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Why are Generic Drugs Being Held Up in Transit? Intellectual Property Rights, International Trade,  
and the Right to Health in Brazil and Beyond

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### Introduction

Most new drugs are protected by pharmaceutical patents, which give the patent holder exclusive control over that drug's supply for 20 years. When the patent term expires, the drug becomes available for generic production by any company. The resulting competition typically leads to dramatic reductions in price. In Brazil, generic drugs are on average 40% cheaper than reference or brand-name drugs.<sup>1</sup> In the United States, the Federal Drug Administration reports up to 85% price differences.<sup>2</sup> Consumers in India have witnessed more than 100-fold price reduction for antiretroviral (ARV) drugs due to generic production.<sup>3</sup> Generics thus play a key role in broadening access to health care, mostly by driving costs down, both in the developing and developed world.

Yet access to generic medicines often depends on a country's ability to import them. Widely known as "the pharmacy of the developing world,"<sup>4</sup> India exports 67% of its drugs production to developing countries that either cannot produce any drugs or whose local production is not enough to meet local needs. India and China are also the world's main suppliers of active ingredients--the raw material for drug production--that support the generic drug industries of several other countries, including Brazil. As will be shown below, even for large countries with a strong and established generic industry, importation channels are essential to making these drugs available. This makes the supply of generic drugs vulnerable to new "border measures" restricting the transshipment of such drugs through some European countries.

Between 2008 and 2009, Dutch authorities confiscated several shipments of generic drugs bound for various developing countries in South America and Africa.<sup>5</sup> Most of the drugs were produced in India, and were seized on *suspicion* of patent and trademark infringement. The shipments contained generic versions of drugs originally developed by large pharmaceutical companies, such as Pfizer and Novartis, who still held patent rights in the European Union.<sup>6</sup> These drugs were not protected by patent in India, however, nor in any of the destination countries for which they were bound. After they were seized, some of the shipments were destroyed, some were returned to India, and a few were eventually allowed to continue on to their destinations.<sup>7</sup>

Negotiations over at least two new international treaties have sought to expand this practice by

mandating border enforcement of intellectual property protections.<sup>8</sup> As a growing number of countries consider such measures, pharmaceutical exporters have a new problem on their hands. Small producers, in particular, may be unable to sustain the financial and legal risks of having their shipments seized. Drug costs may also rise as exporters turn to less efficient shipping routes in order to minimize border risks. As a result, access to essential medicines will be diminished across the developing world.

From a human rights perspective, this new threat to public health poses unique challenges. International human rights law traditionally imagines human rights violations in a primarily national paradigm: each government is responsible for respecting and protecting rights within its own territory. In the case of generic drug seizures in foreign ports, however, human rights are being threatened by the actions of a foreign government. The traditional mechanisms and institutions of state accountability may therefore be inadequate to address this uniquely transnational harm.

In addition, international human rights law remains quite unsure of how to handle the tension between pharmaceutical patents and access to medicines. There is no legal consensus as to whether health should come before patents, or vice versa, or where the appropriate balance between the two legal regimes lies. The reigning compromise has been to permit each country substantial flexibility and autonomy in striking the right balance within its own territory. Yet it is precisely this compromise that is challenged by the new trend toward intellectual property enforcement at transit points. If allowed to stand, border enforcement of pharmaceutical patents will effectively allow European countries of transit to set higher standards for protection than the destination countries would have chosen for themselves.

This article explores these legal and ethical tensions through the particular experience of Brazil. A country of great income inequality, Brazil has succeeded in making drugs broadly available largely because of generic availability. Yet this supply is now at risk due to the political vulnerability of European importation channels, through the new trend of “border enforcement” of intellectual property. This phenomenon requires new scrutiny of the relationship between intellectual property, international trade, and the human right to health. The article first demonstrates the vulnerability of the Brazilian public health system to disruptions of international trade in pharmaceutical compounds. It then explores how international legal institutions might address the unique human rights dimensions of this particular trade dispute.

## **Drug Production in Brazil**

Brazil has garnered worldwide recognition for its public health system.<sup>9</sup> Based on the 1988 constitutional recognition of health as a fundamental right, the Brazilian Public Health System (Sistema Único de Saúde - SUS) offers comprehensive medical coverage to Brazil’s 190 million citizens.<sup>10</sup> The publicly funded system provides universal access to medical services as well as most drugs needed for treatment, at no charge to the patient. Therefore, the use of similar and generic drugs has long been essential to the Ministry of Health’s strategy of access to medicines, both through importation and local production. A brief look at certain aspects of the Brazilian dynamics of access to health, intellectual property rights, and pharmaceutical production may help the reader see the bigger picture.

From 1971 to 1996, Brazil did not offer patent protection for chemical-pharmaceutical products and processes. In practice, this meant that branded drugs could be copied and sold domestically by any company. Until the late 1990s, two types of drugs were available in the Brazilian market: branded and

similar.<sup>11</sup> However, several significant legal and policy changes impacted Brazil's drug industry in the late 1990s. When the World Trade Organization (WTO) was established, patent protection for pharmaceutical products became mandatory under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). This significantly limited similar producers' scope of drug production, as patent rights now made it illegal for them to copy the drugs that were released from there on.

Credibility was another major problem similar drugs faced. In a successful attempt to address this issue (among others), in 1999, Brazil's Law n. 9-787 (The Generic Statute) defined new rules for generic production, which helped assure the population that high quality-low cost medicines were available on the market. Unlike similar drugs, generics are entirely interchangeable with reference drugs, the bioequivalence process being supervised by The Brazilian National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária - ANVISA). A strong governmental campaign launched in 1999 promoting the safety and efficacy of generic drugs was the final trigger to a successful launch. On top of that, strong incentives to the local generic industry were channeled through the Brazilian Bank for Social and Economic Development (Banco Nacional de Desenvolvimento Econômico e Social - BNDES).<sup>12</sup> From 2000 on, generics slowly but steadily started to gain space and force in the Brazilian drug market.

Transnational pharmaceutical companies also started producing generic drugs in Brazil, as they quickly identified the growing market potential. Most generic drug production, however, is still done by public laboratories and private national companies. National pharmaceutical companies have specialized in producing generic versions of branded drugs, supplying over 80% of all generics sold in the Brazilian market,<sup>13</sup> while public laboratories play a key role in providing these drugs to the public health system. In 2010, Farmanguinhos claimed credit for the supply of over 1 billion medicines,<sup>14</sup> which reached the population at no cost through the public health system. Brazil thus has a uniquely strong generics industry today. This industry, however, also has points of vulnerability.

The studies of Gadelha, Quental and Fialho<sup>15</sup> and Radaelli et al.<sup>16</sup> show that since the 1970s the private Brazilian pharmaceutical sector as a whole has been dominated by multinational companies: even though in numbers they represent only 20% of the pharmaceutical companies in Brazil, they hold 80% of the total market share. One notable feature of the transnational drug companies installed in Brazil, however, is the fact that they do not conduct local R&D activities; their local actions consist mainly of finalizing, packing, and distributing medicines.<sup>17</sup>

National companies also invest very little in innovation. When looking at the Brazilian pharmaceutical sector, Gadelha, Quental and Fialho<sup>18</sup> observe that national technological development is minimal, restricted to a very small number of companies and public laboratories. Capanema and Palmeira Filho<sup>19</sup> reach a similar conclusion: there is hardly any local production of new drugs and very little investment in R&D. Looking at the local production of new drug technology in Brazil, Rosina<sup>20</sup> finds there has been little change over the past years: national investments in R&D-- when they exist--are mainly focused on the drug-making process, not on the development of new or improved medicines. This makes the national pharmaceutical industry as a whole heavily limited to branded drugs whose patents have already expired. The Brazilian generics drug industry is thus heavily dependent on the importation of innovations from abroad, making the topic of intellectual property regulation a crucial one.

The Brazilian generics market is also dependent on importation of a more concrete nature. Studies report that over 80% of active pharmaceutical ingredients used in the local production of generic drugs are imported.<sup>21</sup> And in some instances, local generic production has not been able to meet public health needs, thus requiring the importation of fully manufactured medicines. Research conducted by Antunes and Canongia<sup>22</sup> confirms this scenario, identifying the main drugs and active ingredients on which the country is most heavily dependent.

The case of Efavirenz is emblematic in this sense. In May 2007, the Brazilian government issued a compulsory license,<sup>23</sup> which allowed for the production and sales of the drug in the country. It was not until the end of 2009, however, that local production started.<sup>24</sup> For over a year and a half, access to this crucial HIV treatment depended on the importation of a generic version from India. As Gadelha and Maldonado<sup>25</sup> point out, this strong and growing dependency on imports means that national social policies are increasingly vulnerable, to an extent that might actually put the population's well-being at serious risk.

Thus, when it comes to drug production, Brazil certainly does not stand on its own two feet, both on the innovative and generic fronts. Historically and currently, little is invested in the R&D process that might lead to new drugs. And generics production, free from patent protection, remains dependent on either active ingredients or pharmaceuticals that are not locally available, but rather imported. International trade is thus truly at the heart of the Brazilian public health system. Increasingly, this diagnosis is cause for concern. When these channels are threatened, the public health system faces critical shortages of important drugs. An inability to rely on generic drugs would also challenge the financial sustainability of the public health system over the longer term.<sup>26</sup>

### **New Threats to Trade in Generic Drugs**

European Community Regulation No 1383/2003 authorizes border enforcement of intellectual property rights in the European Union (EU), empowering customs agents to seize goods where there is *suspected* infringement of intellectual property rights. The rationale behind such action lies in the so-called "manufacturing fiction," according to which drugs passing through customs are treated as if they were manufactured in and/or bound for the European country where they are found, instead of merely in transit. If in this country the particular product is under patent, then the goods are treated as infringing. Initially designed for copyright infringement only,<sup>27</sup> the European Union regulation now extends to trademarks, patents, and other intellectual property rights,<sup>28</sup> thus giving customs agents the ability to inspect, detain, and seize goods that arrive at any EU port of entry, even if they are only passing through en route to a non-EU destination. This temporary detainment gives the patent rights holder a chance to verify infringement, and in some cases threaten the alleged infringer with destruction of the shipment.<sup>29</sup> In most cases, the process has led to the return of the drugs to their country of origin.<sup>30</sup>

Patent protection has been internationally harmonized to a significant degree by the TRIPs Agreement. All WTO members are now required to extend patent protection to pharmaceutical products and processes. Nonetheless, the situation may often arise that a particular drug under patent in one country is not under patent in another.<sup>31</sup> Some countries, including India, chose not to retroactively extend patent protection to drugs already on the market when the TRIPs changes took effect.<sup>32</sup> Countries also retain flexibility as to many aspects of pharmaceutical protection, including precise legal standards for reviewing patent applications, as well as the ability to issue compulsory licenses. Finally, patents may

also be granted erroneously, due to administrative error or unclear legal standards. In such cases, an issued patent may be challenged and invalidated in a particular domestic jurisdiction, but perhaps not in every jurisdiction for reasons of economy or strategy. Thus, although the broad principles of pharmaceutical patent protection are consistent internationally, it may often be the case that a particular product may be under patent within the European Union, but off patent elsewhere. The effect of border enforcement is to take away this ability of non-EU countries to trade in products that EU countries would consider infringing.

There have been several incidents of drug seizures pursuant to EC regulation 1383/2003, but two in particular have garnered global media attention. The first was a shipment of generic AIDS medicines produced in India and on its way to Nigeria. The drugs were purchased by *UNITAID*,<sup>33</sup> and were not patent protected in either India or Nigeria. As it passed through an airport in Amsterdam in 2009, the shipment was confiscated by Dutch authorities on suspicion of trademark infringement.<sup>34</sup>

The second incident involved a large shipment from India to Brazil of the hypertension drug *losartan potassium*. Dutch authorities seized the 500-kilogram shipment in December 2008 and after a 36-day delay it was sent back to India.<sup>35</sup> Hypertension is one of the main causes of death in Brazil, affecting over 10 million people in the country.<sup>36</sup> The free distribution of hypertension drugs--among which is *losartan* -- through SUS is, thus, an essential part of its public health policy.

India claims that between 2008 and 2009 at least 19 consignments of generic drugs were seized by custom authorities in The Netherlands, "16 of which originated in India."<sup>37</sup>

Given the substantial stakes, countries benefitting from international trade in generic medicines are seeking to challenge this new practice. In 2009, both India and Brazil argued before the Council for TRIPS that the Dutch seizures violated the TRIPS agreement. And in 2010, the same countries<sup>38</sup> requested consultations before the WTO's Dispute Settlement Body, alleging the repeated seizures of generic drugs by European Union customs to be inconsistent with GATT<sup>39</sup> and TRIPS<sup>40</sup> free trade provisions. Asserting substantial trade and public health interests in both consultations, the following countries have officially requested to join the discussions: Turkey, China, Japan, Ecuador, and Canada. There is no way of predicting what the outcome of both disputes will be like, but the fact that proceedings were actually initiated before the WTO is a strong indicator that countries that rely on generics in order to promote and protect the right to health are willing to take the necessary steps to make sure such trade channels remain free.

Unfortunately, the Dutch efforts to enforce EC border measures are no isolated instance, but part of a broader trend extending well beyond Europe. A recently finalized international agreement further regulates intellectual property rights at the borders. The Anti-Counterfeiting Trade Agreement (ACTA) is a plurilateral treaty between Australia, Canada, the E.U., Japan, Mexico, Morocco, New Zealand, Singapore, South Korea, Switzerland, and the United States. While ACTA does not directly address patent infringement of generic drugs in transit, commentators believe that certain provisions do threaten the practice, and could eventually impede global access to medicines, as generic drugs would be subject to seizure on grounds of trademark and trade-dress infringement.<sup>41</sup>

Following the same trend, the Trans-Pacific Partnership (TPP) is under current negotiations between New Zealand, Chile, Singapore, Brunei, the United States, Australia, Peru, Vietnam, and Malaysia. Like

ACTA's, the negotiations of this treaty have been kept secret. The draft text leaked earlier this year by Knowledge Ecology International<sup>42</sup> revealed that the agreement contains specific provisions regarding border measures that mirror the EU Regulation discussed above.<sup>43</sup> These provisions would turn seizures of intransit merchandise into a standard action between TPP Member States, as long as there is any *alleged* intellectual property infringement.<sup>44</sup>

These more recent international negotiations show that current instances of pharmaceutical patent enforcement against goods in transit point toward a broader future trend. Treaties such as these constrain national discretion and set a new standard of "minimum" intellectual property protection. Given the geographical location of all countries involved, they also pose new risks to legitimate global trade in generic medicines. It thus becomes increasingly important to confront the negative implications of this practice for the human right to health.

### **International Trade and the Human Right of Access to Medicines**

The issue at stake before the WTO in the complaints lodged by India and Brazil is whether EU's border measures are against free trade rules and principles, as this is the scope of the WTO's regulation and assessment. Viewed solely in these terms, border enforcement of intellectual property laws is of questionable legality.<sup>45</sup> An underlying issue, however, is the extent to which human rights considerations should inform international regulation on freedom of trade. Can the WTO recognize the significant threat to the human right to health posed by border patent enforcement, as grounding an international legal obligation in its own right? Or must the WTO proceed as if essential drugs were any other commodity, such as steel or cotton? Answering this question requires some nuance.

In theory, international trade obligations and international human rights obligations are of equal standing in the law, neither definitively trumping the other.<sup>46</sup> In practice, however, the two legal regimes are deeply incommensurate. International trade law has fundamentally pragmatic bases. On the level of principle it is committed to open trade, but this principle is subject to pervasive exceptions largely slanted in favor of the industrialized countries. The WTO system stops short of requiring truly free trade in agricultural commodities, and not only permits but mandates restrictions on trade designed to shore up intellectual property protection. Because the substance of international trade law is determined through a deeply political process, its enforcement stage is relatively less complicated. Effective international institutions exist to secure compliance with its terms and breaches of the rules are relatively rare. Human rights law, in contrast, is fundamentally concerned with the dignity of the individual. When interests conflict, this regime generally seeks its solutions through principled interpretation, rather than through political bargaining. Perhaps not surprisingly, the international institutions for human rights enforcement are relatively weak.

The trade and human rights realms have encountered each other previously; the creation of the World Trade Organization was broadly criticized as undermining labor rights. The WTO's IP provisions have also been contested by advocates of the right to health, who correctly identified the regime's pursuit of global patent standards as a threat to access to medicines, particularly in the developing world.<sup>47</sup> Many aspects of the WTO's patent rules represent compromises that may be understood as grudging accommodations of public health demands. The WTO system does not, however, treat access to medicines as a human right. Promotion of health is considered as a domestic policy aim, rather than as an international legal obligation. Within WTO procedures, moreover, human rights claims do not

provide a justification for failure to comply with trade rules. Arguments for human rights may only be used to help interpret ambiguous trade rules.<sup>48</sup>

The dispute over border enforcement presents a new and different angle. As India and Brazil present the argument, the interests of free trade and of human rights in this instance are aligned: the European regulation aims to protect domestic companies from foreign competition through an interference in freedom of trade, which also happens to threaten public health. In theory, the WTO could take notice of the internationally recognized right to health as a relevant factor in interpreting whether border enforcement of patents violates international trade agreements. In practice, however, such a synthesis seems unlikely. The WTO is simply institutionally ill equipped to interpret and apply human rights concepts; its jurisdiction is restricted to the enforcement of trade agreements and its experts are trained and experienced in trade law, not human rights analysis.<sup>49</sup>

Additionally, the international legal status of the human right to health is less clear than many other human rights. The right to health is recognized in the Universal Declaration of Human Rights and the International Covenant on Economic, Social and Cultural Rights (ICESCR), but many countries, including the United States, are not parties to the latter convention. The European Convention on Human Rights does not recognize a right to health. The Charter of Fundamental Freedoms of the European Union contains a health provision that is significantly more modest compared to the ICESCR. Interpreting the human right to health in the context of any specific dispute also involves significant conceptual challenges.<sup>50</sup> These legal and political complexities make it all the more likely that the WTO will choose not to directly address the right to health.

India and Brazil are not obligated, however, to confine their complaints to the international trade system. Arguments from human rights would find a warmer reception in the international institutions specifically created to consider these issues, such as the United Nations Committee on Economic, Social and Cultural Rights or one of the regional human rights systems. Such venues offer powerful opportunities to publicize the human rights concerns raised by border enforcement of pharmaceutical patents. There are, however, challenges and limits to this approach. These human rights institutions are invested with dramatically less power than the trade institutions. For India and Brazil, a victory at the WTO will mean a change in European practice or at least, some form of compensation for India and Brazil. A victory in a human rights forum, in contrast, might not lead to a change in on-the-ground circumstances because of the weaker enforcement mechanisms of these institutions.

Additionally, human rights law dominantly conceives of state responsibility in strongly territorial terms. It accounts for the possibility that the right to health of Brazilian citizens would be violated by actions of the Brazilian government. It has largely not struggled with the possibility that the right to health of Brazilian citizens would be violated by actions of European governments. The structures of human **\*203** rights accountability are simply not designed to handle such external threats. Brazilian citizens harmed by interruption of their access to essential medicines may certainly appeal to the Brazilian court system or to the Inter-American Commission on Human Rights. Neither of these institutions, however, has any authority to order a change in behavior on the part of European regulators.

An appeal to the European Court of Human Rights stands a better chance of yielding an enforceable decision, in light of that institution's jurisdiction over the relevant actors. Politically, however, this regime is beholden to European interests. This includes Europe's increasing embrace of intellectual

property protection as itself a human right.<sup>51</sup> For instance, the 2000 Charter of Fundamental Rights of the European Union provides that “Intellectual property shall be protected,” without acknowledging the tension between such protection and the enjoyment of other human rights.<sup>52</sup> The construction of patent protection in human rights terms is deeply questionable from a doctrinal standpoint.<sup>53</sup> Yet it poses a new hurdle for needy patients who would seek to challenge European measures against generic drugs in European courts.

These dilemmas point to a need for new work in international law to address the problems posed by situations in which the realization and enjoyment of human rights is fundamentally dependent on freedom of international trade. Apart from the situation of access to medicines, topics such as food security and freedom of communication may also raise these issues. The seizure of generic drugs in transit through Europe may thus be a test case that gauges the ability of international human rights advocates and institutions to effectively respond to this unique form of threat to human rights.

In confronting the immediate problem of border enforcement of pharmaceutical patents, the best chance of success will come from strategic use of multiple legal fora. The case of South African litigation surrounding generic production of antiretroviral medicines in 2001 can be particularly instructive. Because South Africa has a constitutional framework favorable to the right to health, public health advocates were able to use domestic litigation to publicly highlight the impact of TRIPS rules on human rights. This transnational legal strategy ultimately led to concessions in trade rules later negotiated at the WTO.<sup>54</sup> Similarly, public health advocates today should not rely solely on proceedings at the WTO to challenge border enforcement of pharmaceutical patents. Proceedings in domestic and international fora that are more receptive to claims based on the right to health can help to politically frame the human impact of border enforcement. Even if these institutions lack the power to require European countries to abandon border enforcement, pronouncements condemning the practice as a violation of human rights would have significant symbolic value. In this way, parallel proceedings in human rights institutions, can ultimately put greater public pressure on European countries not to engage in tactics that threaten health, and influence the outcome in the WTO dispute resolution process.

## Conclusion

Long hailed as a model for the developing world, Brazil’s public health system is under increasing financial pressure as new patent rules restrict its ability to use generic medicines. The newest challenge is border enforcement of European patents against pharmaceutical compounds in transshipment from India to other developing countries. This practice rests on dubious legal grounds, and is being challenged through the WTO dispute resolution process. Bringing a human rights perspective to bear on the issue, however, will require innovative advocacy beyond the confines of the World Trade Organization. More broadly, border seizures of generic drugs also point to the need for new work in international law addressing the problems faced where enjoyment of human rights depends on freedom of trade.

## Footnotes

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- <sup>5</sup> In all of these cases authorities seized the shipments in accordance with the European Community’s Council Regulation No 1383/2003.
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- <sup>7</sup> World Trade Organization, *European Union and a Member State - Seizure of Generic, Drugs in Transit*, DS408, 2010, available at <[http://www.wto.org/english/tratop\\_e/dispu\\_e/cases\\_e/ds408\\_e.htm](http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm)> (last visited May 21, 2012); see also World Trade Organization, *European Union and a Member State - Seizure of Generic Drugs in Transit*, DS409, 2010, 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)> (last visited May 21, 2012).
- <sup>8</sup> The treaties are known as the Anti-Counterfeiting Trade Agreement (ACTA) and the Trans-Pacific Partnership (TPP). The details of these negotiations are discussed later in this article.
- <sup>9</sup> For more detailed information on the dynamics of the Brazilian public health system, see M. S. Guise, D. W. L. Wang, and T. C. de CAMPOS, “Access to Medicines: Pharmaceutical Patents and the Right to Health,” in L. Shaver, *Access to Knowledge in Brazil: New Research on*

*Intellectual Property, Innovation and Development* (London: Bloomsbury, 2010).

- <sup>10</sup> Instituto Brasileiro de Geografia e Estatística, “Censo 2010,” 2011, *available at* <<http://www.ibge.gov.br/home/>> (last visited May 21, 2012).
- <sup>11</sup> Unlike the generic drugs sold in Brazil today, similar drugs were not required to provide proof of bioequivalence. Today, the pharmaceutical market in Brazil is comprised of reference, similar and generic drugs.
- <sup>12</sup> Two main programs were aimed at assisting the generics pharmaceutical industry: (1) support for production and registration of medicines; and (2) support for the importation of equipments. National companies were the ones who mostly benefited from BNDES’ finance lines. Medley, EMS Sigma Pharma, and Eurofarma e Biosintética are examples of companies that made full usage of such programs, renovating their plants and enhancing technical capacity (see Quental et al., *supra* note 1, at 621).
- <sup>13</sup> A. M. Cunha et al., Relatório de acompanhamento setorial: complexo da saúde - indústria farmacêutica, Vol. I. ABDI and UNICAMP 2008, (translation: Sectoral monitoring report: health complex - pharmaceutical industry): at 14.
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- <sup>16</sup> *Id.* (Radaelli et al.) at 34.
- <sup>17</sup> See Quental, Gadelha and Fialho, *supra* note 15.

- <sup>18</sup> *Id.*, at 52.
- <sup>19</sup> L. X. L. Capanema and P. L. Palmeira Filho, “A cadeia farmacéutica e a política industrial: uma proposta de inserção do BNDES,” *BNDES Setorial*, 19, (2004): 23-48, *available at* <[http://www.bndes.govol.br/SiteBNDES/export/sites/default/bndes\\_pt/Galerias/Arquivos/conhecimento/bnset/set1902.pdf](http://www.bndes.govol.br/SiteBNDES/export/sites/default/bndes_pt/Galerias/Arquivos/conhecimento/bnset/set1902.pdf)> (last visited July 15, 2010) (translation: The pharmaceutical chain and industrial policy, a BNDES proposal): at 36.
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- <sup>21</sup> See Cunha et al., *supra* note 13, at 10; E. A. Oliveira and J. Bermudez, “A produção pública de medicamentos no Brasil: uma visão geral,” *Cadernos de Saúde Pública* 22, no. 1 (2006): 2379-2389 (translation: Public drug production in Brazil: a general overview): at 2381.
- <sup>22</sup> A. M. De Souza Antunes and C. Canongia, “Prospecção tecnológica da indústria farmacêutica nacional: fármacos e medicamentos da RENAME com potencial de inovação,” in P. M. Buss, J. da Rocha Carvalheiro, and C. P. Romero (Org.) *Casas, Medicamentos no Brasil: inovação e acesso* (Rio de Janeiro: Ed. Fio Cruz, 2008): 145-165, at 149-155.
- <sup>23</sup> The issuance of this compulsory license was based on national public health concerns. At the time, Efavirenz alone took up a large share of the Ministry of Health’s total budget. For further details, see Guise et al., *supra* note 9.
- <sup>24</sup> At the time, the Ministry of Health alleged lack of technological capacity for immediate local production. The drug is currently produced in Brazil through a partnership between public laboratories and a few private generic companies.
- <sup>25</sup> C. A. Grabois Gadelha and J. M. S. de V. Maldonado, “O papel da inovação na indústria farmacéutica: uma janela de oportunidade no âmbito do complexo industrial da saúde,” in Buss et al., *supra* note 22, at 41-59, 43.
- <sup>26</sup> See Guise et al., *supra* note 9.
- <sup>27</sup> S. P. Kumar, “Border enforcement of intellectual property rights against in transit generic pharmaceuticals: an analysis of character and consistency,” *European Intellectual Property Review and SSRN Research Paper* 2009, at 9, *available at* <[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1383067](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1383067)>.

- 28 Art.135, Council Regulation n. 450/2008.
- 29 See Kumar, *supra* note 27, at 05.
- 30 See Xavier, *supra* note 6, at 02.
- 31 F. M. Abbott, “Seizure of Generic Pharmaceuticals in Transit Based on Allegations of Patent Infringement: A Threat to International Trade, Development and Public Welfare,” *World Intellectual Property Organization Journal* 1, no. 1 (2009): 43-50.
- 32 This was not the case for Brazil. See Guise et al., *supra* note 9, for further information on pipeline protection.
- 33 UNITAID is an international drug purchasing facility that provides medicine and treatment against HIV/AIDS, malaria, and tuberculosis for the poorest people of developing countries who otherwise could not afford them. It is hosted and administered by the World Health Organization (WHO). For further information, see <<http://www.unitaid.eu/>> (last visited May 21, 2012).
- 34 H. G. Ruse-Khan, *Trade Agreement Creating Barriers to International Trade? ACTA Border Measures and Goods in Transit*, Max Planck Institute for Intellectual Property, Competition & Tax Law, Research Paper Series n. 10-10, 2011, at 06.
- 35 See WTO, DS408, *supra* note 7.
- 36 Ministério da Saúde, *Nota informativa: subsidios do Ministério da Saúde frente ao tema e às apreensões holandesas de medicamentos genéricos*, Mimeo, 2010.
- 37 See WTO DS408, *supra* note 7.
- 38 WT/DS408/1, May 19, 2010; WT/DS/409/1, May 19, 2010.
- 39 GATT art. 5 (2): “There shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties.”
- 40 TRIPS Preamble: “Members, *desiring* to reduce distortions and impediments to international

trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade”; and art. 41: “These procedures [enforcement of intellectual property rights] shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.”

<sup>41</sup> See Ruse-Khan, *supra* note 34, and B. K., *ACTA: Risk of Third Party Enforcement for Access to Medicines*, Program on Information, Justice and Intellectual Property. Research paper n. 1, American University Washington College of Law, 2010; S. Flynn, *ACTA’s Constitutional Problem: The Treaty That Is Not a Treaty (Or an Executive Agreement)*, PIJIP Research Paper no. 19., American University Washington College of Law, Washington, D.C., 2011, at 10, reports that:

[ ... ] as the text of ACTA was gradually leaked, and then officially released, during the last year of the negotiation, the substance of ACTA came under broad criticism. In June 2010, nearly 650 international intellectual property experts and public interest organizations from six continents adopted a sharply worded public statement criticizing the proposal as ‘a threat to numerous public interests,’ including to freedom on the internet, basic civil liberties including privacy and free expression, free trade in generic medicines, and to the policy balances between protection and access that lie at heart of all intellectual property doctrines.

<sup>42</sup> Knowledge Ecology International, *available at* <<http://keion-line.org/node/1091>> (last visited May 21, 2012).

<sup>43</sup> Drug-safety testing data is another issue regulated by the agreement that would hinder access to generics worldwide.

<sup>44</sup> Art. 14.4 Each Party shall provide ex officio border measures with respect to imported, exported, or in-transit merchandise, or merchandise in free trade zones, that is suspected of being counterfeit or confusingly similar trademark goods, or pirated copyright goods.

<sup>45</sup> See Abbott, *supra* note 31.

<sup>46</sup> L. R. Heifer and A. Graeme, *Human Rights and Intellectual Property: Mapping the Global Interface* (Cambridge: Cambridge University Press, 2011).

<sup>47</sup> S. K. Sell, “TRIPS and the Access to Medicines Campaign,” *Wisconsin International Law Journal* 20, no. 20 (2002): 418-522.

<sup>48</sup> G. Marceau, “WTO Dispute Settlement and Human Rights,” *European Journal of International Law* 13, no. 13 (2002): 753-814; H. Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, Oxford, 2007.

- <sup>49</sup> *Id.* (Hestermeyer).
- <sup>50</sup> M. Langford, ed., *Social Rights Jurisprudence: Emerging Trends in International and Comparative Law*, 2009.
- <sup>51</sup> L. R. Heifer, “The New Innovation Frontier? Intellectual Property and the European Court of Human Rights,” *Harvard International Law Journal* 49, no. 1 (2008): 1-52.
- <sup>52</sup> *Charter of Fundamental Rights of the European Union*, December 7, 2000, Official Journal of the European Communities, December 18, 2000 (2000/C 364/01), available at <http://wxaw.unhcr.org/refworld/docid/3ae6b3b70.html> (last visited June 16, 2012).
- <sup>53</sup> See Heifer, *supra* note 51.
- <sup>54</sup> L. Forman, ““Rights” and Wrongs: What Utility for the Right to Health in Reforming Trade Rules on Medicines?” *Critical Concepts* 10, no. 10 (2008): 37-52.