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THE RIGHT TO HEALTH VERSUS THE RIGHT TO PROPERTY: CONFLICTS BETWEEN PUBLIC WELFARE AND PRIVATE INTERESTS, THE BRAZILIAN APPROACH

Lilian Martins,* Wilson Almeida,** and Dr. Marcos Aurélio Pereira Valadão***

I. INTRODUCTION

Brazil public health policy concentrates about a quarter of its total investment in research. Technological innovations bring treatment alternatives and a better understanding of diseases in addition to promoting new methods of treatment interventions. In this complex environment, a conflict of interest arises between patent protection for medicines—property rights—on the one hand and ensuring universal access to healthcare on the other hand. This focuses on the debate arising from technological innovation, namely the linkage between health, economic, and social development, implying the need for reforms for public health policy.

This article reflects on the right to health that arises from the right to life, initially covering topics on human rights and public health in the world; the legal model that governs patents and the clash of interests; Brazil’s vulnerability to the consumption of technologically-advanced drugs and the use of flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS);¹ and the final recognition that the reversal of priorities in this area favors inequalities over a fundamental social right, the right to health.

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II. HUMAN RIGHTS AND THE RIGHT TO HEALTH

According to the United Nations (UN), the world population reached seven billion people in October 2011—this level was reached twelve years after a baby born in Sarajevo, who was identified as the six billionth person, and twenty-four years after the five billionth person was born in Bosnia. The arithmetic progression dates and demographic estimates may be more symbolic than strict, but they raise the debate of growth versus sustainability. Will natural resources and life in society sustain seven billion people? Are all individuals having fulfilling livelihoods? Have all people secured their rights to health and well-being? The simple answer to these questions would be: not yet!

The social, political, and economic inequalities in the contemporary world increasingly deviate from the ideals expressed in the Universal Declaration of Human Rights. Structural differences of the countries outline the current global health landscape. On one hand, in developed countries the advances provided by studies in medicine lead to the improvement of a majority of their populations' health. On the other hand, millions of people in developing countries suffer and die from many diseases under sub-human conditions. Scholars, like David Landes, agree that the unbalanced economic development underlying the major differences between wealth and poverty among nations are not the result of chance. Is it fair that humans die without assistance for simple diseases in poor countries? And what can be done as the world's population increases? Malthus's studies in the nineteenth century advanced the notion of disordered population growth, and the World Health Organization (WHO) introduced the concept of public health immediately after World War II. These two variables are important in this study.

Viruses, bacteria, and many other microorganisms have caused more deaths than all wars, earthquakes, and volcanic eruptions. In the fourteenth century, the bubonic plague ravaged Europe, killing 50 million people. The cholera epidemic in 1817 emerged and left hundreds of thousands dead; tuberculosis killed 1 billion people between 1850 and 1950; smallpox left 300 million dead between 1896 and 1980; the Spanish flu pandemic caused 20 million deaths between the years 1918 and 1919; typhus caused 3 million deaths from 1918 to 1922; yellow fever left 30,000 dead between 1960 and 1962; measles caused the death of 6 million each year since its emergence until 1963; and malaria has killed 3 million per

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year since 1980. AIDS, identified in the United States and considered an epidemic by the WHO in 1981, has killed 28 million people.

Across the globe, many deaths occur as consequences of infections and parasitic diseases. There is also a high frequency of cases of cancer and autoimmune diseases and there is a growing demand for transplants and other medical events that require specialized treatment and advanced medicines. All these circumstances lead to the world’s population being directly dependent on complex drugs that require advanced research. It should be noted that the drugs are considered as therapeutic instruments to the medical community, whereas patients view them as a way to achieve remission or relief from symptoms. In general, these specific drugs have very high prices and are inaccessible to most consumers. Arising from this issue—between the need and the access to the medicines—is a new concept that links individual assistance to every human being and links collective health assistance through public policies. From basic sanitation measures, which fought the bubonic plague, to current prophylactic measures used to combat AIDS, to Brazil’s grant for the acquisition and advanced medicines provision through the Unified Health System (SUS)—the issue of public health becomes a central theme. In the population’s health and disease process control, the states’ actions are crucial for individuals’ access to health and well-being. In Brazil, the SUS’s purpose—as a state agency—is to ensure that all citizens have access to health care.

From this perspective, when it comes to public health, Brazil emphasizes public awareness in health surveillance, health services organizations, and vaccination campaigns. All of these government interventions are widely disseminated by the media. Universal access to essential medicines is a highly relevant (and not sufficiently discussed) issue in the public health policy debate when pursuing equal health care delivery that promotes physical and mental well-being in a preventive and curative manner. There are also issues related to biosafety policy that hinders accessibility to medicines.

8. The WHO considers tobacco use an epidemic, and estimates that one billion people will die from tobacco use consequences in the twenty-first century (mostly cancers, but also heart, veins, and lung diseases), which demands high health expenses. The tobacco use problem is more critical in developing countries. See, e.g., Marcos Valadao, Regulatory Tobacco Tax Framework: A Feasible Solution to a Global Health Problem 107–08 (2012).
The patent rights of medicines, and their resulting restrictions outlined below, create important legal issues that affect global health. If these issues are not properly addressed, there may be an increase in socio-economic disparities among nations.

III. THE LEGAL PROTECTION AND CONFLICT OF INTEREST

The central issue of this article is the dilemma between the right to health and the right to property. In this context, the right to health refers to the public interest in decent living conditions and welfare accessibility, including the right to information; culture; development; and in this specific case, the right to access medicines and health procedures that can ensure health in a broader concept. The right to property focuses on private enterprises' interests, such as ownership, free enterprise, free competition, profit, and economic development. The questions that underlie the apparent divide of these two interests are how to promote wider access to medicines and ensure each citizen's individual rights, while protecting the industrial property rights of the drug researchers and product developers. This conflict requires mediation between the fundamental right to health and the right to intellectual property. This issue creates a dilemma with ramifications reaching the constituent fields of law, agreements, and international policies.

In Brazil, Industrial Property Law is regulated by Law No. 9,279, of May 14, 1996. This law states:

Article 6. It shall be assured to the author of an invention or a utility model the right to obtain a patent that guarantees his property, under the conditions established in this Law.

Article 8. An invention is patentable if it satisfies the requirements of novelty, inventive step, and industrial application.

Article 11. An invention and utility model are considered to be new if they are not part of the state of the art.


12. Lei No. 9,279, de 14 de Maio de 1996, DIÁRIO OFICIAL DA UNIÃO [D.O.U.] de 15.05.1996 (Braz.). There is a bill of law pending for approval in the National Congress, which will modify the current Law. See Projeto de Lei No. 5402/2013, de 18 de Abril de 2013 (Braz.), available at http://www.camara.gov.br/proposicoesWeb/fichadetramitacao?idProposicao=572963.
Article 13. An invention is endowed with inventive step provided that, to a technician versed in the subject, it is not derived in an evident or obvious way from the state of the art.

Article 15. An invention and a utility model are considered susceptible of industrial application when they can be used or produced in any kind of industry.

Industrial Property Law regulates the rights related to industrial or commercial activities, subdivided into patents, utility models, industrial designs, geographical indications, and topographies of integrated circuits.\(^\text{13}\)

In regards to medicines, the law grants patent rights for products and processes, assuring the holder exclusivity for a specified period (usually fifteen to twenty years) for exploiting a given invention.\(^\text{14}\) But the innovative technique, which involves the development and production process, will be transferred by state grant. International literature shows significant differences between developed and developing countries in the propensity to use technologically appropriate methods. The developing countries are not a homogeneous group; Asian and Latin American nations, for example, show substantial differences in their developmental stages.

For the pharmaceutical industry, the temporary exclusivity conferred by the patent becomes important for recovering a sufficient return on investment for research expenses. The patented product reduces competition and allows the proprietor to price the products. The resulting drug price is closely related to market factors, and includes the product’s degree of innovation, the amount of competition (based on similar products available for the same health problem), the brand valuation (pharmaceutical marketing), and research investment costs.

Brazilian Patent Law (article 40) grants patent rights for inventions for twenty years (in line with TRIPS); starting from the filing of the request, it cannot run fewer than ten years after the official recognition by the national agency.\(^\text{15}\) The law also allows for the issuing of a compulsory license, by administrative or judicial review (article 68), in cases where the patent holder exercises his rights in an abusive manner, or “abuses his economic power, proven pursuant to law in an administrative or judicial decision” and other particular situations (article 68);\(^\text{16}\) this disposition is particularly important for the issues discussed in this paper and will be properly addressed in part IV.\(^\text{17}\)


\(^\text{14}\) Lei No. 9.279, de 14 de Maio de 1996, D.O.U. de 15.05.1996, art. 40 (Braz.).

\(^\text{15}\) Id.

\(^\text{16}\) Lei No. 9.279, de 14 de Maio de 1996, D.O.U. de 15.05.1996, art. 68 (Braz.).

\(^\text{17}\) Brazilian scholars assume that compulsory licenses for medicine are a tool to grant the fundamental right to health. See, e.g., Thana Cristina de Campos, A Licença Compulsória de Medicamentos como Política Pública de Saúde [The Compulsory
At this point, the legal protection of patents becomes essential for universal access to medicines. This is because, on the one hand, entrepreneurs need to have their rights guaranteed against knowledge and property globalization rights (including the virtual ones). On the other hand, the world population, especially that which inhabits the least developed countries (economically and technologically speaking), cannot remain isolated from the benefits brought by advances in medical research. Seen in this light, the false contradiction between public interest and private interest emerges because no individual right is above the public interest.

This observation is reinforced by Patricia Carvalho, who refers to the private interests' legal limitation. The author warns that property rights are limited when the state grants exclusive ownership of properties in the public interest. Access to medicines should be seen as part of the right to health, constituting "a right for all and the State’s duty"—here a clear evocation of the Constitution of the Federative Republic of Brazil articles 6 and 196, which state:

Article 6. Education, health, work, housing, leisure, security, social security, protection of motherhood and childhood, and assistance to the destitute, are social rights, as set forth by this Constitution. (As amended)

Article 196. Health is a right of all and a duty of the state and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and equal access to actions and services for its promotion, protection and recovery.

Soon after the right to health was enacted, its guarantee to protect against the spread of epidemic diseases was used to justify state intervention. But the state intervened for economic reasons, not just for human rights concerns. Nowadays, the state must stabilize the relationship between health and trade. It is the state's responsibility to ensure access to medicines by producing, acquiring, or partnering state power with industry. It is at the state level, most recently through the regulatory agencies, which determines the law of industrial property through legal devices, organizations, international agreements, and policies.

19. See id.
20. CONSTITUIÇÃO FEDERAL [C.F.] [CONSTITUTION] art. 6, 196 (Braz.).
An effective public policy regarding access to medicines provides a good cost-benefit ratio to states because the prophylactic treatment of diseases may result in cost-effective interventions against a widespread epidemic.

In Brazil, public debate on access to medicines has become more intense since 1996 with the filing of the first lawsuits based on constitutional individual rights, claiming the right to more efficient and advanced medicines to treat HIV, followed by the enactment of the previously mentioned patent law (Law. 9.279/96, regulating the rights and obligations relating to industrial property), and the enactment of Law 9.313/96, which provides free medicines to HIV and AIDS patients. As a result of civil society mobilization, Law 9.787/99 was enacted in 1999, establishing the policy for generic drugs in Brazil.

Brazil’s consolidated pharmaceutical drug laws were contained in new legislation composed of Laws 9.313/96 (Sarney’s Law) and 9.787/99 (Generic Drugs Law), which represented a turning point of the Brazilian government’s position on patent and health care issues especially in: actions concerning innovations and requirements in pharmaceutical production, testing quality and bioequivalence, and prescribing generic drug alternatives. During this period, the Brazilian government faced reactions for which it had to take regulatory measures to address emerging problems, among them, the threat of international retaliation.

Law 9.279/96 (Industrial Property Law), intended to adapt Brazilian law to rules of international law established under the WTO in December 1996, has created more problems. These adjustments in national law—particularly the obligation to grant patents to the pharmaceutical industry—have hindered the universal access in Brazil’s current policy. The problem comes from multilateral agreements signed by WTO members, mainly TRIPS, which established the requirement for recognition of

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24. A Generic Drug is similar to a reference or innovative product. It is intended to be interchangeable, and is usually produced after the expiration or waiver of patent protection or other proprietary rights, proven its effectiveness, safety, and quality product. See Lei No. 9.787, de 10 de Fevereiro de 1999 (Braz.). It makes it easier for a medicine manufacturer, who is not the original patent holder, to initiate production without the extremely difficult initial requirements to market a new medicine.


26. Id.
In other words, TRIPS established the minimum standard for intellectual property protection, i.e., minimum rules that WTO members should adopt in their national laws relating to intellectual property rights. Prior to the issuance of TRIPS, many countries did not recognize patents in the pharmaceutical industry. But it is important to note that nations such as Brazil and Thailand only conducted their previous programs to fight endemic diseases, and the main drugs employed were produced locally and not protected by patents.

The minimum standards established by TRIPS do not equally benefit WTO members because the exclusivity right (the patent attribute) can affect the imported product price, innovations, and information technology availability. Therefore, countries with a greater investment capacity for developing research and technology investment have greater advantages over countries that do not have an organized patents system and do not invest so heavily in technological innovations.

IV. THE USE OF FLEXIBILITIES IN TRIPS AND THE BRAZILIAN APPROACH

Possible abuses arising from TRIPS can be resolved by certain actions and devices. Article 8 of TRIPS, for example, states that WTO members "adopt measures necessary to protect public health and nutrition, and to promote the public interest in vital importance sectors to their socio-economic and technological development sectors, since such measures are consistent with the Agreement." These "necessary measures" aimed at the public interests are called "TRIPS flexibilities," among them are the compulsory license (Article 31); parallel imports (article 6); experimental use (article 30), the Bolar exception (article 30); and the health sector participation in the pharmaceutical patent applications processes (implicit in Article 8). These TRIPS flexibilities can be taken alone or combined, but they have limitations in their application that usually involve actions within the economy and world politics; the countries they consider necessary to apply the flexibilities should be aware of the effects in the international business environment.

Compulsory licensing—with its most immediate effect being flexibility—means temporarily suspending the pharmaceutical patent right and

28. CHAVES, supra note 13, at 15.
29. Id. at 16.
30. Id.
31. CHAVES, supra note 13, at 15.
32. Id. at 18.
33. Id. at 19.
using the patented invention without the invention holder's consent.\textsuperscript{34} The patent breaking resulting from compulsory licensing can only be imposed if the rights deriving from the product exclusivity are improperly exercised by the patent holder or through an agent (usually a drug company). The Law does not allow for the abuse of economic power when it is related to human health. Articles 68 to 74 of the Industrial Property Law address this issue. Article 68 states:

\textbf{Section III} \\
\textbf{Compulsory License}

68. The titleholder shall be subject to having the patent licensed on a compulsory basis if he exercises his rights derived therefrom in an abusive manner, or by means thereof engages in abuse of economic power, proven pursuant to law in an administrative or judicial decision.

(1) The following also occasions a compulsory license:

I. non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process, except cases where this is not economically feasible, when importation shall be permitted; or

II. commercialization that does not satisfy the needs of the market.

(2) A license may be requested only by a person having a legitimate interest and having technical and economic capacity to effectively exploit the object of the patent, that shall be destined predominantly for the domestic market, in which case the exception contained in item I of the previous paragraph shall be extinguished.

(3) In the case that a compulsory license is granted on the grounds of abuse of economic power, the licensee who proposes local manufacture shall be assured a period, limited to the provisions of article 74, to import the object of the license, provided that it was introduced onto the market directly by the titleholder or with his consent.

(4) In the case of importation to exploit a patent and in the case of importation as provided for in the preceding paragraph, third parties shall also be allowed to import a product manufactured according to a process or product patent, provided that it has been introduced onto the market by the titleholder or with his consent.

(5) The compulsory license that is the subject of paragraph 1 shall only be required when 3 (three) years have elapsed since the patent was granted.\textsuperscript{35}

Articles 69 and 70 bring exceptions to the general rule, Articles 71 and 72 deal with the exclusiveness of compulsory licenses, and Articles 73 and 74 regulate how the compulsory licensing is implemented and exercised.\textsuperscript{36}

\textsuperscript{34} Id. at 19.
\textsuperscript{35} Lei No. 9.279, de 14 de Maio de 1996, D.O.U. de 15.05.1996, art. 68 (Braz.).
\textsuperscript{36} Id. at art. 68–74.
These actions relating to compulsory licensing, if taken abruptly, cause the opposite effect to its purpose, i.e., they impede the drug's accessibility because there is no denying the state's dependence to the private sector in the research stages, development, and product commercialization. Government intervention may affect the industry's interest in investment and drug production. But sometimes public interest, according to the law, allows for compulsory license. In fact, the Brazilian government has used this strategy a couple of times.\textsuperscript{37}

The Brazilian government has implemented a health program providing for the free treatment of AIDS.\textsuperscript{38} This program, which began effectively in the early 1990s, has been affected by the high prices of anti-AIDS medicines.\textsuperscript{39} In 2001, the medicine Nelfinavir (anti-AIDS retroviral) was threatened to be subject to compulsory licensing. A state laboratory (Farmanguinhos) would produce the medicine, making it available to the population for a price 40 percent less than the original laboratory (Roche) price.\textsuperscript{40} Other products were under negotiation such as Kaletra, Tenofovir, and Efavirenz, anti-AIDS retroviral drugs manufactured by Abbott, Gilead, and Merck, respectively.\textsuperscript{41} But the Ministry of Health and pharmaceutical companies were able to negotiate lower prices and make Nelfinavir, as well as other AIDS drugs, affordable for the Program.\textsuperscript{42} But prices still increased, and more recently, in 2007, the Brazilian government broke the patent on Efavirenz, allowing the government to buy a generic version of the medicine at a cheaper price.\textsuperscript{43} The measure only applies for public non-commercial use.\textsuperscript{44} First, Brazil imported it from India, and then, starting in 2008, initiated domestic production.\textsuperscript{45} Regarding this issue and the dispute between Merck and Brazilian Health System, Vera Zolotaryova wrote:


\textsuperscript{39} The program is a successful public health program. There was an increase in the survival of patients with AIDS in about five years; the program also promoted a decrease of 80 percent in hospitalization costs, generating economy of approximately $2.3 billion. The success of such program was primarily due to the domestic manufacture of drugs that are used in the treatment and do not enjoy patent protection in Brazil. But the high price of drugs has impacted the program after Patent Law entered into force. See Chaves et al., supra note 25, at 171.


\textsuperscript{41} Campos, supra note 17, at 780.

\textsuperscript{42} Id.


\textsuperscript{44} Decreto No 6.108, de 4 de maio de 2007, D.O.U. de 07.05.2007 (Braz.).

Moreover, Brazil’s use of the compulsory licensing provision was appropriate because it is necessary for Brazil to use the compulsory licensing provision in order to maintain its successful HIV/AIDS program. The cost of Brazil’s HIV/AIDS program is rising, partially due to the high costs of second-line HIV/AIDS medication. In addition, an important part of Brazil’s success in its HIV/AIDS program is due to Brazil’s ability to bargain for lower prices with pharmaceutical companies by threatening to issue a compulsory license. By utilizing the compulsory licensing provision after repeated threats to do so, Brazil sends a clear message to pharmaceutical companies that it is serious about the health of its citizens.\footnote{Vera Zolotaryova, Are We There Yet? Taking “TRIPS” to Brazil and Expanding Access to HIV/AIDS Medication, 33 BROOK. J. INT’L L. 1099, 1121 (2008).}

And by comparing the Brazilian case with the Thai case against Abbott drug manufacturer the same author stated:

Second, Brazil’s situation is different from Thailand because Brazil attempted to negotiate with Merck for two years prior to issuing the license. Although prior negotiations may not have been necessary under the national emergency or non-commercial use exceptions of the compulsory licensing provision, Brazil’s willingness to negotiate an agreement with Merck prior to issuing the license sends a positive signal to pharmaceutical companies by demonstrating that Brazil is serious about patent protection.\footnote{Id. at 1122–23.}

In 2012, the Efavirenz compulsory license was extended for five more years.\footnote{Decreto no 7.723, de 4 de maio de 2012. D.O. U. de 07.05.2012 (Braz.). For a detailed timeline on compulsory licensing in Brazil from the beginning until April, 2008, see Jennryn Wetzler & Ana Ayala, Timeline on Brazil’s Compulsory Licensing (2008).} But Brazil is not alone on this issue. Other countries, including the United States and Canada, have also granted compulsory licenses for drugs, and, in fact, this issue is becoming more relevant.\footnote{See generally, Cecilia Oh, Compulsory Licenses: Recent Experiences in Developing Countries, 1 INT’L J. INT’L PROP. MGMT. 22 (2006); Sangeet Shashikant, More Countries Use Compulsory License, But New Problems Emerge, THIRD WORLD NETWORK (May 19, 2005), www.twinside.org.sg/title2/health.info/twninfohealth004.htm; Martin Khor, Patients, Compulsory Licenses and Access to Medicines: Some Recent Experiences, (2009), available at http://www.twinside.org.sg/title2/IPR/pd/fliptr10.pdf; Colleen Chien, Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?, 18 BERKELEY TECH. L.J. 853 (2003).}

When issuing a compulsory license, the state needs a strategy to compensate for the lack of private sector support. In other words, it must assume responsibility for the production, development, and sale of the products. To this end, the Brazilian government can use state laboratories that are able to produce medicines under compulsory license.\footnote{See generally Shashikant, supra note 49.}

It is important to consider that the compulsory license is temporary, effective only during the time when the product is needed to restore pub-
lic health. The private sector cannot bear the political, budgetary, or state management inefficiency burdens. Compulsory licensing’s usage is subject to an abnormal condition, an example being epidemic outbreaks. In addition to these constraints, the compulsory license also implies that the nation acquires the technological capability and industrial facilities to produce the drug.

The threat of compulsory licensing is regarded as a price negotiation mechanism between the states and the drug industries. In connection with the negotiation, the WTO member countries (in underdeveloped or developing positions) are recommending joint actions with the private sector for research, development, and marketing, always focused on effective technology transfer.

Parallel importation—another “flexibility” under the TRIPS agreement—allows importing a patented drug put on the market by the owner or a third party authorized by the agreement. Regarding the drug’s accessibility, the possibility of parallel importation is significant, since multinational pharmaceutical companies often provide “different prices for the same drug in different countries.” Importing allows purchasing the drug where it is being sold at the lowest price. The import is linked to the compulsory license, since a country can put into practice the importation, and therefore give adequate time for local exploration of the compulsorily licensed drug.

The experimental use flexibility, and the experimental use Bolar Exception, are more linked to scientific and technological work that is required for effective accessibility to drugs. The first flexibility—experimental use—attaches to scientific research using the patented drug, allowing the information use and technological development promotion. The second flexibility, Bolar Exception, also known as “early work,” allows a public or private laboratory to use the patented drug for testing aimed at obtaining the sanitary record in drug regulatory agencies.

The flexibility mentioned here refers to the action taken by the Brazilian government in the pharmaceutical patent applications analysis process, denying the grant to requests that do not meet legal requirements for patents. This is an assignment for the Brazilian Health Surveillance
Agency (ANVISA).\textsuperscript{64} Note that the ANVISA's responsibility in approving patents is not only to interfere in the empowerment process, but it also is a measure for the citizens' protection, preventing the introduction of patented medicines with harmful health effects to the population.\textsuperscript{65} This flexibility combined with the experimental use are medium and long-term measures that can promote the national technological development.\textsuperscript{66}

Another aspect is the so-called Doha Declaration's paragraph 6, which is an amendment to TRIPS, intended to ensure developing countries access to affordable medicines when they do not have domestic manufacturers capable of producing medicines under compulsory license (the effect is a flexibility on article 31(f) of TRIPS, which is the "domestic rule").\textsuperscript{67} In this case, Brazilian manufacturers would be able to take advantage of the provision, as Indian manufactures do, because it provides that member countries "can now export generic pharmaceutical products made under compulsory licenses to meet the needs of importing countries subject to certain conditions."\textsuperscript{68} But there is a lot of criticism on this Doha Declaration regarding its effectiveness in solving developing and less developed countries' needs.\textsuperscript{69}

Among all TRIPS flexibilities in recent years, the compulsory license—perhaps by having an immediate effect—has received strong support from Brazilian citizens, especially because of the antiretroviral drugs made accessible to HIV patients. It is important to observe that, as stated before, this flexibility was implemented only by Brazil in 2007 for the drug Efavirenz, produced by Merck, showing the state commitment to the National STD/AIDS Program and the public health system.\textsuperscript{70}

It is noteworthy that the flexibilities discussed here are based on TRIPS (resulting from international policies). But some rules of international law privilege protect the right to property over the broad access to

\textsuperscript{64} Id.
\textsuperscript{65} Id. at 39.
\textsuperscript{66} See id. at 26–27.
\textsuperscript{67} Lee, supra note 11, at 1398–99.
\textsuperscript{68} Id.
\textsuperscript{69} See Carlos M. Correa, O Acordo TRIPS e o acesso a medicamentos nos países em desenvolvimento [TRIPS Agreement and Access to Drugs in Developing Countries], 2 SUJ REVISTA INTERNACIONAL DE DIREITOS HUMANOS, 26–39 (2005), available at http://www.scielo.br/scielo.php?pid=S1806-64522005000200003&script=sci_arttext&tx19 (as it was put by Lee: "Sources of generic ARV s and other drugs are diminishing. The 2016 deadline by which all countries must become TRIPS compliant steadily approaches. This means that absent a TRIPS-required compulsory license, developing countries will lose access to generic versions of drugs still under patent. Those countries then will have to rely exclusively on patented drugs and, in the absence of competition from generics, pay prices set by the manufacturers. Within a decade, the Doha Declaration's inadequate Paragraph 6 may be the only available mechanism for Africa and other developing countries with insufficient manufacturing capabilities to import essential medicine at competitive pricing. It is time for a renewed focus on how Paragraph 6 compulsory licenses can be reworked to succeed in the future."). See Stacey Lee, Access Denied, ONE (2013), available at http://carey.jhu.edu/one/2013/spring/access-denied/.
\textsuperscript{70} KHOR, supra note 11, at 49.
public health. Additionally, under Brazilian law, one may find internal problems, particularly considering the rules concerning the national patent system and its implementation which, in its applicative instance, undermine the right to health. The main internal problems are the pipeline mechanism and the guidelines in the patent examination prepared by the National Institute of Industrial Property (INPI).71 The administrative difficulties are evident in the congressional voting process when the Ministry of Health is positioning itself against the pharmaceutical analysis process and TRIPS-plus.

As a temporary rule, the pipeline mechanism allows patent applications in technological fields not recognized until Law 9.279/96 (Industrial Property Law) is enacted—two examples being pharmaceutical and food fields.72 Through this mechanism, patent applications are not subject to the formal national patentability analysis (i.e., they are not examined by the criteria for "novelty," "activity," and "industrial application"), because it would have followed the process patent terms abroad.73 In the Brazilian case, the pipeline protected, retroactively, other countries’ filed or already existing patents without considering the adjustment period provided in Act 9.279/96.74

With respect to patent examination guidelines adopted by the INPI, they guide examiners’ function in interpreting the Brazilian patent law on what should qualify for patent protection. But these guidelines are often more extensive than the rules contained in the intellectual property national legislation and are at loggerheads with the goals expressed in the Brazilian Constitution protecting intellectual property (art. 5º, XXIX of the Federal Constitution, 1988), generating several patent grants that did not meet rules in effect, in the country.75 The aforementioned disposition of the Brazilian Constitution states as follows:

Art. 5 [this article lists individual rights]:

XXIX—the law shall ensure the authors of industrial inventions of a temporary privilege for their use, as well as protection of industrial creations, property of trademarks, names of companies and other distinctive signs, viewing the social interest and the technological and economic development of the country.76

The Brazilian Ministry of Health has difficulty in positioning itself against pharmaceutical analysis processes. The Brazilian intellectual property law says that requests for drug patents must obtain the ANVISA’s prior approval because it is relevant to the public health.77 INPI does not publish the ANVISA decisions, leaving the pending patent

71. Chaves et al., supra note 25, at 181.
72. Id.
73. Id.
74. Id.
75. Chaves et al, supra note 25, at 182.
76. CONSTITUI\u00c7\u00E3O FEDERAL [C.F.] [CONSTITUTION] art. 5 (Braz.).
77. Chaves et al., supra note 25, at 182–83.
application—which benefits the patent holder maintaining the product monopoly—while not terminating the patenting process.\textsuperscript{78}

Thus, in Brazil, the draft TRIPS-plus laws represent a significant limitation to the public interest in granting patents on medicines. This is because the draft TRIPS-plus law exceeds the minimum TRIPS requirements to ensure the private sectors rights that are involved in the issue. Some authors cite as an intensification example the bill of law n. 29/ 2006,\textsuperscript{79} which provides the link between patent protection and drug registration (also known as “linkage”). This measure would require the Bolar Exception annulment. The Bolar Exception principle is in the independence between drug registration and the patent term, allowing the proceedings for generic production to have their initiation before the patent expires.\textsuperscript{80} In other words, the Bolar Exception invalidation allows generic producers to get the sanitary registration without waiting for the patent to expire, which would allow them to sell the drugs, allowing the entry of the generic versions in the market.\textsuperscript{81}

V. FINAL REMARKS

The purpose of this article was to analyze how Brazilian law, represented by the Intellectual Property Law and the rules for patent medicines, aims to maintain a state of social welfare allowing all citizens the access to health, while respecting international treaties and agreements that protect intellectual property.

The apparent opposition between the Right to Health and the Right to Property is a controversial subject because it derives from actions pertaining to the legal and political fields. This article reflects on the trade of life, since the growing demographic, evolution, and history regarding the serious diseases or epidemics in this global context evokes increasing demand for new research and new process developments that would restore people’s health and preserve their lives.

In the advancement of medical and pharmaceutical products, technological, economic, and social inequalities that divide developed and developing countries persists. Developing countries do not have the economic, political, nor military power to assert their interests in the international context, and this must be considered in international negotiations. Investments in research and innovation dedicated to the sector are favorable to the developed countries because the multinational corporations are headquartered in such countries. These corporations dominate the market and invariably have better conditions for applying resources to scientific research subsidized by the state.

\textsuperscript{78} Id. at 183.
\textsuperscript{80} See CHAVES, supra note 13, at 24.
\textsuperscript{81} See id.
Under these conditions, will it be acceptable to consider that citizens born in certain countries have more rights to life than others born in less fortunate countries? No! Laws and legal actions exist so that people can receive different treatment, but still be entitled to the same adequate living conditions under the Universal Declaration of Human Rights. Even in the richest nations, it is not possible for all citizens to have the right to the same assistance and the best technologies. Then again, the private sector cannot be punished by having their property (patents) and profits (return on investment applied) expropriated because the state is not able to manage the public health demands.

As exposed in this article, there seems to be an insurmountable conflict between the WTO agenda on drug product patents, creating international trade and protective rules, and the WHO, responsible for promoting health by subsidizing research. In other words, there is a policy contradiction between the economic values represented by the WTO and the public interest in free access to medicines represented by the WHO. Nevertheless, it is worth noting that these two international organizations have established a joint study to address such issues.82 In this study WTO and WHO manage the medicine used for vaccines and other treatments related to various diseases.83 The partnership between the WTO and WHO seeks to harmonize the conflicts of interest between their organizations.

But it is a responsibility of the states, supported by legal authority, which ensures that the right to health outweighs the right to property, especially concerning access to medicines. Medication access for public health is a function which concerns the state. Many times, civil actions are filed in order to ensure the access to medicines, creating highs costs that are invariably charged to vulnerable state budgets. In this sense, countries need to seek alternatives, including partnerships between public and private interests and the use of flexibilities (like compulsory licensing), as mentioned above. This includes cases where the law or legal negotiating tools can be used to pressure the pharmaceutical industry to lower drug prices, making it accessible for the population.

It was observed that the draft law, TRIPS-plus, and other Brazilian intellectual property protection system weaknesses may be a setback in promoting public access to medicines. Since 1998, fifty draft laws concerning drugs and how the pharmaceutical industry works in Brazil have been under consideration in Congress. These include PL 230/03, which limits the substances patent protection rights regarded as drug components manufactured by state laboratories (bill was filed on the table Director Chamber of Deputies) and PL 303/03, which handles compulsory licensing in cases where there are no patent object manufacturing (ap-

83. Id.
pended to PL 139/99 amending Law No. 9279 of May 14, 1996).84

In the Brazilian case, the reflection on the dilemma—public interest versus private interests—is a big challenge, characterized by many impasses involving the pharmaceutical industry, lawsuits, and legislation development. But these impasses are not widely discussed in various spheres involved with the issues. State and civil society should unite to search for alternatives within the current patent system, but, above all, promote national and international discussions on the subject. A more thorough debate will yield more interest, ensuring the public interest to be paramount. It is socially unjust, as well as unsustainable and economically inefficient, for the state to offer public health based on ability to pay rather than on people’s needs.
