



## Comparative study between Brazil, China and India on the usage of compulsory licenses for HIV patented medication

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### *Abstract:*

*In a globalized world there is a growing investment in research and technological innovation together with an eminent need to implement a more specific international document on trade related to intellectual property. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) arose in, therefore, as an attempt to fulfill the gap of the GATT multilateral trading system on the issue, but certain flexibilities can be found as well as be subject to controversies, such as compulsory licensing.*

*An important bargaining tool for the pharmaceutical industry in particular for developing countries, it has been approached differently by Brazil, India and China. Brazil has issued compulsory licensing one for public domestic consumption, India has used several times, which also includes for exports. Indian's aggressive approach has resulted into WTO dispute resolution, which is still ongoing. Finally China, which has not issued compulsory licensing, yet has adopted a least proactive stance on the matter.*

*The three nation's positioning over compulsory licensing is the reflection of their internal needs to combat Human immunodeficiency virus epidemic, and other severe diseases. The linkage between domestic laws, health care and social policies and programs are the driven force to determine their international attitude. As the three governments have applied different focused differently in the three fields, a mutual cooperation approach is paramount for combating HIV epidemic.*

**Keywords:** Brazil, China, India, TRIPS, Antivirals, Compulsory Licensing

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## **GLOSSARY**

### ***Voluntary licenses***

*Voluntary licensing arrangements between a patent holder and another party in a country, or serving the country's market, may afford opportunities for significant cost-containment. As with negotiated discounts, the benefits of voluntary licensing arrangements depend crucially on the terms of the licence.*

### ***Compulsory licenses (non-voluntary licenses)***

*Compulsory licenses allow third parties to use an invention without the patent holder's consent. For example, local pharmaceutical companies may obtain compulsory licenses to produce generic versions of patented medicines or to import generic versions of medicines from foreign manufacturers.*

### ***Parallel Imports***

*When a product made legally (i.e. not pirated) abroad is imported without the permission of the intellectual property right-holder (e.g. the trademark or patent owner). Some countries allow this, others do not.*

### ***Generic drugs***

*A generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product that is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights.*

In a globalized world insofar there is a growing investment in research and technological innovation, *vis-à-vis* an eminent need to implement a more specific international document on intellectual property trading. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) arose, therefore, as an attempt to fulfill the gaps of exiting international documents on the issue.

The TRIPS resulted from the Uruguay Round as an integrated part of the WTO system, being nowadays the most current international legal framework to regulate Intellectual Property Rights trading<sup>2</sup>. It lays down basic standards of intellectual property protection and obligations supported by the Berne and Paris Conventions; enforces and establishes general principles applicable to all IPR enforcement procedure including domestic procedures; and settles disputes

through the World Trade Organization's dispute settlement understanding system<sup>3</sup>.

According to the author Sarah M. Ford, "although TRIPs incorporates portions of the Paris Convention, the Berne Convention, the Rome Convention, and the Treaty on Intellectual Property in Respect of Integrated Circuits, the patent provisions are notably new to international intellectual property law."<sup>4</sup> The TRIPS has indeed came into force in order to establish guidelines on Intellectual Property, somewhat differently from other international legislation, as it will be discussed further in the next chapters.

Amid deadlock of the Paris Convention revision, The Agreement on

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<sup>2</sup> According to the WTO on The TRIPS Agreement for Pharmaceuticals, the negotiations lasted for 3 years to the refusal of developing countries. For them, there were two potential benefits in negotiating the TRIPs: trade-offs and the multilateral system for dispute settlement

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<sup>3</sup> TRIPS came to reinforce the WTO commitments, which include tightening of rules on intellectual property, tariff concessions and market access of service suppliers engaging in this case, the distribution of pharmaceuticals related products.

<sup>4</sup> FORD, Sara M. "Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents." American University International Law Review, Volume 15, Issue 4, 2000. Available at: <<http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1278&context=auilr>>. Accessed: 30 Aug. 2014.

Trade-Related Aspects of Intellectual Property Rights was subject of controversies between developed and least developing countries, through which the key point of divergence was its implementation<sup>5</sup>.

After several years of negotiations, and strong pressure from developed nations, the deadline for implementation finally defined and divided into two: for developed and developing (or least developing) nations<sup>6</sup>. The necessity from the developing countries to implement domestic legislations and regulations was crucial for the WTO to provide them with 10 years (from 1995) to apply the TRIPS agreement entirely<sup>7</sup>. Brazil, for instance, fully implemented the TRIPS in 1996 with the advent of the newly promulgated 1996 Patent law, while India

and China implemented the TRIPS gradually<sup>8</sup>.

The pharmaceutical industry is one of the key fields that posed certain difficulty to the TRIPS implementation, due to costs of investments for technology and R&D as well as the high risks involved. Before the TRIPS, patent protection as a whole was still an underdeveloped area in several countries<sup>9</sup>. Historically, most of the patent holders are located in developed countries, not in the developing ones.

In order to provide a better comprehension on the existing lacunas in the TRIPS, a deep study of the compulsory licensing will be done in the next sections. Subject of controversy, compulsory licensing became an important bargaining tool for the

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<sup>5</sup> Brazil and India strongly opposed the TRIPS due to the fact that it reflects and supports the needs of developing countries, not the developed ones. An agreement was finally reached due to strong pressure from the United States, European Union and Japan.

<sup>6</sup> TRIPS provisions on copyright were mostly adapted from the Berne Convention for the Protection of Literary and Artistic Works and many of its trademark and patent provisions were based on the Paris Convention for the Protection of Industrial Property.

<sup>7</sup> Extensions to the TRIPS implementation can be extended to the years 2013 and 2021 according to the World Trade Organization document. The extension is considered as one of the WTO's flexibilities. See: The World Trade Organization. "Least developed countries' priority needs in intellectual property." Nov. 2012.

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<sup>8</sup> India enacted the TRIPS standards in 2005, while China only signed onto TRIPS in 2001. See: DESALVO, Lyndon. "First Among the BRICs: Brazil's Necessary Challenging of TRIPS." Carleton University. March, 2010. Available at: <<http://people.carleton.edu/~amontero/Lyndon%20DeSalvo.pdf>>. Accessed: 30 Aug. 2014.

<sup>9</sup> Data from the WTO specifies that 50 countries did not grant patent protection for pharmaceutical products; this included a number of developed countries, such as Portugal and Spain, as well as many developing countries, for instance Brazil, India, Mexico and Egypt. India, for instance, for 30 years did not recognize patents for pharmaceuticals before 2005 even with the Patents Act from 1970.

pharmaceutical industry in particular for developing countries.

The Paris Convention of 1883, article 5A (2) brings that:

## **Compulsory Licensing**

According to the World Trade Organization, compulsory licensing is the authorization given by a judicial or administrative authority to a third party for the use of a patented invention, without the consent of the patentee, on various grounds of general and public interest such as lack or absence of working, public health, anticompetitive practices, emergency, national defense. The individual or legal entity that was granted with the compulsory licensing does not need to seek for the rights holder's consent, but the payment of the rights holder thorough fee or royalty for the license is deemed compulsory. (Correa, 2000)

Compulsory licensing (or non-voluntary licensing) is a legal measure laid out in the main international documents such as the Paris Convention of 1883, the Berne Convention and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 31 on the "Use without authorization of the right holder".

Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.<sup>10</sup>

Berne Convention, Article 11bis(2) states that:

It shall be a matter for legislation in the country of the Union to determine the conditions under which the rights mentioned in the preceding paragraph may be exercised, but these conditions shall apply only in the countries where they have been prescribed. They shall not in any circumstances be prejudicial to the moral rights of the author, nor to his right to obtain equitable remuneration which, in the absence of agreement, shall be fixed by competent authority.<sup>11</sup>

Both the Paris Convention and the Berne Convention state the right of use of the

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<sup>10</sup> World Intellectual Property Organization. Paris Convention for the Protection of Industrial Property, 1883. Available at: <[http://www.wipo.int/treaties/en/ip/paris/trtdocs\\_wo020.html](http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html)>. Accessed: 25 Oct. 2014.

<sup>11</sup> World Intellectual Property Organization. Berne Convention for the Protection of Literary and Artistic works. 1886. Available at: <[http://www.wipo.int/treaties/en/ip/berne/trtdocs\\_wo001.html](http://www.wipo.int/treaties/en/ip/berne/trtdocs_wo001.html)>. Accessed: 30 Aug. 2014.

compulsory licensing through domestic regulations. The Paris Conventions goes beyond by mentioning the prevention of abuses. The Paris Convention reveals that a compulsory licensing is a tool against abuses from exclusive rights, while the Bern Convention emphasizes the safeguard of the moral rights of author, who might receive monetary remuneration in case compulsory licensing is issued. Both Conventions do not provide further guidance.

Yet, the term compulsory licensing cannot be found in TRIPS document, but the Article 31 regulates over the ‘use without authorization of the right holder’, which many highlight as being synonyms. The TRIPS sets forth a series of guidelines member nations shall respect prior to implementing compulsory licenses<sup>12</sup>.

TRIPS, Article 31:

(b) ... In the case of public non-commercial use, where the government

or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.<sup>13</sup>

*A priori*, the right of issuing compulsory licenses is allowed by all of the three international documents, however, it continues to be a widely rhetoric issue due to the lack of full and integrated regulation. Much is still relied on domestic laws to determine in which conditions it can be applied. One may conclude that certainly the TRIPS did not fulfill the gaps from the Berne and Paris Conventions.

In order to discuss further the lacunas, in 2011 the WTO members examined forms of compulsory licensing practice in the pharmaceutical industry, which resulted on the Doha Declaration on the TRIPS Agreement and Public Health. For the WTO,

“the TRIPS Agreement does not and should not prevent Members from taking

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<sup>12</sup> FORD, Sara M.. “Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents.” *American University International Law Review*, Volume 15, Issue 4, 2000. Available at: <<http://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1278&context=auilr>>. Accessed: 30 Aug. 2014.

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<sup>13</sup> World Trade Organization. **Uruguay Round Agreement: TRIPS Trade-Related Aspects of Intellectual Property Rights**, 1994. Available at: <[http://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_01\\_e.htm](http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm)>. Accessed: 25 Oct. 2014.

measures to protect public health [...]including the right to grant compulsory licenses and the freedom to determine the grounds upon which licenses are granted, the right to determine what constitutes a national emergency and circumstances of extreme urgency, and the freedom to establish the regime of exhaustion of intellectual property rights”.<sup>14</sup>

The Doha Declaration was elaborated amid discussions and impasses on more effective terms and deadlines. During the negotiations, Europe and the United States pinpointed a series of requirements. While the United States tried to restrict its scope to HIV/AIDS, malaria, tuberculosis, and a small group of infectious diseases, the European Committee advocated liberalizing compulsory licensing to serious public health problems.(McGill, 2009)

The Declaration has provided, therefore, with a mechanism, which waives for both importing and exporting for countries

with manufacturing capacity. However, it is necessary to notify the TRIPS Council *prima facie*, demonstrate insufficient manufacturing capacity, indicate willingness to issue compulsory licensing, provide the terms of the exports such as destination, quantity and duration, and label products.<sup>15</sup>

The Doha Declaration reinforces, indeed, the right of issuing compulsory licenses in the circumstances of national emergency and extreme urgency. The new asymmetric element between the TRIPS and the Doha Declaration is the flexibility to the export of generic drugs, while the TRIPS requires that compulsory licenses shall be issued predominantly for the supply of the domestic market in the license-granting member, or in other words, for public non-commercial use and non-exporting reasons<sup>16</sup>.

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<sup>14</sup> World Trade Organization: 2007 NEWS ITEMS. “TRIPS and Public Health: Canada is first to notify compulsory license to export generic drug. October 2007.” Available at: <[http://www.wto.org/english/news\\_e/news07\\_e/trips\\_health\\_notif\\_oct07\\_e.htm](http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm)>. Accessed: 12 Sep. 2014.

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<sup>15</sup> World Trade Organization. **Doha WTO Ministerial 2001**: TRIPS WT/MIN(01)/Dec/2. Declaration on the TRIPS agreement and public health adopted on 14 November 2001. Available at: <[http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm)>. Accessed: 25 Oct. 2014.

<sup>16</sup> Despite of being issued mostly by developing countries for pharmaceutical products, such as Thailand, India and Brazil, developed countries such as Italy and Canada have also issued compulsory licensing in the past.

The positive aspect of the Declaration was the extension for the TRIPS implementation by developing nations until the year of 2016.<sup>17</sup> The main goal of the Declaration was to balance the needs of developing countries in terms of capabilities and technology. If on the one hand, the Doha Declaration brought new perspectives for the pharmaceutical industry, on the other hand, lack of details and reliance on the nations' determination of these terms.

### **Compulsory Licenses in Brazil**

Brazilian social programs focus on educational campaigns, prevention, as well as on the treatment for existing HIV cases. The government has invested on universal and free treatment to HIV/Aids infected individuals along the years in order to avoid worsening the epidemic like what is experienced in Africa.

The government provides a so-called "cocktail" of 20 different anti-retrovirus drugs (ARV) such as Atazanavir, Tenofovir and Enfuvirtide. Besides, more than 70 laboratories equipped to perform viral load and CD4 cell testing and 14 laboratories carry out genotypic resistance. (Smart, 2005)

The Brazilian anti-Aids program is considered a model response for the United Nations. Due to the success, the country has gained strong support internationally from international organizations, non-actors and developing nations as well as rendered international awards such as the Bill and Melinda Gates Foundation award,<sup>18</sup> and the current directorship of the UNAIDS.<sup>19</sup>

Brazil has worked in cooperation with several developing countries in Latin America, the Caribbean and Africa to combat of the spread of the disease globally through the International Cooperation Program for the Control and Prevention of HIV in

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<sup>17</sup> The Doha Declaration also extended the transition period for LDCs for implementation of the TRIPS obligations from 2006 to 2016. However, the extension is limited to the obligations under provisions in the TRIPS Agreement relating to patents and marketing rights, and data protection for pharmaceutical products.

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<sup>18</sup> In 2003 Brazil became the first nation to win the Bill and Melinda Gates Foundation award for having the best model response to AIDS, due to its innovative and successful treatment program, as well as a host of prevention policies.

<sup>19</sup> Dr. Luiz Loures was appointed Director of the Executive Office in 2009. Currently, he occupied the post of Deputy Executive Director, Programme, for UNAIDS and Assistant Secretary-General of the United Nations.



Developing Nations (PCI) launched in 2002<sup>20</sup>. The main objective of the PCI is to provide technical assistance and knowledge on how to produce ARV medication.

The legislation has also played an important role to regulate and encourage the development of social programs such as the Law 9787 for Generic drugs and the Law 9313 for free health care. Both laws are complementary. Since the government provides free treatment for HIV infected patients, the costs with drugs are high. It is for this reason that generic drugs became a fundamental tool for the Brazilian HIV program.

The Law states:

Health is a right of all and a duty of the State and guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and all the universal and equal

access to actions and services for its promotion, protection and recovery.<sup>21</sup>

The Law 9313 from 1996 provides that free anti-retrovirus medication shall be distributed in the public health system through the SUS (Unified Health System). The Brazilian SUS is responsible for providing, financing health care and distribution of HIV anti-retrovirus, which is very effective. It is therefore the government, through the SUS, the responsible for the supply chain of HIV “cocktail”. (Brasil, 1996)

According to latest governmental statistics, Brazil spends more than \$500 million (or more than R\$1 billion) per year with HIV treatment. In 2012, the expenses with the import of HIV drugs reached \$40 million. Brazil still relies on imports for most of the HIV medication, as the total expenses are clearly high. It is for this reason that the

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<sup>20</sup> The countries supported by Brazil are: Haiti, Paraguay, Guatemala, Uruguay, Cuba, in the Americas, due to the proximity; in Africa and Asia, Cape Verde, Guinea Bissau, East Timor, Sao Tome, Angola and Mozambique, all members of the Community of Portuguese Language Countries. The government considers, therefore, expanding the cooperation to other nations.

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<sup>21</sup> Presidência da República. Casa Civil. Subchefia para Assuntos Jurídicos. Lei Nº 9.313, de 13 de novembro de 1996. (Presidency of the Republic Casa Civil. Cabinet Subcommittee for Legal Affairs. Law No. 9313 of November 13, 1996.) Available at: <[http://www.planalto.gov.br/ccivil\\_03/leis/l9313.htm](http://www.planalto.gov.br/ccivil_03/leis/l9313.htm)>. Accessed: 12 Sep. 2014.

manufacturing of generic drugs became paramount<sup>22</sup>. (UNAIDS, 2012)

Brazilian generic drugs industry is from the 1970s, with moments of failures and success, until the new laws and policies were promulgated in the 1990s. In 1999, Brazil launched the “new” Generic Drugs Campaign and promulgated the Law number 9787 in order to boost the production of generic drugs holistically<sup>23</sup>, which resulted in an increasing acceleration of its generic drug manufacturing industry as well as the decrease the expenditure with drugs purchase. As an example, a daily dose of the antiretroviral drug AZT costs \$10.00 in the United States, but only \$1.08 in Brazil<sup>24</sup>. It reduced considerably the total costs of the AZT for free public treatment.

Despite of the relatively success of the Brazilian generic drugs program, criticism has arisen in the international sphere especially from the United States. In order to understand its rights and limits, the Brazilian

Law will be studied in parallel with the WTO agreement.

On the domestic field, the Brazilian Patent Law regulates compulsory license in the articles 68 and 74 as a temporary *ex officio* for the following reasons: exploration insufficiency, abusive manners, economic power abuse, patent dependency, public interest or national emergence<sup>25</sup>.

Along the years, compulsory licensing became controversial in several industries. In the HVI drugs sector, the issue was has gained widespread international coverage brought to the WTO in different cases respectively.

Compulsory licensing threats pressure manufacturers to lower prices of patented and medicines. This method was extensively used by the Brazilian government against the producers of Nelfinavir, Lopinavir, Efavirenz, Tenofovir e Atazanavir drugs respectively<sup>26</sup>.

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<sup>22</sup>*Ibid.* The access to generic medication reduced the costs by US\$ 95 million over five years.

<sup>23</sup> Law number 9787 also provides that the doctors or pharmacists shall inform the patient the existence of generic drugs, if any.

<sup>24</sup> According to the Brazilian government, a generic drug can be up to 35% cheaper than the patented drug.

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<sup>25</sup> Presidência da República. Casa Civil. Subchefia para Assuntos Jurídicos. Lei Nº 9.279, de 14 de maio de 1996. (Presidency of the Republic Casa Civil. Cabinet Subcommittee for Legal Affairs. Law No. 9279 of May 14, 1996.) Available at: <[http://www.planalto.gov.br/ccivil\\_03/leis/l9279.htm](http://www.planalto.gov.br/ccivil_03/leis/l9279.htm)>. Accessed: 12 Sep. 2014.

<sup>26</sup> Nelfinavir's brand name Viracept was first developed by Agouron Pharmaceuticals. Lopinavir/ Ritonavir under trade names Kaletra or Aluvia, is produced by Abbot Laboratories. Efavirenz is registered as Sustiva, Stocrin, Efavir,

Brasília has strategized in order to delay or refusal to issuing patents. In September 2008, the Brazilian National Institute of Intellectual Property refused to issue the patent of Tenofovir to Gilead pharmaceutical company under the argument that the composition of the drug and the technical process of production did not contain innovative components to justify the monopoly. Later, in 2011 the government decided to produce itself the generic drug of Tenofovir. Indeed, patents may lead to monopoly, and the high prices of the HIV drugs have direct impact into the public expenditure.<sup>27</sup> Manufacturing generics became therefore a feasible alternative to the high costs.

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among others and is produced by Bristol Myers and other manufactures. Tenofovir brand name Viread is manufactured by Gilead Sciences. Atazanavir with brand name Reyataz is produced by Bristol Myers.

<sup>27</sup> A patent is a temporary monopoly granted by the government to an inventor who will enjoy exclusive right to exploit the invention. In India, the term of every patent is 20 years from the date of filing of patent application. In China, the duration of patent for invention is twenty years, the duration of patent for utility model and design is ten years, counted from the filing date. The Brazilian law mandates that the patent term be valid for a minimum of ten 10 years from the date the patent was granted.

Currently, only 8 among the 20 drugs used to treat Brazilian patients, are not patented in Brazil. In this case, the government invests in generic drugs, which are mostly produced by public laboratories.

In order to negotiate better prices with the manufacturers, Brazil has threatened to issue compulsory licenses in different occasions: in 2011 for both Efavirenz and Nelfinavir, in 2003 for Lopinavir, in 2005 for Lopinavir again and Ritonavir, and in 2006 for Tenofovir<sup>28</sup>.

Brazil has finally issued a compulsory license for the first time for the HIV drug Efavirenz based on the public's interest in ensuring that a viable HIV/AIDS treatment is provided by the Brazilian National Health System (SUS). The federal government decided to develop the formulation of the drug and encourage the production of its active component, after failing to lower the prices of the AIDS drug. The government's main argument was based on Efavirenz's price

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<sup>28</sup> UNAIDS, Brief Policy. "Using TRIPS flexibilities Policy Brief to improve access to HIV treatment." Available at: <<http://www.aidsfocus.ch/de/themen/advocacy/politik-und-strategien/unaids-policy-brief-using-trips-flexibility-to-improve-access-to-hiv-treatment>>. Accessed: November 10, 2014.

in Brazil, which costs around \$580 per patient/ per year, in tablets of 600 mg (Bondy; Saggiz, 2012). The price is 136% higher than the price offered by the same company in Thailand<sup>29</sup>.

The Brazilian government had then planned to manufacture domestically Efavirenz through the governmental pharmaceutical manufacturing Farmanguinhos. The outcome was that Brazil did not possess the technology nor the know-how, which resulted into imports of the similar generic drug from India<sup>30</sup>.

As for the Atazanavir, the government plans to start producing it in 2017 when the patent from the producer, Bristol, ends<sup>31</sup>.

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<sup>29</sup>BALASUBRAMANIAM, Thiru. "Brazil Moves on compulsory license after failed talks with drug company." Third World Network Info Service on Intellectual Property Issues May 2007. Available at:

<[http://www.twinside.org.sg/title2/intellectual\\_property/info.service/twn.ipr.info.050701.htm](http://www.twinside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.050701.htm)>.

Access in: September 14, 2014.

<sup>30</sup> The Indian generic drugs became an alternative for developing countries such as Brazil.

<sup>31</sup> Another alternative for developing countries is to wait for the patent of major HIV medication to expire. Due to the bureaucracy, applying or re-applying for patent of pharmaceuticals is costly and may take couple of months. The government may take advantage of either the bureaucracy to register and produce generic medications under public manufacturers, or deny patent protection accordingly.

Various international organizations have vowed in support of compulsory licensing, such as the Médecins Sans Frontières (MSF), World Health Organization and the United Nations. In the Brazilian case, the motivations for the international support has helped the government to take a very proactive stance on the WTO, without stepping back with the threats and accusation from more developed nations.

## **Brazil vs the United States**

The first of the WTO compulsory licensing case happened in 2007. Canada notified the Council for TRIPS of the compulsory license allowing Apotex<sup>32</sup> to use nine patented inventions for manufacturing and exporting HIV anti-viral TriAvir to Rwanda (WTO, 2007).<sup>33</sup> According to the WTO, "Canada's notification comes under paragraph 2(c) of the 30 August 2003 General

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<sup>32</sup>Apotex is a Canadian pharmaceutical corporation and the largest producer of generic drugs in Canada, with sales exceeding \$1 billion a year.

<sup>33</sup> World Trade Organization: 2007 NEWS ITEMS. "TRIPS and Public Health: Canada is first to notify compulsory license to export generic drug. October 2007." Available at: <[http://www.wto.org/english/news\\_e/news07\\_e/trips\\_health\\_notif\\_oct07\\_e.htm](http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm)>. Accessed: 12 Sep. 2014.

Council decision, which requires exporting countries to supply relevant information on the compulsory license to the TRIPS Council, the WTO body comprising all members that is responsible for administering the intellectual property agreement.”<sup>34</sup>

Besides Canada, Brazil, India, Thailand, Indonesia, among others, have also issued compulsory licensing in several occasions.

The TRIPS protects the companies that develop and patent the drugs by granting them twenty years of exclusivity in producing the drug, so only non-patented drugs can be targeted as generic. There are two feasible ways for surpassing this provision legally: through the acquisition or permission from the manufacturer; or through issuing a compulsory licensing, being the last one feasible in case of national emergency.

For the author Natalia Arzeno, “The easiest way for Brazil to produce generic drugs would be by following Article 68 of their 1997 patent law, which requires a foreign company to begin production of the patented product in Brazil within three years of

obtaining the patent”.<sup>35</sup> During this time, if the foreign company does not begin the production, Brazilian manufacturer are legally able to produce generic drugs.<sup>36</sup>

This provision attempts to avoid abuse of economic power associated with holding the patent, however it has been largely criticized, especially by the United States<sup>37</sup>.

The United States brought a case to the WTO in 2011 under the dispute settlement 119 (DS199) stating that the article 68 of Brazilian Patent Code breaches international rules of WTO’s TRIPS agreement, more specifically the articles 27.1 and 28.1, alleging that it discriminates imported drugs<sup>38</sup>.

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<sup>35</sup> ARZENO, Natalia; DIAZ, Rebeca GONZALEZ, Sandra. “Brazil’s Generic Drug Manufacturing Success and the policies that permitted it.” Final Project. December, 2004.

<sup>36</sup> In this text, generic drugs and similar (drugs) are used as synonyms for a better and general comprehension of the generic drug medication manufacturing.

<sup>37</sup> The United States pharmaceutical companies are the major providers of foreign drugs to Brazil. For further information, see: ARZENO, Natalia; DIAZ, Rebeca GONZALEZ, Sandra. “Brazil’s Generic Drug Manufacturing Success and the policies that permitted it.” Final Project. December, 2004.

<sup>38</sup> World Trade Organization. “Dispute Settlement: Dispute DS199. Brazil — Measures Affecting Patent Protection.” Available at:

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<sup>34</sup> *Ibid.*

The Brazilian government counter argued that the law avoids abuse of economic power and holding or monopoly of the patent for a long period without producing it. Its main arguments focused on the violation of the Articles 204 and 209 of the United States Patent Code Title 35<sup>39</sup> against the TRIPS' non-discrimination principle, since it directly incentives and supports small business firms and universities thought government subsidies when they claim a patent on an invention, as well and requires goods covered by federally-owned patents to be substantially produced in the United States in order to ensure patent protection<sup>40</sup>.

The Brazilian representative to the WTO thus stated:

We will be very curious in this regard to hear from the US how it explains

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<[http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds199\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm)>. Accessed: 25 Oct. 2014.

<sup>39</sup>United States Patent and Trademark office. United States of America Consolidated Patent Laws.

<sup>40</sup>Despite the hostilities between Brazil and the United States, which resulted in the denouncing by the Brazilian governmental representatives that the American patent law provides subsidies yet going against the World Trade Organization's national treatment principle, there was no *de facto* dispute settlement against the United States related to this topic in the WTO.

the consistency of Articles 204 and 209 of the US patents code with its own interpretation of Art. 27.1 and 28.1 of TRIPS, especially as regards 'local work' requirements. Under Art 204 ('Preferences for the US industry'), the US patent code requires that small business firms and universities 'manufacture substantially' their invention 'in the United States'. Article 209 of the US patent code also establishes a local-work requirement for federally-owned patents.<sup>41</sup>

After long lasting negotiations, the United States decided to withdraw the case, amid the United Nations General Assembly's meeting over HIV medication and great pressure from NGOS and other non-actors. Both countries agreed therefore to cooperate on intellectual property and fight against AIDS in order to avoid future disputes, through a bilateral consultative mechanism<sup>42</sup>.

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<sup>41</sup>RAGHAVAN, Chakravarthi. "US seeks dispute panel against Brazil over patents." Third World Network. 2001. Available at: <<http://www.twinside.org.sg/title/seek.htm>>. Accessed: 30 August 2014.

<sup>42</sup>Office of the United States Trade Representative. "United States and Brazil agree to use newly created Consultative Mechanism to promote cooperation on HIV/Aids and address WTO patent dispute." June, 2011. Available at: <[http://www.ustr.gov/archive/Document\\_Library/Press\\_Releases/2001/June/United\\_States\\_Brazil\\_agree\\_to\\_use\\_newly\\_created\\_Consultative\\_Mechanism\\_to\\_promote\\_cooperation\\_on\\_HIV-AIDS\\_address\\_WTO\\_p.html](http://www.ustr.gov/archive/Document_Library/Press_Releases/2001/June/United_States_Brazil_agree_to_use_newly_created_Consultative_Mechanism_to_promote_cooperation_on_HIV-AIDS_address_WTO_p.html)>. Accessed: 12 Sep. 2014.

The bilateral consultative mechanism was warmly welcomed by the WTO. Both United States and Brazil compromised to work on feasible solutions over trade and investment related to intellectual property rights related to the HIV medication, as well as being a pioneer to solve the deadlock over the existing dispute settlement 119<sup>43</sup>. Since then, no frictions concerning drug patents between both countries were reported.

This mechanism could be used by India and other developing countries in order to surpass the impasses of dispute settlement, however, until now, it was established by Brazil and United States solely.

Following, compulsory licensing in China will be analyzed. The Chinese HIV approach will be studied in the same rationale as the Brazilian. Domestically, social programs and legislations will be the focus of the next sub-section, followed by the China's international stance.

## **Compulsory Licensing in China**

The Chinese social programs and generic industry has presented different

characteristics and levels of development, which reflects on the country's stance over compulsory licensing in a *lato sensu*.

Chinese HIV programs started with the ongoing "Four Free and One Care" policy in 2003, which has as basic goal provide free antiretroviral therapy to rural residents and the urban poor<sup>44</sup>. Since the "Four Free and One Care" policy<sup>45</sup>, a number of other programs and policies were implemented, such as the "AIDS Regulations", "State Council Notice on Further Strengthening the AIDS Response", the "China Action Plan for HIV/AIDS Prevention and Control (from 2006 to 2010)", the "Five Expands, Six Strengthens", to list few<sup>46</sup>. At least, a broader program was established, the National Free Antiretroviral Therapy Programme, through

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<sup>44</sup> YAMAMOTO, Tadashi Yamamoto; ITOH Satoko, "China, Fighting a Rising Tide: The Response to AIDS in East Asia." Tokyo: Japan Center for International Exchange, 2006, pp. 76-95. Available at: <[www.jcie.org/researchpdfs/RisingTide/china.pdf](http://www.jcie.org/researchpdfs/RisingTide/china.pdf)>. Accessed: 14 Sep. 2014.

<sup>45</sup> The Four free include free ARV treatment for AIDS free HIV testing, free services to prevent mother-to-child transmission and free schooling for AIDS orphans. The program covers only rural residents and urban poor population.

<sup>46</sup> The "Law of Narcotic Control" and the "Drug Rehabilitation Regulations" are the supportive laws for the policies, in other to control narcotics and to provide treatment and rehabilitation of drug addict, since drugs is one of the major sources of HIV transmission.

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<sup>43</sup> *Ibid.*

which the first-line treatment is being provided free of charge<sup>47</sup>.

China has indeed an extensive number of anti-HIV policies, but the effectiveness of their implementation is crucial. Since the first programs and policies were implemented in early 2000s, as improvements occurred steadily.

Despite of the government's to leverage HIV treatment, some main concerns are pointed out in terms of health care. According to the World Health Organization, China suffers from shortage of resources, which few capacitated professionals and highly equipped medical facilities (hospitals and laboratories), together with relatively low quality health care system (WHO, 2005). High quality health care is available in the country in private hospitals, where the cost is high therefore not accessible to the lower income population. Moreover, health insurance is not widely available<sup>48</sup>.

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<sup>47</sup> The first line treatment is composed by doses of Zidovudine (or stavudine), Lamivudine, and Nevirapine. Lamivudine can also be used for Hepatitis B to reduce the number of virus in the body.

<sup>48</sup> Health insurances do not cover HIV treatment.

The average annual cost of antiretroviral therapy is between US\$ 400 and US\$ 1250 per person,<sup>49</sup> which can be subsidized by the government for the first level regimen. The Chinese government has constantly increased budget allocation to HIV programs, but like in Brazil, the total cost with patented medication is responsible for the majority of the medical expenditure. It is for this reason that generic became a solution for many developing nations, as well as compulsory licensing.

In 2012, Beijing released the "Measures for Compulsory Licensing of Patent Implementation". Concerns have been raised questioning whether the Chinese government intends to finally use compulsory licensing, but China has involved in few episodes internationally regarding this controversial issue.

Concerning its generic industry, the promulgation of the Patent law Amendment through the "Measures for Compulsory Licensing of Patent Implementation" in 2012, has raised concerns as well as hopes to the generic industry. Speculations concerning China harshening its stance over compulsory

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<sup>49</sup> *Ibid.*



licensing supported by Brazil and India grows consistently<sup>50</sup>.

Compulsory licensing has been present in the Chinese legislations since 2001. According to the Chinese Patent Law article 48, compulsory licenses may be issued in the case of patent holder refusal to grant voluntary licenses on reasonable commercial terms, or to address a national emergency, an extraordinary state of affairs or public interest needs, as addressed in the article 48. (Correa, 2000)

Article 48 Under any of the following circumstances, the patent administration department [...] may [...] grant a compulsory license for exploitation of an invention patent or utility model patent:

- (1) When it has been three years since the date the patent right is granted and four years since the date the patent application is submitted, the patentee, without legitimate reasons, fails to have the patent exploited or fully exploited; or
- (2) The patentee's exercise of the patent right is in accordance with law, confirmed as monopoly and its

negative impact on competition needs to be eliminated or reduced.<sup>51</sup>

The above legal excerpt numbers the circumstances that the compulsory licensing can be used, when either the patentee fails to have the patent exploited or in case of monopoly.

In order to understand the Chinese government's stance concerning compulsory licensing, it is paramount to analyze the government's positioning on the Doha negotiations as well as to investigate if China has used or threatened to use compulsory licensing in the past years.

As previously highlighted in this paper, the Doha Declaration was elaborated amid discussions and impasses on more effective terms and deadlines especially concerning the rights of developing countries. China supported and has worked closely with India, Brazil, to negotiate better terms between patent protection and public health. Domestically, China took eminent domestic procedures to become the first members to

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<sup>50</sup> Miller Canfield Law firm. "China Allows Compulsory Licensing." December 2012. Available at: <http://www.millercanfield.com/publications-articles-321.html>. Accessed: 12 Sep. 2014.

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<sup>51</sup>Patent Law of the People's Republic of China. State Intellectual Property Office of the PRC.

accept the Protocol amending the TRIPS agreement.<sup>52</sup>

One may say that the People's Republic has not been subject of international criticism like Brazil and India, as its approach towards breaking patents is not as proactive and decisive.

In 2005, China threatened to issue a compulsory license in order to obtain voluntary licenses to manufacture generic Tamiflu<sup>53</sup> amid the bird flu outbreak, topic that is still largely discuss due to the leak information that Guangzhou Baiyunshan Pharmaceutical has reportedly produced the generic in 2012. (Huang, 2012)

The threatening to issue compulsory license can be a government tool to bargain

for better, or to get voluntary license for the generic industry. This approach is similarly done by Brazil, India and China.

The government has considered producing Tenofovir for HIV treatment<sup>54</sup>, which has become a key tool for bargaining, since Gilead Sciences has offered certain concessions, including donation of Tenofovir if it continues to buy the same amount continuously<sup>55</sup>.

In fact, China has not yet issued compulsory licensing *per se*, even though it is a flexible mechanism allowed by the World Trade Organization and related international documents. Discussions on whether to produce generic drugs of patent drugs are eventually part of the issues with compulsory licensing, since the rights of the patent holder is jeopardized. International hostility, more specifically from developed countries strong in medication patents, can be seen *vis-à-vis* as its needs to provide health care to the citizens; and for China, a large receiver of foreign

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<sup>52</sup> HUANG, Yanzhong . "The Compulsory Licensing of Pharmaceuticals: Will China Follow in India's Footsteps?" Council on Foreign Relations. October, 2012 Available at: <<http://blogs.cfr.org/asia/2012/10/01/the-compulsory-licensing-of-pharmaceuticals-will-china-follow-in-indias-footsteps/>>. Accessed: 14 Sep. 2014.

<sup>53</sup> Tamiflu is originally produced by Roche. Tamiflu is the brand name of Oseltamivir, and antiviral drugs that can help reduce the severity of flu symptoms. The other antiviral medications available to treat an infection with the flu virus Zanamivir (Relenza), Amantadine (Symmetrel), and Rimantadine (Flumadine), being Tamiflu is the most prescribed by doctors.

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<sup>54</sup> Tenofovir is produced by U.S.-based Gilead Science Inc.

<sup>55</sup> AL JAZEERA. "China to license copies of patented medicines." January, 2012. Available at: < <http://www.aljazeera.com/news/asia-pacific/2012/06/2012694923223634.html>>. Accessed: 30 Aug. 2014.

investments, needs to balance the pros and cons accordingly.

The next segment will bring a brief overview of compulsory licensing in India, which will finalize the comparative study between Brazil, China and India. Indeed, each of them has strengths and weaknesses in terms of health care and legislation, which can be at the same time complementary to each other though a better cooperation.

## **Compulsory Licensing in India**

India first issued a compulsory license in 2012. Natco Pharma, the Indian generic manufacturer, started producing Nexavar, which is used predominantly for kidney and liver cancer treatment<sup>56</sup>. The original manufacturer of Nexavar, the gigantic German pharmaceutical company, Bayer, has appealed to the Indian Patent Appeals Body, which rejected Bayer's plea in March 2013.<sup>57</sup>

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<sup>56</sup> The generic version of Nexavar is sold at 8,800 rupees (\$160) for a month's dose, while the price sold by Bayer in the Indian market reaches 280,000 rupees.

<sup>57</sup> India's Supreme Court has rejected a bid from Swiss pharmaceutical company Novartis to patent an updated version of its leukemia drug Gleevec in 2013. Gleevec costs around \$2,600 a month, while the Indian generic costs \$175 a month.

The case has taken international dimensions, yet provides Indian HIV drugs manufacturers with hope, since no compulsory license was issued for HIV antivirals.<sup>58</sup>

In total, India has issued four compulsory licenses for Bayer's Nexavar, Roche's Tarceva, Pfizer's Sutent and Novartis's Gleevec, yet there are other upcoming cases.<sup>59</sup> The Indian govern and consequently the Courts have used the law to support the issue compulsory licenses by the government<sup>60</sup>.

The Patent Act contains very broad compulsory licensing provisions. The two

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<sup>58</sup> CHATTERJEE, Patralekha. "India's First Compulsory Licence Upheld, But Legal Fights Likely To Continue". **Intellectual Property Watch**. March, 2013. Available at: <<http://www.ip-watch.org/2013/03/04/indias-first-compulsory-licence-upheld.-but-legal-fights-likely-to-continue/>>. Accessed: 12 Sep. 2014.

<sup>59</sup> LAMATTINA, John. "India's Solution To Drug Costs: Ignore Patents And Control Prices - Except For Home Grown Drugs." In: **Forbes Magazine**. August, 2013. Available at: <<http://www.forbes.com/sites/johnlamattina/2013/04/08/indias-solution-to-drug-costs-ignore-patents-and-control-prices-except-for-home-grown-drugs/>>. Accessed: 12 Sep. 2014.

<sup>60</sup> In several occasions, the Indian Courts rejected appeal from international drug producers to withdraw compulsory licensing. One key example, is the compulsory license for Gleevec. Novartis appeal to the Courts to revoke the compulsory license, without success.

provisions of the Act that allow for compulsory licenses are Sections 84 and 92:

Section 84: the Controller of Patents can issue a compulsory license three (3) years after the issuance of a patent if one of the following conditions is met: 1. The reasonable requirements of the public with respect to the patented invention have not been satisfied; or 2. The patented invention is not available to the public at a reasonable price; or 3. The patented invention is not worked in India.

Section 92: Compulsory licenses can be granted on notification by Central Government: 1. In a case of a national emergency, including a public health crisis, extreme urgency or in the event of public non-commercial use; or 2. For export<sup>61</sup>

If analyzing the Section 84, compulsory licenses can be issued if the patented invention is not available to the public at a reasonable price, being therefore a bargaining tool for the government in order to negotiate better prices. This provision does not infringe international laws. Even though the first Patent Act was enacted in 1970, several amendments occurred. The India Patent Act is in line with the TRIPS and the Doha Declaration.

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<sup>61</sup>The Patents Act of India, 1970. Intellectual Property India. Available at: <[http://ipindia.nic.in/ipr/patent/eVersion\\_ActRules/sections-index.htm](http://ipindia.nic.in/ipr/patent/eVersion_ActRules/sections-index.htm)>. Accessed: 30 Aug. 2014.

In terms of social programs, India launched the first National AIDS Control Support Project in the 1992, which has been updated and renewed according to the needs, which has as main objective to accelerate AIDS prevention programs<sup>62</sup>. The Indian government and the World Bank<sup>63</sup> finance the project equally, which respond for around 90% of the costs treatment for all the HIV patients<sup>64</sup>. (UNAIDS, 2012)

The Indian government has acknowledged the necessity to expand its social programs for HIV infected patients. Unlike Brazil, India is yet to elaborate a more consistent social program. It is for reasons that the government has focused on producing medication domestically and pursuing a very strong generic drug industry.

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<sup>62</sup>Currently, the project is on the third edition, called. NACP-III. Despite of the several programs and policies, one may say that the NACP-III is currently the main governmental program.

<sup>63</sup>Developing countries rely on external sources to finance HIV treatment, which can come from the World Bank, other development banks and international NGOs. The governments still have huge costs as a whole.

<sup>64</sup>The government does not cover further health needs such as surgery, and no health insurance is provided for HIV infected yet. In both China and India, the majority of the population does not enjoy health insurance, so they have to rely on the public health system for HIV and related diseases treatment.

As the world's largest producer and exporter of generic medication, India aims to protect its generic drug industry. According to the author John LaMattina on the article "India's Solution To Drug Costs: Ignore Patents And Control Prices - Except For Home Grown Drugs" published on the Forbes Magazine,

[...]the Indian government sets prices for drugs that are patented, but this is not just for expensive medications. There are now 348 drugs that have price caps. However, India has now introduced a new element to this policy. Drugs that have some form of innovation that can be attributed to Indian researchers can be IMMUNE from price controls for five years. Three types of innovation can qualify for this benefit: 1) drugs that arise from indigenous R&D; 2) improvements by an Indian company on a process for making an existing drug; 3) development of a new drug delivery system by Indian R&D.<sup>65</sup>

The high costs of medication, for a developing country where health care is not universal remain as main issue<sup>66</sup>. If on the one

hand, foreign patent drugs can have price caps and be subject to compulsory license, which may include generic manufacturing and exports, on the other hand, legal incentives can be implemented to Indian drugs.

The UNAIDS report 'Together We Will End AIDS' from 2012 mentioned India's effort to combat HIV case not only domestically, but worldwide.<sup>67</sup>

India has contributed enormously to the AIDS response through its capacity to manufacture generic antiretroviral drugs in the private sector. With 80% of these drugs being generics purchased in India, several billion dollars have been saved over the past five years to several countries worldwide.<sup>68</sup>

Controversially, the Indian generic drugs export has faced extensive criticism over its stance over foreign patent drugs. The WTO dispute DS408, 'European Union and

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<sup>65</sup>LAMATTINA, John. "India's Solution To Drug Costs: Ignore Patents And Control Prices - Except For Home Grown Drugs." In: **Forbes Magazine**. August, 2013. Available at: <<http://www.forbes.com/sites/johnlamattina/2013/04/08/indias-solution-to-drug-costs-ignore-patents-and-control-prices-except-for-home-grown-drugs/>>. Accessed: 12 Sep. 2014.

<sup>66</sup> India has the lower costs with HIV medication if compared with China and Brazil, due to its generic industry. However, basic medical care is not free

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and universal, like in Brazil. Moreover, free public health can be highly inefficient, like in China. Even though the government subsidizes with around 90% of the HIV treatment total costs, extra costs and poor health care still pose challenges.

<sup>67</sup> Also, according to the report, all of the BRICS members (Brazil, the Russian Federation, India, China and South Africa) are leading the way in assuming greater responsibility for their domestic HIV responses.

<sup>68</sup> Joint United Nations Programme on HIV/AIDS (UNAIDS). Together we will end AIDS. "UNAIDS / JC2296E". 2012. P. 112.

a Member State - Seizure of Generic Drugs in Transit'<sup>69</sup>. The dispute settlement is still under consultation, since the parties involved have not reached agreement. Generic drugs from India to multiple destinations were seizure when transiting in the Netherlands, which according to the European Union the case violates the principles of intellectual property rights, since parallel imports are done permission of the intellectual property owner.

Amongst other claims, India referred to the TRIPS article 31 and the Doha Declaration to support its rights to issue compulsory licensing as well as export domestically manufactured drugs. The DS408 gained support from other the destined nations in Latin America and Africa, such as Brazil, that has complained at the WTO and initialized consultations through the DS409.<sup>70</sup>

If comparing Brazil and India, both governments have adopted incisive and

proactive stance to support the issuing of compulsory licensing in the international level. Despite of the consequences, Brazil and India have been strong in representing other developing countries and better or cheaper access to patented drugs for key diseases.

## Recommendations

India, China and Brazil has defended at the WTO the right of developing country to access HIV medication, as Lyndon DeSalvo defends:

Brazil's actions towards the TRIPs regime is one of the best, if not the best, example of a developing nation challenging an international institution to secure their national interests. In confronting IPRs—a topic at the “heart of the global political economy” and at the top of the advocacy agenda—Brazil has become a crucial leader for developing nations in the struggle for access to pharmaceuticals.<sup>71</sup>

Amongst the three nations, Brazil has proved to have a more developed and interconnected legal framework, free and universal HIV treatment, and third, a very

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<sup>69</sup> World Trade Organization. “DISPUTE SETTLEMENT: DISPUTE DS408. European Union and a Member State — Seizure of Generic Drugs in Transit.”

<sup>70</sup>World Trade Organization. “Dispute Settlement: Dispute DS409. European Union and a Member State — Seizure of Generic Drugs in Transit.” Available at: <[http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds409\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm)>. Accessed: 12 Sep. 2014.

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<sup>71</sup> DESALVO, Lyndon. “First Among the BRICs: Brazil's Necessary Challenging of TRIPs. March, 2010. Pp.3.

proactive stance internationally, which has indeed positive and negative effects.

Brazil prepared and defended a proposal to the United Nations to view the fight against HIV/AIDS epidemic worldwide as a matter of human rights<sup>72</sup>. The proposal was later on adopted by the United Nations Commission, resulting on the Human Rights' Declaration. Moreover, innumerable international organizations, non-governmental organization, think tanks and other international players have supported that HIV epidemic is not only a matter of national emergency but also human rights.

The Brazilian initiative to take the lead and be the voice for other developing countries, can be seen a positive bargaining tool yet it may bring negative consequences related to its relations with the United States and the European Union.

Still on the international aspect, China has adopted unique foreign policy characteristic of "responsible stakeholder" and avoided being involved with controversial issues such as exports of generics and compulsory licensing as many times as India and Brazil. China has supported India and Brazil in the United Nations, which shows its commitments to enhance HIV treatment.

The next recommendation concerns controversies related to manufacturing and export of generics, and issuing of compulsory licensing, which may be subject of serious consequences in the international relations.

India has focused on the manufacturing of cheaper HIV drugs for both domestic consumption and exports, which brought the nation to the current leading position on the matter.

United States Trade Representative(USTR) Releases Annual Special 301 Report on Intellectual Property Rights provides that India and China together with 10 other countries are on the United States intellectual property right watch list for failing enforce measures to avoid 'theft' of

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<sup>72</sup> The proposal on HIV/AIDS as a matter of human rights, which includes affordable treatment for patients was introduced in the Human Rights Commission by Brazil. The resolution resulted from the meeting was successful and ended up with 56 cosponsors (including some EU members and Norway). The resolution was adopted on a roll-call vote by 52 votes against nil, with one abstention from the United States of America.

copyrighted property<sup>73</sup>. The USTR's report grave concerns about misappropriation of trade secrets, and incremental progress on many other significant intellectual property rights and market access challenges. *Verbi gratia* India has been involved with dispute resolutions within the WTO due to the seizure of generic medicine to export,<sup>74</sup> which contributes for the country to be in the watch list. 'Disrespect' to IPR is still a topic of concern especially in the pharmaceutical industry, which limited number of stakeholders detain the patent of most of the drugs.

The recommendation relies on the necessity to manufacture generic drugs within the TRIPS' flexibilities, and use the compulsory licensing to a lesser extend.

The last recommendation concerns governmental efforts to treat HIV. Compared to India and China, Brazil has the best free and universal health care relatively good

quality for a developing country, supported by a strong legal framework, which considers the right of treatment as a matter of human rights. The costs of free health care is a feasible argument, but the endanger of the epidemic is an even stronger. Availability of right resources, good quality, effective education and treatment, together with a legal framework for enforcement are paramount for the success of HIV social programs.

To conclude, the recommendations are based of the rationale of equilibrium between necessity to combat the HIV spread and the need to act within the terms of the TRIPS. It is fundamental for the members to apply fully its terms, however, the TRIPS provides flexibilities such as compulsory licensing for determined cases, which, despite of the controversies, does not infringe the international laws<sup>75</sup>. A mutual cooperation approach is paramount in areas where one or another has concrete achievements in order to truly enhance HIV response.

## Conclusion

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<sup>73</sup> Other nations on the watch list are Canada, Argentina, Algeria, Chile, Indonesia, Israel, Pakistan, Russia, Thailand, Ukraine and Venezuela. Canada, even though is a developed country, has already issued compulsory license and is opened to issue more if necessary.

<sup>74</sup> United States Office of the President. "USTR Releases Annual Special 301 Report on Intellectual Property Rights." January, 2013.

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<sup>75</sup> Two flexibilities are addressed to the TRIPS. One is the deadline for implementation of the terms stipulated by the TRIPS, and the second one is the legitimate use of compulsory licensing in case of public emergency.



The Agreement on Trade-Related Aspects of Intellectual Property Rights is nowadays the most significant international documents to cater to the international aspects of the international property rights as a whole. Whoever, the lack of detailed provisions enhances discussions over its flexibilities, more specifically concerning compulsory licensing.

Compulsory licensing became one of the most controversial topics within the TRIPS due to the imbalance between safeguarding the pharmaceutical industry, its investments and R&D, and the need to combat epidemic diseases such as the HIV. Developing countries see compulsory licensing as an essential tool to bargain for competitive prices of key medication or to develop their own generic drug industry and it has been issued in several occasions since the ratification of the TRIPS in 1995/1996.

Brazil, India and China's positioning over compulsory licensing is the reflection of their domestic laws, health care and social policies and programs towards the combat of the HIV epidemic.

The Brazilian social program on HIV is a model response for the United Nations, through which the government's educational campaigns, prevention as well as universal and free treatment HIV infected patients supported by developed legal framework became success. Internationally, Brazil has a strong know-how on the WTO system and voiced for the rights for all developing countries to have better access to patented drugs for HIV. Despite of its strong stance, the government has issue done compulsory licensing for public domestic consumption in the past.

India, on the contrary, has used compulsory licensing several times, which contributes to its strong generic drugs industries for both domestic and international consumption. The government's aggressive approach has resulted into the WTO dispute resolution DS048, which is still ongoing. India's tendency is to fortify its internal legal framework as well as it's social assistance to HIV patients, but the quality of health care and additional costs still pose challenges.

The Chinese policies and legislations became amplified yet perplexing, reflects the efforts the government has allocated to the HIV epidemic in the recent years. However,

China has the least effective domestic response to the HIV epidemic socially and legally, if compared to Brazil and India, mostly due to the high costs of the treatment, low quality of service and scarcity of resources.

Internationally, China has adopted a cautious stance. The government has timidly threatened to issue compulsory licensing in the past, in order to avoid clashes with the United States and other patent holder nations, but on the other hand, has advocated together with Brazil and India and within the United Nations the combat of the HIV spread as a matter of human rights. This is positive aspect could also be implemented by Brazil and India.

The cooperation among Brazil, India and China in the three spheres of social programs, legislations and international stance is paramount for the success of HIV response not only domestically but also globally. Brazil has indeed effective HIV care, India has strong generic industry and China's international positioning has proven to be more effective.

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