduced the scope of claims, since part of the application lacked novelty, inventive step or were related to non patentable matter. In other cases, the demands were to clarify the object of protection or to enhance disclosure.

In other cases, ANVISA's participation in the process led INPI to change its view regarding the granting of the patent application, which would have been granted if it was not for ANVISA's participation. That happened in 90 cases. An emblematic case that shows how ANVISA's collaboration with INPI in the analyzes of pharmaceutical patent applications can protect public health is the case of docetaxel, an anti-mitotic chemotherapy medication used mainly for the treatment of breast, ovarian, and non-small cell lung cancer. INPI had first issued a decision for the granting of the patent filled by Aventis Pharma S/A<sup>5</sup>, but ANVISA denied its prior consent based on the lack of inventive step. INPI, after ANVISA's decision, changed its previous exam and denied the patent. The granting of this patent 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. Thanks to the participation of ANVISA, which brought the medicine to the public domain, the government could promote the local production of this drug through a partnership between national laboratories.<sup>6</sup>

In conclusion, ANVISA's participation on the analyzes of pharmaceutical patent applications, in addition to preventing the granting of numerous undeserved patents, also corrected dozens of

<sup>5</sup> Patent application n. PI9508789-3.

<sup>6</sup> Ministry of Health, 2012: <http://portalsaude.saude.gov.br/portalsaude/mobile/visualizarNoticia.cfm?cod=7952&tipo=noticia>

inaccuracies in applications that in INPI's view would be ready for approval, reducing or clarifying the scope of the object protected by the patent.

For that reason, WHO has identified the participation of public health authorities in the analyses of pharmaceutical patent applications as being a positive measure to protect public health since it helps to prevent concession of frivolous patents.<sup>7</sup>

Therefore, GTPI believes that the ANVISA "prior consent" model is very important to avoid the grant of undeserved patents that could harm access to medicines and should be followed by other countries. In order to avoid some misinterpretations of the role of the health sector analysis of the patent applications, it should be very clear on the patent law that the health authority is entitled to analyse the fulfillment of all the patentability requirements established by the patent law. This clarity can avoid misleading interpretations of the law as it was sometimes observed in Brazil.

#### d) Patent oppositions

The TRIPS Agreement references Members rights to have opposition proceedings in Article 62.4:

Procedures concerning the acquisition or maintenance of intellectual property rights and, where a Member's law provides for such procedures, administrative revocation and inter partes procedures such as *opposition*, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of Article 41 (emphasis added).

There is nothing in TRIPS otherwise referencing or limiting the adoption of opposition procedures – indeed TRIPS Article 62.1 allows Members to require certain procedures and formalities. The opposition system, both pre-grant and post-grant, is crucial to ensure that all relevant information is reviewed before a decision is made. By bringing through oppositions elements that may have gone unnoticed by the examiner, third parties such as academics, NGOs, companies, can help to improve the quality of the patent examination.

Brazilian IP law states that any person can question the validity of a patent already granted through the judicial channel (art. 56). At the administrative level, any person can also request nullity up to six month after the granting of the patent (art. 51). However the mechanisms currently in place to challenge a patent before it is granted are much more limited. For these situations, the Brazilian IP law adopted the model of "support to examination" (art. 31), according to which interested parties can present arguments and documents to the examiner, but the examiner is not obliged to take these information into account. This makes the participation of third parties at the pre-grant stage very fragile.

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<sup>7</sup> Final Report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health, CIPIH/2006/1,p. 134.

In the scope of ongoing discussions on how to improve the patent law, proposals have been made for Brazil to adopt a more reasonable opposition procedure that (1) allow pre-grant opposition by any interested party until the end of the patent examination, (2) allow the patent applicant to respond with 60 days of the publication of the opposition, (3) allow the commission of expert technical opinions, (4) require clarifications from the patent applicant, and (5) requires written and reasoned response to each filed opposition. Such procedures are desirable to add to the quality of patent examinations by securing inputs and analysis that can result in the deterrence and weeding out of unmeritorious patent applications.

In brief, opposition systems that allow pre and post grant oppositions, that allow the participation of any person, that don't impose restrictive timelines for opposition to be presented and that oblige patent offices to take arguments presented through opposition into account are beneficial to open up access to medicines and improve the quality of the patent system.

#### e) Parallel importation

According to WTO's definition<sup>8</sup>, **parallel importation** is when a product manufactured legally overseas is imported by another country without the consent of the patentee. The legal principle in this case is "exhaustion", the idea that once a patent holder has sold a batch of its product on the market, his/her patent rights to those specific goods are exhausted and he/she cannot prevent their resale to other countries. The TRIPS Agreement (article 6) confirms that none of its provisions, can be used to address the issue of exhaustion of intellectual property rights. The decision is entrusted to domestic law.

Parallel importation has been incorporated into Brazilian patent law, albeit only in a limited way, since its use is restricted to situations in which a compulsory license has been issued in virtue of abuse of economic power (art. 68, 4), or in cases of national emergency and public interest (art. 10, Decree 3.201/99). Brazil adopted the rule of national exhaustion of rights (art. 43, IV), which is the most restrictive, ensuring greater protection to patent holders. There is currently a law bill (PL 139/99) working its way through the National Congress to change the national exhaustion regime currently adopted by Brazilian patent law to the international exhaustion regime, which would allow for a more embracing incorporation of this measure. However, in GTPI's opinion the change currently proposed by Bill 139/99 is not the best possible implementation of the parallel importation provision. If approved, Bill 139/99 would allow any interested party to import the product where there is a lower price, only if the product has been placed on market by the patentee or with his/her consent. GTPI believes that parallel imports should not be limited to products placed on the market by the patentee or with his/her consent but should also be allowed to import generic products, provided they are legally available in the market in the country from which it is being imported.

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<sup>8</sup> World Trade Organization (WTO), Glossary and Fact sheet: TRIPS and pharmaceutical patents – obligations and exceptions.

Parallel importation is an extremely crucial mechanism for policies related to access to medicines, since it allows the importation of medicines from wherever they are sold at the lowest price. Therefore, we encourage South Africa to adopt the most comprehensive interpretation of this measure in order to maximize its benefits to access to medicines.

#### e) Compulsory licensing and government use

According to WTO definition, **compulsory licence** is when a government issues a license to companies or individuals that are not the patent owners to manufacture, use, sell or import a product under patent protection without the consent of the patent holder. The TRIPS Agreement allows compulsory licensing as part of the Agreement's overall attempt to strike a balance between promoting access to existing drugs and advancing research and development of new drugs. Nevertheless, the term "compulsory licensing" does not actually appear in the TRIPS Agreement. Instead, it uses the phrase "other use without the authorization of the right holder".

Compulsory licensing has been incorporated by Brazilian legislation and can be issued for a number of reasons. Article 68 of Brazil's patent law stipulates that a patent shall be subject to compulsory licensing if its owner exercises the rights therein in an abusive manner or abuses economic power. The same article also establishes that a compulsory license may be granted when the patented product is not exploited inside Brazil or when the sale of the protected product fails to satisfy the needs of the market (the "local working" requirement). Compulsory licenses may also be issued in cases of dependent patents, under the terms provided for in Article 70 of the patent law. Finally, Article 71 states that a compulsory license may be issued in cases of national emergency or public interest declared by the Federal Executive Authorities. The grant of a compulsory license in case of national emergency or public interest is further regulated by a Presidential Directive issued in 1999 and improved in 2003 to increase governments power to take action.

In Brazil, the threat of compulsory licenses was initially the main strategy employed to pressure drug companies in price negotiations for ARV medications. Official pharmaceutical laboratories were able to provide the Ministry of Health with a credible threat of local production. Drug companies preferred to lower the price of their products rather than have them produced by Brazil's domestic industry. However, this negotiation strategy grew increasingly less effective and the prices achieved in later rounds were unsatisfactory. The average annual expenditure per patient in 2005 rose and this increase in costs put the sustainability of the National STD/AIDS Program at risk.

The use of compulsory licensing has been widely supported by Brazilian civil society as a means of countering the threat posed to the sustainability of the universal access policy by the high costs of medicines. The mechanism was used for the first time in Brazil in 2007, for the drug efavirenz. The cost per patient per year in Brazil had stood at US\$580 since 2003, while on the international market prices could be found that were three times as low. After lengthy negotiations with Merck, the only offer the company made was to reduce prices by 2%, which

was unacceptable. Brazil declared efavirenz to be of public interest in April and the compulsory license was issued in May 2007.

The price dropped from U\$ 580 to U\$ 158 when Brazil started to purchase the generic version of the drug produced in India, thanks to the issuance of the Compulsory Licence. Over five years, the savings following the compulsory license were around U\$ 103.600.000<sup>9</sup>. This compulsory license has illustrated the government's commitment to the sustainability of its policy of free access to HIV/AIDS treatment in a context where patented drugs are sold at exorbitant prices that are unaffordable for the vast majority of developing countries. Furthermore, the possibility that the government could, as it has indicated, make further use of compulsory licensing for other medicines is extremely positive, since it is a move to assure the sustainability of not only the National STD/AIDS Program, but also the entire public health system.

However, Brazilian patent law brings unnecessary limitations to the use of compulsory licenses, such as: 1) Article 68 – Defines that compulsory license may be granted when the patented product is not exploited inside Brazil, unless this production is economically impracticable. 2) Article 69 defines cases where a compulsory license could not be granted due to justification presented by the patent holder. Both limitations are being addressed by the ongoing patent law reform in Brazil aiming to remove the “economic impracticability” as a justification for not exploiting the patent in the country and to revoke article 69. GTPI support these changes because they allow for a more efficient use compulsory licenses.

**Government Use** is an authorization issued by a government for third parties to exploit the patented product exclusively in the public sector. In comparison to compulsory license, government use can be a simpler way to facilitate the use of generic versions of patented products in the public sector. The difference between compulsory licenses and government use is that the first one allows the exploitation of a patented product by third parties both in the public and private sectors, while the government use implies the exploitation exclusively in the public sector. This important flexibility has not been properly implemented in Brazil's legal framework. Government use is only allowed in case of a compulsory license previously issued for public interest or national emergency. Under the current patent law reform, there is a bill to fully adopt the government use as mechanism that is independent from compulsory license. This is an important reform that can improve the capacity of the government to overcome a patent barrier that is causing harm to public policies.

We believe that South Africa's patent law should fully incorporate the government use provision.

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<sup>9</sup> Source: Ministry of Health, 2012.

## **TRIPS-plus measures that have to be avoided**

Despite all the harm caused by the patent system on public health policies, both private companies and developed countries governments still push to increase the scope of intellectual property rights. It is important that South Africa does not incorporate on its patent law any TRIPS-plus measures. Below we highlight some of this measures and the Brazilian experience related to them.

### f) linkage

Linkage is a TRIPS-plus measure that aims to condition the market approval of a drug to the expiry of its patent. In practice, linkage between patents and drug market approval raises an additional barrier to the entrance of generic drug on the market, since the market approval process for a generic version of a drug can only begin after the expiry of the patent. In other words, it delays competition and amounts to a de facto extension of patent terms, which is against public health interests.

Linkage is not included in the Brazilian law. However, there has been attempts to include this TRIPS-plus provision at the National Congress. We believe that South Africa should not include provisions like this in its national legislation.

### g) Data exclusivity

The TRIPS Agreement requires countries that require the presentation of results of tests as a condition of approving the marketing of a new chemical entity for pharmaceutical or agricultural use shall protect these data against unfair commercial use (article 39.3). Thus, TRIPS does not requires the grant of an exclusive right over such data (data exclusivity), but only data protection. If an exclusivity right is granted for test data, this could result in additional regulatory hurdles for the marketing authorization of generic products.

Data exclusivity prevents the drug regulatory authority to grant market approval for a therapeutically equivalent generic version of a medicine based on the comparison of test results presented by the originator medicine. Therefore, generic producers that normally only have to demonstrate that their product is therapeutically equivalent to the original one, become obliged to carry out its own tests showing the safety and efficacy of the medicine. Such tests are expensive and unnecessary, since the originator company already performed them and the results are at the disposal of the regulatory authorities. The unnecessary repetition of clinical tests is also against ethical principles set for research with human beings (Helsinki Declaration). As result, generic producers either give up to register their products or need to offer it at higher prices to recover the expenditures with the clinical tests. Data exclusivity is completely different from patent protection, but gives a monopoly right even in the absence of a patent or after a patent term is over.

In Brazil, the legislation does not provide for data exclusivity for pharmaceutical products for human use. However, some companies are trying to obtain data exclusivity by filling judicial cases. In order to avoid that, there is a bill at analyses in the National Congress under the current patent law reform. We believe it is important for South Africa legislation to be clear that it will not grant exclusivity over test data necessary for the market approved of pharmaceutical products.

#### **4. Conclusion**

We, from Brazilian Civil Society Organizations, support and defend the sovereignty of Brazil and South Africa 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.

Despite all the analysis showing the lack of sustainability of this model based on patents, both private companies and developed countries governments still push to increase the scope of intellectual property rights, through legal actions and new trade agreements

By reforming patent laws, developing countries can prevent abuses and evidence even more the failures of the system. In the end, it is important to clarify that measures like making the patent examination more strict are not to confront companies that develop medicines, neither a way to discourage innovation. By the contrary, its a way of demanding the increasing of real innovation instead of questionable innovations, that rarely bring real benefits to the health of populations. This is the only way to evidence that there is a global innovation crisis. Instead of weakening our laws to hide this crisis, we must strengthen them in order to ensure that a much needed debate on a reform of the system based on patents to reward innovation finally happens.

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#### **5. More about GTPI/Rebrip**

The Working Group on Intellectual Property (GTPI), created in 2003 and since then coordinated by Abia (Brazilian Interdisciplinary Aids Association), became the only group in Brazil advocating for a public interest perspective in the field of access to medicines and IP – with focus on collective actions and resistance to the granting of undeserved pharmaceutical patents. The core of GTPI's mandate is to work for expanded access to Aids drugs as a way to promote the rights of PLHIV and to defend the right to health.

The creation of GTPI, composed by several civil society organizations, including human rights, HIV/Aids and consumers rights NGOs, as well as researches and social activists, was an



important step to strengthen civil society ability to follow-up IP related decisions and highlight the risks to the sustainability of Brazilian response to Aids.

In order to secure the sustainability of the Brazilian Aids program, which provides universal treatment with Antiretroviral drugs (ARVs) to more than 300,000 people today, GTPI has taken several actions based on the existing legal framework providing for public health safeguards within the IP system. Some examples are:

Drug	Problem	GTPI's actions	Outcomes
Efavirenz  Used by more than 80,000 people	In 2006, the patent holder was charging high prices in Brazil and refusing major price reductions	Push for the use of compulsory license	Compulsory License issued, enabling local production  Price reduction: From U\$ 580 to U\$ 158,00 per patient/year
Lopinavir/ritonavir  Used by more than 50,000 people	In 2005, this drug represented 30% of the National Aids Program expenditures on medicines. The government officially declared that the sustainability of the program was at risk.	Pioneer collective lawsuit (Civil Public Action) asking for a compulsory license before Brazil had ever emitted that type of license for any other drug  Patent opposition to avoid monopoly extension	The civil Public Action still under judgment  One patent application that would extend the monopoly was rejected
Tenofovir  Used by more than 60,000	Undue monopoly situation	Two patent oppositions to avoid monopoly situation	Rejection of the patents, enabling local production  Price reduction: From U\$

people			1368,00 to U\$ 807 per patient/year
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Also, GTPI has taken a case to the highest level of the Brazilian judiciary by questioning the granting of 1,182 patents, most of them for drugs, done by means of a mechanism called pipeline, which is a clear example of a harmful provision unnecessarily adopted in Brazil's IP law.

All these actions were complemented by the mobilization of public opinion through publications, articles published on important vehicles and trainings provided for individuals and organizations.

GTPI's experience also relies on a strong collaboration with civil society groups from the global south. Some examples are: A patent opposition for the drug tenofovir filled by GTPI in India, together with a local NGO; a complaint presented jointly with groups from Colombia, Peru and Ecuador to the Permanent Court of the Peoples and a publication organized by GTPI that brings landmark cases of civil society struggle for access to medicines in Brazil, Colombia, China, India and Thailand.