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ABSTRACT

This article addresses the system of intellectual property law in Brazil and its relation to the country's policy of universal access to AIDS medicines. It also presents the key working strategies of a Brazilian civil society group – GTPI/REBRIP – to tackle the main problems and challenges that are identified.

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KEYWORDS

Intellectual property – Essential medicines – HIV/AIDS – Civil society – TRIPS

ACCESS TO MEDICINES AND INTELLECTUAL PROPERTY IN BRAZIL: REFLECTIONS AND STRATEGIES OF CIVIL SOCIETY

Gabriela Costa Chaves, Marcela Fogaça Vieira and Renata Reis

1. The HIV/AIDS epidemic in Brazil

The policy of universal access to antiretroviral (ARV) treatment in Brazil has produced some important results. From 1997 to 2004, the country saw a 40% reduction in mortality and a 70% reduction in morbidity; from 1993 to 2003, the average age at death from AIDS increased by nearly five years, reflecting a significant increase in life expectancy.[1] Furthermore, there was a reduction of 80% in hospitalizations, generating a cost saving to the tune of US$2.3 billion.[2]

These figures demonstrate that access to proper ARV treatment over the past 10 years has substantially transformed the lives of patients and the methods of controlling HIV infection, improving quality of life for people living with AIDS, increasing their life expectancy, reducing the transmissibility of the virus and causing a significant decline in mortality rates. The Brazilian program establishes the importance of assuring universal access to treatment for all who need it.

According to estimates from the World Health Organization (WHO), nearly 6.5 million people in low- and middle-income countries are in urgent need of ARV treatment. However, due primarily to patent protection and high prices charged by drug companies, only 1.3 million people actually receive treatment. Nearly 80% of the 3 million people who die each year from AIDS have no access to the available medicines.[3]

Brazil is one of the few countries in the world that has a policy of universal free access to AIDS treatment. The National STD/AIDS Program estimates

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that some 546,000 people are infected with the HIV virus in Brazil. Of these, 180,000 take ARV drugs to treat the disease.[4] The Ministry of Health's budget for purchasing antiretroviral drugs in 2007 was R$984 million.[5] Authoritative estimates demonstrate that 80% of this money is used to acquire 11 patented medicines and 20% is spent on 7 drugs that are manufactured domestically by Brazilian companies.[6]

The fact that such a huge portion of the budget is being spent on patented medicines has put the sustainability and universality of this healthcare policy in jeopardy.[7]

Access to proper treatment is essential for thousands of people infected with AIDS in Brazil to live more dignified lives. The Brazilian government has both a legal and moral obligation to provide full treatment to all those who need it. The initial success of the STD/AIDS Program was largely attributed to the local manufacture of drugs that did not enjoy patent protection in Brazil. Today, a growing portion of ARV drugs are either patented or have patents pending in Brazil. These patents could make the country's policy of universal free access to AIDS treatment unsustainable.

2. The policy of universal free access to ARVs in Brazil

The adoption of the universal treatment policy occurred within a favorable historical timeframe in virtue of Brazil's democratization process, which intensified after 1985. This movement resulted in an overhaul of the country's constitutional structure with the promulgation of the new Constitution of the Federative Republic of Brazil in 1988.[8]

The "Public Health Movement" dated back to the 1970s and was comprised of medical professionals and students. This movement played a key role in securing the constitutional recognition that "healthcare is the right of all citizens and the duty of the State" (Article 196, Brazilian Constitution).[9] This new constitutional provision spurred the development of a public health system. The challenge then emerged to establish a public healthcare system that obeyed the fundamental principles of universality, integrality and equality in access to healthcare services for all forms of treatment – without prejudice or privilege of any kind. In this enviroment, Brazil's current public health system came into being, now known as the Unified Health System (SUS) and regulated by Laws 8080/90 and 8142/90. Of particular importance is that SUS coverage allows for "full therapeutic treatment", including pharmaceuticals, which implies the obligation of the State to provide medicines for all who need them.

When it came to tackling the HIV/AIDS epidemic in Brazil, the first official program was set up in São Paulo in 1983 after consultations between

the organized gay community and State Health Department officials. As a nationwide response, the Brazilian national government created the National AIDS Program in 1986.[10]

In 1985 and 1986, the first two non-governmental organizations (NGOs) were created to combat the epidemic: the AIDS Prevention Support Group (GAPA) in São Paulo and the Brazilian Interdisciplinary AIDS Association (ABIA) in Rio de Janeiro. This resulted in a string of prevention campaigns and initiatives to combat discrimination and prejudice, and also to build solidarity amongst affected populations.[11] Meanwhile, the number of people seeking treatment was also on the rise.

The first AIDS medicine on the market was zidovudine (AZT), which the United States Food and Drug Administration (FDA) approved for use against HIV/AIDS in 1987. The Brazilian Ministry of Health made the drug available in 1991. But just as AZT use in Brazil was growing more widespread, transnational pharmaceutical companies were launching new medicines to control AIDS. Monotherapy with AZT alone was deemed ineffective, and so combined therapy (known colloquially as a "cocktail") became the recommended treatment internationally.[12]

As AIDS treatment advanced, many doctors began to prescribe medications that were not yet officially recommended by the Brazilian healthcare system. The uneven pace between the emergence of new products, their incorporation by the public health system and the acute need for new treatment regimens for some individuals who were already resistant to existing drugs led many to take legal action in the courts to secure access to the medications they needed.

The first lawsuits claiming individual entitlement to the latest medicines began to be filed in 1996, with courts ruling in favor of the patients. The main arguments they employed drew on the principles embodied in the Federal Constitution, the Organic Health Law 8080/90 and the various State Constitutions, emphasizing the right to healthcare and the right to life.[13]

Also in 1996, amid widespread social mobilization and pressure from the National AIDS Coordination Authority, Law 9313 was approved. It is also known as the Sarney Law after the senator who proposed it. This law strengthens the existing legal framework guaranteeing free access to ARVs. The approval of this law decisively improved the National AIDS Program's structure for purchasing medicines.

While it would be an exaggeration to claim that the lawsuits over entitlement to medicines were a decisive factor behind the approval of Law 9313/96, it is fair to say that the legal battles waged by AIDS NGOs helped to shape a favorable environment for the approval of the law. That is to say, the exercise of a right by the citizenry contributed to a more structured and better organized response from their government. An important driving force behind

the ongoing process of constructing and implementing a policy of free access to ARVs in Brazil was the legal mobilization of civil society.

Another factor of considerable importance in the implementation of Brazil's universal access policy was the ability to produce ARV medicines locally. Domestic public enterprises and private drug companies were able to produce these drugs at much lower costs than those charged by transnational companies. Production of these drugs began in the early 1990s, since the intellectual property law in force at the time (Law 5772/71) did not include recognition of patents for pharmaceutical products and processes.

However, in addition to the Sarney Law, 1996 also saw the approval of a new Intellectual Property Law (Law 9279/96), completely overhauling the existing legal regime that permitted medicines to be produced locally at affordable prices. The obligation to grant patents to the pharmaceutical sector was imposed by an international agreement, the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). This agreement radically changed this situation and seriously undermined the universal access policy in force in Brazil.

Brazil's new intellectual property law sought to adjust to the rules of international law established within the framework of the World Trade Organization (WTO), which had been created less than two years earlier in December 1994. Member States signed a series of multilateral agreements, among them the TRIPS Agreement, which established the obligation to recognize intellectual property for all fields of technology, including the pharmaceutical sector.

Accordingly, countries had to modify their domestic legislations to bring them in line with TRIPS, which for many meant they had to recognize patents in fields of technology that were poorly developed internally, while transnational companies based in developed countries enjoyed greater market protection. In the case of medicines, an essential component in guaranteeing the right to health, TRIPS established that they be treated like any other merchandise, dealing a blow and raising obstacles to the implementation of heath policies, as we shall see later in this paper.

II. Access to medicines and the system of intellectual property in Brazil: principal characteristics and problems

As we have seen, the creation of the WTO in 1994 and the signing of the TRIPS Agreement obliged all the organization's member states to alter their domestic legislations and recognize a minimum standard of protection for intellectual property in all fields of technology, including pharmaceuticals. However, the TRIPS Agreement granted delayed phase-in periods for developing and least-developed countries that did not previously recognize patents in some fields of

technology – such as pharmaceutical products and processes. Developing countries would have until 2005 to incorporate the minimum protection standards into their domestic legislations. Least-developed countries were granted a further extension until 2016, in accordance with the provisions of the Doha Declaration on the TRIPS Agreement and Public Health, signed in 2001.

The objective of the patent protection system introduced by the TRIPS Agreement was to contribute to the promotion of technological innovation and to the transfer and dissemination of technology in a manner conducive to social and economic social welfare (Article 7) and to permit members to adopt measures necessary to protect public health and to promote the public interest in sectors of vital importance to their economic and technological development (Article 8).

The TRIPS Agreement, then, permits member countries to include in their legislations some flexibilities and public health safeguards. The main flexibilities built into the TRIPS Agreement are: compulsory licensing (Article 31), parallel imports (Article 6), experimental use (Article 30), Bolar exceptions (Article 30) and health sector participation in analyzing pharmaceutical patent claims (implicit in Article 8), each of which will be analyzed later in this article.

However, Brazil did not make use of the 10-year transition period granted by the WTO to recognize patents in the field of medicines. This period, offered to developing countries that did not previously recognize pharmaceutical patents, could have allowed domestic pharmaceutical companies to garner the strength to compete with transnational drug companies specializing in Research and Development (R&D). Brazil used less than two years of the transition period, altering its law in 1996, although it only came into effect in May 1997.[14] Furthermore, Brazilian legislation failed to adopt some of the flexibilities permitted by TRIPS and, in some areas, went much further than what was required by the Agreement.

Since then, other challenges have emerged that threaten the country's policy of universal access to AIDS medicines. The greatest such challenge has been the increase in the cost of treatment with new patented drugs that are not manufactured domestically. Medical guidelines increasingly require these drugs to substitute or complement previous treatments. In addition to this, there has also been an increase in the number of patients receiving treatment.

1. TRIPS flexibilities in Brazilian legislation and the use of compulsory licensing

The Brazilian Intellectual Property Law (LPI) included some of the flexibilities of the TRIPS Agreement that are in the interest of public health (Table 1). These flexibilities are mechanisms intended to mitigate the adverse effects of the rights conferred on patent holders, with a view to restoring the balance between intellectual property rights and the right of access to knowledge.

Table 1: Flexibilities built into the TRIPS Agreement in the interests of health[15]

FLEXIBILITIES	DEFINITION
Compulsory Licensing	**Provided for in Article 31 of the TRIPS Agreement** When a government licenses companies or individuals that are not the patent owners to manufacture, use, sell or import a product under patent protection without the consent of the patent holder. The TRIPS Agreement allows compulsory licensing as part of the Agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. Nevertheless, the term "compulsory licensing" does not actually appear in the TRIPS Agreement. Instead, it uses the phrase "other uses without the authorization of the right holder".
Parallel Imports	**Provided for in Article 6 of the TRIPS Agreement** When a product manufactured legally overseas is imported by another country without the consent of the owner of the intellectual property rights. The legal principle is "exhaustion", the idea that once a patent holder has sold a batch of its product on the market, its patent rights are exhausted as to those specific goods and it cannot prevent their resale to other countries. This trade is sometimes called the "grey market."The TRIPS Agreement confirms that none of its provisions, with the exception of those dealing with non-discrimination, can be used to address the issue of exhaustion of intellectual property rights. The decision is left to domestic law.
Bolar Exception	**Provided for in Article 30 of the TRIPS Agreement** This allows manufacturers of generic drugs to use a patented invention to obtain marketing approval prior to patent expiration, without the permission of the patent owner.
Experimental Use	**Provided for in Article 30 of the TRIPS Agreement** Allows researchers to use patented inventions in their research, in order to understand the invention more fully. Reverse engineering depends upon experimental use.
Health sector participation in analyzing pharmaceutical patent claims[16]	**Implicit in Article 8 of the TRIPS Agreement** Refers to the participation of Ministry of Health officials in the processes to analyze pharmaceutical patent claims.

In the case of health, these flexibilities have two different types of goals, one that is more immediate and another for the medium- and long-term. Compulsory licensing, parallel imports and the Bolar exception are flexibilities whose goal is immediate, that is, obtaining medicines at more reasonable prices either by making generic drugs or by importing products that are sold internationally at lower prices.

Compulsory licensing has been incorporated by Brazilian legislation and can be brought into play for a number of reasons. Article 68 of Brazil's intellectual property law stipulates that a patent shall be subject to compulsory licensing if its owner exercises the rights therein in an abusive manner or abuses economic power. The same article also establishes that a compulsory license may be granted when the patented product is not exploited inside Brazil or

when the sale of the protected product fails to satisfy the needs of the market (the "local working" requirement). Compulsory licenses may also be issued in cases of dependent patents, under the terms provided for in Article 70 of the LPI law. Finally, Article 71 states that a compulsory license may be issued in cases of national emergency or public interest declared by the Federal Executive Authorities.

The Bolar exception, meanwhile, was incorporated through an amendment to the LPI, with Law 10196/2001 adding item VII to Article 43. The use of this flexibility has a twofold advantage for the country: in addition to promoting quicker entry of generic drugs into the market, it also enables information on the invention to be used for research.

Parallel imports have also been incorporated into Brazilian law, albeit only in a limited way, since its use is restricted to situations in which a compulsory license has been issued in virtue of abuse of economic power (Art. 68, paras. 3 & 4, LPI). There is currently a bill of law (PL 139/99) working its way through the National Congress to incorporate this flexibility in full. This is an extremely important mechanism for drug access policies, since multinational pharmaceutical companies usually set different prices for the same drug in different countries. If domestic legislation permitted parallel imports, Brazil would be able to import medicines from wherever it is sold at the lowest price.[17]

Experimental use and health sector participation in analyzing pharmaceutical patent claims are flexibilities with medium- and long-term goals, since they are designed to encourage domestic technological development either by using the information disclosed about the patent or by blocking the concession of exclusive rights for claims that do not meet the legal patentability requirements.

Experimental use is permitted in Brazil by Article 43, II of the LPI law. It represents one of the ways of striking a balance between the interests of the patent holder and the national interests of a country, as it allows patented information to be used to promote domestic scientific and technological development. This scientific experimentation can be conducted by any research laboratory, either public or private.[18]

Health sector participation in analyzing pharmaceutical patent claims was incorporated by Law 10196/2001, which added Article 229c to Brazil's intellectual property legislation. This mechanism determines that pharmaceutical patents may only be awarded with the prior consent of the Brazilian National Sanitary Supervision Agency (ANVISA), the government watchdog responsible for the safety and quality of medicines in Brazil.

Given the importance of the topic and the essential nature of pharmaceutical products, Brazilian lawmakers considered patent-granting important enough for each case to warrant the most rigorous and technical

examination possible by the State. Prior consent by ANVISA is not, therefore, simple interference in the patent-granting procedure. It is a measure to protect patients, by preventing drug patents from being awarded when they are undeserved.[19]

Prior consent is in full compliance with the TRIPS Agreement, which in Article 8 permits members, when formulating domestic laws, to adopt the measures necessary to protect public health and promote the public interest in sectors of vital importance to their socio-economic and technological development. The pharmaceutical sector should qualify under this provision.

Although these TRIPS flexibilities have all been incorporated into Brazilian legislation and are compatible with international rules governing the matter, it is another matter as to whether the country will actually exercise these powers to obtain medicines at more affordable prices. Actual exercise of TRIPS flexibilities has been limited, not only in Brazil but also in almost all developing nations. More recently, some developing countries have made use of them, particularly compulsory licensing, as a means of widening their access to treatment. Prominent examples include Thailand[20,21] and also Brazil in 2007.[22]

In fact, compulsory licensing has already been used on several occasions by a number of countries, including some in the developed world.[23] It is important to note that despite publicly taking a stance against the issue of compulsory licenses for the treatment of diseases such as AIDS, developed countries, such as the United States of America for example, have made use of these licenses when their own interests are at stake.

In Brazil, the threat of compulsory licenses has been the main strategy employed to pressure drug companies in price negotiations for ARV medications. The Oswaldo Cruz Foundation's official pharmaceutical laboratory, called the Drugs Technology Institute, or Farmanguinhos for short, was able to provide the Ministry of Health with a credible threat of local production should stalled negotiations necessitate a compulsory license. Drug companies have preferred to lower the price of their products rather than have them produced by Brazil's domestic industry.[24]

However, since the Brazilian government had never actually issued a compulsory license for the domestic production of medicines, this negotiating strategy grew increasingly less effective and the prices agreed in later rounds were unsatisfactory. In 2004 and 2005, for example, the price of nelfinavir and efavirenz remained unchanged, while the price of lopinavir/ritonavir was cut by just 1%. The discounts secured for the new drugs tenofovir and atazanavir were respectively 5.2% and 7.7%. Indeed, the average annual expenditure per patient in 2005 rose to R$6,124, on a par with the figure in 1998.[25] This increase in costs has undermined the sustainability of the National STD/AIDS Program.

In 2005, during a round of negotiations with the drug company Abbott to lower the price of lopinavir/ritonavir (Kaletra®), used at the time by some 17,000 people, the Brazilian government set the stage for a compulsory license by declaring, in an official decree, that the medicine was of public interest and that the company would have to offer a lower price. After months of talks, the Ministry of Health struck a deal with Abbott, accepting a fixed price of US$1,380 per patient per year until 2011, regardless of the increase in demand or variations in international prices. Furthermore, the deal also came with a guarantee that no compulsory licenses would be issued for this drug in Brazil. Many civil society groups considered it a bad deal and clearly TRIPS-plus, since it included clauses that are more restrictive than those adopted by TRIPS.[26]

The failure to issue a compulsory license in this case prompted member organizations of the Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/REBRIP) to file a "civil public action" (or a class action) to compel the federal government to issue a compulsory license for lopinavir/ritonavir Kaletra®. The strategy employed by GTPI/REBRIP will be examined in detail later in this article.

The use of compulsory licensing has been widely supported by Brazilian civil society in recent years as a means of countering the threat posed to the sustainability of the universal access policy by the high costs of medicines. Nevertheless, the mechanism was used for the first time in Brazil in 2007, for the drug efavirenz. The cost per patient per year in Brazil had stood at US$580 since 2003, while on the international market prices could be found that were twice as low. After lengthy negotiations with Merck, the only offer the company made was to reduce prices by 2%, which was unacceptable. To put it in perspective, this price was twice as high as the one Merck offered Thailand after that country issued a compulsory license for the same medicine.

Brazil declared efavirenz to be of public interest in April and the compulsory license was issued in May 2007.[27] While preparations for local production are underway at two public laboratories (Farmanguinhos and Lafepe), the generic version of the drug has been imported from India since July of 2007 at a cost of R$365 (or approx. US$ 190) per patient per year,[28] a third of the price offered by Merck.

This compulsory license has illustrated the government's commitment to the sustainability of its policy of free access to HIV/AIDS treatment in a context where patented drugs are sold at exorbitant prices that are unaffordable for the vast majority of developing countries. Furthermore, the possibility that the government could, as it has indicated, make further use of compulsory licensing for other medicines[29] is extremely positive, since it is a move to assure the sustainability of not only the National STD/AIDS Program, but also the entire public health system.

2. Limitations of the Brazilian system of intellectual property protection

Although Brazil has adopted nearly all the flexibilities of interest for public health provided for in TRIPS, there are some internal problems both in its patent legislation and in the way it is implemented that can be detrimental to public health. Of these, the following stand out:

a) pipeline mechanism;
b) guidelines for examining patents adopted by the National Industrial Property Institute (INPI)
c) difficulty implementing the role of the Ministry of Health in the process of analyzing pharmaceutical patents (prior consent);
d) TRIPS-plus provisions being voted in the National Congress.

a) Pipeline mechanism

Until it was altered in 1996, intellectual property legislation in Brazil banned the concession of patents for some fields of technology, such as food and pharmaceutical products and processes. This ban was lifted by the country's new Industrial Property Law (Law 9279/96), which, in view of the conditions laid out in the TRIPS Agreement, recognizes patent protection for all areas of technology. The agreement requires all WTO members to provide patent protection for inventions in all technological sectors.

However, when it altered its legislation to comply with TRIPS, Brazil went beyond the obligations that had been taken on internationally and included in the new law a provision to validate patents that had never been filed in Brazil, but had been filed and granted overseas. This is known as the pipeline mechanism.

The pipeline mechanism is a temporary provision whereby applications were accepted for existing patents in fields of technology that Brazil did not previously recognize, enabling patent protection for, among other things, food and pharmaceutical products. Pipeline patent applications would only be subject to a formal analysis and would follow the terms of the patent granted overseas, not being submitted to the Brazilian patent office, the National Industrial Property Institute (INPI), for a technical analysis of the patentability requirements – novelty, inventiveness and industrial application. The pipeline mechanism was not required under the TRIPS Agreement.

Worse still, pipeline patents have granted protection to inventions that were already in the public domain. Brazil applies the principle of absolute novelty for patents, meaning that if the technology filed for patent protection is already part of the state of art,[30] anywhere or at any time, it cannot be protected.[31] The

inventions protected by the pipeline mechanism were already known in the state of art, since they had already been published abroad. And because the patent requests were filed in Brazil after the period of priority[32] had expired, the inventions were already in the public domain and no longer qualified for protection.

The concession of pipeline patents is, therefore, a frontal violation of the principle of non-withdrawal from the public domain, whereby knowledge, once in the public domain, can never again be removed. Passage into the public domain means the asset is shared by everyone and the people collectively acquire the right to keep it available and prevent its individual appropriation.[33]

Although they are often confused, Brazil's pipeline mechanism is neither the same nor the equivalent of the mailbox rule provided for in the TRIPS Agreement that exists in other countries, such as India. The mailbox rule establishes that from "day one" of TRIPS (1995), national patent offices can receive patent requests in areas not previously recognized and hold them in a "mailbox" for review after the domestic patent law comes into effect. In the case of pipeline patents, retroactive protection was possible for items filed or already patented in other countries, even after the period of priority. Therefore, it permitted the concession of patents for knowledge that was already patented abroad even before "day one" of TRIPS. Furthermore, pipeline patents are not subject to any technical analysis by the Brazilian patent office.

Pipeline patents have had a significant impact on sensitive areas of social interest and also on the country's technological and economic development. According to data released by the INPI, within the legal timeframe of one year from the publication of Law 9.279/96, no less than 1,182 pipeline requests were filed,[34] of which more than half have already been granted and the rest is under review.[35]

Efavirenz, a drug for which Brazil recently issued a compulsory license, is protected by a patent obtained through the pipeline mechanism. That is to say, when the drug's patent claim was filed in Brazil, it did not fulfill the patentability requirement of "novelty" (since the information on the invention had been published abroad five years previously).[36] In other words, this active ingredient could have been produced generically in Brazil, like it was in India.

Other medicines that are crucial to tackle the HIV/AIDS epidemic, such as lopinavir/ritonavir, abacavir, nelfinavir and amprenavir, also acquired their protection through the pipeline mechanism, as did the cancer drug imatinib (known commercially as Glivec or Gleevec).

Given the huge impact of pipeline patents in Brazil, the GTPI decided to legally dispute this mechanism for granting patents. This case will be examined later in this article in the section that addresses the main working strategies of the GTPI.

b) Guidelines for examining patents adopted by the INPI

The job of the INPI, an independent federal agency linked to the Ministry of Development, Industry and Foreign Trade, is to enforce the rules governing intellectual property in Brazil, taking into consideration its social, economic, legal and technical function, in accordance with intellectual property legislation and the Brazilian Constitution. One of its responsibilities, therefore, is to analyze patent applications in various areas of knowledge, including medicines.

To analyze requests for drug patents, the INPI drafted the "guidelines for examining patent applications in the areas of biotechnology and pharmacy filed after 31/12/1994".[37] This document is designed to help examiners interpret the Brazilian patent law and so determine what does and what does not qualify for patent protection. However, these guidelines are much broader than the rules contained in Brazil's intellectual property legislation and they are also inconsistent with the objectives of the Brazilian Constitution for protecting intellectual property (art. 5, item XXIX of the Constitution), causing countless patents to be granted in breach of the prevailing rules in the country.

The following examples are worth mentioning to illustrate the problem: the LPI does not permit protection for mere discoveries (article 10) or for applications that do not fulfill the novelty requirement (article 11). However, the INPI guidelines do allow for the possibility of protecting new uses for known products, facilitating the practice known as evergreening to the detriment of protection for real pharmaceutical innovations. Another clear example of the guidelines conflicting with the law is their permission to patent DNA sequences, under the justification that they are merely chemical compounds and not a part of living beings.

c) Prior consent from ANVISA

According to Brazilian legislation on intellectual property, applications for pharmaceutical patents must obtain the prior consent of ANVISA. Prior approval is required in virtue of the importance of public health,

The main problem implementing this flexibility lies in the fact that the INPI does not publish the decisions in which ANVISA does not grant prior consent, which prevents the failed patent application process from being completed. This means that the patent claim remains pending and the would-be owner enjoys a *de facto* monopoly.

d) TRIPS-plus legislation

In addition the problems highlighted above, there is another complication that needs to be addressed on the subject of intellectual property in Brazil. A number

of bills are currently making their way through the National Congress that, if approved, would represent the inclusion of TRIPS-plus measures in Brazilian legislation.

TRIPS-plus measures are forms of protection for intellectual property that are more restrictive than those mandated by TRIPS.[38] They generally benefit the interests of patent holders to the detriment of the public interest and are, as a rule, included in bilateral trade agreements negotiated between developed and developing countries. Even though Brazil is not currently negotiating any bilateral deals involving intellectual property protection, bills introducing these measures are still being voted in the Brazilian Legislature, and we need to be on the alert so they are not approved. This is very plain evidence of how TRIPS-plus measures can be implemented by developing countries separately from bilateral or regional free trade agreements.

An example of this is Bill of Law 29/2006, which aims to include a TRIPS-plus measure by establishing a linkage between drug registration and patent protection. If approved, it will, in practice, annul the Bolar exception flexibility provided for in Brazilian law. This case will be examined in more detail further ahead, when we address the working strategies of the GTPI.

III. The GTPI/REBRIP and its role: main working strategies to tackle the existing problems and challenges

Given the importance of continuing public policies such as universal access to antiretroviral treatment and the challenges and obstacles imposed by the new rules on intellectual property protection, Brazilian civil society groups, with the support of international organizations, decided to join forces to address this pressing and complex issue. In 2001, they formed the Working Group on Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/REBRIP).

REBRIP is a network of NGOs, social movements, unions and independent professional associations that are engaged in the processes of regional integration and trade, and are committed to the construction of a democratic society grounded in economic, social, cultural, ethical and environmentally sustainable development. These organizations pursue alternative forms of integration that contrast with the logic of trade and financial liberalization prevailing in the economic agreements currently being negotiated.[39]

Due to the ongoing debate on intellectual property on the international stage and the impact caused by international trade agreements on a local level, it grew necessary to set up a group specifically to address topics concerning intellectual property and its repercussions on Brazilian society's access to knowledge. This was the context behind the creation of the GTPI, which has

been coordinated by the Brazilian Interdisciplinary AIDS Association (ABIA) since its creation in 2001 (having been reappointed coordinator in the last two meetings of REBRIP). The GTPI is comprised of several Brazilian civil society groups and two international organizations, in addition a number of activists and researchers.[40]

The GTPI works primarily on the following fronts in an attempt to minimize the negative impact of the patent system in Brazil:

1) Identifying alternatives that can widen access to medicines;
2) Strengthening cooperation among countries from the Global South to promote information sharing and possible joint efforts by civil society;
3) Shaping and mobilizing public opinion on the social impact of intellectual property trade agreements;
4) Monitoring international forums that discuss the topic of intellectual property and access to medicines.

Hemispheric cooperation is key to tackling the issue of intellectual property and access to medicines, since the changes to the legal framework in the field of intellectual property have had a far more profound impact on countries from the southern hemisphere. In fact, there always was and still is an imbalance between developed and developing nations in terms of technological development, in terms of their capacity to handle the intricate technical workings of the latest pharmaceutical patents in their national patent offices and, primarily, in terms of the purchasing power of their populations to afford patented medicines. This is what makes cooperation among countries from the southern hemisphere, both by organized civil society and by governments, so vital to the success of the efforts of Brazilian civil society.

This cooperation is aimed at establishing new partnerships for the purpose of broadening dialogue and sharing information, methodologies and working technologies, in addition to promoting the active engagement of domestic and international civil society in working out agreements between the governments of their countries. The sharing of information will help each country achieve tangible results, while respecting the particularities of each nation. A good example of this liaison between organizations from the Global South is their input for examining patents, which will be addressed later in this paper. Since the same patent applications are filed in different countries, the same arguments questioning whether to grant a specific patent can also be used by organizations from other countries.

Another important working strategy of the GTPI is the education of individuals, social movements and organizations that work in areas affected by the system of intellectual property. The subject of intellectual property, most

notably the issue of pharmaceutical patents, is normally viewed as a topic for specialists that is little understood by these organized groups. The GTPI has developed specific methodologies to address the topic, publishing information booklets (on domestic and international legislation and on key issues such as compulsory licensing in Brazil[41]) and organizing thematic workshops and activities for all audiences to demonstrate how intellectual property affects their lives and their work.

The GTPI has also sought exposure in the domestic and international media as a way of shaping public opinion on the topic. We believe that the concepts and theories about the link between patents and innovation are up for dispute and that the engagement and visibility of civil society is extremely important.

Furthermore, the GTPI also considers it important to participate in initiatives that, besides discussing the impacts caused by the current system of protection for intellectual property, aim to actually come up with new models and alternatives. The debate on other ways of stimulating invention has been intensifying between leading international players and we believe that more emphasis should be given to the collaboration of southern hemisphere countries, since these nations are the main victims of the current system. This is why we consider it so important to monitor the discussions and negotiations playing out in the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) of the World Health Organization.

On a national level, the GTPI's advocacy agenda has taken shape and its inclusion on the list of influential players on the subject in Brazil is justified by the concrete actions that it has taken in recent years. We would like to highlight four such actions taken by the GTPI that are designed to assure and widen access to medicines in Brazil, primarily for the treatment of HIV/AIDS. These are: (a) a civil public action to issue a compulsory license, (b) input for patent examination in the INPI and a patent annulment case, (c) legal opinions on bills and (d) petitioning the Brazilian Attorney General on the constitutionality of pipeline patents. We shall now briefly address each of these actions and their main outcomes:

a) Civil public action to issue a compulsory license

The cost of purchasing the drug Kaletra® (a combination of the active ingredients lopinavir and ritonavir), produced by Abbott Laboratories, represented approximately 30% of the National STD/AIDS Program's expenditure on medicines in 2005. This exorbitant amount led the Brazilian government to enter into negotiations with Abbott to reduce the price of the drug.

After failed attempts at negotiation, Brazil's then Minister of Health in June 2005 declared Kaletra® to be of public interest. This declaration was the first step towards issuing a compulsory license for reasons of public interest, since it would enable domestic production of the drug at a lower cost and a transfer of technology. At the time, Brazil was paying US$1.17 per tablet of Kaletra®. But estimates were putting the production price by local firm Farmanguinhos, in the event of the compulsory license being issued, at US$0.41.[42]

However, at the same time that it declared Kaletra® of public interest, the Brazilian government also gave Abbott a timeframe in which to offer a lower price for the drug and so avert the compulsory license from being issued. And so, in October 2005, a contract was signed between the Brazilian government and Abbott to supply the drug.[43] The deal, which did indeed lower the price, also came with clauses that conflicted with the national public interest, such as an obligation not to issue a compulsory license, no technology transfer or foreign direct investment to manufacture the drug locally, and fixing the stipulated price until the end of 2011, when the drug patent would be close to expiring.

Once the agreement was signed, civil society organizations from the GTPI, in conjunction with the Public Prosecution Service, filed a civil public action – the first of its kind in Brazil – against the government and Abbott demanding that a compulsory license be issued for lopinavir/ritonavir. A favorable judicial decision would enable local production of a generic version of the drug.[44]

The case received a negative preliminary decision, on the grounds that issuing a compulsory license would trigger retaliation by the developed world and possible shortages of the drug, while the very capacity of domestic industry to produce the medicine in Brazil was also called into question. Preliminary decisions, however, are decisions based on a preliminary analysis of the strength of the case and by no means represent the final judicial decision.

In order to counter the arguments used in the preliminary decision, the GTPI, with the support of the international organization Doctors Without Borders/Médecins Sans Frontières (MSF), enlisted domestic and international specialists in 2006 to assess the technical capacity of four Brazilian pharmaceutical firms (two public and two private) to produce antiretroviral medicines. The specialists determined that the Brazilian firms do indeed have the capacity to produce both first-line and second-line antiretroviral drugs.[45] These results were corroborated by two additional studies conducted simultaneously in Brazil by the Clinton Foundation and the United Nations Development Program (UNDP). Local firms could, therefore, fully supply domestic demand for the drug and until production got up to speed, the medicine could be imported from other countries where the patent holder sells it.

These arguments were employed in the civil public action to influence the

ruling of the judge, since the unfavorable preliminary decision is, as the expression already suggests, only preliminary and does not shut the door on the case. The civil public action is still in the discovery stage and is awaiting judgment.

b) Inputs for patent examination in the INPI and patent annulment case

In 2006, GTPI member organizations also attempted to exploit administrative channels to prevent the Brazilian patent office (INPI) from granting undue patents for essential medicines. The group submitted inputs for the examination of two patents: the first referred to an application by Abbott for a second patent for the lopinavir-ritonavir combination (Kaletra®) and the second was for a patent application made by Gilead for its tenofovir disoproxil fumarate medication (Viread®).

Inputs for patent examination are a provision contained in Brazilian intellectual property law that permits any interested parties to submit documents and information to assist in the examination of patent applications being analyzed by the INPI (article 31, LPI).

The purpose of the two submissions to the INPI was to present the technical grounds for not granting patents for these two antiretroviral drugs. The inputs called into question the patent claims of each medicine using different arguments. In the case of tenofovir disoproxil fumarate, each of the substances described were known in the state of art before the application's filing date. The active ingredient that combats AIDS is tenofovir, which has been known since 1989, and the other compounds developed have no new technical effect for a specialist in the subject, since they are standard practices used in organic synthesis. This application for an invention patent, therefore, does not present any inventiveness.[46]

In the case of lopinavir/ritonavir, the company filed a second patent application ("divisional patent application") for the product. To complicate matters, the first patent was conceded through the pipeline mechanism – a provision of Brazilian law considered by many jurists to be unconstitutional, permitting patents to be granted without an evaluation of the patentatability requirements prescribed by law. The problem is that there are no legal provisions for divisional applications when the parent application is a pipeline patent. These types of patent applications, therefore, cannot be approved by the INPI because they do not meet the patentability requirements imposed by Brazilian law.

Still on the subject of the GTPI's involvement in the granting of patents, in mid-2007 its members filed a patent annulment case that questioned the validity of a patent awarded for a diagnostic kit. Not only are patents not permitted for diagnostic kits in Brazil, in accordance with the permission

contained in TRIPS, but the patent in question was also granted through the pipeline mechanism.

This case is still in its early stages in the courts and doubts have been raised about the legitimacy of civil society organizations filing this kind of legal action. But if the legitimacy is accepted, the GTPI has plans to file other such cases questioning the legality of patents granted unduly for essential supplies in Brazil.

c) Legal opinions on bills

Another form of involvement by the GTPI consists of accompanying congressional bills on the subject of intellectual property. The purpose of this is to prevent the approval of laws that conflict with the public interest and escape huge subsequent expenditures. It is, therefore, a preventative action strategy.

On this topic, we highlight two cases in which the GTPI has intervened:

- inclusion of antiretroviral drugs on the list of unpatentable subject matter;
- linkage between drug registration and expiry of intellectual property rights.

The first case refers to Bill of Law 22/2003, which plans to include ARV medicines on the list of subject matter not entitled to patent protection in Brazil. In 2005, GTPI member organizations sent representatives involved in the analysis of the bill a legal opinion advocating its approval. The bill is in full compliance with the underlying principles of the Brazilian Constitution, which gives the right to health and the right to life precedence over the commercial rights and economic interests of pharmaceutical companies. Furthermore, it also conforms to international regulations on the subject, which, while recognizing industrial property rights, also admits that developing countries like Brazil can and should adopt measures to protect public health and assure access to medicine for everyone in extreme cases of epidemics, such as AIDS. The analysis of the bill was favorable, but it still needs to be voted in the House of Representatives.

The second legal opinion[47] opposes the approval of Bill of Law 29/2006, which intends to link the registration of a drug to the expiry of its patent. The opinion was submitted to senators and representatives involved with health concerns. In practice, linkage between patents and drug registration raises an additional barrier to the entrance of generic drug on the market, since it links the start of the registration process for generic versions of a drug to the expiry of the patent. In other words, it delays the onset of competition and amounts to a *de facto* extension of patent terms, which is completely at odds with public

health interests. If this bill is approved, it will effectively remove the Bolar exception from Brazilian law. An opinion has already been filed to shelve the bill, but this needs to be analyzed by the Senate standing committees.

d) Petitioning the Brazilian Attorney General

Towards the end of 2007, the GTPI presented the Brazilian Attorney General with a petition[48] demonstrating the unconstitutionality of the two articles of Brazil's intellectual property legislation that created the pipeline mechanism for granting patents. The petition calls on the Attorney General to bring a Direct Case of Unconstitutionality (ADIN) against the pipeline mechanism before the Supreme Court, since civil society organizations do not have the standing to file this kind of legal case.[49]

The ADIN process permits a thorough examination, on a federal level, of the constitutionality of Brazilian laws or normative acts. In other words, it can be used to call into question whether any given piece of federal or state legislation is consistent with the country's Constitution. The issue is judged directly by the Supreme Federal Court – the highest court of law in Brazil – and a declaration of unconstitutionality results in the law in question being removed from the legal system and prevented from having any legal effect.

Pipeline patents were granted during the *vacatio legis* period of Brazil's current intellectual property law, which was altered in 1996. They are in breach of the Constitution because they have conferred patent protection on knowledge that was already in the public domain, violating the vested right of the people. They are also in breach of the purposes established by the Constitution for protecting intellectual property, since they do not serve the economic or technological interests of the country. There is, therefore, nothing to justify these patents. A report commissioned by the authors of the petition estimates that these pipeline patents have cost Brazil in the billions of dollars.

This type of mechanism to revalidate patents was adopted in very few nations other than Brazil and some of these countries, for example Ecuador, have already declared it to be inconsistent with the intellectual property protection system adopted internationally.[50]

The purpose of the petition is to open an ADIN case, in other words to demonstrate that pipeline patents are unconstitutional. Nevertheless, it was also considered important for the case to demonstrate that pipeline patents are not part of the international intellectual property protection system and, in some respects, are inconsistent with it. This strategy was designed to prevent the rules of the international intellectual property protection system from being used adversely when questioning these patents before the Brazilian Judiciary,

which, as we have already seen, occurred with the preliminary decision on the civil public action to force a compulsory license for Kaletra.

Therefore, the petition demonstrated that the pipeline mechanism was not adopted as a requirement of any international trade deal sealed by Brazil and also that it is inconsistent with the TRIPS Agreement and both the Paris Convention for the Protection of Industrial Property (PCPIP) and the Patent Cooperation Treaty (PCT) of the World Intellectual Property Organization (WIPO).

A number of letters have been received from international civil society organizations that specialize in the field expressing their support for the GTPI's initiative and corroborating the arguments on the inconsistency of pipeline patents with the international system.[51] These letters of support also highlight the importance of the initiative on an international level, primarily because of the leadership role Brazil plays on the international stage on issues related to intellectual property and public health.

Indeed, Brazil has taken the lead in recent years to ensure that the intellectual property protection rules adopted on an international level do not pose a risk to the public health systems of developing nations. However, on a domestic level, the country has adopted an approach that consistently gives preference to intellectual property rights before public health, in stark contrast to the attitude it displays in international forums. But calling into question the legality of pipeline patents, which are so blatantly at odds with public health interests, is another step towards making the discourse already adopted on the international stage start to prevail inside Brazil.

Finally, we should emphasize that pipeline patents are far from being a problem of the past. As we have already mentioned, hundreds of patent application filings are still pending a decision by the INPI. And countless other cases, for which patents have already been granted and are nearing their expiry date, are working their way through the Brazilian Judiciary with a view to having their protection terms extended.[52]

The petition was registered in late December 2007 and the GTPI is awaiting an audience with the Brazilian Attorney General to address the case.

IV. Final remarks: a brief evaluation of the strategies adopted, the results obtained and the main challenges ahead

Civil society faces a host of challenges in its attempt to keep policies for universal access to medicines out of reach of intellectual property rules. These challenges include finding alternatives inside the current patent system, by forcing the use of the TRIPS flexibilities, and also monitoring international discussion on the subject, especially on "innovation and access", which implies the discussion of new models of protecting industrial property.

The complexity of the topic and the amount of time needed to accompany the discussions are major hurdles in the way of civil society's involvement in matters of intellectual property protection. Consequently, the production of informative material in accessible language and demonstrations of the impact this system has on people's daily lives are crucial for society to fully grasp the issue. Training courses for activists and civil society organizations with a direct interest in the issue have also proven to be invaluable.

The strategies proposed by Brazilian civil society reveal the importance of the challenges both today and also for the future of developing countries, and they can be grouped into three approaches: (a) a product-by-product perspective; (b) the domestic patent system; and (c) the need to reform the international patent system. The first involves the constant monitoring of newly approved drugs and the barriers to their access. We feel it is very important to strengthen cooperation between developing countries, since they will probably all confront the same problems with the same medicines. The second is related to the overall domestic patent system and its impact on the country's health policies. This broader perspective poses structural challenges for the ongoing implementation of health policies. Finally, the most challenging of these approaches is to consider alternative means of stimulating new drug development that do not necessarily involve intellectual appropriation, notably the system of patents, which puts prices out of reach of the most vulnerable populations.

We believe, therefore, in the importance of strengthening civil society and reinforcing its networks to improve information sharing, support for domestic problems and the search for joint alternatives to counter the negative impacts that patents have on access to health.

Finally, we believe that the courts can and should be used as a potential channel for defending collective rights, principally because: (a) it is a means of finding alternatives inside the current patent system in force in Brazil; (b) it is a means of raising public awareness about the negative impacts that intellectual property rights have on access to health; (c) it is a means of promoting participation and involving the Judiciary in the adoption of measures to pressure the Executive to use TRIPS flexibilities for the protection of public health.

Concerning the use of existing flexibilities, particularly compulsory licensing, the recent case of efavirenz provided a window into how society at large views the issue. While there was heavy pressure in the mainstream media against the compulsory license issued by the Brazilian government, many groups supported the public interest and the importance of the measure. These groups have been pressuring the government to use the flexibilities for the protection of public health as part of an HIV/AIDS and healthcare agenda. Furthermore, there was significant international support for the adoption of the compulsory license.[53]

This case also demonstrated that the Brazilian government is committed to its policy of universal access to treatment and healthcare. Nevertheless, there were some key conditions in place that enabled the government to take this step: the important precedent opened by Thailand when it issued a compulsory license and the ability of the international pharmaceutical market to supply the licensed drug. This supply reduced the possibility of there being a shortage of the drug.

However, the battle is by no means over and there are many other barriers to be crossed. It is well known that the price of new antiretrovirals is rising and that a larger slice of the Ministry of Health's budget goes on buying these drugs. A growing number of patients are taking second-line AIDS drugs that are patented in Brazil. Furthermore, the very latest medicines are also patented in other developing countries that produce generic drugs, such as India. In other words, should a compulsory license be issued for these new drugs, the market will not be able to supply them and the only alternative will be domestic production.

There are numerous developments and numerous contexts to monitor if we are to properly accompany what happens not only on a national level, but also on the international stage, since the decisions taken in this arena have a direct impact on the domestic system. Furthermore, it is also important to monitor what goes on in the domestic systems of other developing countries, since it is highly likely that the same will also happen in your country.

This is why it is vital for groups working in the field to share information and experiences, so they can develop joint strategies to tackle the problems they have in common and adapt successful experiences to their own specific contexts. This is the primary objective of this article.

NOTES

1. BRAZIL, National STD/AIDS Program, *Aids no Brasil,* available at <www.aids.gov.br/data/Pages/LUMIS13F4BF21PTBRIE.htm>, last access on 25 October 2007.

2. BRAZIL, National STD/AIDS Program, Resposta + Brasilia, 2005. Available at <http://www.aids.gov.br/data/documents/storedDocuments/%7BB8EF5DAF-23AE-4891-AD36-1903553A3174%7D/%7BEE03B6A9-6598-423D-BCF9-D41DBFC04408%7D/resp-posit01web.pdf>, last access on 21 January 2008.

3. WORLD HEALTH ORGANIZATION (WHO), *Progress on global access to HIV antiretroviral therapy: a report on '3 by 5' and beyond,* Geneva, 2006. Available at <http://www.who.int/hiv/fullreport_en_highres.pdf>, last access on 30 October 2006.

4. BRAZIL, National STD/AIDS Program Indicator Monitoring System, available at <http://

sistemas.aids.gov.br/monitoraids2/abrir.asp?valor=234>, last access on 22 January 2008.

5. Consultation made by email to the National STD/AIDS Program on 15 August 2007.

6. BRAZIL, General Coordination of Pharmaceutical Assistance Support Actions - CGSAF/DAF/SCTIE, in Dirceu B GRECO, *Desafios da epidemia de Aids após 10 anos de terapia anti-retroviral.* 2007. Available at <http://www.aids.gov.br/data/documents/storedDocuments/%7BA07528E1-7FB7-4CC7-97AD-B7CB17C9CA85%7D/%7B73A9984F-4F25-4E3D-AA91-10E82E30A86E%7D/ADESAO-01GrecoBrasilia-19-06-07%20%20%2003.pdf>, last access on 22 January 2008.

7. On this subject, see: BRAZIL, National STD/AIDS Program, *A sustentabilidade do acesso universal a anti-retrovirais no Brasil,* Brasilia, 2005. Available at <http://www.aids.gov.br/data/documents/storedDocuments/%7BB8EF5DAF-23AE-4891-AD36-1903553A3174%7D/%7B0938AD30-E212-4E08-AE96-7C96622C85A3%7D/Cons._nacional_sustentabilidade.doc>, last access on 21 January 2008.

8. M.A.G KINZO. *A democratização brasileira – um balanço do processo político desde a transição*. São Paulo em Perspectiva, vol.15, number 4, São Paulo Oct/Dec 2001.

9. S. ESCOREL, *Reviravolta na Saúde. Origem e articulação do Movimento Sanitário*, Rio de Janeiro, Fiocruz, 1999.

10. BRASIL, National STD/AIDS Program, *História do Programa Nacional - AIDS vinte anos - Esboço histórico para entender o Programa Brasileiro.* Available at <http://www.aids.gov.br>, last access on 27 February 2007.

11. Idem.

12. M. SCHEFFER, A. SALAZAR, K. GROU, *O Remédio via Justiça Um estudo sobre o acesso a novos medicamentos e exames em HIV/Aids no Brasil por meio de ações judiciais*, Brasilia, Ministry of Health, 2005.

13 M.A. OLIVEIRA, A. ESHER, "Acesso universal ao tratamento para as pessoas vivendo com HIV/Aids no Brasil". In J.A.Z. BERMUDEZ, M.A.OLIVEIRA, A. ESHER (orgs.), *Acceso a Medicamentos: derecho fundamental, papel del Estado*. Rio de Janeiro, ENSP/Fiocruz, 2004, pp 233-250.

14. BRAZILIAN INTERDISCIPLINARY AIDS ASSOCIATION (ABIA), *Patentes: por que o Brasil paga mais por medicamentos importantes para a saúde pública?,* 2006, available at <www.abiaids.org.br>, last access on 22 January 2008.

15. World Trade Organization (WTO), *Glossary and Fact sheet: TRIPS and pharmaceutical patents – obligations and exceptions*, available at <www.wto.org>, consulted on 21 January 2008.

16. G.C. CHAVES, M.A. OLIVEIRA, *A proposal for measuring the degree of public health–sensitivity of patent legislation in the context of the WTO TRIPS Agreement,* Bulletin of the World Health Organization, 85 (1), 2007, pp 49-56.

17. G.C. CHAVES, *Patentes farmacêuticas: por que dificultam o acesso a medicamentos?,* Rio de Janeiro, ABIA, 2006. Available at: <http://www.abiaids.org.br/cedoc/publicacoes>, last access on 22 January 2008.

18. Idem.

19. LIMA, Luis Carlos Wanderley, Coordinator of intellectual property at ANVISA. Available at <http://comvisa.anvisa.gov.br/tiki-read_article.php?articleId=80&PHPSESSID=e40a0286138454e3702a6bec26c8ae07>. Consulted on 22 January 2008.

20. Thailand, Ministry of Public Health and the National Health Security Office, *Facts and evidences on the ten burning issues related to the government use of patents on three patented essential drugs in Thailand,* 2007. Available at <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf>. Last access on 3 May 2007.

21. KIJTIWATCHAKUL, K. *The right to health.* Thailand: Médecins Sans Frontières-Belgium (MSF-B), Pharmacy network for Health Promotion (PNHP), Thai health Promotion Foundation and Third World Network, 2007.

22. N. FORD, D. WILSON, G.C. CHAVES, M. LOTROWSKA, K. KIJTIWATCHAKUL, *Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand,* AIDS 21 Suppl 4:S21-S29, 2007.

23. On this subject, see the study produced by Knowledge Ecology International (KEI), *Recent examples of the use of compulsory licenses on patents*, available at <http://www.keionline.org/misc-docs/recent_cls.pdf>. Last access on 22 January 2008.

24. J.A.Z BERMUDEZ, M.A. OLIVEIRA, G.C. CHAVES, "O Acordo TRIPS da OMC e os desafios para a saúde pública". In J.A.Z. BERMUDEZ, M.A. OLIVEIRA, A. ESHER (orgs.), op.cit., pp. 69-90.

25. A. GRANJEIRO, L. TEIXEIRA, F.I. BASTOS, P. TEIXEIRA, "Sustainability of Brazilian policy for access to antiretroviral drugs", *Revista de Saúde Pública,* 40 (supl.), 2006. Available at: <http://www.scielo.br/pdf/rsp/v40s0/en_09.pdf>. Last access on 22 January 2008.

26. GTPI, *Acordo do Governo Brasileiro com a Abbot Frustra Expectativas dos Brasileiros,* 13 July 2005, available at <http://www.rebrip.org.br/_rebrip/pagina.php?id=659>. Last access on 10 January 2008.

27. CHAVES, G.C. *Perguntas e respostas sobre o licenciamento compulsório do medicamento Efavirez no Brasil.* Rio de Janeiro: ABIA, 2007. Available at: <http://www.abiaids.org.br/cedoc/publicacoes/artigos.aspx?lang=pt&mid=6&smid=2&siid=7&fg=Materias%20Informativos>. Access on 21 January 2008.

28. BRASIL. Chega ao Brasil 1º lote de efavirenz genérico usado no tratamento da AIDS. Brasília, Radiobrás, 02 de julho de 2007. Available at: <http://www.agenciabrasil.gov.br/noticias/2007/07/02/materia.2007-07-02.7585739203/view>. Access on 20 March 2008. The value paid per pill (600 mg) is R$ 1 (real). Each adult person takes one pill per day, totaling R$ 365 (reais) patient/year or US$ 190 patient/year (considering official exchange rate of R$1.91 to 1 USD, valid for the day of the shipment).

29. BRAZIL, Speech by the President of the Republic, Luiz Inácio Lula da Silva, at the ceremony to sign the compulsory license for the drug efavirenz. Planalto Palace, Brasilia, 4 May 2007. Available at <http://www.imprensa.planalto.gov.br/download/discursos/pr128-2.doc>, last access on 22 January 2008.

30. State of art is all technological information made accessible to the public in Brazil or abroad, by

means of written or oral disclosure, by use or in any other way, before the filing date of the patent or utility model application (art. 11, para. 1, LPI).

31. Denis B. BARBOSA, *Pipeline: uma inconstitucionalidade patente*. Available at <http://denisbarbosa.addr.com/27.rtf >. Last access on 3 December 2007.

32. According to Article 4 of the Paris Convention for the Protection of Industrial Property, any person who has filed an application to patent an invention in a given country will have a period of 12 months to make the same filing in other countries. This period is known as the "period of priority".

33. Idem. [perhaps cite the Duke Center for the Public Domain articles]

34. Patent Database of the National Institute of Industrial Property, consultation made in October 2007: <www.inpi.gov.br>.

35. J. A. Z. BERMUDEZ, R. EPSZTEJN, M.A. OLIVEIRA, L. HASENCLEVER, *O acordo TRIPS da OMC e a Proteção Patentária no Brasil: Mudanças recentes e Implicações para a Produção Local e Acesso da População aos Medicamentos*, Rio de Janeiro, Ensp-Fiocruz/OMS, 2000, p. 131.

36. B. CORIAT, F. ORSI, C. d'ALMEIDA, *TRIPS and the international public health controversies: issues and challenges*, Industrial and Corporate Change Advance Access, November 2006, pp. 1- 30.

37. Brazil. National Industrial Property Institute (INPI), available at <http://www.inpi.gov.br/menu-esquerdo/patente/pasta_manual/DiretrizesQuimica.pdf/view?searchterm=diretrizes>. Consulted on 22 January 2008.

38. P. DRAHOS, *Bilateralism in Intellectual Property. Report commissioned by Oxfam GB as part of its Cut the Cost of Medicines Campaign*, OXFAM, 2001. Available at <http://www.oxfam.org.uk/what_we_do/issues/trade/downloads/biltateralism_ip.rtf>. Last access on 25 January 2008.

39. For more information, see <www.rebrip.org.br>.

40. National: ABIA, GIV, GAPA-SP, GAPA-RS, GESTOS, GRAB, Pela Vidda-SP, Idec, Conectas Human Rights, RNP+ Maranhão, National Federation of Pharmacists. International: Oxfam, Doctors Without Borders.

41. ABIA, *Patentes Farmacêuticas: por que dificultam o acesso a medicamentos?,* 2006, available at <http://www.abiaids.org.br/_img/media/cartilha_patentes.pdf>, last access on 21 January 2008. Idem, *Perguntas e Respostas sobre o Licenciamento Compulsório do Medicamento Efavirenz no Brasil,* 2007, available at <http://www.abiaids.org.br/_img/media/EFAVIRENZ.pdf>, last access on 21 January. Idem, *Propriedade Intelectual: interfaces e desafios,* 2007, available at <http://www.abiaids.org.br/_img/media/Anais_Rebrip_web.pdf>. Last access on 21 January 2008.

42. *Técnicos da Saúde, Indústria e Comércio analisaram proposta da Abbott referente ao Kaletra,* National AIDS Agency, 19 August 2005. Available at <http://sistemas.aids.gov.br/imprensa/Noticias.asp?NOTCod=66822>. Last access on 10 January 2008.

43. Brazil, Ministry of Health, *Acordo entre o Ministério da Saúde e o Laboratório Abbott,* available at <http://www.aids.gov.br/data/documents/storedDocuments/%7BB8EF5DAF-23AE-4891-AD36-1903553A3174%7D/%7B132F255F-85A2-4939-8626-0BB7EE507C72%7D/AIDS.BR_.pdf>. Last access on 21 January 2008.

44. R. REIS, *Patentes farmacêuticas, acesso e produção de ARVs,* Boletim ABIA, Rio de Janeiro, Aug-Oct. 2006.

45. J. M. FORTUNAK, O.A.C. ANTUNES, *A produção de ARV no Brasil – uma avaliação*, Rio de Janeiro, ABIA/MSF, 2006. Available at: <http://www.abiaids.org.br/media/ARV.pdf>. Last access on 22 January 2008.

46. ABIA, *Patentes: por que o Brasil paga mais por medicamentos importantes para a saúde pública?,* 2nd edition revised, 2006. Available at <http://www.abiaids.org.br/_img/media/patentes_GTPI.pdf>. Last access on 21 January 2008.

47. Opinion available at <http://www.deolhonaspatentes.org.br/media/file/Proj_Leis/PL29_manifestacao_gtpi_rebrip.pdf>. Last access on 21 January 2008.

48. Petition available in full on the website of Conectas Human Rights: <http://www.conectas.org/noticia.php?not_id=192>. Last access on 22 January 2008.

49. Parties that may legitimately file a Direct Action of Unconstitutionality (ADIN) are listed in Article 103 of the Brazilian Constitution. They are: the President of the Republic; the Directing Board of the Federal Senate; the Directing Board of the Lower House; the Directing Board of a State Legislative Assembly or of the Legislative Chamber of the Federal District; a State Governor or the Governor of the Federal District; the Brazilian Attorney General; the Federal Council of the Brazilian Bar Association; a political party represented in the National Congress; a confederation of labor unions or a professional association on a nationwide scale.

50. Decision available at <http://intranet.comunidadandina.org/Documentos/Procesos/1-AI-96.doc>. Last access on 15 December 2007.

51. At the time this article was completed in January 2008, the groups and researchers who had sent letters of support were: Fundación IFARMA - Colombia; Oxfam International; Thai Network of People Living with HIV/AIDS; (TNP+); AIDS ACCESS Foundation; Thai Foundation for Consumers; Thai Rural Doctors Society; Thai Chronic Renal Failure Network; Thai Alternative Agriculture Network; Thai Parents Network; Thai Rural Pharmacist Society; Thai NGOs Coalition on AIDS; FTA Watch; Drug Study Group; Prof. Kevin Outterson (Boston University School of Law); Prof. Brook K. Baker (Northeastern University School of Law); Knowledge Ecology International (KEI); Third World Network; Lawyers Collective HIV/AIDS Unit; Indian Network for People Living with HIV/AIDS; Delhi Network of Positive People; Alternative Law Forum; Cancer Patients Aid Association and ActionAID India.

52. According to consultations made with the Regional Federal Tribunals in November 2007.

53. Petition in support of the Compulsory License for the Drug Efavirenz in Brazil. Available at <http://www.agenciaaids.com.br/arquivos/lista_abia.doc>.Last access on 21 January 2008.

RESUMO

O presente artigo aborda o sistema de proteção à propriedade industrial vigente no Brasil e sua relação com a política de acesso universal a medicamentos para tratamento da AIDS. Ainda, apresenta as principais estratégias de atuação de um grupo da sociedade civil brasileira - GTPI/REBRIP – em relação aos principais problemas e desafios identificados.

PALAVRAS-CHAVE

Propriedade industrial – Medicamentos essenciais – HIV/AIDS – Sociedade civil – TRIPs

RESUMEN

El presente artículo aborda el sistema de protección a la propiedad industrial vigente en Brasil y su relación con la política de acceso universal a medicamentos para el tratamiento del SIDA. También presenta las principales estrategias de actuación de un grupo de la sociedad civil brasileña –GTPI/REBRIP– en relación con los principales problemas y desafíos identificados.

PALABRAS CLAVES

Propiedade industrial – Medicamentos esenciales – VIH/SIDA – Sociedad civil – TRIPS