Intellectual Property Rights and Access to ARV Medicines:

Civil Society Resistance in the Global South

Brazil
Colombia
China
India
Thailand

2009

SUPPORT

ABIA
Associação Brasileira Internacional de AIDS

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Forword

Despite the devastating consequences that the HIV/AIDS epidemic had on a worldwide scale which resulted in immense human suffering, irrecoverable socioeconomic losses, and transformed demographic behavior, there has indeed been some positive repercussions in several areas of human knowledge. Advances in the permanent quest for solutions in confronting the epidemic have characterized not only the biomedical area – despite the inexistence of a vaccine – but also a broad range of sectors of the social organized movement. These positive results have included the enduring advocacy of human rights, the championing of gender equity, and, the negation of stigma and discrimination against groups of society, who have been traditionally marginalized and politically disenfranchised.

In the vast universe that feels the impact of the HIV epidemic, the intellectual property (IP) area, which is the target of this publication, has been dominated by the dynamic between the search for scientific advances and the view that access to medications is an unalienable human right. The interface of these two values has cumulated in the mobilization of social segments demanding that neither be compromised, resulting in legislative achievements through the utilization of judicial mechanisms.

Currently, the discourse surrounding HIV and IP is focused on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the wide utilization of its safeguards, which aim at increasing the access to anti-retroviral medicines. This discourse, however, calls for the involvement of national governments and international organizations. Furthermore, this involvement should be based on the need to establish access to medicines according to the principles of human rights and not on the commercial concept of “exclusivity.”
It is clear to us that this quest for effective mechanisms that guarantee access to essential medicines in full respect of human rights has just begun. However, we also acknowledge that the achievements represented in this publication are an important step towards this objective.

The Working Group on Intellectual Property – GTPI/REBRIP – and the Brazilian Interdisciplinary AIDS Association – ABIA – have been at the forefront of this discussion in Brazil and aided other countries’ mobilization and advocacy coordinated efforts aiming at the achievements herein recorded.

PEDRO CHEQUER
Country Coordinator
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Introduction

Even prior to the availability of drugs for the treatment of HIV and AIDS, during the 1980s, groups and organizations that worked with HIV in various countries emphasized the importance of access to the discoveries and inventions that would control this epidemic. In the beginning, the groups and activists that demanded treatment pressured scientists to develop effective and safe medications for people living with HIV/AIDS (PLWHA) that would be readily made available on the market. The collective battles of these groups in the United States and Europe have been anthologized. For instance, ACT-UP\(^1\), an American activist group lobbied and organized mass protests, successfully pressuring scientists and pharmaceutical companies to adjust the first doses of AZT to tolerable levels. Up to that moment, AZT doses were too high and caused more harm than good to patients. By the second half of the 80s, AZT became the first drug possible to effectively treat HIV. Activists also worked toward access to other drugs that followed AZT, such as DDI and DDC, and demanded for the quick approval and availability of these drugs for PLWHA, primarily living in the United States\(^2\).

Starting from the 1980s, Activist movements related to HIV/AIDS are characterized by an ambiguous relationship with the scientific establishment, including the government bodies that monitored clinical trials (e.g. CDC, FDA\(^3\)) and pharmaceutical companies that financially backed-up many of these studies. On one hand it has been important to pressure scientists for new drugs, but on the other it has also been

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\(^1\) AIDS Coalition to Unleash Power - ACT UP is a diverse, non-partisan group of individuals united to direct action to end the AIDS crisis.


\(^3\) Centers for Disease Control and Prevention and Food and Drug Administration from the United States.
important to be critical of scientists and companies concerning ethical issues related to clinical trials and access. During the 1990s, activists for AIDS treatment engaged in battles that became more complex each day. In 1996, the XI International AIDS Conference, held in Vancouver, Canada, made public the news that antiretroviral drugs (ARV), when used in combination, could effectively control HIV progression in the human body. This completely transformed the context of the response to control HIV. The combination of three or more drugs diminished the impact of HIV and kept the virus in check for much longer. These clinical findings changed AIDS from being a fatal disease to one that could be treatable and considered chronic.

The combination of medicines, in conjunction with the expectations of their impact, also brought the preoccupation of high prices set by the pharmaceutical companies that researched and launched the medications on the market. The cost for treatment was financially feasible for only a small part of patients – either from developed countries, or the higher income persons from the developing world.

Compounding this anxiety at the time, was the implementation of the TRIPS Agreement in the recently-created World Trade Organization (WTO) in the mid-1990s, which enacted stricter patent rules for all fields of technology including medicines, thus, facilitating the entrenchment of pharmaceutical industrial monopolies. Consequently, countries that had the capacity to produce generic antiretroviral medication had their production limited or dismantled by the imposition of new patent laws obligated by the TRIPS Agreement and WTO. In this new context, the world has remained divided by those that produce and market medicines and those who need these medicines. The inequalities of access have determined those who can benefit from new therapeutic schemes (generally speaking, patients from richer countries) and those that will die due to lack of the same medications (the millions of patients from poorer countries).

4 Agreement on Trade-Related Aspects of Intellectual Property Rights.
At the end of the 1990s, a growing mobilization of civil society groups from various countries in the developing world organized themselves in opposition to economic abuses, inequality in access, and violations of basic human rights, such as the right to life and health. Abuses were being practiced in many countries by international pharmaceutical companies with the corroboration of weak governments that did not prioritize the lives of their citizens. The fight for access to medications, which had been so evident in the richer countries of the North in the 80s, intensified in the poorer countries of the South in the last years. Not only did they have to enhance the scope of their actions, but they also had to incorporate other concerns to their objectives, such as international commercial law, economic laws, and legislation about intellectual property law.

During the current decade, much has advanced in regard to access to medication due to the local and international mobilization of people living with HIV/AIDS, NGOs, and diverse governmental sectors in different countries. Nevertheless, challenges remain for the ultimate goal of universal access for all people in need of medications.

The objective of the present publication is to narrate part of the recent history and the many struggles related to advocacy for access to medicines of engaged civil society. Through the experiences of five middle-income countries—Brazil, China, Colombia, India, and Thailand—we present the reader the perspective of local civil society organizations about the national impact of intellectual property protection and access to medications.

These five countries were chosen due to their accumulated experience in this field, their capacity to produce generic medication, their activist efforts, and the exchange of ideas and information that already exists between them. This exchange is based on the common conviction that the fight for fair access to medications must be done through the promotion of democratic processes and the protection of human rights, including in the economic sectors. Since 2006, the authors of these texts have worked in conjunction in a serious of initiatives with the objective of reinforcing local and international petitions for access to medications.
Some of these actions and developments described in the publication are more than simple records of the context and the battles here recorded. We also intend to demonstrate the possibility of South-to-South cooperation from our own voices and perspectives.

We hope that the publication will serve to galvanize solidarity between people in the fight for just access to medications. Furthermore, we pretend that the challenges and results here described and analyzed will call attention to the importance of the contribution of organized civil society in the search for justice and for a better world.

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CRISTINA PIMENTA  
ABIA
1. Brazil

ACCESS TO MEDICINES AND INTELLECTUAL PROPERTY IN BRAZIL:
A CIVIL SOCIETY EXPERIENCE

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ABSTRACT

During the last decade the Brazilian civil society organizations have played a crucial role in the implementation and sustainability of universal access to AIDS drugs in the country. The following text intends to shed light on that experience, notably on the current effort of a group of non-governmental organizations (NGOs) that work together in the fields of public health, HIV/AIDS, and intellectual property. This article addresses the Brazilian system of intellectual property law in respect 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 – in tackling the main identified problems and challenges that it has identified in that regard in the field.
The following text intends to shed light on the Brazilian civil society experience, notably on the current effort of a group of non-governmental organizations (NGOs) that work together in the fields of public health, HIV/AIDS, and intellectual property.

The entrenchment of the newly established intellectual property laws of recent years has directly impacted public health and the access of essential medications. The new world order demands new efforts of collaboration for an efficient social response. The Working Group on Intellectual Property (GTPI) of the Brazilian Network for the Integration of Peoples (REBRIP) was created with the objective to usher in an agenda of resistance through the identification of appropriate strategies within this context. REBRIP is an umbrella network of social movements, NGOs and labor unions in Brazil.

GTPI's success was made possible due to its interdisciplinary dialogue and collaboration with movements and organizations of diverse backgrounds – e.g. HIV/AIDS organizations, human rights, consumers’ rights, etc.

Authors of mixed backgrounds, formations, and nationalities have written about the Brazilian response to the AIDS epidemic and, more recently, about the role of NGOs in the area of intellectual property and access to medicines. However, little has been written from the eyes of organized civil society. Thus, this article is our attempt to tell our own story – the story of GTPI – and to analyze the Brazilian context from a collectively constructed view.

As we will demonstrate in this text, Brazil has paid a high price in legislative terms in the area of intellectual property for its domestic decisions that conform to international commitments. Newly adapted legislation has impacted the public policy of technology and industry and has conflicted with the best execution of public health policy, thus, undermining its implementation. Within this context, we will relate the significant measures that GTPI has taken in addition to delineate the current challenges of maintaining a balance between intellectual rights and the right to health.
I. INTRODUCTION: GENERAL OVERVIEW OF AIDS IN BRAZIL AND THE UNIVERSAL TREATMENT POLICY

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 as a direct consequence of HAART. From 1993 to 2003, the average life expectancy for AIDS patients increased by nearly five years, reflecting a significant increase in quality of treatment. Furthermore, there was a reduction of 80% in hospitalizations, generating a savings of US$2.3 billion.

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 a study carried out by the World Health Organization (WHO), UNAIDS and UNICEF, at the end of 2007, 33.2 million people were living with HIV/AIDS, 2.1 million of which were children. In that same year there were 2.5 million new infections and 2.1 million AIDS-related deaths. This research also indicates an increase of 950,000 people receiving antiretroviral treatment from the end of 2006 to the end of 2007. Nevertheless, only 31% of people that needed ARV treatment in developing countries were receiving it in 2007. It is also worth emphasizing

that of these 31% of people that had access, 97% only received first-line treatment—medication that is not legally protected by patents.

As stated by estimates from the World Health Organization (WHO), nearly 6.5 million people in developing and lesser-developed countries are in urgent need of ARV treatment. However, due primarily to patent protection of medications and high prices imposed by drug companies, only 1.3 million people can afford treatment. Nearly 80% of the 3 million people who die each year from AIDS had no access to the available medicines.  

Brazil is one of the few countries in the world that provides universal free access to AIDS treatment. The National STD/AIDS Program estimates that some 630,000 people are infected with the HIV virus in Brazil. Of these, 190,000 undergo ARV treatment. Data from the General Coordination of Pharmaceutical Assistance to Strategic Medication of the Ministry of Health indicated that Brazil had a budget of R$ 600.928 million for the procurement of antiretroviral medication. From this amount, 32.67% was spent on nationally produced medications in contrast with 67.33% spent on imported patented drugs. The fact that such an immense portion of the budget is being spent on patented medicines has placed the sustainability and universality of this healthcare policy in jeopardy.

To live more dignified lives, access to proper treatment is crucial for thousands of people infected with HIV/AIDS in Brazil. The Brazilian government has both a legal and moral obligation to provide full treatment to all who need it. The initial success of the national STD/AIDS Program has largely been attributed to the local manufacture of drugs that

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6 Brazil, National AIDS Program, 2008. Presentation during the XVII International AIDS Conference, Mexico City, Mexico.
did not enjoy patent protection in Brazil. Nevertheless, the growing portion of ARV drugs—patented or with patent pending—could make the national policy of universal free access to AIDS treatment unsustainable.

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

The implementation of its 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

Dating back from the 1970s, the “Public Health Movement” was initially 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 environment, Brazil’s current public health system came into being, now known as the Unified Health System (SUS), regulated by Federal Laws 8080/90 and 8142/90. Of particular importance is that SUS coverage provides “integrated therapeutic treatment”, including pharmaceuticals, which implies the obligation of the State to provide medicines for all who are in need.

In tackling the HIV/AIDS epidemic in Brazil, the first official program, established in São Paulo in 1983, was the result of collaboration between the organized gay community and State Health Department. In 198610,

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as a nationwide response, the Brazilian national government created the National AIDS Program.

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 not only in a string of prevention campaigns and initiatives to combat discrimination and prejudice but also in the strengthening of solidarity amongst affected populations. Meanwhile, the number of people seeking HIV/AIDS treatment was also escalating.

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 for the public in 1991. But just as the administration of AZT in Brazil was growing more widespread, transnational pharmaceutical companies were launching new medicines to control AIDS. Monotherapy with AZT alone was deemed inadequate. Therefore, the combined therapy (known colloquially as a “cocktail”) became the recommended treatment internationally.

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

The first lawsuits claiming individual entitlement to the latest medicines were 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 Federal Law 8080/90 and the various

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11. Idem.

State Constitutions, emphasizing the right to healthcare and the right to life.\textsuperscript{13}

Also in 1996, amid widespread social mobilization and pressure from the National AIDS Coordination Authority, Federal Law 9313—or the Sarney Law, named after the Senator who proposed it—was approved. This law strengthened 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 Federal 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 ordinary citizens contributed to a more structured and better organized response from the government. An important driving force behind the ongoing process of constructing and implementing a policy of free access to ARVs in Brazil was the mobilization of civil society in the judicial realm.

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

In addition to the Sarney Law, 1996 also witnessed the approval of the new Industrial Property Law (Federal Law 9279/96) that completely overhauled the existing legal regime by undermining medicines to be produced locally at affordable prices. The policy of universal access would, however, be undermined by international agreements that imposed the obligation to grant patents to the pharmaceutical sector, thus, radically transforming the context of HIV/AIDS treatment in Brazil.

Brazil’s new intellectual property law sought to incorporate 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 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which established the obligation to recognize intellectual property rights for all fields of technology, including the pharmaceutical sector.

Accordingly, countries had to modify their national legislations to bring them in line with TRIPS. For many countries this meant they had to recognize patents in fields of technology that were poorly developed internally, while transnational companies from the developed world enjoyed greater market protection. TRIPS has established that medicines, an essential component guaranteeing the right to health, be treated in the same fashion as other merchandise. As we shall see later in this paper, this has harmed and hampered the implementation of health policies.

II. ACCESS TO MEDICINES AND THE SYSTEM OF INTELLECTUAL PROPERTY IN BRAZIL: PRINCIPAL CHARACTERISTICS AND PROBLEMS

As already observed, the creation of WTO in 1994 and the signing of the TRIPS Agreement obliged all 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 transition 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, at the same time, 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). These will be analyzed later in this article.

Brazil, however, did not take advantage 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 strengthen their capacity 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, which came into operation in May 1997.14 Furthermore, Brazilian legislation failed to adopt some of the flexibilities permitted by TRIPS and, in some respects, 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 Industrial Property Law (IPL) includes 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 the aim of 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

<table>
<thead>
<tr>
<th>FLEXIBILITIES</th>
<th>DEFINITION</th>
</tr>
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| Compulsory Licensing| Established in Article 31 of the TRIPS Agreement. When a government issues a license to companies or individuals that are not the patent owners to manufacture, use, sell or import a product under patent protection without the consent of the patent holder. The TRIPS Agreement allows compulsory licensing as part of the Agreement’s overall attempt to strike a balance between promoting access to existing drugs and advancing research and development of new drugs. Nevertheless, the term “compulsory licensing” does not actually appear in the TRIPS Agreement. Instead, it uses the phrase “other use without the authorization of the right holder”.

| Parallel Imports    | Established in Article 6 of the TRIPS Agreement. When a product manufactured legally overseas is imported by another country without the consent of the patentee. The legal principle in this case is “exhaustion”, the idea that once a patent holder has sold a batch of its product on the market, his/her patent rights to those specific goods are exhausted and he/she cannot prevent their resale to other countries. The setting of this trade is sometimes referred to as the “grey market.” |

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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 entrusted to domestic law.

<table>
<thead>
<tr>
<th>FLEXIBILITIES</th>
<th>DEFINITION</th>
</tr>
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<tbody>
<tr>
<td>Bolar Exception</td>
<td>Established in Article 30 of the TRIPS Agreement. This allows manufacturers of generic drugs to use a patented invention to obtain marketing approval—e.g. from public health authorities—without the permission of the patent owner and prior to patent expiration.</td>
</tr>
<tr>
<td>Experimental Use</td>
<td>Established in Article 30 of the TRIPS Agreement. Allows researchers to use patented inventions in their research for the purpose to better understand the invention. Reverse engineering depends upon experimental use.</td>
</tr>
<tr>
<td>Health sector participation in analyzing pharmaceutical patent applications</td>
<td>Implicit in Article 8 of the TRIPS Agreement. Refers to the participation of Ministry of Health officials in the processes of analyzing pharmaceutical patent applications.</td>
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</table>

In the case of health, these flexibilities have two different goals, one that is more immediate and another that is more medium- and/or long-term. Compulsory licensing, parallel imports and the Bolar exception are flexibilities whose goal is immediate, that is, procuring 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 into Brazilian legislation and can be utilized for a number of reasons. Article 68 of Brazil’s industrial property law stipulates that a patent shall be subject to compulsory licensing if its owner exercises the patent right in an abusive manner or exploits economic power. The same article also establishes that a compulsory license may be granted when the patented product is not

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exploited inside Brazil or when the sale of the protected product fails to satisfy the needs of the market (the “failure to work” requirement). Compulsory licenses may also be issued in cases of dependent patents, under the terms provided for in Article 70 of the IPL 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 IPL, with Federal Law 10196/2001 integrating 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 facilitates research through the dissemination of information on the invention.

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, IPL), or in cases of national emergency and public interest (art. 10, Decree 3.201/99). There is currently a law bill (PL 139/99) working its way through the National Congress to incorporate this flexibility in full. This is an extremely crucial mechanism for policies on drug access, 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 they were sold at the lowest price.17

Experimental use and health sector participation in analyzing pharmaceutical patent applications are flexibilities with medium- and long-term goals. They are designed to encourage domestic technological development through either utilizing disclosed information about the patent or through impeding the concession of exclusive rights for patent applications that do not meet the legal patentability requirements.

Experimental use is permitted in Brazil by Article 43, II of the IPL law. It represents one of the ways of striking a balance between the interests of the patent holder and national interests, as that it allows patented

information to be used to promote domestic scientific and technological development. Scientific experimentation can be conducted by any research laboratory, either public or private.\(^{18}\)

Health sector participation in analyzing pharmaceutical patent applications was incorporated into the IPL 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 this 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 because it prevents drug patents to be 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 then qualify under this provision. The WTO has already expressed that countries can institute different mechanisms of analysis in determined areas for patent requests. The aim of this is to align national policy with the principles and objectives of the TRIPS Agreement, thus upholding Articles 7 and 8. In that regard, having different mechanisms of analysis does not violate the principle of non-discrimination established by Article 27 of TRIPS\(^{20}\).

\(^{18}\) 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>, last access on 22 January 2008.

The chief issue in implementing this flexibility lies in the fact that the Brazilian Patent Office (INPI) does not publish the decisions, for which ANVISA does not grant prior consent. This complicates the rejection of a patent application. This means that the patent claim remains pending and the would-be owner enjoys a de facto monopoly.

Although all these TRIPS flexibilities have been incorporated into Brazilian legislation and are compatible with international rules, it is another matter as to whether the country will actually exercise these safeguards to obtain medicines at more affordable prices. Actual practice 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 enhancing the scope of their access to treatment. Prominent examples include licenses issues in Thailand\textsuperscript{21,22} and Brazil in 2007\textsuperscript{23}.

\begin{table}[h]
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\textbf{Box 2: Compulsory license of the medication Efavirenz in Brazil} \\
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Although the Brazilian IPL is from 1996 and the priority date of Efavirenz is from 1992, Efavirenz is a patented product in Brazil. This was possible because Brazil adopted the \textit{pipeline mechanism}, a legislative provision that grants patent protection retroactively. In 2007, Efavirenz was utilized by 75,000 patients, who represent 38\% of the patients undergoing treatment. It is expected that this percentage will increase with each year. Each dose of Efavirenz was marketed for about R$ 3 (US$ 1.59/dose or an annual cost of US$580/patient), representing a total cost of R$90 million/year.

Since November 2006, the Brazilian government attempted to negotiate a price reduction with the patentee of this medication—Merck Sharp & Dohme—emphasizing two important points: \\
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\end{table}


\textsuperscript{22} KJITIWATCHAKUL, 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.

a. Merck Sharp & Dohme was selling Efavirenz at cheaper prices in countries at the same development level but with less people in need of treatment as Brazil.

b. Indian generic versions were much cheaper – as cheap as US$ 0.45/dose or an annual cost of US$ 164.25/patient (Cipla, Ranbaxy and Aurobindo).

Merck, however, did not present an acceptable proposal to the Brazilian government, ignoring the size of the national demand—which has been growing each year. Merck disregarded Brazil’s commitment to universal access and the fact that current treatment protocol calls for the use of Efavirenz as one of the medications for first-line treatment.

Initially, the company presented a proposal of a reduction of only 2% in price. After the courts declared Efavirenz an issue of public interest, Merck reduced the price by 30%.

The government considered Merck’s proposal as unsatisfactory and finally in May of 2007 issued a compulsory license for the initial import of generic versions produced in India and, thereafter, for locally manufactured generics. While local production were still being prepared by two public laboratories (Farmanguinhos and Lafepe), since July 2007 the generic version of the medication has been imported from India at a cost of R$ 365 per patient/year²₄, a third of the price offered by Merck.

Just for the year 2007, the acquisition of cheaper versions of Efavirenz represented an initial savings of US$ 30 million. By 2012, the year of its patent expiration, the estimate in savings will arrive at US$ 236.8 million as new patients who need treatment increase in the next years.

It is important to emphasize that the strengthening of national policies related to the access of medications benefits not just Brazil’s national budget. It also boosts the government’s credibility to negotiate prices of other medications and to stimulate the capacity of national pharmaceutical production and the transferring of technology.

The domestic production of non-patented ARVs in the early 1990s—by both public and private laboratories—was pivotal factor in the implementation of
Brazil’s universal access policy. Firstly, domestic generic prices were much cheaper than its imported counterparts. Secondly, local production facilitated the development of technological capabilities that were fundamental in estimating the costs of production for other patented ARVs.

Brazil submitted its first batch of the medication Efavirenz, produced by the official pharmaceutical laboratory of the Oswaldo Cruz Foundation, the Technological Institute in Fármacos or Farmanguinhos, in January of 2009 at a price of R$1.35/dose, 45% of the Merck price before the compulsory license.

Although the national production of medication is recognized by the public health movement as essential, it cannot be denied that the fundamental objective of our fight is the guarantee of access to medications. In that sense, the combination of strategies, which were the importation of generic medication from India followed by the national production of this medication, were fundamental in the success of the license.

In fact, compulsory licensing has already been used on several occasions by a number of countries, including some in the developed world. 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 Ministry of Health received reports from Farmanguinhos that informed about their industrial capability to produce ARV medicines locally if there were an impasse in price negotiations or if a compulsory license were issued. Drug companies have preferred to lower the price of

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24. Brasil, Chega ao Brasil 1º lote de efavirenz genérico usado no tratamento da AIDS. Radiobrás, Brasília, 02 de julho de 2007. Available at <http://www.agenciabrasil.gov.br/noticias/2007/07/02/materia.2007-07-02.7585739203/view>, last access in 20 March 2008. The price for dose of adult use (600 mg) was from R$1. Each adult takes one dose per day, a total cost of R$ 365 per patient/year or US$ 190 per patient/year (considering the official exchange rate is R$ 1.91 on the receiving date of the batch).


their products rather than to have them produced by Brazil’s domestic industry.\textsuperscript{27}

However, since the Brazilian government at the time 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 par with the figure in 1998.\textsuperscript{28} 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\textsuperscript{®}), used at the time by some 17,000 people, the Brazilian government set the stage for the issue of 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 negotiation, 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\textsuperscript{29} in Brazil.

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\textsuperscript{30} is extremely positive news, since it is a move to assure the sustainability of not only the National STD/AIDS Program, but also the entire public health system.

III. The GTPI/REBRIP and Its Role: Main Working Strategies to Tackle the Existing Problems and Challenges

Given the importance of preserving public policies such as universal access to antiretroviral treatment in spite of 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).

Created in 2001, REBRIP is an umbrella 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 current logic of trade and financial liberalization prevailing in the economic agreements currently being negotiated.\textsuperscript{31}

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


\textsuperscript{31}For further informations visit our: <www.rebrip.org.br>.
The GTPI works primarily on the following fronts in an attempt to minimize the negative impact of the patent system in Brazil:

1) Incorporating advocacy strategies such as filing legal and administrative actions with the objective to mitigate the impact of intellectual property regulations in the access to essential medications;

2) Strengthening South-South cooperation among countries 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;

5) Identifying alternatives that can widen access to medicines;

South-south cooperation is key in 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 in 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

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domestic and international civil society in generating 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 contribution for the process of examining and granting 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 could 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 and even less so by society in general. However, the GTPI has developed specific methodologies to address this topic, publishing information booklets (on domestic and international legislation and on key issues such as compulsory licensing in Brazil33) 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 to that system. 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, particularly the implementation of the last resolution approved in 2008 (WHA61.21), the “Public Health, Innovation and Intellectual Property Global Strategy and Plan of Action34”.

On a national level, the GTPI’s advocacy agenda has taken shape and its inclusion on the list of influential players on intellectual property 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) pre-grant opposition in the INPI and the filling of patent annulment cases, (c) writing position papers and presenting submissions on law bills, (d) petitioning the Brazilian Prosecutor General requesting that he file a petition questioning the constitutionality of the patents made under the pipeline mechanism (ADI n°. 4234) to the Supreme Court (STF) of Brazil which culminated in the filling of a Direct Action on Unconstitutionality n°. 4234, (e) public campaigning, (f) South-South joint actions and (g) the presentation of two cases in the Permanent Court of the People (PCP) of European transnational companies. 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

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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 at US$0.41\textsuperscript{35} by local firm Farmanguinhos in the event of a compulsory license being issued.

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 in order to avert the issue of the compulsory license. And so, in October 2005, a contract was signed with the Brazilian government keeping Abbott as the supplier of the drug\textsuperscript{36}. The deal, which did indeed lower the price, also came with clauses that conflicted with the national public interest. Such clauses were an obligation not to issue a compulsory license, no responsibility for technology transfer or foreign direct investment to manufacture the drug locally, and a stipulated price fix until the end of 2011, when the drug patent would be close to expiring.

Once the agreement was signed, civil society organizations from GTPI, in conjunction with the Public Prosecution Service, filed a civil public action\textsuperscript{37} – 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\textsuperscript{38}.


\textsuperscript{37} Law suit n.º 2005.34.00.035604-3, 15ª Vara Cível da Justiça Federal da Seção Judiciária do Distrito Federal.

\textsuperscript{38} R. REIS, Patentes farmacêuticas, acesso e produção de ARVs, Boletim ABIA, Rio de Janeiro, Ago-Out. 2006.
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. In addition, 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. 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 performed at anticipated levels, 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 awaiting judgment.

b. Pre-grant oppositions in the INPI and the filling of patent annulment cases

In 2006, GTPI member organizations also attempted to capitalize on administrative channels to prevent the INPI from granting undue patents for essential medicines. The group presented two pre-grant oppositions: the first referred to an application by Abbott for a second patent of the

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lopinavir-ritonavir combination (Kaletra®) and the second was for a patent application made by Gilead for its tenofovir disoproxil fumarate medication (Viread®).

Pre-grant oppositions 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, IPL).

The purpose of the two oppositions in INPI was to present the technical grounds for not granting patents for these two antiretroviral drugs. The oppositions 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 from the perception of a specialist in this subject, the other compounds developed have no new technical effect since they are standard practices used in organic synthesis. This application for a patent, therefore, does not present any inventiveness. In March 2008, the opposition confirmed to the INPI that the United States Patent and Trademark Office (USPTO) had denied the granting of the patent for this medicine. The Brazilian government had been spending R$72 million a year for tenofovir, while the generic version of this medication could have been bought for eight times less. In September 2008, the INPI denied a patent grant for tenofovir and Gilead filed a petition on March 13th of 2009 requesting for the revision of this decision. As of the publishing of this book, the INPI still has not examined the matter.

In the case of lopinavir/ritonavir, the company filed a second patent application (“divisional patent application”) for the product. The first patent had been conceded through the pipeline mechanism – a provision of Brazilian law considered by many jurists to be unconstitutional. This mechanism facilitates patents to be granted without an evaluation of the patentability requirements prescribed by law. The problem is that there is

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no legal provision 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.

In respect to filings of patent annulments, in mid-2007 GTPI 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 TRIPS legislation, but the patent in question was also granted through the pipeline mechanism, which will be later analyzed.

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 intends to file other such cases questioning the legality of patents granted unduly for essential goods in Brazil.

c. Writing position papers and presenting submissions on law bills

Another form of involvement by the GTPI consists of writing position papers and presenting submissions to accompany congressional bills on the subject of intellectual property and its impact on public health. In the executive branch, the discourse on public policy on intellectual property has been related to various other areas a number of times. In this regard, the GTPI has always stressed sending position papers on respective discourses that could have negative repercussions on public health. In the legislative branch, there are various law bills making its way through the congress that, if approved, will result in the adoption of TRIPS-plus regulations in Brazilian law or the exclusion of important flexibilities for public health41. The GTPI monitors over the progress of these bills, and, in

41. TRIPS-plus measures represent forms of protection of intellectual property more restrictive than the ones imposed by TRIPS and also the exclusion of the safeguards permitted by the Agreement. Generally, these measures aim to protect the interest of patent owners in the detriment of public interest. These measures are often contained in bilateral trade agreements negotiated between developed and developing countries. Brazil isn’t currently in negotiations or bind by any bilateral agreements with intellectual property clauses. However, such measures are present in law bills within the Brazilian legislative. Therefore its necessary to monitor these measures in order that they are not approved.
that regard writes statements that are sent to all the involved congressmen. It also participates in public hearings requested by congressmen to present its opinion on the law bill at hand. Lastly, in the judicial branch, besides filing briefs, the GTPI submits petitions and participates in public hearings.

Table 4: Cases undertaken by GTPI/REBRIP in view of measures related to intellectual property rights for medicines in Brazil

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<th>SUBJECT</th>
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<td>Bill of Law 22/2003 (non patenteability of ARV medicines)</td>
<td>This Bill of Law plans to include ARV medicines on the list of subject matter not entitled to patent protection in Brazil. In 2005, GTPI member organizations sent a legal opinion advocating its approval to representatives involved in the analysis of the bill. The bill is in full compliance with the underlying principles of the Brazilian Constitution, which gives precedence to the right to health and the right to life 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 still awaits approval in the House of Representatives.</td>
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<td>Bill of Law 29/2006 (linkage)</td>
<td>This Bill of Law intends to condition the registration of a drug to the expiry of its patent. This practice is known as linkage, a TRIPS-plus measure that establishes a relation between drug registration and patent protection. 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. GTPI submitted</td>
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<td>a legal opinion(^{42}) against the approval of this bill. An opinion has already been filed to shelve the bill, but this needs to be analyzed by other Senate committees.</td>
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<td>Guidelines for examining patent applications</td>
<td>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.</td>
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<td>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”(^{43}). 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.</td>
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<td>For instance, the INPI guidelines allows for the possibility of protecting new uses for known products and independent patent applications on polymorphs, facilitating the practice known as evergreening(^{44}) to the detriment of protection for real pharmaceutical innovations.</td>
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<td>In 2007, INPI began to review its guidelines and GTPI drafted an opinion about the subject, highlighting the need to consider the impact of patent protection in public health and the negative</td>
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\(^{43}\) Evergreening practices in pharmaceutical field are characterized by strategies adopted by patent holders to extend their monopolies beyond the initial 20 years of protection, even in the absence of any additional benefit for the patients. This practice aims to delay the entry of generic medicines in the market, avoiding competition.
Aims of Bills 2511/07 and 3995/08

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<th>Bills of Law 2511/07 and 3995/08 (use claims and polymorphs)</th>
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| Bill of Law 2511/07 aims to prohibit patent protection for new uses for known products. Bill of Law 3995/08 aims to prohibit patent protection for polymorphs. Both are making their way through the Brazilian Congress. Although these types of patent protections are extremely harmful to public health, they are being granted by the Brazilian patent office (INPI).

Patent protection for use claims allows the grant of protection that does not represent real pharmaceutical innovations. In that case, what is being protected is a new use of a product that is already known and, therefore, the product is not new. Use claims in the pharmaceutical field can be distinguished in two kinds: first medical indication and second medical indication (which includes third, fourth, fifth, etc. indications). First medical indication is the first pharmaceutical use of an already known composition that was not previously used for treatment purposes. Second medical indication is a new pharmaceutical use for a composition that is already known and is already therapeutically used. In both case it a new use for a known product. And exactly because the product is already known, there can be no patent protection since the claims do not meet the novelty patentability standard (article 27, TRIPS and article 8th, IPL). Besides lacking the novelty requirement, new uses are mere discoveries of a new effect of a known substance, since nothing has been changed in the previously used product. Therefore, there is no new invention, but only a new use...
SUBJECT ACTION ADOPTED BY GTPI/REBRIP

for an already existing invention. It is important to say that discoveries are not patentable under Brazilian IP law (article 10, IPL). Furthermore, there is another possible objection to the patentability of use claims: lack of industrial applicability. In fact, patents protect products or processes and use claims aims to protect the effect of the substance on the body, not the product as such or its method of manufacture. Therefore, use claims are substantially equivalent to a patent over a method of therapeutic treatment, which are not patentable in Brazil (article 10, VIII, IPL).

Polymorphism is an intrinsic property of matter in its solid state, that is to say, they may exist in different physical forms, which may have different properties more or less pharmaceutically significant. Since polymorphism is a natural property, polymorphs cannot be considered a human invention; they are discovered normally as part of routine experimentation. Therefore, they are not patentable. Furthermore, the search for a polymorph that presents a better solubility and bioavailability is obvious for a person skilled in the art and the method because such is already described in prior art. Therefore, there is no inventive step. Only if the patent claim is for a new process for identifying a polymorph, only then it might be granted – if the patentability standards are met. Independent patent applications on polymorphs themselves, that is, the products, cannot be granted.

The decision of granting patent protection for both use claims and polymorphs is related to the definition of the patentability standards, which each country has the possibility to interpret in its own way. The definition of such criteria constitutes a key aspect of patent policy, with implications in other areas, such as industrial and public health policies. The patentability standards – novelty, inventive step and industrial application – may be interpreted in different ways, and countries and specialists do not necessarily adopt the same interpretation. The interpretation of the patentability standards is not a technical issue, but a political decision, especially in the pharmaceutical field.

Besides the document drafted by GTPI regarding the revision of INPI’s guidelines for examining patent applications, which addressed the possibility of granting patent protection for use
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<td>claims and polymorphs as mentioned above, GTPI also wrote a legal</td>
<td>In its legal opinion, GTPI present arguments in favor of the approval of the law and also used examples of other countries that do not grant patent protection for use claims – such as India, Argentina and the Andean Community countries. GTPI also presented the <em>Guidelines for the examination of pharmaceutical patents: developing a public health perspective</em>, written by Dr. Carlos Correa and published by the World Health Organization – WHO, in which it is recommended that countries should not grant patent protection for use claims and polymorphs. The legal opinion was sent to all congressmen involved in the analyses of the bill, which is still ongoing. In April 2009, these bills of law received an opinion favorable to their approval by the first of three House of Representatives committees that will analyze them.</td>
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<td>opinion in Bill of Law 2511/07 and is writing a complementary opinion</td>
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<td>about Bill of Law 3995/08. In its legal opinion, GTPI present</td>
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<td>applications for pharmaceutical patents must obtain the prior consent</td>
<td>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. However, the pharmaceutical industry and the Brazilian patent office (INPI) are against ANVISA's prior consent. In several occasions, ANVISA's prior consent was questioned in the Executive, the Legislative and the Judiciary. Regarding the Executive, GTPI drafted a document in favor of ANVISA's prior consent, highlighting the benefits this measure can bring to public health. As a result, in May 2008 a decree was published regulating the prior consent and making it stronger.</td>
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<td>of public health sector)</td>
<td>In the Legislative, there is a bill of law regarding ANVISA's prior consent and patent claims made by the pipeline mechanism. GTPI is writing a legal opinion about Bill of Law 3709/08, in which will be defended that patent claims made by the pipeline mechanism must also obtain ANVISA's prior consent to be granted. In August 2009, GTPI will participate in a public hearing summoned by the House of Representatives about this bill of law.</td>
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<td>Bill of Law 3709/08</td>
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<td>Public hearing about the right of health in the Supreme Court</td>
<td>In April 2009, Brazilian Supreme Court held a public hearing about public health issues in Brazil. GTPI, represented by Conectas Human Rights, participated in this hearing highlighting the negative impact of patent protection in prices and in public health policies. The biggest problem appointed by government officials in the cases in the Supreme Court is the lack of public resources. In this context, GTPI highlighted the importance of asking why the government pays high prices for health services, especially essential medicines. The analyzes of the prices government pays for health services and the impact of intellectual property rights in those prices is essential to the search for sustainable solutions to access to health services and medicines by the population.</td>
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<td>Intellectual property and innovation</td>
<td>In June 2009, the Senate held a public hearing about intellectual property rights and innovation. GTPI sent to all senators a document that demonstrated the failure of the international intellectual property system, which has not been able to fulfill the objectives for which it was adopted — promote innovation and transfer of technology among countries. In fact, the patent system has become an instrument of blocking competition, other than protecting new inventions. In the pharmaceutical field, the document highlighted what is being called as an innovation crisis, since most of the products released by the pharmaceutical industry in the past year are not really new, but new versions of old medicines. The document also draws attention to the problem of neglected diseases, which has no investment in research and development because they do not have market appeal.</td>
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d. Petitioning the Brazilian Prosecutor General

At the end of 2007, the GTPI presented the Brazilian Prosecutor General with a petition that demonstrated the unconstitutionality of the two articles of Brazil’s industrial property legislation that created the pipeline mechanism for granting patents. The petition called on the Prosecutor General to bring a Direct Action of Unconstitutionality (ADI) against the pipeline mechanism before the Supreme Court, since civil society organizations do not have the standing to file this kind of legal case.

A Direct Action of Unconstitutionality (ADI) is a judicial instrument that permits a thorough assessment of the constitutionality of a law or normative act by federal authorities. That is to say, through ADI it is possible to question whether the determined legislation is consistent with the Federal Constitution. The Supreme Court – the highest court of law in Brazil – judges directly the ADI, and a declaration of unconstitutionality results in the law in question being removed from the legal system to prevent it from having any legal effect.

The pipeline mechanism, whose constitutionality was questioned in our petition, is a provision that validates patents from fields of technology that Brazil had not traditionally recognize as patentable, such as food and pharmaceutical products. 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 national economic or technological interests. There is, therefore, nothing to justify these patents.

Pipeline patent applications would only be subject to a formal analysis and would follow the terms of the patent granted overseas, not being

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48. 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.
submitted to the Brazilian patent office, the INPI, for a technical analysis of the patentability requirement – novelty, inventiveness and industrial application.

Worse still, pipeline patents have granted protection to inventions that were already in 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, anywhere or at any time, it cannot be protected. 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 inventions were filed in Brazil after the period of priority had expired, the inventions were already in public domain and no longer qualified for protection.

The concession of the 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.

Although they are often confused, Brazil’s pipeline mechanism is neither the same nor equivalent to the mailbox rule established in the TRIPS Agreement, which exists in other countries such as India. The mailbox rule provides that from “day one” of TRIPS (1995), national patent offices can receive patent requests in areas not previously recognized as patentable and hold them in a “mailbox” for review after the domestic patent law in line with TRIPS 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

49. The state of the art consists of everything that became accessible to the public prior to the filing date of the patent application, by means of a written or oral description, by use or by any other means, in Brazil or abroad, except as provided in Articles 12, 16, and 17. (art. 11, § 1º IPL).


51. According to the article 4 of the Paris Convention (CUP), any person who has duly filed an application for a patent, has a deadline of 12 months to deposit the same application in other countries. This deadline is known as “priority period”.

the concession of patents for knowledge that had already been patented broad even before “day one” of TRIPS. Furthermore, pipeline patents are not subject to any technical analysis by the Brazilian patent office.

This type of patent revalidation mechanism was adopted only in a few countries besides Brazil. In a few of these countries, such as in Equator, it has been declared incompatible with the international intellectual property system.

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 9.270/96, 1,182 pipeline requests were filed, of which more than half have already been granted and the rest is under review. A report commissioned by the authors of the petition estimates that these pipeline patents have cost Brazil in the billions of dollars.

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 application was filed in Brazil, it did not fulfill the patentability requirement of “novelty” (since the information of the invention had been published abroad five years previously). In other words, this active agreement could have been produced generically in Brazil, like it was in India.

Indeed, Brazil has taken the lead in recent years to ensure that intellectual property protection rules adopted on an international level do not pose a threat 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

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contrast to the attitude it displays in international forums. But calling into question the legality of pipeline patents, which are so bluntly at odds with public health interests, is another step towards a congruous discourse on both the national and international stage.

In May of 2009, the Brazilian Prosecutor General filed an ADIN questioning the constitutionality of the pipeline mechanism. This brief is of great interest to industrial sectors. At the moment of publishing of this article, various associations linked with the industrial sectors have already filed their own *amicus curiae* brief. The *amicus curiae* listed on the brief are: the Associação Brasileira de Sementes e Mudas (ABRASEM), Associação Brasileira de Química Fina (ABIFINA), Associação da Indústria Farmacêutica de Pesquisa (INTERFARMA) e Associação Brasileira das Indústrias de Medicamentos Genéricos (Pro Genéricos). At the same time, however, diverse organizations of GTPI have filed their own amicus curiae briefs: the first brief was signed by CONECTAS Direitos Humanos and GAPA São Paulo and the second brief was signed by the Brazilian Interdisciplinary AIDS Association (ABIA), Médicos Sem Fronteiras Brasil (MSF), Grupo de Incentivo à Vida (GIV), GAPA RS, Instituto de Defesa do Consumidor (IDEC) and the Federação Nacional dos Farmacêuticos (FENAFAR). At the moment, the only *amicus* brief admitted by the court was from the Associação da Indústria Farmacêutica de Pesquisa (INTERFARMA). We trust, however, our brief will accompany the development of the ADIN, and with great anxiety, we hope that the Supreme Court will return to society the patents unjustly withdrawn from the public domain.

**e) Saúde em Rede campaign – galvanizing popular participation**

As we have already observed, in recent years, a civil society offensive has opposed TRIPS-plus legislations through law bills in the House of

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57. Originated from United States legislation, the *amicus curiae* (friend of the court) allows third parties interested in the action to manifest the judiciary's decision.

58. The petitions filed by the organizations of GTPI will be available for consultation in the Supreme Court of Brazil website (http://www.stf.gov.br), in the ADI/4234.

Representatives and through the attempt to effectively employ the flexibilities of pharmaceutical patents. In regard to this issue, GTPI has decided to organize and to institute a national campaign of safeguarding to influence the principal policymaking channels that concern the cases in question: both legislative and executive. In this manner, on December 1, 2008, the Saúde em Rede campaign (www.saudeemrede.org.br) was launched targeting the Brazilian population with the goal to impact the legislative committees that monitor over law bills and the Multi-sector Group on Intellectual Property60 (GIPI).

The campaign61 was constructed with the aid of social networking through the worldwide web, in order to influence decision makers. 30 million pamphlets were printed and were distributed in various major cities62 in Brazil with the objective to inform the public on pharmaceutical patents and their impact on people living with HIV/AIDS. The pamphlets indicated the campaign website, both of which had similar esthetic schemes, so that the public could identify the advocacy operation easily. The website user could fill out his/her information and send a message to GIPI and the principle committee representatives with the click of a mouse.

The experience of the mass campaign has been extremely positive, facilitating a diverse public outreach, in particular, emphasizing its youth outreach. Most importantly, this promoted a channel of direct communication between the population and the government.

As we have already informed, at the end of 2008, the GIPI decided to obstruct the extension of pharmaceutical patent flexibilities. The law bill concerned with TRIPS-plus, also already discussed in this paper, is still advancing through the legislative process. The campaign ”saúde em rede” continues to exist and the site is still functioning with the purpose of reaching out to a greater number of people and the ears of policymakers.

60. According to information of the Ministry of Development, Industry and Commerce the GIPI was created essentially because of the necessity of cohesion and consistency of the government’s public policy related to intellectual property.
61. The campaign was possible only because of the effort and collaboration of the company RS2 Comunicação (http://www.rs2comunicacao.com.br) that supported the GTPI.
62. The pamphlets were distributed in a variety of locations such as movies, theaters, bars, restaurants, universities, galleries, cultural centers, etc.
Civil society groups from developing countries confront various challenges in handling the topic of intellectual property from a public health perspective. The first of these challenges is in understanding its impacts and, as a consequence, identify strategies to resist the current policy model. Secondly, this topic is essentially international; watchdog capabilities and the incorporation of international statutes are very difficult to include on local agendas. We cannot underestimate linguistic barriers, the lack of human and financial resources, and the special dynamic of each local context.

Nevertheless, the possibility of strengthening cooperation between the South is embodied in a spirit of solidarity due to the challenges related to Southern budgets in guaranteeing access to the same essential patented medications.

The emblematic example was the filing of a brief from Abbott against the issuing of a compulsory license by the Thai government for the medication lopinavir/ritonavir (Kaletra®) in 2007. This initiated worldwide protests and the mailing of letters of support and solidarity to the Thai population. In another case that occurred in 2006 and 2007, an intense international campaign was mobilized against the complaint from the company Novartis in India in opposition to the public health safeguards in the patent law (Section 3d). In Brazil, members of GTPI/Rebrip made a huge effort to shed light on this case, collecting signatures for a petition “Novartis Drop the Case63”. This was mailed to Novartis and the Indian government asking for a pro-health policy brief.

As stated earlier, the request of an ADIN against the pipeline patents is similar to the case above, in that it received support of various organizations and distinguished specialists from developing countries64.

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63. Petition organized by Doctors Without Borders. Available at: <http://www.msf.org/petition_india/international.html>

64. The organizations and researchers that sent letters of support were: 1 - Fundación IFARMA - Colômbia; 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 e ActionAID India.
Besides the efforts of solidarity and the visibility of problems of local actions, groups of civil society have looked for an exchange of experiences in international spaces, such as the International AIDS Conferences, the Social World Forum, the International AIDS Society, etc.

In 2008, a step was taken in the strengthening of activities between groups from India and Brazil, as follows in Box 3 below:

**Box 3: Brazilian organization questions patent applications in India**

Patent applications related to the ARV tenofovir could be submitted in India with early priority in the second half of the 1990s, despite the fact that its technical analysis could only take place after 2005. Generally speaking, generic pharmaceutical companies could produce patented products, however, the Indian Office of patents hindered the marketing of tenofovir.

On July 26th, 2008, the Brazilian Interdisciplinary AIDS Association (ABIA), in conjunction with the Indian organization Sahara (Centre for Residential Care and Rehabilitation), presented a petition against the patent for tenofovir in India. ABIAs initiative in filing this brief in India was based on the fact that this patent decision had had a global impact on the procurement of the main active ingredient for local generic production of the drug. Insofar as it had undermined the possibility to buy the principal active ingredient for local production or the generic version in the case of its exhaustion in Brazil and other developing countries. This was particularly significant in Brazil, considering the fact that a patent was not granted for tenofovir there. If the patent were granted in Brazil, India’s refusal to grant this patent in India would preserve the notion that the issuing of a compulsory license for the medication is a necessity for temporary importation, which was demonstrated in the case of Efavirenz.

In virtue of Indian NGO petitions opposing the patent applications of tenofovir since 2006, Gilead established voluntary license contracts (VLC) with generic pharmaceutical companies in India. This limited them to export to a number of defined countries, of which was excluded Brazil and other developing countries. Gilead had already assumed that the submission of its petition was already its exclusive right. Cipla was the only company that did not accept these licenses.

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65. More information about Mail-box available in the following web site: <http://www.lawyerscollective.org/amtc/mailbox>


g. The Permanent Court of the People – second session on European transnational companies in Latin America and the Caribbean

In May 2008, the GTPI presented two cases about Human Rights violations practiced by European transnational pharmaceutical companies in the Permanent Court of the People (PCP) at the second session about transnational European companies in Latin America and the Caribbean, which was held in Lima, Peru. These cases represented violations on the right of health in Brazil regarding the direct impact of the protection of intellectual property law on access to medicines. The case represented not only a violation to the human right to health, but also to intellectual property laws, in that transnational pharmaceutical companies were attempting to undermine the utilization of public health safeguards.

In one case, the Swiss transnational pharmaceutical company Roche was accused of violating the right to health of the Brazilian population and Brazil’s sovereignty, in that it had attempted to interfere in internal legislation through judicial briefs aimed at excluding a safeguard system in intellectual property legislation adopted from the previous agreement of ANVISA. The PCP condemned Roche for undercutting access to medications in Brazil.

In the other case, the German transnational pharmaceutical company Boehringer Ingelheim was denounced for both violating rights to health and for breaching ethical standards in research. The company had not registered nor marketed a medication in Brazil that was clinically tested on the Brazilian population. The GTPI concluded that for Boehringer Ingelheim Brazilian subjects could run the risks of research, but could not benefit from the drug. The absence of registration impeded the access to the medication. This case was presented at the PCP as a narrative and not as an accusation. In virtue of the disclosure of the event, the company entered in contact with the secretary of GTPI and informed that they had requested the registration of the medicine. This company’s contact, which demonstrated explicitly its preoccupation with its image in face of this presentation before the PCP, was evaluated as a victory for the GTPI.
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 prioritize policies for universal access to medicines over intellectual property rules. These challenges include finding alternatives inside the current patent system, by forcing the use of the TRIPS flexibilities, and also monitoring the international discourse on this 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 barriers in the way of civil society’s involvement in matters of intellectual property protection. Consequently, in order that society fully grasps this issue, the production and distribution of informative material, in accessible language, and demonstrations the impact of this system on people’s daily lives are crucial. Training courses for activists and civil society organizations with a direct interest in these issues have also proven to be invaluable.

The strategies proposed by Brazilian civil society reveal the main challenges of today and the future in 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 more than likely confront the same problems with the same medicines. The second strategy 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 mean 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, and 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.68

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 is used to buy

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 developmental contexts to monitor if we are to properly follow what happens on both the national and, particularly, 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 similar scenarios may happen in Brazil.

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.
2. Colombia

Civil Society Participation and the Compulsory License Request for Lopinavir-Ritonavir (KALETRA® – ABBOTT).

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ABSTRACT

On May 8th of this year, the Colombian government denied a request made by Colombian civil society (CSOs) to issue a compulsory license for the life-saving drug Kaletra®. Not constituted as a matter of public interest, the government argued that patients needing Kaletra® were all insured, therefore, did not need to worry about paying for treatment. This justification is troubling in that it does not recognize a finite budget—of the government or of insurance companies—for ARVs. If the government is unable to increase its budget, supplying proper treatment for people living with HIV/AIDS (PLWHA) will be at risk.

Another current event—the negotiations of three free trade agreements (FTAs) between Colombia and the United States, the European Free Trade Area (EFTA) and the European Union and their potential influence on ARV affordability and access—are also of great interest to Colombian civil society. These FTAs would establish TRIPS-plus+ standards, increase the scope of patentable material, and extend patent lifetime in Colombia. A survey made by IFARMA and “Mision Salud” concluded that the FTA would result in an escalation in ARV prices, a needed increase in budget for healthcare, and, in the case of an unchanged budget, a decrease in life years for PLWHA. In response, CSOs have taken an active role in rounds of FTA negotiations, lobbying for the affordable medical access of PLWHA.

This precariousness that surrounds the government’s CL denial for Kaletra® and the establishment of a Colombia-US FTA have further energized Colombia’s PLWHA and representative NGOs to continue on the fight for guaranteed access to medications for PLWHA. They point out that national and international data has demonstrated that ARV access can be guaranteed through generic competition, which decreases ARV costs from 54 to 98%. In the particular case of Kaletra®, prices can be reduced from US$ 3,600 to US $ 398 per patient per year—an 85% reduction. The government has already applied a special measure of its price control policy to reduce the price to US $ 1,100, which IFARMA celebrates as a CSO triumph. Nevertheless, IFARMA is still fighting for a price decrease to $396 per patient. For that reason, a civil society alliance consisting of PLWHA, the Table of Organizations working on HIV/AIDS, Mision Salud Foundation and IFARMA Foundation are preparing a class action lawsuit against the government, demanding the declaration of public interest and the compulsory license for Kaletra®.

Alongside Colombian CSOs, affiliate international CSOs were mobilized to demonstrate in front of the headquarters of Abbott, the multinational pharmaceutical company that produces Kaletra®, in Chicago, Mexico City, Tabasco, Tijuana, and Bogotá. One of the slogans used, “for the right of health, no more patents” reminds us that in the face of an unprecedented and merciless epidemic, extreme demands must be made by a unified public. The Colombian case exhibits this undeniable linkage between access of treatment and the integrity of intellectual property and the ongoing battle to find a balance between both perceived rights.
INTRODUCTION

Some developing countries have recently issued compulsory licenses (CL) for pharmaceutical drugs, primarily antiretrovirals (ARVs) that are currently at the center of intellectual property debates and subject to many compulsory licensing applications around the world. There are several reasons for this situation. On the one hand, ARVs may mean the difference between life and death, as they reduce mortality dramatically and extend life expectancy. On the other, ARVs arrive on the market at high prices (for the last ten years, ARVs have been the most expensive drugs on the market, together with anticancer / biotechnological medications and new vaccines) making them unaffordable for patients and governments in most developing countries. It is important to remember that antiretroviral therapy is a lifelong treatment and must be combined, taking three or four drugs each day. However, generic options demonstrate that ARVs can be ten times (or even more) less expensive than ARVs protected by IP rights.

Since the TRIPS Agreement has been adopted by almost every developing country, granting patents for pharmaceuticals has become mandatory. Before TRIPS, most countries did not grant patents for medicines, due not only to humanitarian reasons, but also industrial policies. Patents confer the right to exclude third parties from the commercial exploitation of the patented item. Nevertheless, there are flexibilities that allow exploitation without the consent of the owner, in order to protect public interests, in emergencies or under extremely urgent circumstances. Compulsory Licenses (CL) are the most obvious examples of TRIPS flexibilities, used frequently in the past by many of the more developed countries.²

From the Big Pharma standpoint, CL must clearly be the last resort, to be used only under extreme circumstances. With the argument that compulsory licensing breaches patents, they claim that its use could

² Going deeper into CL history during recent years, Knowledge Ecology International (KEY) presents a very detailed review of this matter on its web page: www.key.org Helen Thoen recently published an interesting review of innovation in pharmaceuticals, including a historical overview of CL: The Global Politics of Pharmaceutical Monopoly Power, AMB Diemen (2009), available for download at: www.msfacess.org. Specifically with regard to CLs issued in developed countries, consult the review by Xavier Seuba, presented to the National Academy of Medicine in Colombia in October 2008: Naturaleza y fundamento de las licencias obligatorias, available at: www.ifarma.org
endanger the global system of pharmaceutical innovation by weakening incentives to invest in R&D activities seeking new drugs. For this reason, every CL request has faced fierce opposition from powerful pharmaceutical lobbies, particularly in the media. This argument certainly sounds ridiculous when analyzing the weight of the global market shares held by most developing countries, as nations with market shares of less than 1% do not have the slightest effect on the global accounting of these huge enterprises.

Normally, a CL is issued through a government decision, with or without varying degrees of involvement from civil society organizations (CSOs). This has been the case in Brazil, Malaysia, Thailand, Zambia, Mozambique and other developing countries. With or without pressure from CSOs, these governments took over the reins. The situation in South Africa is rather different: despite the notable commitment of civil society organizations calling for compulsory licensing, the South African government has not shown any intentions of challenging the power of the pharmaceutical industry. Although South African CSOs are well known for their advocacy capacities, no CLs have been issued there so far. In fact, some analysts feel that the voluntary license granted by Bristol Myers Squibb to Aspen Pharmaceuticals might well be considered a response to heavy pressures from CSOs.3

Colombian CSOs faced a similar situation. Almost a year ago, an alliance of four organizations requested a CL for Kaletra®, which is a combination of two protease inhibitors (lopinavir and ritonavir), but on May 8 the government decided that there is no justification for this CL and refused to grant it, arguing that there is no demonstrated justification for this public interest.

The alliance consists of the National Network of People living with HIV-AIDS, the Cadre of Organizations working on HIV-AIDS, the Mision Salud Foundation Mission on Health and the IFARMA Foundation. As far as we know, there was some intention of negotiating a good price for Kaletra® with Abbott in order to avoid political fallout for the Colombian government on issuing a CL, following Brazil’s example with the same

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3 It is the opinion of KEY and also of Helen Thoen, in cited documents.
product in 2005. The Colombian government is eager to support Big Pharma claims because it is still awaiting formal approval of a Free Trade Agreement with the United States, already signed but still pending congressional authorization.

During discussions between the organizations in this alliance, we realized that we are facing a very unfair and inefficient system for promoting innovation worldwide. New drugs are usually shielded by patents or data protection, which confers exclusivity in the market. Exclusivity implies high prices, and high prices in developed countries (usually with “third payer” systems) do not trigger access crises, except for those excluded from the market. But for the developing countries, this means unaffordable prices, with most drugs paid for directly by patients and their families. The World Health Organization (WHO) estimates that one third of the global population lacks regular access to essential medicines.

For the last three years, intensive discussions at the WHO have been seeking new approaches for promoting innovation in medicines. The current system is not working, due mainly to its profit-driven approach.

From the standpoint of the CSO involved in this CL request, Kaletra® is just one example of the distortion of the intellectual property system for medicines. But the main problem seems lie within the system itself. So we are slipping away from promoting flexibilities and instead moving towards the elimination of IP protection on drugs. The new slogan of the Alliance is: For the Right to Health: No Patents.

The following pages present the facts and the discussions, with our analysis of this process, highlighting the role of CSOs in the CL request for lopinavir-ritonavir.

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4 Certainly they represent an important number of people in some rich countries, particularly in USA, where around 40 million people are out of the market, out of the health system and out of the media coverage.
The CSOs

On July 16, 2008, an alliance of organizations representing civil society in Colombia presented a compulsory license request for lopinavir-ritonavir to the Industry and Trade Superintendency, which is the national authority for intellectual property. This ARV was patented in Colombia and marketed under the international Kaletra® brand by Abbott Laboratories. This request was presented three months earlier to the patent owner, Abbott Laboratories, calling for voluntary compliance with the TRIPS requirements, with no answer.5

The alliance of organizations is led by the Cadre of NGOs working with HIV-AIDS and the Colombian People Living with HIV-AIDS Network (RECOLVIH: Red Colombiana de Personas con VIH). The Cadre of NGOs is a nationwide association that includes regional and local organizations working with HIV-AIDS. Both organizations address human rights for PLHIV, particularly access to full treatment. Some of the organizations in this group offer counseling, treatment and support services for PLHIV. The RECOLVIH national network includes HIV positive people working to improve lives and guarantee rights, particularly access to treatment.

These organizations have been very active on the Colombian scene, engaging in most of the participative schemes organized by the government and United Nations agencies. Both are part of the Country Coordination Mechanism for the Global Fund and the National Council on AIDS, and also represent CSOs in the UN Group on HIV AIDS.

The Compulsory License request was also presented by IFARMA and Mision Salud, which have ample experience in negotiations and policy discussions on intellectual property and access to medicines, including the recent Free Trade Agreement with USA (Colombia FTA). In fact, during the FTA discussions, these organizations got together to present the impacts of intellectual property issues on access to treatment, demanding the exclusion of IP provisions in the FTA. Although these discussions were very

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5 The obligation to apply for a voluntary license is addressed in the TRIPS Agreement, particularly for anti-competitive practices. In our case, we asked for a CL because of public interest, which does not impose this obligation. Nevertheless, in an effort to avoid any argument against the procedure, we decided to complete this step.
heated with highly qualified participants, on the bottom line this FTA was a political priority for the government, and it was established, despite strong opposition from the CSOs and other sectors.

The Mision Salud, whose steering committee includes representatives of the Roman Catholic Church, played a leading role in the amendment of the Colombian and Peruvian FTAs imposed by the bipartisan agreement of the US Congress. Backed by the Roman Catholic Church in the USA, and with strong support from OXFAM USA, Mision Salud visited many members of Congress, asking them to include the IP chapter in the bipartisan agreement. It is important to remember that Peru and Colombia were forced to modify the chapters on labor and environment, in order to protect US workers and enterprises from unfair competition due to weak regulations in these fields. After the efforts of the CSOs, IP was also included, reducing and limiting some of the obligations agreed in the signed text.6 Some of the TRIPS flexibilities, including Compulsory Licenses, were addressed in the wording agreed by the governments in a side letter, but were then included in the main text after the bipartisan amendment.

IFARMA and Mision Salud have also been acknowledged as consumer representatives on drug access issues, with IFARMA as the representative of Health Action International in Latin America at the IGWG negotiations on IP at the WHO. Both organizations are part of the CSO alliance for the surveillance of the FTA between the Andean countries and the European Union. They contributed to the development of a tool for assessing the impacts of IP changes derived from the FTAs on prices, consumption, IP protection and finally on access to medicines. Developed in association with the WHO, this tool has been adopted by a consortium of international institutions, to conduct this type of assessment in a large number of developing countries. The consortium includes the International Centre for Trade and Sustainable Development (ICTSD), UNDP, the World Bank Institute, WHO/PAHO and Health Action International. The methodology has been applied in Uruguay, Costa Rica, Dominican Republic, Colombia, Peru, Bolivia, India, Thailand and Jordania, among others.

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6 The Democratic Party majority imposed modifications that included the conversion of an obligation related patent extensions for offsetting delays in an option, limitations on data protection (no more than five years, with the option to calculate the exclusivity period from the first registration in any country) and the reduction of linkage into an obligation to publish health registration applications. It also included an explicit mention of flexibilities.
The Andean countries are currently negotiating a Free Trade Agreement with the European Union, with IFARMA and Mision Salud engaged an intercontinental alliance overseeing the intellectual property provisions. The EU is asking for a five-year patent extension and eleven years for data protection, as well as many additional enforcement measures.

An interesting aspect is that the Cadre of organizations working with HIV AIDS and RECOLVIH has been pressured by Abbott in very subtle ways. On the one hand, they contacted some of the regional organizations, especially those offering treatment for patients receiving Kaletra®, inviting them to join a program offering discounts and other advantages, such as financial support for activities. As a result, two organizations submitted letters to the table coordination asking to be separated from the CL request. One regional organization resigned from the Cadre. It is interesting to note that Abbott presented this split to the Ministry of Social Protection in order to undermine the public interest request.

In the particular case of the RECOLVIH, Abbott organized a national meeting of HIV/AIDS activists, in order to set up a new substitute network. Scheduled for the end of May, this meeting included substantial financial support for activist pursuits and the promise of backing for the new network.

On the other hand, we faced an intense campaign through the e-networks of people working with HIV/AIDS, essential medicines and intellectual property, questioning the quality of generic medications. Some activists opposed the CL as it might result in generic medicines with questionable or undemonstrated quality, endangering patients through the risk of consuming substandard drugs. This discussion has recurred frequently among activist groups in the past. Some groups have even been identified as brand defenders receiving financial support from Big Pharma, arguing that most generic ARVs are less effective and cause more adverse effects than the original medications. This argument has been upheld even when bioequivalence is demonstrated, which could be the case in Colombia, since two of the generic alternatives (Cipla and Ranbaxy) are prequalified by WHO.
The CL request was not preceded by prior price negotiations, which is normal practice in other countries. This is because there is no single national purchaser for ARVs in Colombia, as in most of the developing countries. The Colombian Health System has different private and public institutions operating in a competitive setting. This fragmentation results in massive discrepancies in domestic drug prices, as well as between Colombia and its neighbors. In the case of Kaletra®, the public health system pays a rock-bottom price of US$ 1,683 per patient each year, while private institutions may expend as much as US$ 4,449.7

This is why a patient requiring a first line treatment with AZT+3TC+EFV can cost US$ 1,000 per annum, but if the treatment includes lopinavir-ritonavir, (which is an alternative product for first line treatment) this cost may soar to US$ 2,000 or even US$ 6,000.

In a country with a nominal per capita GDP of US$ 4,193 and some 50% of its population living in poverty, relatively few people can afford these prices.

One of the problems arising from access to high-cost medicines in the developing countries (including HIV, cancer, transplants, dialysis, intensive care, biotechnological medicines etc., and also therapies that require intensive use of technology) is that there are not enough consumers able to afford these treatments that would justify their introduction to the market. This is why there are various mechanisms separating access from individual payment capacity in these developing countries. Some of them use insurance systems8, National Health Systems with some schemes providing high-cost medicines free of charge,9 or subsidies under huge welfare schemes, such as the Global Fund10.

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7. Data from a survey conducted by the Processum consulting firm for the Ministry for Social Protection. The document was obtained from PAHO Colombia website, but it is not currently available on this site. Copies could be obtained from the authors.
8. This is the case of Colombia, where high cost drugs are part of the compulsory health plan, including ARVs.
9. As occurs in Brazil, where federal and regional governments establish special budgets that offer high cost drugs to patients, and also in many other countries, where court orders (constitutional claims, judicial mandates etc.) force governments to provide patients with these drugs.
10. Very extended in the least developed countries, particularly in Africa.
Internationally, there is some dispute over the extent to which these third payer mechanisms comply with industrial support policies, as they may expand markets that do not really exist, and to what extent they foster public health interests.

In the particular case of Colombia, ARVs are part of the group of essential medicines that are encompassed by the compulsory health plan with hardly any restrictions. Nevertheless, public and private insurance companies have been developing mechanisms shifting the burden to patients, restricting use and reducing their costs by charging them to patients. These are some examples:

- **Imposing geographical, administrative and time-consuming barriers for distributing ARVs.**
- **Imposing additional barriers through the ‘convenient’ deployment of stigma and discrimination.**
- **Imposeing pressures calling for the use of exception mechanisms that are underwritten by the whole system.**

NN is a 32-year old woman, who decided to suspend ARV treatment on her own accord two years ago. She used to receive medications from her insurance company (Social Security Institute) but the monthly effort to obtain the medicines had become more and more torturous. Each month she had to apply to the courts for a temporary restraining order in order to obtain a document that she then presented at the pharmacy in exchange for her ARV treatment. She would often do this several times each month as the medicines were rarely in stock.

The legal and administrative procedures were constantly revised by the insurance company, forcing her to spend a week of each month meeting all these bureaucratic requirements. The outcome: unable to comply with the time demands of her work, NN lost her job. The insurance company was then free of any obligations, since the right to healthcare is related to the monthly payment of a portion of her wages.
While she searched for a new job, the treatment was interrupted several times and the process of obtaining ARVs became so complicated that she was finally forced to suspend her treatment. She now has a high viral load and a severe pulmonary infection that is undermining her chances of survival.11

The Social Security Law guarantees assistance to PLHIV; however, there are still some gaps in obtaining this assistance. In most of the cases, patients must seek exceptional ways to receive the prescribed treatment. Exceptions have become the rule. A survey carried out by the Public Defender’s Office (a watchdog institution set up to ensure that public and private enterprises fulfill their duties) noted that 30% of law suits claiming fundamental rights were for healthcare services in order to save lives. Of this 30%, 70% corresponds to medicines and procedures already authorized by government and included in the compulsory health plan.12 Quite clearly, insurance companies are blatantly breaching the right of access to medication.

Some surveys conducted by the institutions represented in this request showed that the high costs of these products are an obstacle to access and a breach of patient rights. Not only do treatment costs curb the coverage expansion of the health system, but they also force patients who benefit from any kind of insurance to wade through masses of paperwork, legal procedures and displacements, including thinly veiled mechanisms of discrimination. Many of these patients drop out of treatment in order to avoid these problems, shortening their life expectancy.

Although insurers are partly responsible for this, we also believe that intellectual property regulations and the way they have been exported to developing countries are the causes of high prices and limited access to medicines. Suffering and premature death is thus avoidable.

11. Summary of a “life story”, part of a qualitative survey on impact of FTA on access to ARVs conducted by the Girasol Foundation and IFARMA in 2008 as a part of the campaign on Trade Agreements are Women’s Concerns in the context of the global campaign on Fair Trade: My Rights Are Not Negotiable from Oxfam, the Ford Foundation, Corporación SISMA Mujer and the Universidad de la Salle in Colombia. Not yet published.
In terms of costs, the patent granted to Kaletra® has pumped its price up far higher than potential prices in a competitive environment. As previously stated, in 2008, the Colombian government spent some US$ 1,683 a year on each patient taking Kaletra®, while costs for private institutions may top US$ 4,449 patient/year. If the entire state system bought in at US$ 1,683, this medicine would cost US$ 2,144,633 per year.

However, generic versions of lopinavir-ritonavir are available in many countries for less than US$ 800. Through an agreement reached between generic manufacturers and the Clinton Foundation, this cost can be brought down to US$ 550 patient/year, which is 67.3% less than the cheapest Abbott product in Colombia. A license authorizing generics to compete on this market would result in immediate price slashes for this medication, with savings of US$ 1,443,647. This figure is equal to 9,080 people being treated with first line products at generic prices (Clinton Foundation 3TC, AZT, NVP, US$ 159 per year).

Estimates based on data from a study conducted by the Ministry of Social Protection and UNAIDS13 show that some 1,257 PLHVI / AIDS were taking Kaletra® in 2005. Data from other sources,14 using a sample of insurers from health system, reported that the unit consumption of this product soared from three million in 2004 to around six million in 2006, doubling in just two years. In these two years, Kaletra® accounts for almost a quarter of total expenditures on ARV.

Moreover, the prices paid by Colombia for lopinavir-ritonavir are higher than those paid by its neighbors in the Andean Community: Abbott offers Ecuador a price of around US$ 1,000 per patient per year, while a generic version is available in Peru for US$ 765. By next year, the price of lopinavir-ritonavir might drop to US$ 550 per patient/year in Peru and Bolivia, depending on the offer of the Clinton Foundation. Meanwhile, Colombia spends two or three times more than its neighbors for ensuring public access to this drug and far more for private access.

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14. Data from Pharmarketing, including consultations with eleven insurers.
There is an important additional consequence of high prices, ratched up by intellectual property protection. As these products are very profitable, their manufacturers and marketers tend to allocate massive investments to increasing consumption, using methods that may even overstep the ethical boundaries for advertising medications.

These cases are becoming more frequent, including Rofecoxib and Gabapentin. These practices have recently included disease-mongering, which is designed to generate markets for ineffective drugs like cholesterol reducers and erectile dysfunction pills. In Colombia, this is quite evident in the specific case of lopinavir-ritonavir, which was strongly marketed due to its high price and patent protection, tripling its use over the past three years.

In discussions examining the impacts of intellectual property rights and access, IP patents are frequently presented as necessary and even indispensable for developing new products, providing incentives for pharmaceutical innovations. However, reality indicates that the industry tends to exaggerate its role in pharmaceutical innovation, concealing public sector contributions. Based on NIH 1995 data, Public Citizen affirmed that 55% of the outlays allocated to innovation in HIV-AIDS treatment had been borne by public funds in the USA, stressing state contributions in the development of products such as: Captopril, Enalapril, Ranitidine, Acyclovir, Fluoxetine, Tamoxifen, Paclitaxel, AZT, Didanosine, Lamivudine, Saquinavir, Abacavir, Stavudine and Nevirapine.

At the international level, whenever discussions arise on Compulsory Licenses, pharmaceutical companies argue that reductions in their revenues will undermine their capability to invest in medical research and development. Innovation is a high risk activity that necessarily involves high costs, so constraints on profits might well curtail innovations.

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17. IFARMA-ACCION INTERNACIONAL POR LA SALUD L.A. Estructura del mercado de medicamentos ARV y Oncológicos en los países de la Subregión Andina (Bolivia, Colombia, Chile, Ecuador, Perú, Venezuela) y recomendaciones de estrategias de negociación de precios. Study prepared for the Pan-American Health Organization (PAHO). November 2007
18. www.publiccitizen.org
We reviewed the Abbott figures at a global level, in order to estimate the magnitude of such losses.

<table>
<thead>
<tr>
<th>CONCEPT</th>
<th>VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net sales</td>
<td>25,914,238</td>
</tr>
<tr>
<td>Operating earnings</td>
<td>4,578,545</td>
</tr>
<tr>
<td>Earnings for continuing operations</td>
<td>3,606,314</td>
</tr>
<tr>
<td>Research and development</td>
<td>2,505,649</td>
</tr>
<tr>
<td>Number of employees</td>
<td>68,697</td>
</tr>
</tbody>
</table>


Assuming that total sales of Kaletra® in Colombia might reach some US$20,000,000\(^\text{19}\) in the best-case scenario and assuming that a CL would remove these earnings entirely, Abbott would face a reduction in net sales from almost 26 billion to almost 26 billion: down from 25,914 billion to 25,894 billion.

Back to the facts. After the presentation of the compulsory license request in July, the CSOs met with the patent authority and the Minister for Social Protection. The patent authority, which is the Industry and Trade Superintendancy, expressed its commitment to issue the license, if recommended to do so by the Minister for Social Protection. This act would imply that access to lopinavir-ritonavir could be considered as a matter of public interest.

Consequently, this decision was transferred to the Minister for Social Protection, who explained that this type of decision must be analyzed carefully and asked for three months to study all aspects involved. During

\(^{19}\) Data from the Ministry of Social Protection provided on May 4 indicates that 5,829 patients received Kaletra® in 2008, at an average price of US$ 3,443 patient/year - US$ 20,069,247
these three months they held some meetings with the patent-holder, Abbott, with no CSOs present. At least one of those meetings was hosted by the Colombian Presidency.

At the end of this three-month analysis period, the Ministry issued a letter stating that there was a legal grey area on the institution empowered to declare public interest, and passed the ball to the Superintendency, which responded in the same way.

About a month later, the Government issued a specific regulation for the declaration of public interest in the case of compulsory licenses, stating that the competent ministry must undertake the process for establishing the public interest, setting up a special commission and opening a legal procedure that involves all the stakeholders, also set a three months deadline for conducting this study. This legal provision was issued in November 2008.

The Ministry set up the special commission mentioned in the decree and began the proceedings, notifying Abbott as a third party and requesting information from insurers, as well as public and private institutions treating patients with ARV in Colombia.

On January 24, 2009 activists in Mexico (Mexico City, Tabasco and Tijuana), the United States (Chicago) and Colombia (Bogotá) demonstrated in front of the Abbott offices against the prices charged by Kaletra® prices, while press conferences were organized by the AIDS Healthcare Foundation and local groups. From the standpoint of the Colombian groups, this was a way of stepping up the pressure, as there has been no answer to the CL request, and some kind of delay strategy is being deployed by the government.

On December 1, the National Commission on Medicine Prices included lopinavir-ritonavir in the Regulated Freedom category. Under the current Colombian price policy for medicines, there are three categories: Monitored Freedom, Regulated Freedom and Direct Control. Almost all medicines are allocated to the first category, with a few drugs in dominant market positions assigned to the Regulated category. As far as we know, there are currently no drugs under Direct Control.
It is important to note that the decision to bring Kaletra® under regulation was issued after almost two years of delays. Current regulations on drug prices have been in place since 2006, requiring certain drugs with special implications for public health - such as anti-retrovirals and cancer drugs - be included in this category. The CSOs had to mobilize and request a CL in order to obtain this decision from the government, which we consider an outcome of our advocacy efforts.

Once a medicine is under Regulated Freedom, its price must be compared with benchmarked prices and, if significantly higher, the government must adjust the price. Prompted by this obligation, the National Prices Commission surveyed some neighboring countries with interesting results, shown in the following table:

<table>
<thead>
<tr>
<th>Kaletra® Prices in neighboring countries</th>
<th>US$ per patient per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Country</td>
<td>Colombia</td>
</tr>
<tr>
<td>Public</td>
<td>3,443.00</td>
</tr>
<tr>
<td>Private</td>
<td>3,296.16</td>
</tr>
</tbody>
</table>

Consequently, on May 4 the government decided to bring Kaletra® down to the average price, with a significant drop in prices for patients and for the Colombian Health system, which we also consider a result of our efforts.

Nevertheless, we have just been informed that the Peruvian government has obtained an important reduction for the generic version of lopinavir-ritonavir that may be as low as US$ 396 per patient per year. This is the outcome of discussions between the Clinton Foundation and the provider, combined with the bargaining capacity of the Peruvian MOH. This price is almost one third of the public price and one quarter of the private price reached through the Colombian decision. We thus urged the Ministry for Social Protection to give serious consideration to issuing a declaration of public interest in order to obtain this additional reduction in prices.
We were advised that there was an intention to reach a good price agreement with Abbott, as it had occurred in Brazil with the same product. Informally, we knew that the Ministry held meetings with Abbott, proposing some US$ 900 PPY. As far as we know, Abbott rejected any agreement and the government decided to act through the Price Commission.

Our requests were not heard and the Ministry finally informed us of its decision to deny our petition on May 20, considering that access to lopinavir-ritonavir is not a matter of public interest. The main argument was that practically all patients requiring Kaletra® were covered by some insurance scheme in Colombia, and do not need to pay in order to obtain this medication. It is important to stress that this argument was presented by Abbott at the very start of the process.

On the other hand, CSOs are preparing a Class Action lawsuit to be filed with the Courts, requesting a declaration of public interest and the compulsory license. This is a very complex situation for the government, as it apparently should not refuse to issue the CL due to the national and international political costs of such an unpopular measure. But there are certainly many ties and commitments to Big Pharma, so it seems that issuing a CL is also not a feasible option.

**HIV/AIDS in Colombia**

From 1983 through to December 2005, 46,815 cases of AIDS were notified to health authorities; 28,060 PLHIV, 10,283 with AIDS and 7,055 deaths.²⁰ By 2005 an estimated 171,504 people²¹ were living with HIV or AIDS, based on a prevalence rate of 0.6921%. This is a concentrated epidemic that affects vulnerable groups whose prevalence rates range from 1.7% to 18%.

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²⁰ Instituto Nacional de Salud, January 2006. (NIH)
HIV/AIDS still ranks third among the causes of death among men between 15 and 44 years old, after homicides and accidents. The number of years of life lost through HIV/AIDS increased eightfold from 1991 to 2002, reaching a cumulative figure of 544,488 years. This figure soared to 165 years of life per 100,000 inhabitants in 2005, compared to only 25 years in 1991. Worse still, most victims are young and productive, imposing heavy economic and social burdens on individuals, families and the country as a whole.

Regarding Millennium Development Goals (MDGs), Colombia is committed to keeping the prevalence rate of this epidemic under 1.2 by 2015, with better access to treatment, lower mortality rates, less mother-to-child transmission, and wider use of condoms as a preventive measure. One of the main policies formulated for different scenarios is to step up ARV treatment coverage to universal levels. The 2008 - 2011 Strategic Plan identifies this as a core strategy. It is important to note that when ARV treatment was launched in Colombia, the mortality rate plummeted from 57% in 1996 to 13% in 2001, dropping to 9% in 2005. In this case, access to treatment is clearly a life or death issue.

According to the UNGASS report, only 54.8% of the necessary treatment is covered for people requiring care in Colombia. It is estimated that among all those diagnosed, some 23,000 people require ARV treatment. Reports based outside appraisals suggest that 72% of diagnosed people are covered. This encouraging figure indicates the commitment to universal coverage accepted by Colombia’s health system, as proposed by the Millennium Development Goals in order to guarantee effective access to all-round good quality healthcare services.

The health system in Colombia is similar to the structure in the USA, with a regulatory authority (MSP) and a limited number of insurers. A compulsory tax on wages or incomes is earmarked for the health system,

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with a universal health plan providing minimum coverage that must be offered by all insurers to all patients.

ARVS are part of the compulsory health plan. Shortfalls in coverage (the most optimistic figures indicate some 80% of total population, but we estimate this at effectively around 65%) could explain the gaps in treatment coverage. As already discussed, the mechanisms deployed by insurers to avoid the costs of ARV treatments result in exception-based systems that delay the effective distribution of medications.

Kaletra® is listed in the compulsory plan, rated as a second choice first-line treatment alternative. However, as already mentioned, there is an intensive campaign encouraging doctors to prescribe this product, and urging patients to request it.

**THE LOPINAVIR-RITONAVIR PATENT**

As the efficacy of lopinavir-ritonavir is extremely well known in terms of combating the virus, we feel that the patent granted in Colombia is at the very least open to discussion from a technical standpoint. This ARV is a combination of known protease inhibitors, with one of them (ritonavir) being an old product. In order to obtain patents in almost all countries, products must fulfill the requirements of novelty, inventive step and industrial application. At the time the patent application was filed, ritonavir fell within the public domain, with no novelty. It is important to stress that the Colombian Patent Office applies stringent criteria for defining what is patentable, in contrast to the USPTO or EMEA, where virtually any request for a patent is almost always granted, including patents for uses, new formulations, salt isomers, and certainly for combinations.

Combinations are a major field for controversy in developing countries, where stringent patentability criteria are important from a public health perspective. While in the developed world there is a tendency to protect IP rights to an extreme extent, access-related
issues dominate contemporary discourse on public health in the developing countries. 25

In these countries – including Colombia – combinations have traditionally been considered as non-patentable. Two reasons support this doctrine: first, combining two known products does not imply invention. Second, this seems to be a therapeutic scheme, constituting an explicit exclusion of patentability under the TRIPS Agreement.

In fact, the lopinavir and ritonavir molecules are very similar, and this could be considered a typical example of incremental innovation. Well known molecules with recognized efficacy are subjected to physical and chemical reactions to check which one works best. In this particular combination, one of the molecules blocks the metabolic path of the other, increasing blood levels and prolonging its action. How can this be considered as unexpected or surprising? As far as we understand, this was the main argument for granting a patent in Colombia.

Taking these matters into account, representatives of civil society organizations requested the competent authorities to declare the nullity of the patent, arguing that this ARV combination is not innovative and has no inventive step, actually constituting a treatment modality, due to the nature of the combination. However, legal proceedings are very slow and complex in Colombia, as in almost every country, with judicial authorities that lack experience in these matters. After the TRIPS Agreement, the roles of Governments and Courts expanded significantly in terms of protecting the rights of patent holders. Once a patent is granted, challenges are difficult, expensive and time-consuming, with many other measures buttressing the rights held by patentees.

In the particular case of Kaletra® in Colombia, firm measures were implemented to enforce the rights held by Abbott, to the extent of applying illegal court decisions. When searching for generic alternatives when the Compulsory License was finally granted, we discovered that an Indian supplier (Cipla) had obtained registration for lopinavir-ritonavir from

25. For a technical discussion of this matter, see Correa, Carlos. ICTSD. Guidelines for the examination of pharmaceutical patents. Available at www.ictsd.org.
the Colombian Health Regulator (INVIMA). Another Indian supplier (Ranbaxy) had also applied for registration, and a local manufacturer was working to develop a formula. In the case of Cipla, a judge ordered to INVIMA to freeze the registration, while the judge was ordered to suspend the evaluation in the other case and halt the application.

There is a type of intellectual property measure for medicines called linkage, between patents and registration, which is not included in the current legal framework in Colombia. This was proposed by USA during discussions on the Free Trade Agreement, but despite heavy pressures and feeble resistance from the government, it was not included in the final text.

For all these reasons we decided to use the flexibility of a Compulsory License.

**LEGAL FRAMEWORK**

The members of the Andean Community did not issue product patents for pharmaceuticals prior to 1993, acknowledging only process patents. After WTO was set up, the Andean Countries decided to make the 2000 - 2005 transition period for the developing countries to incorporate TRIPS into local legislation into a showcase assuring the international community of their commitment to free trade. The TRIPS Agreement under WTO and Decision 486/2000 adopted by the Andean Community has regulated patents and intellectual property in Colombia until now.

The TRIPS Agreement and Decision 486 cover twenty years of patents for pharmaceutical products, including compulsory licenses in case of emergency, extreme urgency or the public interest, as well as non-competitive practices.

Regarding Compulsory Licenses, Articles 61 - 69 in Chapter VII of Decision 486 include an extension of the TRIPS provisions. It is possible to issue a CL three years after the patent is granted, if there is no exploitation of the product, on the understanding that imports constitute a type of exploitation. Additionally, CLs may also be issued in the public interest, in
case of emergency or on the grounds of national security. In this case, it seems that there is no need to apply for a voluntary license previously. It is also possible to apply for a CL due to anti-competitive practices, especially abuse of a dominant position and for dependent patents.

Colombia issued Resolution Nº 17585/2001, which is a specific regulation on compulsory licenses listing the procedures to be followed in case of public interest, emergency or extreme urgency. Once the special condition is demonstrated in any of these cases, the patent authority may announce its intention to license the pertinent patents to all stakeholders. This is a very specific case, as a CL is usually issued in response to a request from a local enterprise or from a government entity in most countries.

Once some stakeholders request a CL, the patent authority defines the amount of royalties to be paid by the licensee, the duration of the CL and any other special conditions.

Although procedures for defining emergencies are well established in most countries, including Colombia, this is not the case with extreme urgency and the public interest. After the Doha Declaration, this must be a justified decision taken by the Ministry of Health, taking into account the severity of the situation and the relevance of the prices, in order to facilitate the national response.

The Colombian Congress defined HIV-AIDS as a matter of public interest through the AIDS Act (Law Nº 972/2005). It also established government powers to deploy the TRIPS flexibilities, when appropriate, in order to ensure access to medicines for people in need.

Nevertheless, after lengthy discussions, the government decided to issue a special regulation establishing the process for defining a situation affecting the public interest. Decree Nº 4302/2008 defines the authority competent to decide on declarations of public interest in any branch of government, together with detailed procedures, deadlines and special conditions.

This Decree removes the government’s power of declaring public interest at its own discretion. When declarations of public interest become a bone
of contention between applicants and outside stakeholders, the government relinquishes its right to act in representation of the population, turning any declaration of public interest into a dispute among the stakeholders.

Although a very vague way of conferring exclusivity on first entry medicines by the health authorities, data protection was included in Colombian law through Decree Nº 2085/2002. Similar to patents, data protection prevents competitors from marketing a protected medicine for five years. This Decree also includes a public interest exemption, as in the case of patents.

On November 22, 2006, the governments of Colombia and the USA signed a Free Trade Agreement, which has been approved by the Colombian Congress and Constitutional Court, but is still awaiting approval by the US Congress. The FTA public document contains a chapter on intellectual property (Chapter 16) that establishes TRIPS plus standards, imposing more stringent standards than those set forth in the WTO TRIPS Agreement. This strengthening of intellectual property rights (IPRs) will have consequences that affect many different fields: technology transfers, research and development, and marketing medications.

As aspect of particular importance is that the FTA includes patent extensions that compensate unjustified delays in award and registration processes and the extension of patentable matters, including pressure for usage patents; minor modifications to known molecules, combinations, polymorphs, salts, isomers etc; data protection (which was established in Colombia in 2002 through Decree Nº 2085, as mentioned); and linkage between patents and health registration.

A survey conducted in Colombia by IFARMA and Misión Salud in 2007 on the potential impact of the FTA on access to treatment for HIV/AIDS, using the above-mentioned methodology, reached the following conclusions:

National and international evidence shows that generic competition slashes ARV prices by 54% to 98%

By 2020, the FTA will pump up the average prices of ARVs by 2% to 42%, depending on the regulations. In turn, these increases trigger higher health
system budget requirements for these medications, ranging between US$ 0.5 and 13 million a year. If the government is unable to allocate these funds, this might well curtail supplies of these medications, affecting 380 to 12,800 patients who would potentially lose 5.3 to 9.9 years of life.

By 2020, the IP provisions in the FTA would produce a 53% increase in the prices of protected medicines on the ARV market, ratcheting up average prices by some 19% and requiring an additional US$ 6 million in funding. If the budget were not increased, this would bring down ARV use by 19%, affecting 4,000 to 6,000 patients needing ARV treatment, who would lose 5.3 to 9.9 years of life.

If usage patents are allowed, this would result in a 9% price hike by 2020, with a budget increase of US$ 3 million. Should it not be possible to allocate this additional budget funding, 1,900 to 2,900 patients would be affected, losing 5.3 to 9.9 years of life.

The possibility of granting patents for minor modifications, combinations and uses of medicines implies a 12% increase in ARV prices by 2020, requiring US$ 4 million. Not increasing the budget would bring down use by 12% and affect 2,500 to 3,800 patients who would lose 5.3 to 9.9 years of life.

The field with most impact on the PLHIV life expectations is data protection. These effects could be cushioned by limiting its application in terms of time and the type of products qualified to receive this type of protection.

By 2020, data protection for ARVs could cause a 67% increase for protected medicines (with no competition), resulting in a 32% increase in average prices, at a cost of US$ 10 million. Not allocating these funds would affect 6,600 to 10,000 patients.

Establishing links between patent and registry offices would affect some 400 patients by 2020, who would not receive ARV treatment.

Full adoption of the FTA with no exceptions or measures designed to lessen these damages described may well lead to a monopoly holding some 81% of the ARV market in Colombia by 2020. This would lead to a
42% hike in ARV prices and a budget increase of US$ 13 million. Without this budget increase, the treatment of 8,500 to 12,800 patients would be adversely affected.

Civil society organizations played an important role in discussions on intellectual property and access to medications, participating in all rounds of the FTA negotiations with the aim of putting the public interest before the concerns of the pharmaceutical companies. These private interests were constantly brought to the fore by the US Trade Representative in a remarkable, insistent and systematic manner.

The assertive stance adopted by the Peruvian and Colombian health sectors and Ministries of Health was particularly noteworthy at the FTA negotiations, where the final decision to accept the US conditions was taken for political reasons.

As mentioned previously, pressures from some US and Andean NGOs and the religious authorities prompted the Democratic majority in Congress to approve the Modification Protocol for the Environment, Labor and Intellectual Property Chapters.

The IP modifications include: no obligation to grant patent extensions in compensation for delays for pharmaceutical products; some constraints on data protection to avoid extensions of more than five years, and the possibility of calculating this protection from the day of the first registration in the country of origin. Linkage was curtailed, introducing only the obligation to publicly disclose all applications for registration, while avoiding any obligations to block them for patented products or to inform the patent holder.

The protocol makes provision for using the flexibilities described in the TRIPS Agreement and the DOHA Declaration, specifically those claimed by civil society for requesting a Compulsory License for lopinavir-ritonavir based on reasons in the public interest.

The difficulties faced by the Colombian government for obtaining Congressional approval of the FTA are public knowledge, with Democrats trying to block these discussions due to human rights concerns. It seems
as though much time will be required before its approval, if it is approved at all.

Nevertheless, Big Pharma has ample resources and deep pockets for reaching its goals. Since 2007, the Andean Countries have been discussing a FTA with the European Union, which includes a very stringent chapter on IP. With tougher clauses on patent extensions, data protection and enforcement, this has important implications for the public health sector.

**CONCLUSION**

**No Patents campaign**

During discussions with PLHIV/AIDS activists, as well as public health and legal practitioners, a very interesting point emerged, related to our efforts to obtain a CL and based on expectations that more licenses will have to be requested in future as new products appear on the market. In fact, we are already discussing Tenofovir, which is not yet registered in Colombia but is addressed by a special type of Orphan Drugs Law.26 We are also discussing the dramatic situation of cancer and arthritis drugs whose costs are soaring to unprecedented levels.

A conviction is emerging that a CL constitutes a case-by-case solution that is very costly and highly complex. However, the main problem is the patent system itself. As WHO Resolution Nº 61.2127 demonstrates, intellectual property protection has not been advantageous for developing countries, partly as there is no innovation for neglected diseases, and also because innovations are out of reach for people and health systems due to soaring prices.

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26. Orphan drugs are covered by special regulations in the developed countries in order to promote innovation, defining special market conditions for medications designed for a small number of patients suffering from uncommon diseases. In the developing countries, this may be applied through waivers of registration and customs requirements in order to streamline imports and sales.

27. Available at www.who.int
We also explored a very interesting argument on the use of patented products, which postulates that when someone consumes a patented product and pays the high price resulting from IP protection, another person is excluded from access to this product elsewhere. If this involves a life-saving medicine, it appears that the price paid by the whole of humankind for these products consists of the lives of needy people in poor countries. This is a very dramatic side effect of these drugs, which save some people at the cost of deaths among those excluded from access.

During our demonstrations in front of the Abbott headquarters, we used slogans such as: For the Right to Health, No More Patents; Free Market for Drugs, No Patents, etc.

We are also considering an initiative urging civil disobedience through not consuming or prescribing patented products. As this must certainly be handled through an international campaign, we would like to close this paper with an invitation to discuss this proposal.
3. China

MULTI-SECTOR APPROACHES ON IMPROVING ACCES TO ARVs IN CHINA

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Since China launched its national HIV/AIDS treatment program in 2003, the issue of ARV access has become a major obstacle to expanding treatment and prolonging patients’ lives. Examining the efforts and limitations of multiple stakeholders in the process of attaining full access to ARVs in China, this paper presents and analyzes the problems surrounding ARV access in China from different standpoints, focusing on the epidemic situation, capacities and constraints on domestic production, legal and policy barriers hampering access to ARVs, and noteworthy civil society responses and advocacy for ARV access. This paper not only describes how national stakeholders play their respective roles in the process of reaching national objectives in terms of access to ARVs, but also offers a comparative view of international stakeholders and practices respectively. This comparison in turn assists us in exploring and testing out ways for China to overcome the obstacles blocking access to ARVs.
NGO development and advocacy in China for access to ARVs

A. China Global Fund Watch Initiative and China Access to Medicines Research Group

Established in Beijing in November 2007, the China Global Fund Watch Initiative serves as an independent watchdog over the activities of Global Fund for Fighting AIDS, Tuberculosis, and Malaria, especially for programs in China. Under the direction of lawyer and civil society activist Jia Ping, the Initiative’s higher mission is to promote the development of civil society in China – and hence good governance and public participation – by fostering the development of grassroots HIV/AIDS NGOs and building partnerships among NGOs, governments, academics and private sector to address problems of common concern.

Pursuing its mission, the Initiative has established its status as a leading legal and technical resource center for NGOs and civil society organizations in China, especially those working in the field of HIV/AIDS. In addition to legal research, community-based organization development and advocacy for marginalized groups, GF Watch is also committed to pushing for better access to drugs for those suffering from HIV/AIDS. In July 2008, GF Watch published the first Chinese translation of ‘Intellectual Property and Competition Law’, which marked an important step in promoting the application of international law to issues arising from access to drugs in China.

Looking ahead, the China Global Fund Watch Initiative (CGFWI) will continue to support the development of a meaningful, pluralistic civil society by encouraging transparency, oversight and participation among all stakeholders. It intends to serve as a leader, encouraging civil society readiness and responses to the many non-traditional crises facing Chinese society today.

In 2008, based on the institutional setting of the Global Fund Watch initiative, a loose coalition was set up as China’s Access to Medicines research group, with the three co-authors of this paper serving as its core members. Consisting of civil society activists, professional researchers and practitioners, government officials and international experts in fields such as public health, law, intellectual property and political science, this group defines its mission as producing
technical analyses and knowledge to ensure preparedness, soliciting international expertise and knowledge based resources, and conducting policy advocacy for better access to medicines in China and the developing countries.

To date, it has published the Chinese translation of Professor Carlos Correa’s work on ‘Intellectual Property and Competition Law: some issues of developing countries’ with the GF Watch, and the Chinese version of ‘The Right to Life’, which reviews the history of the battle fought by Thai civil society for compulsory licensing of essential medicines. In the coming years, the group hopes to be the leading think tank and technical resources center for civil society, government and practitioners on issues arising from access to medicines in China, linking its advocacy efforts to the international movement urging access to essential medicines.

Realizing the complexity of advocating for better access to medicines in China, the group now bases its work on advocating a practical compulsory license mechanism for China, by providing technical commentaries and advice to legislative bodies, civil service agencies and legal practitioners. Within this process, access to ARVs is currently the top priority case study.

B. Background of NGO development in China

China now faces a host of internal, domestic crises that the government alone cannot manage, including HIV/AIDS prevention and treatment. Effective government responses to these crises require the active participation of non-governmental organizations and across-the-board cooperation among government, business, civil society, academia, and the media. A vibrant civil society is thus crucial for addressing these non-traditional issues.

The worldwide battle against HIV/AIDS has demonstrated that the grassroots participation of civil society is an essential ingredient for preventing and controlling this disease. Nevertheless, the Chinese government still remains wary of NGOs, reluctant to relinquish control and determined to find ways to ‘manage’ them, always alert to the possibility that ‘non’ government could become ‘anti’ government.

China currently has some 700,000 people living with HIV/AIDS. Among high-risk populations and patient communities, men-having-sex-with-men
(MSM) groups are obviously much better organized. People living with HIV/AIDS (PLHA) – especially in high-prevalence and tightly controlled provinces like Henan – are also striving for stronger political voices. But within the most marginalized, disadvantaged, and vulnerable sectors of Chinese society, grassroots organizations remain lamentably weak and unrecognized, especially PLHA groups.

Although crucial for combating HIV/AIDS in China, the development of NGOs is still in a difficult situation with limited public spaces. Generally speaking, local governments implement the public policies established by central government in China. But this vertical government structure, which obviously lacks transparency and accountability, means that local governments must seek support for carrying out policies established by the central government, severely weakening the effects and efficiency of these policies at the local level.

Moreover, inefficient implementation or even misguided policies mean that conflicts are concentrated more at the local level. For instance, the central government decided to deal with the consequences of the blood transfusion scandal that triggered an epidemic of HIV/AIDS in the Henan province during the mid-1990s. However, the local government in Henan is concerned about extended accountability, and thus has been adopting a passive approach by blocking the access to the courts for PLHA suing for compensation for HIV/AIDS infections transmitted through blood transfusions. This approach has in turn worsened relationships between local activist patients and government agencies. Because this situation has been dragging on for so long, conflicts between local activists and local governments are also long-lasting.

Misunderstanding and distrust between the government and NGOs have been one of the main barriers blocking HIV/AIDS intervention and treatment in China. Although – under different circumstances – the government declared that NGOs are useful, there is no concrete evidence of any improvement in their legal and political status. There are over 300 NGOs working in the HIV/AIDS field at the moment, including some sixty to seventy grassroots PLHA groups all over China. But most of these grassroots PLHA groups lack legal status, which means they cannot register easily as NGOs under current Chinese laws. The provisions governing NGO registration in China now have a dual management structure. This means that before
registering as NGOs, these organizations – grassroots groups, NGOs or GONGOS – must first appoint a supervisor (like a ‘godmother’) corresponding to the field where the organization works, allowing the NGO to register with the civil affairs department of the government. This requirement not only imposes an institutional constraint on NGO development in China, but also fosters a mutual lack of understanding and trust between the NGO community and the government.

Difficulties in expanding public spaces and the diversity of voices among NGOs also impose double burdens on PLHA groups. On the one hand they must obtain treatment in order to survive, while on the other hand they must also find ways to become more visible and influential in order to raise funds and maintain their collective identity and voices. Although other NGOs working directly or indirectly with HIV/AIDS issues may not be dealing with such life and death issues, their struggles for more public spaces and channels for expression are similar. Nevertheless, while limited resources often cause competition among groups, Chinese local NGOs are collectively playing an increasingly important role in the public sphere. The NGO involvement on the issue of access to ARVs is an example of these NGO collective advocacy efforts.

C. Civil society responses on access to ARVs in China

Although the government adopted the Four Free and One Care\(^2\) policy in 2003 for providing treatment to HIV/AIDS patients, which now covers part of their treatment, the number of patients assisted by this program has

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2. Editor’s note: “The Four Free and One Care policy reduces the HIV/AIDS related stigma. The policy includes 1) Free Voluntary Counseling and Testing (VCT); 2) Free ARV drugs to AIDS patients who are rural residents or people with financial difficulties living in urban areas; 3) Free ARV drugs to HIV infected pregnant women to prevent mother-to-child transmission, and HIV testing of newborn babies; 4) Free schooling for children orphaned by AIDS; 5) Care and economic assistance to the households of people living with HIV/AIDS. According to the policy, HIV/AIDS affected people are given necessary economic assistance, and those who can still be productive are encouraged to continue working to increase their income.” Available at [http://www.asiasociety.org/speeches/longde.html](http://www.asiasociety.org/speeches/longde.html), last access in 24 June 2009.
been increasing over the past few years, while difficulties in obtaining newer ARVs persist and are even getting worse. In addition to starting large-scale second-line treatment in response to widespread drug resistance, some old issues still remain unresolved. For instance, as one of the essential drugs in both first and second-line treatments, TCU is still available only through drug donations with no generic version, which undermines the sustainability of future drug supplies. Under these circumstances, NGOs – including the PHA groups – have been striving to improve the accessibility of ARVs over the past few years.

I. Technical capacity building and information sharing by International Groups

International groups that have been actively working on the issue of access to ARVs in China include Médecins Sans Frontières (MSF), the Clinton Foundation, the Third World Network (TWN) and the UK Department for International Development (DFID). A number of UN agencies have also become involved in different ways. While working individually on the issue of access to medicines, these international groups also take action together, either loosely or in semi-organized ways. For instance, the World Health Organization (WHO) and UNAIDS have established a technical working group mechanism in China on AIDS treatment and prevention, which includes government agencies, clinical sectors, NGOs, PLHA representatives, drug companies and experts as multi-stakeholders. Within this working group, there is a subsidiary technical working group focused on access to medicines with members and lawyers from international NGOs such as MSF, TWN and the Clinton Foundation. This subsidiary technical working group deploys the independent capacities of its members representing each organization for drawing up collective advocacy strategies.

Individually, the international groups have been making efforts in capacity building and information sharing, as well as direct advocacy for improving access to ARVs in China.

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3. UN agencies in China that have been involved into the issue of access to ARVs at different levels include WHO, UNAIDS, UNDP and UNICEF
For instance, as one of the leading international NGOs working on access to medicines, MSF established its China team in 2004, aligned with its international Campaign for Access to Essential Medicines.\(^4\) While running two HIV/AIDS projects in China, \(^5\) MSF has been translating its publication on access to medicines and intellectual property into Chinese, in addition to writing analyses on access to ARVs in China, the 3TC case, and access to fixed-dose combinations containing 3TC. Moreover, MSF has been sharing information at annual meetings with local NGOs and PLHA groups, updating the drug availability situation and analyzing obstacles, as well as organizing conferences with local medical communities and government agencies on access to medicines, intellectual property and medical R&D. Such information sharing and efforts to build up technical capacities have helped mainstream the notion of intellectual property, especially patent barriers blocking access to ARVs and the concept of compulsory licensing as a means of overcoming patent obstacles. MSF campaigners Ms. Suerie Moon and Ms. Hu Yuanqiong have been giving presentations on access to ARVs issues to PLHA communities, academics, officials and generic drug producers. With support from Chinese patent attorneys\(^6\) and pharmacists\(^7\), they have also completed patent searches and summaries of the patent status of key ARVs in China. In August 2006, with Chinese patent attorney firm Anboyda as the co-signee, MSF filed a patent opposition against the Gilead patent application in China on Tenofovir Disoproxil Fumarate (TDF), a reverse nucleotide analog that is a key factor for second-line AIDS treatment. Although this case still remains open, MSF set an example for other NGOs on how to handle future similar legal action, as the first international non-profit organization filing a patent opposition in China.

International groups also work with Chinese local partners on broader discussions concerning access to medicines. For instance, in September

\(^4\) The MSF campaign for access to essential medicines started in 1999 and is recognized as the first call for international responses to the institutional situation that results a lack of drugs in the developing countries.

\(^5\) MSF started two collaboration projects on HIV/AIDS in China. One is in Nanning city, Guangxi Zhuang autonomous region, operated by MSF France; the other is in the Xiangfan prefecture, Hubei province, operated by MSF Belgium. The Xiangfan clinic operated by MSF Belgium was handed over to the local partner in 2008 when the collaboration agreement expired. The Nanning clinic operated by MSF France is still functioning.

\(^6\) Especially patent attorney Mr. Xu Guowen and Ms. Liang Qingfeng from the Anboyda patent firm in Beijing

\(^7\) Especially MSF pharmacist Ms. Elodie Jambert
2007, in response to the intergovernmental working group process on public health, innovation and intellectual property, the WHO, MSF, TWN and the Chinese Medical Association organized a two-day international workshop, with support from the offices of WHO, UNDP, and UNAIDS in China. This workshop extended the approach, moving away from overcoming existing patent barriers and instead seeking newer incentive mechanisms for access to medicines and medical innovation. International experts and Chinese government officials and experts attended this meeting.

Groups also participated in the legislative process either individually or collectively from a public health perspective. From 2006 to 2007, MSF and TWN have submitted several comments on the Chinese patent law revision. In 2007, MSF, TWN and the Clinton Foundation submitted joint comments on the revised drug registration regulation. In 2008, the China Global Fund Watch Initiative (CGFW), a watchdog NGO founded by lawyer Mr. Jia Ping, prepared comments on the law jointly with MSF and TWN. Although international pharmaceutical corporations imposed heavy pressures on China for stronger patent protection, such comments from public health groups are valuable for strengthening counter-arguments and buttressing user-friendly intellectual property rules for the public health system in China.

II. Chinese local NGOs advocacy for improving access to ARVs

As international NGOs are putting their efforts into building up technical capacity through direct advocacy, Chinese local NGOs and PLHA groups are also acting specifically, calling for improved access to ARVs. Leading NGOs working on HIV/AIDS issues have either individually or collectively integrated the dimension of advocating for better access to ARVs into their respective work strategies, and have implemented these strategies in many different ways.

During the first collective effort by the PLHA community in China in August 2006, 591 PLHA and NGO activists representing 7,501 people in fifteen provinces and municipalities co-signed a letter opposing the TDF patent application filed by Gilead. This letter was submitted to SIPO, MOH, the national CDC and SFDA by two leading PLHA activists – Meng Lin and Li Xiang. They also discussed the TDF case with the MOH and the national
CDC during the Toronto World AIDS Conference that year. It took only a few weeks to collect the signatures, reflecting strong civil society demands for secure ARV supplies. The PLHA community demonstration also buttressed the concurrent opposition filed by MSF, and the TDF opposition filed in India and Brazil by local communities. The TDF opposition was thus the first attempt by the Chinese AIDS community to participate in an international movement calling for access to medicines at the local level.

Following up on the experiences gained from the TDF opposition, the International Treatment Preparedness Coalition (ITPC) / China, a PLHA based advocacy coordination network linked to China AIDS Care founded by PLHA activist Thomas Cai, brought Chinese drug advocacy into contact with international actions. In 2007, after Thailand issued a compulsory license for EFV and LPV/r, its manufacturer (Abbott) stopped registering new drugs in Thailand in retaliation. In reaction, international AIDS communities decided to organize a global boycott of Abbott. The ITPC / China network thus organized a local boycott on Abbott in Henan in support of Thailand and the global boycott. A local advocacy coordination network, ITPC / China also attempted to work closely with various activist groups and coordinate collective actions. In 2008 and 2009, through efforts by its country coordinator Mr. Zhou Ji, ITPC / China coordinated two political petitions on improved access to ARVs and compulsory licenses, co-signed by PLHA representatives and submitted to the central government during the annual National People’s Congress (NPC) session.

It is not only Beijing-based groups that are playing an important role in heading up the AIDS advocacy drive in China. More and more local groups outside Beijing have been growing and accepting more proactive roles in calling for local access to ARVs. Among others, Shanghai Beautiful Life, a PLHA support group led by Mr. Zhou Yi, and Henan HIV/AIDS Watch, a PLHA support and advocacy group led by Mr. Duan Jun, have showed strong leadership and advocacy capacity in 3TC advocacy. In December 2007 and March 2008 respectively, these two groups highlighted local shortages of 3TC

8. Founder of Ark of Love, a Beijing-based PLHA support and advocacy group
9. Founder of Mangrove, a Beijing-based PLHA support organization, now working as the executive director of China HIV/AIDS Information Network, a Beijing-based information NGO
with immediate responses and drug shipments from both the central and local CDC and health departments. This process not only strengthened demands for overcoming barriers blocking access to 3TC, but also provided invaluable emergency response experience for grassroots NGOs.

More importantly, local groups have started to realize the need and importance of growing professionally, creating round-table mechanisms for seeking solutions. While international groups provide the concepts, experience and technical support needed to advocate better access to medicines, local groups must tailor this information and adapt these skills to their own contexts in order to draw up suitable and sustainable advocacy strategies.

In February 2008, CGFW, in conjunction with the Chinese Academy of Social Science, organized a roundtable workshop on access to ARVs and intellectual property. It invited participants from the PLHA community, international NGO representatives including MSF and TWN, leading Chinese intellectual property exports, government officials from SIPO, SFDA, the Ministry of Trade and consultants from the MOH. This was the first time that a Chinese NGO organized a theme-specific round-table where multiple stakeholders discussed the issues of access to ARVs and intellectual property policies.

Faced by the need to build up expertise among local sectors, the Access to Medicines research group was set up, with the authors of this paper being its key members. Its mission is to disseminate knowledge and expertise to local communities in China, bridging professional gaps between China and the international community on issues of public health and intellectual property. As a research group, it also networks with international and domestic experts working on intellectual property policies in developing countries with different standpoints and goals, stockpiling knowledge, skills and expertise for the growing Chinese community working in this field. These attempts at more professional and multi-sector approaches should help civil society play a more inspiring role, driving the entire access to medicines movement forward in China.

While civil society is progressing in this field, many issues still remain unresolved. For instance, different players calling for easier access to ARVs in China now face a common problem: the lack of practical experience in making good use of patent law flexibilities guaranteed by international and domestic laws. This is also the case for the NGO sector. Despite much effort,
NGOs still lack the technical capacity and professional approach needed to conduct effective advocacy actions, especially grassroots groups. Other unresolved questions for NGOs include:

- How to further simplify the technical knowledge and information on access to ARVs and intellectual property within the PLHA community?
- How to balance and assess advocacy goals as a community and with the goal of individual organizational development?
- How to fine-tune relationships between NGOs and government sectors?
- And how to balance out the priorities of local communities and international donors?

Finding answers to these questions will be a major challenge for the NGOs, but they must do so in order to ensure a more effective civil society movement for better access to ARVs. This means that international collaboration with NGOs in other developing countries facing challenges similar to those in China becomes especially important for Chinese NGOs.

The subsequent sections of this paper illustrate the political, legal and policy contexts of access to ARVs in China, forming a multi-sector structure working on issues arising from access to medicines. The authors hope this information and analysis will serve as a solid basis for building up experience and sharing information with NGOs from other developing countries.

**INTRODUCTION: THE AIDS EPIDEMIC SITUATION AND CHALLENGES OF ACCESS TO ARVs IN CHINA**

Since 1985, when the first AIDS patient was reported in China, the spread of this epidemic has become alarming. Currently, HIV+ people are living in all 31 provinces, autonomous regions and municipalities directly under the central government, totaling some 700,000 cases, \(^{10}\) with 85,000 of them

\(^{10}\) See [http://news.xinhuanet.com/politics/2008-12/01/content_10436744.htm](http://news.xinhuanet.com/politics/2008-12/01/content_10436744.htm), report of the Ministry of Health press release on November 30, 2008
being people living with AIDS. Referring to the ‘Summary of Chinese Healthcare Reform and Development in 2008’ published by the Chinese Ministry of Health, the total number of deaths due to HIV reached 34,864, with 264,302 cases of HIV + AIDS. During the first nine months of 2008, there were 6,897 deaths and 44,839 new HIV+ cases.

The AIDS epidemic in China is currently characterized as follows:

First, AIDS is spreading rapidly in China, with the number of new cases of HIV+ rising more than 30% p.a. between 1995 and 2000. This trend caused so much concern that the Chinese Ministry of Health issued a warning in 2002 that these figures might soar to ten million – nearly 1% of the entire Chinese population – by 2010, unless effective and drastic measures were taken. Fortunately, due to the tremendous efforts made by all the stakeholders, especially the launching of the national HIV/AIDS treatment program, this gloomy scenario did not become a reality.

Second, the epidemic appears to be more severe in poor provinces than in wealthier areas. Correlating this with substantial regional income gaps, more people with HIV+ live in the poorer Central and Western Provinces, where living standards are relatively low. It is estimated that around 80% people with HIV+ live in rural areas.

Third, young people are the most vulnerable segment of the population. According to the statistics released by the Chinese National Center for Disease Prevention and Control (national CDC), nearly 52% of people with HIV+ are between 20 to 29 years old, with a further 31% between 30 and 39 years old. Bearing in mind that more than 80% of people with HIV+ are between 20 and 39 years old, HIV constitutes a significant challenge for the labor market in China. If the HIV situation worsens among the working age population, productivity could be affected, with regional poverty possibly worsening due to labor shortages and the heavy financial burdens of this disease.

Fourth, the most vulnerable segments of the population are sex workers, drug users and men who have sex with men (MSM). Immigrant workers are also at risk. Unsafe sex?lack of knowledge about STDs and an ineffectual disease oversight system have greatly increased the risks for these vulnerable
groups. In recent years, infections caused by high-risk behavior – either sexual or drug-related – have become a trend in China.11

Fifth, despite these problems, joint efforts by many stakeholders – including government agencies, academics, NGOs and grassroots organizations – have curbed the rapid spread of HIV/AIDS in China, especially in urban areas. In 2008, there were 755 new HIV cases in Beijing, down 22.4% (218 fewer cases) than the figures for 2007. Several decisions on HIV prevention and control have proven effective, with all the stakeholders called upon to make even greater contributions.

In 2004, the Chinese government launched its Four Free and One Care Policy. Through this program, rural or urban HIV/AIDS patients who have not joined the basic medical insurance programs are offered access to free ARV drugs and treatment in designated hospitals. The CDC provides free consultation and primary screening for HIV antibodies at different levels. Pregnant HIV patients receive free consultations and guidance on pregnancy and birth, as well as drugs preventing mother-to-child transmission. The local government also provides free education and psychological treatment for orphans whose parents have died of HIV. Furthermore, the government not only provides treatment and care for HIV+ and AIDS patients, but also provides them with public subsidies and even job opportunities, when possible.

However, the main stumbling blocks slowing the prevention and treatment of HIV/AIDS in China are still quite significant. Ordinary people in China, especially those living in rural areas or migrant workers, still lack knowledge of HIV/AIDS. At the national and local levels, the government does not have sufficient capabilities and resources to deal with this serious problem. Aggravating this situation even more is the fact that blood safety is still a matter of concern, together with the sustainable availability and affordability of ARV medications for the treatment of HIV/AIDS.

Although the government promises to provide free ARVs for HIV patients, these are mainly first-line ARVs, which eventually become non-functional because HIV as becomes resistant to these drugs. China still relies on

donations for one key first-line ARV – lamivudine (3TC) – from its multinational manufacturer, instead of producing this drug domestically, due to the company patent on the manufacturing process. The situation is even worse for all second-line ARVs, because they are patented by multinational companies, so that no local manufacturer can produce them due to patent protection.

**DOMESTIC PRODUCTION OF ARVs IN CHINA**

Despite the desperate need to improve the availability and the diversity of ARVs in China, its domestic pharmaceutical industry is still unable to respond effectively to this situation, not because it lacks capacity, but rather because complex industrial and regulatory structures impose constraints that prevent the industry from producing ARVs domestically.

The pharmaceutical industry is an indispensable sector of the Chinese economy, accounting for 2.55% of its overall GDP in 2007. Its total output rose from RMB 17.81 billion in 2000 to RMB 63.62 billion in 2007\(^{12}\) – 2.6 times more. The pharmaceutical industry ranked eighteenth among all industrial sectors by industrial added value (RMB 22.87 billion).

In 2007, there were 6,913 pharmaceutical manufacturers in China, of which 5,748 posted earnings of more than RMB 5 million, accounting for more than 80% of the total figures of the Chinese pharmaceutical industry.\(^{13}\) There are 1.37 million people working in the pharmaceutical industry, 1.74% of the total labor force in China, with some 49,832 qualified as scientists or engineers.\(^{14}\)

Despite this vast production capacity, China’s exports are still quite limited. In 2007, the Chinese pharmaceutical industry exported products worth US$ 9.9 billion, accounting for only some 1.35% of the world’s pharmaceutical

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\(^{14}\) The Statistical Yearbook of High-Tech Industry of China, 2008, Ministry of Science and Technology
trade. As far as the revealed competitive advantage (RCA) is concerned (which compares the ratios between Chinese pharmaceutical exports x world pharmaceutical exports with all Chinese exports x all world exports), the RCA index has been dropping, down from 0.72 in 1995 to 0.17 in 2007, which means that China’s pharmaceutical industry is comparatively uncompetitive.

Taking China’s huge manufacturing capacity into consideration, this lack of competitiveness reflects lingering systemic problems. There are various reasons for this lack of competitiveness, including an inappropriate export structure. Antibiotics, bandages, cotton-buds, penicillin and vitamin B are the main export products, with a concentration ratio of only some 57%, which is far lower than other countries (EU 84%, USA 75%, India 74%), meaning that China has no dominant pharmaceutical product for export.

Another structural problem is that Chinese companies tend to apply pricing strategies, competing with each other by simply lowering export prices instead opting for other competitive strategies. But unreasonably low prices for exported goods may not only undermine product quality, but also slash profit margins, blunting the competitive edge of the entire industry in global markets.

Another key obstacle is the patent protection system for pharmaceutical products. In China, 90% of pharmaceutical companies rely on generic drugs, with inadequate investments in innovation. The patent protection system prevents the distribution and production of generic versions of innovative patented drugs and stops newly invented medicines from entering the generic market. The threat of potential patent lawsuits, combined with the China’s lack of confidence and experience in this area, makes local manufacturers extremely cautious about generic production, and they prefer to work with off-patent products that are somewhat out of date.

The situation is exactly the same for ARVs or any other drug for the treatment of HIV/AIDS. Although China is committed to more innovation in this area, most products are still generic.

As mentioned, the free ARVs provided by the government program are primarily first-line drugs. With rising drug resistance in first-line treatment, the need for second-line drugs is significant. To date, one of the essential first-
line ARVs – lamivudine (3TC) – which can also be used for second-line treatment, still depends on international donations. As multinational companies in China are patenting all second-line ARVs and no local manufacturer may produce them due to patent protection, access to free second-line ARVs under the government program remains a thorny issue.

The Chinese pharmaceutical industry has a huge production capacity, but to a large extent works only with off-patent products due to patent protection. At the end of 2008, China was able to produce Zidovudine (AZT), Stavudine (D4T), Nevirapine (NVP), Didanosine, Lamivudine, Efavirenz (EFV) and Indinavir (IDV), which are registered with the State Food and Drug Administration. Their administration options include tablets, capsules and injections.

According to a survey conducted by Chinese officials and WHO experts in Liaoning, Zhejiang, Shandong and Shanghai in 2006 and 2007, the Chinese pharmaceutical industry is strong on reverse engineering, being well able to produce generic ARVs (including second-line medications) once their patents expire. Although this capacity improves patients’ chances of receiving a sustainable supply of first-line ARVs, patent protection will probably stop local companies from producing generic drugs for domestic use.

Through workshops or seminars organized by UN agencies, NGOs, or law firms, the main stakeholders urging improved access to ARVs have gradually realized the importance of the relationship between intellectual property, innovation and public health. Although people are aware of the concept of parallel imports, Bolar exceptions and above all compulsory licensing, experience in the use of these mechanisms is still lacking.

Several Chinese government entities – including the Patent Office (SIPO), the Drug Regulatory Authority (SFDA), and the Trade / Investment Regulators (MOFCOM, NDRC) – have already established a system for the use of TRIPS flexibilities on medicines and public health. However, the actual deployment of these flexibilities still remains at zero, as no-one has yet taken the initiative of wielding this mechanism. Although most stakeholders are eager to make full use of this flexibility, they fear costly and time-consuming lawsuits, while cloudy political and economic outlooks discourage them from using the system. Most of NGOs, especially at the grassroots level, lack expertise and knowledge in this significant area, leaving their demands toothless. As a
result, we suggest that closer coordination is required for training, sharing information, distributing legislative information and organizing other practical methods, especially between NGOs and manufacturer associations.

DEVELOPMENT OF CHINESE PATENT LAW AND ITS IMPACT ON ACCESS TO MEDICINES

As mentioned, the Chinese government launched the national HIV/AIDS treatment program in 2004, which included providing free ARVs to rural AIDS patients and patients living with difficulties in cities and townships. However, sustainable access and availability of ARV drugs is still not fully resolved. Patent protection and other regulatory practices play an important role in undermining the accessibility of ARVs in China.

Case Study of Lamivudine (3TC)

When China’s national treatment program began, four drugs chosen for the first regimen were available generically in China because their patent status did not block local production. But the combination of ddl and d4T was not recommended by the WHO due to its toxic profile. Instead, the WHO recommended using lamivudine (3TC), a drug often used in a different formula to treat Hepatitis B in China. When the national treatment program began, there was no appropriate formulation of 3TC available in China for HIV/AIDS treatment. In the retail market, the only formula for treating Hepatitis B was available from the inventor company GlaxoSmithKline (GSK). The situation remained unchanged until 2004, when GSK made a limited donation of 3TC to Chinese government for its national HIV/AIDS treatment program. Although more than five years have passed since the free ARVs policy was adopted, China’s national HIV/AIDS treatment program is still

15. The regimen chosen at the beginning was zidovudine (AZT) or stavudine (d4T)+ didanosine (ddl)+nevirapine (NPV)
relying on GSK donations of 3TC and is not permitted to commence local production of this drug like some of the other ARVs.

Ironically, while China relies on GSK donations of 3TC for treating HIV/AIDS patients and no generic versions of 3TC are available in Chinese market, China is one of the major suppliers of 3TC Active Pharmaceutical Ingredient (API) to the rest of the world.\(^{17}\) This is because there are a number of exclusive rights over 3TC, including patent rights, that block the market entry of generic 3TC.

The original 3TC patent was filed by GSK in China in 1990, when it did not grant patents on pharmaceutical products, but only on their manufacturing processes. Because a patent can be applied only at a particular point in time, GSK could not request such protection in China – so no product patents protect 3TC in China.

Nevertheless, there is a group of process patents covering the 3TC manufacturing process that provide suspiciously strong and broad protection, which also affects 3TC as an end product. In 2007, GSK published a statement\(^ {18}\) on its website, announcing that it owned five process patents that were still valid in China. GSK further claimed that “the protection provided by Patent Nº 99126580.7 thus extends to all finished products of lamivudine that are suitable for pharmaceutical use,” adding that “any unlicensed manufacture, sale or use of a finished pharmaceutical product of lamivudine will breach this patent.”\(^ {19}\)

However, the application for Patent Nº 99126580.7 (expiring in 2011) was a divisional application of Patent Nº 94109429.4, which was in turn a divisional application of the old 3TC Patent Nº 91102778.5 filed in 1991 – a process patent by nature. Since divisional applications cannot go beyond the scope of disclosure contained in the initial application,\(^ {20}\) the GSK patent

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\(^ {17}\) By the date of this paper, four Chinese pharmaceutical companies obtained registration for generic 3TC products, but no actual production has yet began and no generic versions of 3TC are available on the Chinese market. Registration information on generic 3TC can be found on the Chinese State Drug and Food Administration website: [http://app1.sfda.gov.cn/datasearch/face3/dir.html](http://app1.sfda.gov.cn/datasearch/face3/dir.html) (searched on February 17, 2009, Chinese only)


\(^ {19}\) Id.

\(^ {20}\) Art 43 of the Rule of Implementation of Patent Law
can only be a process patent, as product patents were not available at that time in China. It is therefore surprising that GSK claims that such a patent can block all finished products with 3TC.

Other than patent protection, 3TC is also covered by a number of other regulatory shields that can block local production. These protections include drug administrative protection, new drug protection and data exclusivity. Though these protections have expired and a number of Chinese companies obtained drug registration for generic 3TC in 2008, the misleading and abusive statement mentioned above, issued by GSK on its active process patents for 3TC, still hinders Chinese generic companies from moving forward. The road leading towards generic 3TC in China is thus still blocked. Difficulties in producing and importing 3TC in China also result in a lack of fixed-dose combinations containing 3TC, which are widely used in other countries for HIV/AIDS treatment. The case of 3TC is only one example of how patent implementation hampers access to medicines in China.

The following text offers a brief overview of the development of Chinese patent law, its impact on access to ARVs, how it has been responding to the public health needs, and the problems that remain in the current law.

**Three Revisions of Chinese Patent Law and its relevance to public health**

Chinese Patent Law was first issued in 1985 and has been revised three times: in 1992, 2000 and 2008.

According to the 1985 Patent Law, no patent rights may be granted for the following subjects: 22

- Methods for the diagnosis or treatment of diseases
- Pharmaceutical products or substances obtained by chemical processes.

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21. Id. 8

22. According to Article 65.4 of the TRIPS Agreement, if a developing country did not provide product patent protection in a particular area of technology when the TRIPS Agreement came into force (January 1, 1995), it had up to ten years to introduce the prot
The first two patent revisions were conducted in 1992 and 2000, with the 1992 revision having significant implications for access to medicines. In 1992, set against the background of a US-China Bilateral Memorandum of Understanding on intellectual property protection, Chinese Patent Law was revised for the first time. The 1992 revision extended patent protection terms from fifteen to twenty years as from their filing dates. Although medical diagnosis and treatment methods were kept non-patentable, the 1992 revision opened the door to granting patents on pharmaceutical products, three years prior to the TRIPS Agreement (1995) that bound WTO members to issue patents on pharmaceutical products. Also, because the 1992 Patent Law revision predated the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), China did not benefit from the Transitional Arrangement Clauses of TRIPS for product patents on medicines when joining the World Trade Organization (WTO) in 2000.23

Chinese Patent Law completed its third revision in December 2008, following the development of the TRIPS Agreement under WTO rules. These developments include the Doha Declaration on the TRIPS Agreement and Public Health in 2001,24 the decision on the implementation of Paragraph 6 of the Doha Declaration in 200325 handed down by the WTO General Council, and the Amendment Protocol to the TRIPS Agreement adopted in 2005.26 The third revision of Chinese Patent Law integrated the new TRIPS development on compulsory licensing of medicines, which allowed for more proactive steps in safeguarding public health at the domestic level. With the improved notion of TRIPS flexibilities, the third revision also integrated some new mechanisms in favor of access to medicines. The following section will explain the relevant provisions in more detail.

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23. According to Article 65.4 of the TRIPS Agreement, if a developing country did not provide product patent protection in a particular area of technology when the TRIPS Agreement came into force (January 1, 1995), it had up to ten years to introduce the protection. But for pharmaceutical and agricultural chemical products, the country had to accept patent applications filed from the beginning of the transition period, though the patent did not need to be granted until the end of this period. See also: http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm

24. See: http://www.wto.org/english/theWTO_e/minist_e/min01_e/mindecl_trips_e.htm

25. See: http://www.wto.org/english/tratop_e/TRIPS_e/implem_para6_e.htm

26. See: http://www.wto.org/english/news_e/pres05_e/pr426_e.htm
Flexibilities under current Chinese Patent Law in safeguarding public health

The third Patent Law revision ushered in several improvements fostering access to medicines, buttressing the compulsory licensing mechanism, with integrated parallel importation, and Bolar exception provisions. Flexibilities that help improve access to medicines can also be found in other legislations referring to drug patent issues, for instance, drug registration regulations.

A. Compulsory licensing

The initial version of Chinese Patent Law introduced compulsory licensing mechanisms in 1985, but no compulsory license has ever been issued in more than two decades of development of China’s intellectual property system. In 2003, the State Intellectual Property Office (SIPO) issued the Order Nº 34 – Measures on the Compulsory License for Exploitation of a Patent – in order to standardize the procedures for issuing compulsory patent licenses, such as the content of the application, the hearing of the application, the content of the decision, etc. In 2005, in response to the new TRIPS development on public health issues, SIPO issued Order Nº 37 – Measures to Implement Public Health-Related Compulsory Licensing – aiming to integrate the provision in the Doha Declaration and the WTO General Council decision on the implementation of paragraph 6 of the Doha Declaration with the Chinese patent law system. Under Order Nº 37, public health was defined as a type of national emergency that is eligible for compulsory license applications, enacted by Article 49 of the 2000 Patent Law. In addition, this allows China to use the flexibilities under TRIPS and the WTO General Council decision to import and/or export medicines made under compulsory licenses. SIPO Orders Nº 34 and Nº 37 formed the basis for revising the compulsory license rules in the third Patent Law amendment.

The third revision of Chinese Patent Law strengthened its compulsory licensing provisions even more. First, a compulsory license may be issued on the grounds of preventing anti-competitive practices that might have significant

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implications on access to medicines. If the original manufacturers establish excessively high price policies constituting anti-competitive practices with adverse effects on generic producers, compulsory licenses could be issued on anti-trust grounds. Second, compulsory licenses may be issued for government use during national emergencies or when in the public interest, under the provisions set forth in Article 49. Third, compulsory licenses may be issued for public health purposes and products made under such licenses may be exported to eligible countries in compliance with international rules.28

B. Parallel imports

The third revision added the rule of parallel imports under Article 69 (1). Parallel imports refer to goods imported outside the distribution channels of the patent owner. Accordingly, after the first sale of a patented product by the patent owner or its authorized agents, the patent right is deemed to be exhausted. This product may be imported by a party from a third country where the same product is under patent and sold at a higher price, and such imports are not considered as breaching patent rights. Parallel imports are a useful tool for managing drug costs, especially for responding to different country pricing policies adopted by pharmaceutical companies.

C. Bolar exception

The Bolar exception is added under Article 69(5) as a non-infringing practice, allowing generic drug manufacturers to produce an item before its patent expires, for the purpose of applying for registration from the national drug administration agency. A corresponding provision can be found under Article 19 of the Measures for Drug Registration Regulation, issued by the State Drug and Food Administration. This Article allows a generic drug application to be filed two years before the patent expires. The Bolar exception rule will play a positive role in the speeding up the introduction of generic competition on the drug market, which will in turn help make drugs more affordable for patients.

28 This clause aims mainly at integrating the TRIPS Protocol Amendment provision into the patent law, but a detailed explanation of 'eligible countries' would be subject to upcoming clarification on the implementation regulation that is currently under review.
Issues outstanding under the Chinese Patent System on access to medicines

Although remarkable progress has been made in Chinese Patent Law, responding to public health needs, the current patent system still presents issues that might well affect access to medicines.

A. Patentability criteria

Chinese patentability criteria established the basic threshold for patent protection, as a rational design and firm implementation of patentability criteria can prevent patents from being granted unreasonably, and can also protect patent offices in developing countries from being trapped in political disputes over compulsory licensing. In other words, patentability could be deemed the fundamental safeguard that ensures an even balance between patent rights and public interests, requiring judgment at a very early patent examination stage in order to screen out illegible applications right from the start. International treaties establish the general principles for examining patent applications: a product must be novel, innovative and industrially applicable in order to be granted a patent. However, there are no binding rules under international laws that define patentability criteria in detail, such as precisely what ‘novel’ or ‘inventive’ means. Patentability criteria are thus the key flexibilities for domestic patent law, and countries have full autonomy to establish their own criteria and decide which inventions warrant patent protection.

This notion is particularly important when examining applications for patents on chemical and pharmaceutical products. A broad definition of patentability might allow patents for minor alterations to an existing chemical compound. For instance, ‘evergreening’ patents is a strategy widely used by pharmaceutical companies, through patent applications based on ‘new uses’ for existing medicines, or special new forms (i.e. salts, crystals, optical isomers, etc) of an existing chemical molecule, or even simple combinations of two or more chemical compounds in order to extend patents on existing medicines.29

International researchers have suggested that broad definitions of patentability are not desirable for the developing countries. For instance, to prevent patent evergreening, the UK Intellectual Property Rights Commission Report suggested that developing countries avoid making ‘new uses’ of known products patentable.\(^{30}\)

Chinese Patent Law establishes novelty, innovative steps and industrial applicability as the basic principles when examining patent applications. In practice, the patentability criteria for pharmaceutical products are regulated in the guidelines drawn up for patent examiners, issued by SIPO. The current patentability criteria for examination practices allow broad recognition of pharmaceutical patent applications. For instance, the Brazilian Patent Office rejected a patent application submitted by the US-based drug company Gilead on an essential HIV/AIDS medicine – Tenofovir Disoproxil Fumarate (TDF) – in 2008,\(^ {31}\) on the grounds that it lacked inventiveness, as TDF is a salt form of a known chemical compound. However, Chinese patentability ranks salt forms as patentable, which might open the door to patents for minor changes to known chemical compounds.

Chinese patent examination also ranks ‘new uses’ of known compounds and combinations of chemical compounds as patentable, which might well hamper the introduction of affordable generic medicines. For instance, in August 2006, in response to requests from civil society in Thailand and India, GSK issued a global announcement withdrawing a specific patent application on its ARV product Combivir, which is a combination of 3TC and AZT. In many countries, this withdrawal might well pave the way for introducing generic versions of Combivir, since combinations alone are not patentable. However, GSK did not file any withdrawal request with the Chinese Patent Office for this patent application. Although this specific application was rejected by the Chinese Patent Office for lacking novelty, GSK still holds a market monopoly over Combivir for its basic combination, which has been patented in China.


B. Data exclusivity

Article 39.3 of the TRIPS Agreement requires member states to protect confidential experimental data from unreasonable disclosure. However, during the TRIPS negotiation process, it was agreed that data protection does not imply a ‘data exclusivity’ protection that might stop generic drug registration applications from referring to the original data. The World Health Organization (WHO) Report on Public Health, Innovation and Intellectual Property (CIPIH Report) also pointed out that data protection under Article 39.3 of TRIPS does not prevent drug administration agencies from using the original data for the purpose of granting approvals for generic medicines. This means that data exclusivity can further delay the introduction of generic medicines to the market. Additionally, data exclusivity might also hinder generic drug approvals under compulsory licenses, thus making the use of these compulsory licenses impossible.

Current Chinese law establishes a six-year protection period for data exclusivity under Article 35 of the Drug Administration Law Implementation Rule. As a result, no generic application would be approved within six years of the original manufacturer receiving drug registration approval. This has the potential impact of introducing generic versions when the original manufacturer does not hold a patent in China or when compulsory licensing is used. Although Article 35.3 (1) of the drug Administration Law Implementation Rule states that ‘data exclusivity’ may be annulled when in the ‘public interest’, no link has been made with this provision of Patent Law. For instance, if a compulsory license is issued for a specific drug during the data exclusivity period, the implementation of the compulsory license could be delayed as generic companies might not be able to obtain production approval based on the original manufacturer’s data. The third Patent Law revision did not include a clause on annulling data exclusivity in the public interest. This might be a point of concern for future research.

The development of Chinese Patent Law in terms of public health interests also required greater familiarity with international patent rules, adjusting and gradually integrating them with domestic law. This process did not run

smoothly because China was on the one hand bombarded by heavy international pressures demanding stronger intellectual property protection and firmer enforcement, while on the other, it was faced by the rising costs of providing sustainable public health services. Moreover, as China initially lacked experience in deploying the flexibilities of the patent system – despite some revised provisions intended to ease tensions between patent protection and public health – learning how to use these flexibilities still requires further efforts from several stakeholders.

**Challenges and Ways Forward: Closing Remarks**

As briefly mentioned in this paper, although government agencies are becoming more aware of the need to break down patent barriers blocking sustainable access to ARVs in China, the flexibilities offered by the current Patent Law have never been deployed, particularly compulsory licensing. Furthermore, there are also issues in the current legal system that may constitute potential risks that might jeopardize the future use of patent law flexibilities for public health purposes. Although civil society has become more proactive in advocating better access to ARVs, the actual effects have been limited. One of the main reasons might be that many sectors in China are not familiar with the international system and its rules. Due to this lack of information, training and hands-on experience, people prefer cautious approaches rather than more concrete actions. However, this situation is improving as the language of compulsory licensing – placing public health before patents – becomes mainstreamed in many different sectors.

Nevertheless, challenges still remain for driving the NGO machine ahead. First, although government agencies are aware of the importance of making better use of the patent flexibilities, inter-sector collaboration is still weak. In order to test the legal waters, the government needs stronger political will and tighter inter-sector collaboration for reaching practical solutions. Second, domestic empirical research and analysis are seriously lacking. Although SIPO has commissioned important theme-specific research projects on the need to revise patent law, further empirical research is required, focused on public interests. In this respect, intellectuals and professionals must become
more involved, with more practical research and analysis among practitioners. Third, private sector involvement is still weak. Domestic industry must play a more visible role in improving access to ARVs and enhancing production quality standards. Finally, the involvement of civil society has proven vital for movements urging better access to medicines in other countries, but this potential has not yet been fully explored in China. A more coherent and professionalized approach by civil society is crucial for future efforts advocating better access to ARVs in China.
4. India

INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES: DEVELOPMENTS AND CIVIL SOCIETY INITIATIVES IN INDIA*

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ABSTRACT

A primary objective of the Lawyers Collective HIV/AIDS Unit in India is the guarantee for universal access to medication for PLWHA. According to a revised estimated in 2001, there are approximately 2.5 million PLWHA living in India. The Lawyers Collective understands that an integrated health care system that emphasizes both prevention and treatment is necessary to confront this disease. Thus, the Lawyers Collective wages a constant battle within India’s courts to secure affordable ARVs for PLWHA.

Based on a survey made by the Lawyers Collective, the Affordable Medicines and Treatment Campaign (AMTC) demanded that India’s 2005 patent law include public health safeguards and exclude TRIPS+-plus provisions. Largely due to this collective effort, India’s patent law was amended to prevent evergreening practices by pharmaceutical companies. Other engagement with the government and intellectual property law includes turning in submissions on public policy and intellectual property to the parliament. Such submission topics include patent limits for pharmaceuticals with new chemical entities, drug pricing, data exclusivity and patent linkages. Civil society organizations in India have also participated in public demonstrations to oppose patent abuse by pharmaceutical companies and patents applications for ARVs. Such opposition included the patent for Combivir, a combination of lamivudine and zidovudine. A massive civil society protest was held in Bangalore outside the office GlaxoSmithKline, the producer of Combivir. Subsequently, in 2007, GlaxoSmithKline withdrew its patent applications for Combivir in India and Thailand.

Although national and local NGOs have had numerous victories in the fight for access to medications, the Lawyers Collective realize that the ultimate victory for universal access must be made in a spirit of international collaboration. “In each of our countries, as we struggle to increase access to medicines, we face various limitations, including those of resource and capacity constraints. It is therefore crucial that we engage in greater coordination with patients’ groups, civil society and public health groups in other countries to draw upon their experiences and to support their endeavours to ensure greater, and ultimately universal, access to medicines for all.”
I. EVOLUTION OF THE HIV/AIDS EPIDEMIC IN THE COUNTRY AND ITS NATIONAL LEGAL FRAMEWORK

A. Contextual framework of the epidemic in India

The first HIV case in India was detected in 1986 in Madras, the capital of the southern state of Tamil Nadu. From then until the early 1990s, HIV was detected primarily amongst persons from vulnerable communities – sex workers, injecting drug users and men who have sex with men. The estimated figures gradually rose, and in 2000, it was estimated that approximately 3.86 million people (0.77 per cent adult prevalence) were living with HIV in India. By 2003, it was estimated that approximately 5.1 million people (0.9 per cent prevalence) were living with HIV in India. However, in 2006, the Government of India downsized the estimates after utilising the UNAIDS/WHO workbook method of estimation. According to the 2006 revised estimates, India has approximately 2.47 million people living with HIV.

B. Legal framework related to the right to health, services and treatment in general

The Constitution of India, which is the supreme law in India, came into force in 1950. It includes a separate chapter on fundamental rights. All laws and actions of the State have to be in accordance with the Constitution of India. Any law that violates any of the fundamental rights is void and can be struck down by the courts.

The Constitution of India recognises the right to life and the right to equality of all persons. These rights are available to all persons, whether citizens or...

3. Article 13 of the Constitution of India.
4. Article 21 of the Constitution of India provides as follows: No person shall be deprived of his right to life and personal liberty except according to procedure established by law. Article 14 of the Constitution of India states that “[t]he State shall not deny to any person equality before the law or equal protection of the law”.

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non-citizens. The Constitution of India does not specifically recognise the right to health as a fundamental right. However, over the years, the Supreme Court of India has interpreted the right to life recognised by Article 21 of the Constitution of India to include the right to health. It has held that Article 21 of the Constitution imposes an obligation on the State to preserve life. It has further held that providing adequate medical facilities is an essential part of the obligation undertaken by the Government in a welfare State, and the State cannot deny this obligation. In a case relating to the non-availability of facilities in government hospitals for treatment of persons who had sustained serious injuries, the Supreme Court held that the State cannot plead financial constraints as an excuse for non-performance of its constitutional or statutory obligations to provide adequate medical services to preserve human life. However, in a subsequent case, the Court held that no right is absolute and that fundamental rights can be subjected, in certain cases, to financial constraints. In this case, however, the issue was whether a person could claim reimbursement of medical expenses at the rate of treatment in a private hospital when the same treatment was available at public hospitals at a lesser cost.

Chapter IV of the Constitution of India, which provides for Directive Principles of State Policy, casts certain obligations on the State. Article 47 of the Constitution of India specifically imposes on the State the responsibility of improving public health. In this context, the Supreme Court of India has held that maintenance and improvement of public health have to rank high amongst State obligations as these are indispensable to the very physical existence of the community.

5. Certain other fundamental rights such as the freedom of speech and expression, freedom of movement, and freedom of trade, business and profession are available only to citizens of India.
Thus, the right to health is now considered a fundamental right under the Constitution. It is therefore possible to approach the courts to challenge State actions that affect a person’s health.

International law requires countries to provide treatment to persons living with HIV. Being a dualist state, treaties and international agreements are not enforceable in India unless they have been domesticated into municipal law. However, the Supreme Court of India has, time and again, invoked various international human rights instruments. It has held that international instruments can be read to expand the fundamental rights guaranteed under the Constitution of India.\(^\text{12}\) The \textit{Protection of Human Rights Act, 1993} specifically provides for the protection of human rights contained in the ICESCR and the \textit{International Covenant on Civil and Political Rights} (ICCPR). Therefore, the rights set out in the ICESCR and ICCPR can be enforced through courts.

India is a signatory to the \textit{International Covenant on Economic, Social and Cultural Rights} (ICESCR), which recognises the right of every person to the highest attainable standard of physical and mental health.\(^\text{13}\) Article 12.2 of the ICESCR specifically requires States to take certain steps to achieve full realisation of the right to the highest attainable standard of physical and mental health, including steps for the prevention, treatment and control of epidemic, endemic, occupational and other diseases. General Comment No. 14, which explains the content of the right to the highest attainable standard of physical and mental health under Article 12 of the ICESCR, sets out certain core obligations of States. This includes an obligation to provide ‘essential drugs’ as defined under the WHO Action Programme on Essential Drugs.\(^\text{14}\) Since 2002, antiretrovirals (ARVs) to treat HIV have been included in the WHO’s Model List of Essential Medicines.\(^\text{15}\) Apart from this, the

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\(^{14}\) General Comment No. 14 on the right to the highest attainable standard of health (2000), E/C.12/2000/4, (General Comment No. 14). Paragraph 43 of General Comment No. 14 states that State parties have certain core obligations which they have to satisfy.

\(^{15}\) ‘Essential Medicines WHO Model List’, (12\textsuperscript{th} list, April 2002), available at at: \url{http://www.essentialdrugs.org/files/ed2002core.doc}. See also ‘Essential Medicines WHO Model List’ (15\textsuperscript{th} list, March 2007), available at \url{http://www.who.int/medicines/publications/08_ENGLISH_indexFINAL_EML15.pdf}. 

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Declaration of Commitment on HIV/AIDS, 2001 (UN Declaration of Commitment) adopted by the United General Assembly Special Session on HIV/AIDS commits member states, including India, to provide progressively and in a sustainable manner the highest attainable standard of treatment for HIV/AIDS.\textsuperscript{16}

These international instruments clearly oblige India to provide treatment, including treatment for opportunistic infections and ARVs, to persons living with HIV in India. It is possible to urge before courts that the right to health under the Constitution of India has to be given effect to in the context of India’s obligations under the ICESCR as elaborated in General Comment No. 14 and the UN Declaration of Commitment.

C. Legal framework for industrial property with emphasis on pharmaceutical patents

The Indian legal system provides protection to various industrial property rights – patents, designs, trademarks and geographical indications.

India owes its unique position as the supplier of generic drugs to the world to its patent law.

Pre-1972

During the British colonial rule, protection for inventions was statutorily introduced in India for the first time in India in 1856. The law underwent several changes, including changes to provide protection to designs. Subsequently, the Patents and Designs Act, 1911 was passed, which for the first time, brought the patent system under the control of a Controller of Patents. The Patents and Designs Act, 1911 provided patent protection to products, including drugs, and processes. Through a subsequent amendment, the period of protection was increased from 14 years to 16 years.\textsuperscript{17}


\textsuperscript{17} See generally “History of Indian Patent System”, available at http://ipindia.nic.in/pr/patent/patents.htm.
It is important to note the development of the pharmaceutical industry in India – both before and after India gained independence from British rule in 1947. Under British rule, Indian pharmaceutical companies faced several disadvantages such as availability of raw materials at higher prices than those available to European manufacturers, inferior raw materials, and restrictions on movement of goods from one province to another.\textsuperscript{18} Interruption of imports due to the Second World War gave a fillip to the establishment of more Indian pharmaceutical companies. From meeting 13 percent of the country's pharmaceutical requirements in 1939, the Indian pharmaceutical companies met 70 percent of the country's requirements by 1943.\textsuperscript{19}

The impact of patents on the Indian pharmaceutical industry began to be seen in the 1940s and 1950s. The late 1940s and the 1950s witnessed the release of new synthetic drugs into the world market by multinational pharmaceutical companies.\textsuperscript{20} These new synthetic drugs were, however, patented by multinational pharmaceutical companies.\textsuperscript{21} Most Indian pharmaceutical companies, which had till then concentrated on research into manufacturing technologies and processes, were unable to manufacture the new drugs due to the patents on these drugs.\textsuperscript{22} The patent system, coupled with regulatory disadvantages, led to the loss of dominance of the Indian market by Indian pharmaceutical companies in the 1950s and 1960s.\textsuperscript{23} By 1970, the market share of the Indian pharmaceutical industry had fallen to 32 per cent.\textsuperscript{24}

\textsuperscript{18} Sudip Chaudhuri, \textit{The WTO and India's Pharmaceuticals Industry}, Oxford University Press, Delhi, 2005, page 23.
\textsuperscript{19} Chaudhuri, pages 22 and 24.
\textsuperscript{20} Chaudhuri, page 26.
\textsuperscript{21} Chaudhuri, page 27.
\textsuperscript{22} Chaudhuri, pages 26–27.
\textsuperscript{23} For example, the licensing policy allowed diversification of production and expansion to those companies which were already existing license holders. With better resources at their disposal, foreign pharmaceutical companies were able to introduce newer products into the market. Subsequently, the government disallowed further licensing for formulations unless the corresponding bulk drugs were manufactured within two years. This operated to the disadvantage of Indian companies who had to comply with this more stringent requirement to introduce new formulations. For more, see Chaudhuri, pages 25–29.
\textsuperscript{24} Chaudhuri, page 18.
By 1970s, prices of drugs in India were amongst the highest the world. This was because of the patent system which prevented Indian pharmaceutical companies from manufacturing the patented drugs and thus restricted competition.

1972–1995

In 1972, the *Patents and Designs Act, 1911* was repealed and the *Patents Act, 1970*, came into force. The new law abolished product patent protection for pharmaceuticals and agrochemicals and only protected process patents for these sectors. Further, in case of a process patent, an inventor could only claim protection for the best process known to her for the manufacture of a pharmaceutical product. The period of protection was reduced from 16 years under the 1911 Act to a maximum of seven years.

By this time, research and development units of the Centre for Scientific and Industrial Research (CSIR) laboratories and public sector pharmaceutical companies, set up by the Government of India in the 1950s and 1960s, had been successful in developing new processes for drug manufacture and shared their knowledge with the Indian pharmaceutical companies. This enabled Indian pharmaceutical companies to introduce new drugs into the market using non-patented processes. During this period, India also introduced other regulatory changes relating to pharmaceuticals and foreign exchange, which restricted the number of multinational pharmaceutical companies in India and the drugs which they could manufacture. Thus, the amendments in the patent law and other regulatory changes permitted competition, increased production and decreased dependency on drug imports. All these, combined with price control of drugs, led to a fall in the prices of drugs in India.

29. Chaudhuri, page 133.
30. See generally, Chaudhuri, chapters 2 and 4.
The Indian pharmaceutical industry, in a short span of two decades, transformed India from an import-dependent market to a self-sufficient country in drug production with the lowest drug prices in the world.

1995–present

In 1994, the Marrakesh Agreement establishing the World Trade Organization (WTO) was signed. Being a signatory to this, India was required to comply with the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). Under the TRIPS Agreement, all WTO member states are required to provide product patent protection to inventions in all fields of technology, including pharmaceuticals, for a minimum period of 20 years. However, because India did not recognise product patent protection for pharmaceuticals, it had until 1 January 2005 to amend its patent law. In the interregnum, India was required to allow filings of patent applications relating to pharmaceuticals, which would be kept in a mailbox and examined after 1 January 2005 and also allow grant of exclusive marketing rights subject to certain conditions.

In India, laws are generally made by the Legislature consisting of the country's elected representatives. Central laws that apply to the whole of India are made by Parliament. However, the Constitution of India allows the President to promulgate an Ordinance if Parliament is not in session if circumstances require immediate action.31 Such an Ordinance ceases to operate in two ways. Firstly, after Parliament is reconvened, both Houses of Parliament may pass resolutions disapproving the Ordinance. Secondly, the Ordinance automatically lapses six weeks after Parliament reconvenes.32

As the Indian Parliament had not amended the patent law as required by the TRIPS Agreement and Parliament was not in session in December 1994, the President of India promulgated the Patents (Amendment) Ordinance, 1994 to allow mailbox filings and grant of exclusive marketing rights. However, once Parliament reconvened, it did not pass a law to amend the patent law and the Patents (Amendment) Ordinance, 1994 lapsed. In the meantime,

31. Constitution of India, article 123(1).
32. Constitution of India, article 123(2).
even after the Ordinance lapsed, filings of patent applications for pharmaceuticals continued under an administrative scheme.

In 1997, the European Union took India to the World Trade Organization’s Dispute Settlement Board for its failure to statutorily provide for mailbox filings and exclusive marketing rights. After the Dispute Settlement Panel ruled against India, it was required to pass a law to give effect to the provisions relating to mailbox and exclusive marketing rights. However, as Parliament was not in session, the President of India once again promulgated an Ordinance. This time, however, Parliament subsequently adopted the amendments and passed the Patents (Amendment) Act, 1999. In 2002, Parliament further amended the patent law to introduce certain changes such as extending the patent term to 20 years.

International and domestic events during this interregnum period from 1995 to 2005 underscored how access to medicines in India and elsewhere would be impacted once the product-patent regime came into force in India. In 1996, it was discovered that certain ARVs taken in combination could halt viral replication and make HIV a chronic, manageable condition. However, priced at over USD 10,000 per patient per year, these crucial, life-saving drugs were out of reach of millions of people living with HIV in developing and least developing countries. In 2001, Indian pharmaceutical companies were able to offer the same ARVs at USD 350 and lower costs per patient per year. The absence of product patent protection for pharmaceuticals in India was what allowed Indian pharmaceutical companies to make generic versions of these drugs and fixed dose combinations. This resulted in increased access to these crucial life-saving drugs.

At the same time, public health crises, especially that of HIV, TB and malaria, led to the adoption of the Declaration on the TRIPS Agreement and Public Health (Doha Declaration) in 2001 by the WTO Ministerial Council. The Doha Declaration reaffirmed that the TRIPS Agreement contained flexibilities which could be used by member countries in order to promote access to medicines for all.

In December 2004, the Indian Parliament still had not amended the patent law to comply with the requirement of providing product patent protection
for pharmaceuticals and agrochemicals as required by the TRIPS deadline of 1 January 2005. On 26 December 2004, therefore, as Parliament was not in session, the President of India once again promulgated an Ordinance, the Patents (Amendment) Ordinance, 2004, to ensure compliance with the 1 January 2005 deadline.

The Ordinance was, however, introduced without any deliberation or transparency. Civil society and public health groups, including Lawyers Collective HIV/AIDS Unit, engaged in public demonstrations, media and legislative advocacy to ensure the introduction and retention of public health safeguards in the Indian patent law.

Subsequently, when Parliament convened in February-March 2005, the Patents (Amendment) Bill, 2005 was tabled. During the debate, Parliamentarians voiced their concern on the impact of a product patent regime on the prices of drugs. They identified “evergreening” of patents – where an innovator company that has obtained a patent on a new chemical entity seeks to enlarge its monopoly by seeking and obtaining patents on new forms or by claiming new uses for that entity – as a problem that would result because of the product patent protection for pharmaceuticals. Parliament, therefore amended, the patent law to attempt to prevent evergreening. At the same time, the Government assured Parliament that it refer two contentious issues – restricting patenting of pharmaceutical substances to only new chemical entities and patenting of microorganisms – to a Technical Expert Group to be appointed by the Government.33

The patent law contains several substantive safeguards to check evergreening of patents. Section 3 of the Indian Patents Act, 1970, enumerates lists out what are not considered “inventions” and therefore cannot be granted a patent. Firstly, section 3(d), even before the 2005

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33 Accordingly, a Technical Expert Group, chaired by Dr. Mashelkar, was set up by the Government in April 2005. After a series of hearings, the Technical Expert Group submitted its report to the Government in December 2006 recommending that it would not be TRIPS compliant to restrict patenting of pharmaceutical substances to new chemical entities. The Report was criticised for various reasons, including a lack of legal reasoning. Following a revelation of plagiarism of the Report’s key findings from the submissions of a foreign multination pharmaceutical-industry funded group, the Report was withdrawn. A revised Report reiterating the same conclusions was submitted to the Government in March 2009.
amendment, excluded mere discovery of new properties or new uses of known substances from patentability.\textsuperscript{34} Thus, second medical uses of known substances cannot be patented in India. Secondly, section 3(d), as amended in 2005, states that discoveries of new forms of known substances are not inventions, unless there is a significant enhancement in the known efficacy of the known substance. For example, if a patent applicant wishes to patent a polymorph of a known salt (A), the patent applicant must show that the particular polymorph is significantly more efficacious than the known efficacy of the known salt (A). The explanation to section 3(d) clarifies that salts, esters, ethers, polymorphs, combinations, etc are deemed to be new forms of known substances.\textsuperscript{35} Thirdly, section 3(e) of the Patents Act, 1970 disallows patenting of admixtures, which result merely in the aggregation of the properties of the components.\textsuperscript{36}

Interestingly, India also amended the definition of inventive step to make it more stringent. Section 2(1)(ja) of the Patents Act, 1970 requires a patent applicant to show that the invention constitutes technical advance or economic significance or both \textit{and} it is not obvious to a person skilled in the art.\textsuperscript{37}

The law also contains procedural safeguards to prevent frivolous patenting. The Patents Act, 1970 allows any person to file a pre-grant opposition before

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\textsuperscript{34} Section 3(d) of the Patents Act, 1970, as it now stands, reads as follows: “The following are not inventions within the meaning of this Act,—(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substances, unless they differ significantly in properties with regard to efficacy.” (emphasis supplied).

\textsuperscript{35} Ibid.

\textsuperscript{36} Section 3(e) of the Patents Act, 1970 reads as follows: “The following are not inventions within the meaning of this Act,—(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance.” (emphasis supplied).

\textsuperscript{37} Section 2(1)(ja) of the Patents Act, 1970 reads as follows: “2(1) In this Act, unless the context otherwise requires—(ja) “inventive step” means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art” (emphasis supplied).
\end{flushright}
a patent is granted. There are also several provisions to challenge patents that have been granted. Firstly, a post-grant opposition can be filed within one year of the publication of grant of a patent. Secondly, a revocation proceeding can be initiated at any time after the grant of a patent.

Thus, the Indian patent law has certain provisions that can prevent frivolous patents from being granted. It remains to be seen whether the Indian Patent Office applies the patentability standards in a strict manner to ensure that the public health interest is safeguarded. However, the spate of patents granted to pharmaceuticals in India raises questions as to how public health safeguards are being implemented.

D. Historical framework of the right to treatment of persons living with HIV and AIDS, particularly with respect to access to medications

As stated earlier, even in early 2001, the majority of persons living with HIV in developing and least developing countries including India were unable to afford the crucial, life-saving drugs that makes HIV a chronic, manageable condition.

In the 1980s and 1990s, there were several reported instances of discrimination against PLHIV and violation of the rights to consent to testing and confidentiality in Indian hospitals. Vulnerable communities too faced discrimination in the healthcare sector on account of the stigma associated with being a drug user or sex worker and that of being HIV-positive or perceived to be HIV-positive. Therefore, in 1999, Sankalp Rehabilitation Trust – a non-governmental organisation working with drug users – with technical and legal assistance from Lawyers Collective HIV/AIDS Unit, filed a petition before the Supreme Court of India, seeking directions on protocols for consent for HIV testing, confidentiality and anti-discrimination. As will be discussed later, the Supreme Court of India has recently passed interim directions in this case and other related cases that were clubbed together.

38. Section 25(1) of the Patents Act, 1970.
39. Section 25(2) of the Patents Act, 1970.
40. Section 64 of the Patents Act, 1970.
Before antiretroviral treatments became available, the only way to manage HIV was to ensure prompt treatment of opportunistic infections. The Government of India's initial response to the HIV epidemic focussed primarily on preventing the spread of HIV and little attention was paid to the care and treatment of PLHIV.

In the early 2000s, under the National Guidelines for Clinical Management of HIV/AIDS, drugs to treat opportunistic infections were to be made available by the State AIDS Control Societies free of cost. However, in actual practice, even these drugs were not available to PLHIV who needed them.

In the meantime, even after the prices of first line ARVs came down in 2001, many PLHIV in India were still unable to afford ARVs. Despite this, the Government of India appeared reluctant to provide ARVs.

For about three years from 2001 to 2004, the Government provided ARVs only for preventive purposes – prevention of mother to child transmission programmes and post-exposure prophylaxis for health care workers – in a limited way. Between April 2000 and July 2001, the National AIDS Control Organisation conducted a feasibility study for prevention of mother to child transmission. Based on the feasibility study, in December 2001, the Government scaled up access to prevention to mother to child transmission.

However, for the vast majority of PLHIV, ARVs remained out of reach. It was only in April 2004 that the Government of India commenced its ARV roll-out programme, under which first-line ARVs were provided to PLHIV at eight centres in six high prevalence states and the National Capital Territory of Delhi.


Since the initiation of the ARV roll-out in 2004, the availability of treatment sites and the number of PLHIV on treatment has been upscaled. PLHIV, who had initiated ARVs prior to 2004, were also absorbed into the government ARV roll-out programme. As of December 2008, first-line ARVs are provided at 197 centres across the country, and at least 193,795 PLHIV are receiving first line ARVs. Increasingly, PLHIV across the country who are experiencing drug resistance need the second-line treatment. However, the second-line ARVs are not available to all who require it under the roll-out. In January 2008, the Government of India commenced a pilot second-line roll-out programme in the cities of Mumbai and Chennai. Second line treatment is available only to those residing in these cities and those who are first line ARVs from the government roll-out. Thus, many PLHIV in other cities and districts who require second-line treatment continue to be denied treatment.

Courts in India have also played a role in increasing access to treatment, both in individual cases and at a larger level.

For instance, in 2000, LX, a prisoner who needed antiretroviral treatment, approached the Supreme Court of India because, though medically indicated, LX was not being provided ARVs. The Supreme Court of India directed the Government of India to provide antiretroviral treatment to LX at the All India Institute of Medical Sciences – a premier medical institution in New Delhi, India. The Supreme Court directed that the treatment be continued even after LX was released from jail. After the ARV roll-out was initiated, the Court directed that LX should be shifted to the ARV roll-out programme, if possible. However, in case it was found that the medicines under the ARV roll-out were not the same as or could not substitute the medicines that LX was already receiving, LX was to continue receiving his old regimen and the Government of India was to reimburse AIIMS for the costs of treatment.

46. LX v. Union of India and others, Supreme Court of India, Civil Writ Petition No. 7330 of 2000 (5 May 2004).
In October 2008, the Supreme Court of India passed interim directions in *Sankalp Rehabilitation Trust v. Union of India* and other cases relating to the issue of treatment of HIV, which have been clubbed together.\(^{47}\) The interim directions are based on a common minimum understanding arrived at between the parties after discussions held between the Government of India and the Petitioners in the multiple cases and the Indian Network for People Living with HIV/AIDS. These directions include the humane treatment of PLHIV with dignity and care, setting of link ART centres in certain districts, ensuring availability of free drugs for opportunistic infections, testing kits, safe working environment.\(^{48}\) However, several unresolved issues remain, such as the inclusion of tenofovir in the first line regimen and scaling up second line treatment.

Apart from these, another urgent issue that has not yet been addressed is the provision of treatment for co-infections, such as Hepatitis C. In the north-East of India, where Hepatitis C prevalence is high, a tragic story of PLHIV being able to access ARVs but dying of Hepatitis C because of lack of access to treatment for Hepatitis C is assuming huge proportions.

Thus, India is a long way off from realising universal access to treatment for PLHIV.

**II. LOCAL PRODUCTION OF ANTIRETROVIRALS**

**A. Profile of local production of ARVs**

Thus far, the robust Indian pharmaceutical industry has ensured that several generic versions of all first-line ARVs are available. This has been possible largely due to the absence of the product patent protection for pharmaceuticals until 2005.


\(^{48}\) Ibid.
At least eight private pharmaceutical companies are engaged in production of ARVs, which also meet WHO’s pre-qualification standards. Most of them manufacture the active pharmaceutical ingredients as well as formulations.

It is also important to bear in mind that this situation exists because most first-line ARVs are pre-1995 molecules. The situation is different with respect to second- and third-line ARVs. Fewer companies are engaged in production of second-line ARVs.

Another factor that has to be borne in mind is the impact of the new product patent regime on Indian pharmaceutical companies. It is inevitable that some of the pharmaceutical companies will merge and some be taken over. In fact, a few such as Ranbaxy Ltd. and Matrix Laboratories Ltd. have already been taken over. Also, it is expected that some Indian pharmaceutical companies will now focus on the markets in the United States and other regulated markets, especially as more drugs go off-patent.

The state of public-sector pharmaceutical companies in India is not very encouraging. Further, none of them presently manufacture ARVs. However, if required, the Government can explore the option of production of ARVs by the public sector pharmaceutical companies.

**B. Influence of local production of ARVs in the level of access to medicines**

As has been stated earlier, it was the local production of ARVs that led to the fall of prices of first-line ARVs worldwide in 2001. Prices have fallen from over USD 10,000 per patient to USD 350 per patient per year in 2001 and further reduction to USD 132 per patient per year. The low prices have made it easier for the government to scale up access to ARVs. However, the higher prices of second-line ARVs is a consideration that appears to affect the government’s decision to scale up access to second line ARVs slowly.


III - Performance of the Transnational Pharmaceutical Companies in the Country

A. Performance of transnational pharmaceutical companies that affect access to treatment with ARVs in India

Several transnational pharmaceutical companies have a presence in India, either in the form of an India office or in the form of Indian subsidiary companies. However, very few of these Indian subsidiaries have production facilities in India. The foreign pharmaceutical companies primarily import drugs into India.52

Until now, the presence of a strong Indian pharmaceutical industry has cushioned India from the adverse effects of the policies of the transnational pharmaceutical companies.

Further, the Indian drug regulatory law makes it unlikely that transnational pharmaceutical companies can threaten to withhold the introduction of new drugs in the Indian market. Under the Indian law, even though a multinational pharmaceutical company may not register its drug in India, it is still possible to introduce generic versions of the drug in India. A provision in the Indian drug regulatory law allows the Drugs Controller General of India to grant marketing approval for generic versions of drugs on a showing of bioequivalence to an already approved drug.53 For drugs that have been introduced in the world market but have not been registered in India by the originator companies for marketing, the Drug Controller General of India can rely on the marketing approval in other countries to determine the safety and efficacy of the drug. There have been instances in the past where generic versions of drugs have been introduced in India even before the originator introduced them in the Indian market.54

B. Current strategies of foreign companies that affect access to medicines

As in most developing and least developing countries, there is a sustained effort by foreign transnational companies to bring about changes in domestic

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52. Chaudhuri, pages 142–144.
laws and policies in order to maximise their monopoly and increase their profits. If the transnational companies are successful in their efforts, the changes brought about at their behest will necessarily have an adverse impact on access to medicines.

The strategies adopted by transnational pharmaceutical companies in India are manifold.

Firstly, a huge number of pharmaceutical patent applications are pending before the Indian Patent Office. A significant portion of these are filed by foreign pharmaceutical companies. Some of them file multiple patent applications relating to the same drug. A perusal of the patents granted reveals that despite public health safeguards in the patent law, many patents on pharmaceuticals are being granted by the Indian patent office. Thus, for example, the Indian patent office has granted patents on valganciclovir, a prodrug of an already known substance, and pegasys, a pegylated form of an already known substance.

Secondly, one needs to guard against the dangers that may be inherent in voluntary licences. For example, Gilead Sciences, Inc. has entered into voluntary licences with several Indian pharmaceutical companies relating to tenofovir, an ARV.\(^{55}\) It appears that these voluntary licences contain certain restrictions on the Indian pharmaceutical companies with respect to sourcing of active pharmaceutical ingredients and the markets in which the drugs produced under the licence could be exported. Interestingly, several Indian pharmaceutical companies, which had filed pre-grant oppositions against Gilead’s patent application for tenofovir, have withdrawn their patent oppositions. Thus, voluntary licences may actually inhibit competition and thus indirectly maintain high costs of medicines.

Thirdly, foreign pharmaceutical companies, either individually or as an association, are advocating the introduction of TRIPS-plus requirements in the Indian law. Thus, for example, the Organisation of Pharmaceutical Producers in India, the association of foreign pharmaceutical companies, has repeatedly

called upon the Government of India to introduce data exclusivity\(^{56}\) and patent linkages\(^{57}\) and amend section 3(d). Both these are clearly TRIPS-plus provisions and, if introduced, will have an adverse impact on the availability and affordability of medicines.

Fourthly, foreign pharmaceutical companies have started approaching the courts in order to bring about a policy change. For instance, in 2008, Bayer Corporation filed a case before the Delhi High Court against the Government of India and an Indian pharmaceutical company seeking the introduction of patent linkages.\(^{58}\) The case relates to sorofenib tosylate, an anti-cancer drug used to treat advanced renal cancer. Bayer Corporation, which has been granted a patent for sorofenib tosylate in India, has sought directions from the court restraining the drug regulatory authority from granting marketing approval to Cipla’s generic version of sorefenib tosylate as it would allegedly violate Bayer’s patent. A decision is awaited in this case.

Thus, civil society needs to be extremely vigilant to the attempts of pharmaceutical companies on various policy issues that affect access to medicines.

\[\text{IV. PERFORMANCE OF LOCAL CIVIL SOCIETY IN RESPECT TO AIDS TREATMENT AND ACCESS TO ARVs AND INTELLECTUAL PROPERTY}\]

\[\text{A. To what extent have the rules of intellectual property been noticed as a barrier for treatment access by the organised civil society?}\]

Fortunately, Indian civil society has always been cognisant of the dangers posed by intellectual property and access to medicines. Even prior to the TRIPS Agreement, several local civil society groups, including the National

\(^{56}\) Data exclusivity is a system under which the drug regulatory authority cannot rely on the safety and efficacy data of an originator company to grant marketing approvals to generic versions. TRIPS only requires data protection, not data exclusivity.

\(^{57}\) Patent linkages is a system whereby the drug regulatory authority is prevented from granting marketing approval to generic versions of patented medicines, either for as long as the patent subsists or without notifying the patent holder.

\(^{58}\) Bayer Corporation v. Union of India and Others, Writ Petition No. 7833 of 2008. For further details, please refer to www.lawyerscollective.or
Working Group on Patent Law, opposed the impending change in the patent regime. The People’s Health Movement has also been a part of this.

In 2001, Lawyers Collective HIV/AIDS Unit conducted a national consultation on the impact of the impending patent regime on access to medicines, especially ARVs. As a result, the Affordable Medicines and Treatment Campaign (AMTC) was launched. AMTC is an informal coalition of networks of PLHIV, NGOs and individuals. This coalition, along with other stakeholders, initiated advocacy efforts to ensure that the amendments to the patent law in 2005 included public health safeguards and excluded TRIPS-plus provisions. It was partly due to the joint efforts of civil society and public health groups, including Lawyers Collective HIV/AIDS Unit, that section 3(d) was amended to prevent evergreening and the provision relating to pre-grant opposition was retained in the Patents Act, 1970.

Once the patent law was amended, civil society groups had to engage in oppositions against patent applications.

At the same time, civil society groups including Lawyers Collective HIV/AIDS Unit were involved in making submissions to the government on various policy issues relating to intellectual property rights. Thus, for example, civil society groups, including Lawyers Collective HIV/AIDS Unit, have made submissions before the Technical Expert Group headed by Dr. Mashelkar which was examining the question of whether it would be TRIPS-compliant to limit patents for pharmaceuticals to new chemical entities. They have also presented before the Committee on Data Exclusivity arguing against the introduction of data exclusivity in India and the Department Related Parliamentary Standing Committee on Commerce on patent law. Civil society is also engaged in dialogue with the government on various issues such as drug pricing, data exclusivity and patent linkages.

**B. Incorporation by organised civil society of intellectual property in their agenda and strategies adopted.**

After the product patent regime came into force, civil society groups have been working to oppose patent applications prior to the grant of patents and also challenging the validity of patents that have been granted by the Indian patent office.
The first patent opposition filed by civil society in India related to *Gleevec*, a crucial anti-cancer drug used to treat chronic myeloid leukemia (CML). The litigation history dates back to before 2005 when the product patent regime came into force in India for drugs. In 1998, Novartis AG filed a patent application in India for the beta-crystalline form of imatinib mesylate (*Gleevec*). This was filed as a mailbox application that would be examined only after 1 January 2005. In April 2002, Novartis AG started marketing *Gleevec* in India. Several Indian pharmaceutical companies launched generic versions at between Rs. 8,000 to Rs. 12,000/- per month. In 2003, Novartis AG obtained an EMR in India. Based on this EMR, Novartis AG filed suits before the Madras and Bombay High Courts against Indian pharmaceutical companies that were marketing imatinib mesylate. Holding in Novartis AG’s favour, the Madras High Court restrained seven Indian pharmaceutical companies from marketing or distributing generic versions of imatinib mesylate. Interestingly, the Bombay High Court ruled against Novartis AG, which allowed certain Indian manufacturers to continue the production of generic versions of imatinib mesylate. The grant of an EMR thus led to a reduction in the number of sources for generic versions of imatinib mesylate. This meant that CML patients had to purchase the drug at Novartis AG’s of USD 250059 per month. Cancer Patients Aid Association (CPAA), a patient’s group, was impacted by this. Earlier, CPAA would earlier purchase generic versions of Gleevec at subsidised rates of USD 80 or less per month and offer it to their patients. In 2004, CPAA, with technical and legal assistance from Lawyers Collective HIV/AIDS Unit, challenged the grant of the EMR to Novartis AG before the Supreme Court of India. However, while the case was pending, the patent law was amended and the provisions relating to EMRs were deleted. This case therefore became infructuous.

Once the new patent regime came into force, Novartis AG’s patent application was examined by the Indian patent office. CPAA, with assistance from Lawyers Collective HIV/AIDS Unit, then filed a pre-grant opposition to oppose the grant of a patent to Novartis AG for the beta-crystalline form of imatinib mesylate. Upholding the challenge, the Indian Patent Office rejected Novartis AG’s patent application holding that it did not meet the patentability criteria under Indian law, including section 3(d).

59. 1 USD = approximately Indian rupees 50.
Novartis AG then filed cases before the Madras High Court challenging not just the Indian Patent Office’s decision, but also section 3(d) of the Patents Act, 1970. It asked the court to strike down section 3(d) of the Patents Act, 1970 as it violated the TRIPS Agreement and the Constitution of India. The Madras High Court rejected Novartis AG’s plea. Recognising that section 3(d) had been amended by Parliament in order to prevent evergreening and ensure access to medicines, the Madras High Court upheld the constitutional validity of section 3(d). Observing that only the WTO Dispute Settlement Board had jurisdiction to examine whether a domestic law was TRIPS-compliant, the court refrained from examining the issue of whether section 3(d) was compliant with the TRIPS Agreement.

Even as the litigation was pending in court, there was a mass mobilisation across the world to raise awareness about this case. PLHIV networks joined in the movement and coordinated with other health groups and international civil society to protest Novartis AG’s actions. Protests were held across various cities in India. The All India Drug Action Network launched a “Boycott Novartis” campaign. Civil society groups engaged in media and legislative advocacy to raise awareness about the case. Simultaneously, international organisations such as MSF and Oxfam worked with Indian civil society members on a “Drop the case” campaign. The Novartis case provided a unique opportunity to build the capacity of Indian civil society in matters relating to patents. It also brought networks of PLHIV together with other civil society stakeholders to rally together for the cause of access to medicines even though the drug in question was an anti-cancer drug, a drug that did not directly affect PLHIV.

In 2006, a PLHIV group filed the first civil society patent opposition against an ARV. The drug in question was Combivir, a combination of lamivudine and zidovudine. The filing was followed by coordinated advocacy actions against GlaxoSmithKline, the patent applicant, in Thailand and India. A massive civil society protest was held in Bangalore outside the office GlaxoSmithKline. Subsequently, in 2007, GlaxoSmithKline withdrew its patent applications for combivir in India and Thailand.

This has been followed by several oppositions to patent applications on ARVs and drugs to treat opportunistic infections and co-infections.
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<td>Zidovudine/ lamivudine</td>
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<td>Nevaripine Hemihydrate (syrup)</td>
<td>Boehringer Ingelheim</td>
<td>Positive Women’s Network and Indian Network for People Living with HIV/AIDS</td>
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<td>Gilead Sciences, Inc.</td>
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<td>Tenofovir or TD</td>
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<td>Atazanavir</td>
<td>Novartis AG</td>
<td>Karnataka Network for People Living with HIV/AIDS and Indian Network for People Living with HIV/AIDS</td>
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<td>Lopinavir</td>
<td>Abbott Laboratories</td>
<td>Delhi Network of Positive People, Network of Maharashtra by People living with HIV/AIDS and Indian Network for People Living with HIV/AIDS</td>
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<td>Pegasys</td>
<td>F. Hoffmann-La Roche AG</td>
<td>Sankalp Rehabilitation Trust</td>
<td>Post-grant opposition rejected</td>
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In a first victory for PLHIV networks, the Indian Patent Office rejected Boehringer Ingelheim’s patent application for nevirapine hemihydrate – the pediatric formulation of Nevirapine – on the basis of a pre-grant opposition filed by the Indian Network for People Living with HIV/AIDS and the Positive Women’s Network.

The struggle to increase access to medicines in India is not restricted to anti-HIV drugs. As discussed above, the landmark litigation relating to section 3(d) of the Patents Act, 1970 took place in the context of imatinib mesylate, an anti-cancer drug. Similarly, the issue of patent linkages is being litigated in the context of sorafenib tosylate, an anti-cancer drug. Here again, Cancer Patients Aid Association, with technical and legal assistance from Lawyers Collective HIV/AIDS Unit, has intervened and been impleaded as a party in the case. The intervention of patients’ groups is crucial as it provides an opportunity to place before the courts not just the legal pleas relating to the issue at hand but also the impact of the directions sought by multinational pharmaceutical companies on access to medicines.

Civil society has also been engaged in capacity building of PLHIV networks and other patients’ groups on various issues related to intellectual property. There has also been community mobilisation against unfair practices of pharmaceutical companies. For instance, in a show of solidarity, civil society and public health groups in India protested outside Abbott’s office in Mumbai against Abbott’s decision to withdraw seven drugs from the registration process in Thailand.

Another front that civil society stakeholders are coalescing together is that of free trade agreements. The Government of India is presently negotiating free trade agreements with the European Union and Japan, amongst others. The lack of transparency in the negotiation process and the texts of previous FTAs concluded by these countries raises the possibility that the FTAs being negotiated with India could introduce provisions that may impact access to drugs. Strategies adopted by civil society include writing letters to the government and engaging in public demonstrations.

Thus, civil society groups are attempting to incorporate issues relating to intellectual property in their agenda. However, much more needs to be done to build the capacity at the grass-root level and effectively mobilise the people against moves that would prejudicially affect access to medicines.
C. Principal results and gains, if any, reached until the present moment

There have been some positive results due to the involvement of civil society in the campaign to ensure access to medicines. There is now better awareness about intellectual property issues amongst certain patients’ groups. PLHIV networks have also aligned with broader health groups in mass actions described above.

From the point of view of litigation, the major success has been the decision of the Madras High Court upholding the constitutional validity of section 3(d) of the Patents Act, 1970. Another positive output has been the decision of the Indian Patent Office rejecting the patent application relating to nevirapine hemihydrate.

Engaging with the Government has proved to be effective thus far. Continuous efforts of civil society, public health groups and other stakeholders has meant that India has not yet given in to the demand for TRIPS-plus provisions on several issues. Till date, the Indian civil society has been successful in opposing the introduction of provisions relating to data exclusivity and patent linkages.

D. Main challenges for the future

The main, if long-term, challenge for any country with a socio-welfare commitment is the realisation of the right of every person to access treatment.

An immediate challenge is to ensure that treatment is available to all PLHIV who need them. This includes treatment for opportunistic infections such as second-line TB and other co-infections such as Hepatitis C as well as second-line and further ARV regimens. The demand for second-line treatment far outstrips the present access, and this needs to be addressed immediately.

In order to ensure that patents do not pose a barrier to access to medicines, it is important to track the patent status of key drugs. Where necessary, civil society groups would have to file pre-grant oppositions to oppose the grant
of patents. In cases where patents have been granted, mechanisms in the patent law to challenge granted patents, such as post-grant oppositions and revocation proceedings, have to be utilised.

India, thus far, has not utilised the provisions relating to compulsory licensing. In cases where patents are posing a barrier to access to medicines, it would be important for civil society to advocate the use of compulsory licensing.

Several policy issues of concern are presently being deliberated upon by the Government. These include data exclusivity, patent linkages, a bill to stimulate public research and development similar to the Bayh-Dole Act of the United States and free trade agreements being negotiated with Japan and the European Union. It is important that civil society and public health groups, and more importantly patients’ groups, engage with the government to ensure transparency and inclusion of all concerned persons in the decision-making processes and to ensure that public interest and the right to health is not compromised.

We face a daunting task of ensuring universal access to medicines. We know that we cannot achieve this, if we work in isolation. In each of our countries, as we struggle to increase access to medicines, we face various limitations, including those of resource and capacity constraints. It is therefore crucial that we engage in greater coordination with patients’ groups, civil society and public health groups in other countries to draw upon their experiences and to support their endeavours to ensure greater, and ultimately universal, access to medicines for all.
5. Thailand

ACCESS TO AIDS TREATMENT AND INTELLECTUAL PROPERTY RIGHTS’ PROTECTION IN THAILAND

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ABSTRACT

The purpose of this paper is to share our experiences about the ongoing campaign for access to medicines in Thailand through the contemporaneous battle against the AIDS epidemic. Section I of this paper offers a brief introduction to the AIDS epidemic in Thailand. Section II discusses the legal framework (e.g. IP laws) and some legal battles that have taken place in order to access affordable antiretroviral drugs (ARVs), illustrating the important role played by HIV/AIDS patients, their advocates, and other Thai civil society members in these battles. This Section also describes the circumstances under which compulsory licenses were issued by the Thai government starting in 2006 for ARVs and other essential medicines. Section III recounts the growth in the local production of ARVs in Thailand, and the resulting decrease in the cost for treating Thais living with HIV/AIDS. Section IV documents the monopolies held by transnational pharmaceutical companies in the Thai market due to the current patent system. Moreover, this Section notes the lobbying and campaigning efforts undertaken by these pharmaceutical companies to not only strengthen intellectual property rights, but also to thwart Thailand’s effort to access medicines with the legal exercise of TRIPS provisions. Section V briefly discusses the efforts by the USTR to incorporate TRIPS-plus provisions into the US-Thailand Free Trade Agreement as a way to create barriers and roadblocks to Thai efforts to access affordable, quality medicines. Finally, Section VI articulates the seven strategies Thai civil society members will advocate for in their continued fight to gain access to medicines to battle HIV/AIDS and other diseases.
I. BRIEF HISTORY OF THE HIV/AIDS EPIDEMIC IN THAILAND

The first reported cases of HIV infection in Thailand appeared among Thai male homosexuals in 1984. In 1987 and 1988, there was an explosive spread of HIV infection mainly among injecting drug users (IDU), which then spread to sex workers and their clients in 1989 and 1990. By 1990 and 1991, mother-to-child transmission cases were reported in many provinces in Thailand. Faced with rapidly rising numbers of new HIV infections, the Thai government initiated a nationwide, multi-sector prevention campaign that was highly successful in preventing risky behaviour among commercial sex workers and their clients, thus significantly reducing the rate of new infections among these groups. The success of Thailand’s strong national response to HIV/AIDS was due to the effective mobilisation of government, NGOs, and the private sector. Without this initial success, estimates from the Asian Epidemic Model (AEM) suggest that the current rate of HIV infection would be 14 times higher than it is today.5

By 1999, an estimated 1 million people were living with HIV in Thailand, of which 100,000 people were in need of treatment. However, only 5 percent of those in need were receiving treatment due to the high cost of imported antiretroviral drugs (ARVs). At that time, it was also estimated that there would be 50,000 newly infected people annually. In 2007, the Thai Working Group on HIV/AIDS estimated that the accumulated number of people living with HIV/AIDS in Thailand was 1,102,628, including 50,620 children, and a cumulative total of 558,895 AIDS related deaths6. Out of an estimated number of 546,578 people living with HIV/AIDS, approximately 13,9367 people were newly infected.

Some of the sharp 7-year decline in both new infections and AIDS related deaths can be partly attributed to ongoing prevention activities. However, the main reason for the dramatic reduction in AIDS related mortality and

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6 Thai Working Group, 2007
7 Ibid.
morbidity is almost entirely due to the greatly improved access to ARVs — particularly to the generic ARVs produced by the Government Pharmaceutical Organization (GPO) — coupled with an extremely strong civil society movement aimed at enhancing access to ARVs in Thailand. Despite these successes, HIV infection rates have not decreased in injecting drug users (IDU) and men who have sex with men (MSM). Furthermore, new infection rates among female teenagers and married women are on the rise. Therefore, Thai civil society advocates continue to battle the HIV/AIDS epidemic through fighting for greater access to medicines, particularly ARVs.

II. EVOLUTION OF THE THAI LEGAL FRAMEWORK FOR ACCESS TO HEALTHCARE THROUGH THE BATTLE TO RESPOND TO THE HIV/AIDS EPIDEMIC


Since 1985, the US government has put strong pressure on Thailand to increase patent protection. This pressure has primarily taken the form of threats of trade sanctions. Thai academics, lawyers, nongovernmental organisations (NGOs) and health advocates formed an alliance called the Drug Study Group to monitor this pressure in 1985. However, public awareness about these issues remained low at the time, and despite the efforts of the Drug Study Group, intellectual property protections increased.

In 1992, under US government pressure, Thailand passed the Thai Patent Act which created Thailand’s legal framework for intellectual property protection, including pharmaceutical products. This Act introduced pharmaceutical product patent protections to Thailand and extended patent life from 15 to 20 years. A “Safety Monitoring Programme” (SMP) was also introduced to provide market exclusivity for new drugs registered in Thailand that had been granted a patent elsewhere between 1986 and
1991. The SMP provision allows a period of two years’ market exclusivity (renewable on request of the pharmaceutical company) for the purposes of collecting post-marketing surveillance data. In 1999, the Thai Patent Act was further amended, disbanding the Pharmaceutical Patent Review Board which resulted in a lack of a price control mechanism for patented pharmaceuticals.

In 1994, Thailand, like all other members of the World Trade Organization (WTO) became a signatory of the Trade Related Aspects of Intellectual Property Rights (TRIPS). TRIPS is an international agreement, administered by the WTO, that creates a minimum legal standard for the protection of intellectual property. Under TRIPS, developing countries had until 2000 to enact intellectual property right protections into their laws. Under the 1992 Patent Law, Thailand was already TRIPS-compliant, even before this international agreement was signed! Thus, Thailand lost a total of 13 years in which it could have significantly developed its domestic drug industry, producing new generics with their own dosage form preparations and expanding their market to the ASEAN countries. This inability to develop a local pharmaceutical industry with R&D capacity continues to be a major barrier to fight the HIV/AIDS epidemic, as discussed further in Section III.

B. Mobilisation of Thai Civil Society and HIV/AIDS Patient Groups to Fight for ARVs and Universal Healthcare

The right to treatment for people living with HIV/AIDS (PLWHA) is at the forefront of the fight for access to medicine in Thailand. Although NGOs and academic communities have played an important role in influencing government policy related to HIV/AIDS, it is the strength of the PLWHA

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10. In actuality, developing countries had until 2005 to modify their laws to be TRIPS-compliant because a five-year waiver was granted to developing countries.
network that has been critical in ensuring access to treatment not only for PLWHA but also for other groups living with chronic diseases.

Starting in the mid-1990’s as PWLHA peer support groups, Thailand now has over 1,000 PWLHA groups and over 100,000 PWLHA members nationwide who have become a very strong social movement for access to treatment. The organisational structure of these groups, the Thai Network for People living with HIV/AIDS (TPN+), is shown in Figure 1. Despite the majority of members being farm labourers, factory workers, or unemployed with little in the way of formal education beyond primary school, they have learned how to protect their basic rights and how to challenge barriers to access to medicine caused by intellectual property protections.
Although there was little or no access to ARVs in Thailand prior to 2001, TNP+, along with AIDS Access Foundation (a local NGO), and MSF Belgium (an international NGO) started to focus on improving access to prevention and treatment of opportunistic diseases in 1999 before expanding the fight to improving access to ARVs in 2002.

1. Legal Challenges by Thai Civil Society to ddI, Combid, and others

On May 1, 2001, the AIDS Access Foundation and two HIV patients sued Bristol-Myers Squibb (BMS) and the Thai Department of Intellectual Property (DIP) over the Thai patent for ddI (Thai patent 7600) at the Thai Central Intellectual Property and International Trade Court. The plaintiffs alleged that BMS, the patentee, and DIP intentionally deleted the dose restriction of ddI written in the initial patent application after the publication of the application. Consequently, it broadened the scope of the patent to claims of all drug strengths, rather than the limited drug strength of up to 100 mg in the original patent application.11 On October 1, 2002, the court noted that the removal of the dose range extended the patent protection beyond the scope of the initial application; thus, ruling that BMS and DIP must correct the claims in the Thai patent 7600 by adding the range of patentable ddI of up to 100mg only.12

Finally, this court case not only corrected the ddI patent, but it also set a very important precedent. For the first time, Thai patients were allowed to sue as plaintiffs, something that had never been done before.13 The court reached this conclusion based on the concepts of human rights and the right to health and the Doha Declaration.

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11. This was a matter worth litigating because at the time, scientists at the GPO Research and Development Institute were trying to develop a generic version of ddI. The only way a generic version of ddI could be marketed without violating BMS’s patent was if the dosage level was over 100mg. See also The Road of Ordinary People Fighting against Big Issues: Lessons Learned from Revoking the ddI Patent, by Weeraboon Wisartsakul, July 2004.

12. This would allow for the development and marketing by GPO of a generic version of ddI whose dosage was over 100mg.

13. Later this grant of legal standing was extended beyond Thai patients to include Thai consumers.
On October 28, 2002, a second IP court case was brought against BMS by the Foundation for Consumers and AIDS patients. This litigation argued for the revocation of BMS’s ddI patent for three reasons. First, BMS applied for this product patent on July 7, 1991, before the new amended Patent Act was officially enacted on October 1, 1992. Second, there was no novelty in this invention — the information on this drug had been disclosed and it had already been on the market before it had been patented. Third, this invention was trivial and not an inventive step worthy of a patent extension. A final ruling was never issued on this case because BMS decided to settle the case by “dedicating” the ddI patent to the Thai people in December 2003.

Thai civil society advocates also raised a number of pre-grant objections to the publicized patent applications. For example, the Health and Development Foundation filed an objection to Glaxo Smith Kline (GSK) regarding its Combid® patent application of the combined formula of Lamivudine and Zidovudine, because both of these active ingredients are not patented in Thailand. Another example is when the GPO filed an objection to the patent applications of ddI pellet, and the use of nevirapine hemihydrate in liquid dosage form (Table 9).

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Claims</th>
<th>Filing date</th>
<th>Date filed objection</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>ddI pellet</td>
<td>Process and Product</td>
<td>17/05/99</td>
<td>14/02/2003</td>
<td>In process</td>
</tr>
<tr>
<td>AZT + 3TC</td>
<td>Formula AZT + 3TC + Glidants (Combid®)</td>
<td>27/10/97</td>
<td>11/05/2000</td>
<td>Abandoned</td>
</tr>
<tr>
<td>Nevirapine</td>
<td>Use nevirapine hemihydrate in liquid dosage form</td>
<td>18/08/98</td>
<td>27/02/2001</td>
<td>In process</td>
</tr>
</tbody>
</table>

The Combid® pre-grant opposition was challenged both in Thailand and India. The cooperation between Thailand’s and Indian’s civil society through the exchange of information and strategic movements resulted in
the abandonment of this patent application both in Thailand and India.\(^{(14)}\)

Finally, this Thai social movement, also challenged the validity of Glaxo Smith Klein’s “evergreening patent” for the drug combination of lamivudine+zidovudine. The strategies used included legal challenges to the patent, such as the filing of pre-granted opposition, and the mobilisation of large numbers of people in demonstrations both in Bangkok and Delhi. Finally, Glaxo Smith Klein withdrew its application both in Thailand and India in 2006.

### 2. Campaigning for Universal Healthcare

One of the most successful access to medicine advocacy campaigns spearheaded by Thai civil society resulted in the passage of the National Health Security Act of 2002. This Act provides universal healthcare coverage (UC) to nearly 75% of the Thai population or 47 million people who are not covered either by the Civil Servant Medical Benefit Scheme (CSMBS) or Social Security Scheme (SSS). ARVs treatment (HAART) has been included in the UC pharmacy coverage scheme since October 2006, again, only after significant pressure from Thai civil society. Moreover, the 2007 Thai Constitution\(^{(15)}\) enshrines this support for UC by explicitly stating that “A person shall enjoy an equal right to receive standard public health service, and the indigent shall have the right to receive free medical treatment from State's infirmary. The public health service by the State shall be provided thoroughly and efficiently. The State shall promptly prevent and eradicate harmful contagious diseases for the public without charge.”

### 3. Campaigning for the implementation of CLs

Even though the US succeeded in forcing the WTO to accept the TRIPS Agreement, it was also forced to accept a balance between intellectual property monopolies and the need to maintain a ‘breathing space’ for solving problems caused by the patent system. This took the form of TRIPS


\(^{(15)}\) Section 51 of Part 9 Right to Public Health Service and Welfare
“flexibilities” articulated in the 2002 Doha Declaration on the TRIPS Agreement and Public Health. Compulsory licensing (CL) by a government for public, non-commercial use is one of these special conditions with which countries can override drug patents in order to save lives.\textsuperscript{16}

The prices of ARVs are out of reach for many in the developing world, leading to a high percentage of Thai PLWHA not being able to access treatment. The daily ARVs cost is about 2 - 10 times the daily wage of a Thai worker. Most Thai PLWHA who need ARVs cannot afford the medication. Thus, during 22 – 23 December 1999, about 100 PLWHA and NGOs camped out in front of Ministry of Public Health building demanding that the government authorities grant a CL for ddI tablets to produce a cheaper generic version of the drug. The Thai government refused to issue a CL out of fear of U.S. trade sanctions, so it sent a letter to the U.S. President Bill Clinton asking if the US would impose trade sanctions if it issued a CL. The White House responded by sending a letter that confirmed the country's right to grant a CL under TRIPS Agreement. Nevertheless, even after receiving this response, the Thai Minister of Public Health still refused to issue a CL for ddI.

Finally, on November 29, 2006, the Minister of Public Health (Mongkol Na Songkla) announced the first CL granted by the Thai government for ARV drug Efavirenz. This CL was followed by the granting of CLs for six other drugs as shown in Table 10.

\textbf{Table 10} The chronology of CL issuances in Thailand:

<table>
<thead>
<tr>
<th>ARVs</th>
<th>29 Nov 2006</th>
<th>CL on Efavirenz.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>24 Jan 2007</td>
<td>CL on Ritonavir+Lopinavir</td>
</tr>
<tr>
<td>Heart Disease Medicine</td>
<td>25 Jan 2007</td>
<td>CL on Clopidogrel</td>
</tr>
<tr>
<td>Cancer Drugs</td>
<td>4 Jan 2008</td>
<td>CL on Docetaxel</td>
</tr>
<tr>
<td>CL on Erlotinib</td>
<td>25 Jan 2008</td>
<td>CL on Letrozole</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CL on Imatinib</td>
</tr>
</tbody>
</table>

\textsuperscript{16} The ability to issue CLs is in the Thai Patent Act, but it was never utilized until 2006.
Thailand’s issuance of the indicated compulsory licenses was not a coincidence. Rather, it was the result of years of endless agitation and advocacy by Thai civil society to get these CLs issued.

It was also consequence of a phenomenal collaboration of global significance, with the participation of several national and international sectors — even over 20 US Congressmen came out to support Thai CLs.

Looking back at the past campaign for ddI access, the movements’ actors consisted of:

- Liaison groups coordinating with networks dealing with the issue: AIDS ACCESS Foundation, the Foundation for Consumers, and the Health and Development Foundation acted as a link to transfer and disseminate information to networks of AIDS NGOs and PLWHA;

- Academic and information groups: the Drug Study Group, the Social Pharmacy Action Research Unit, the Health and Development Foundation, Médecins Sans Frontières-Belgium (Thailand) and the Government Pharmaceutical Organization’s Research and Development Institute, whose academics helped analyze the problems of ddI patenting in Thailand and abroad; and

- Lawyers from the Law Society of Thailand.

As documented in **Tripartite Fight for Patients’ Rights** by *Prachachat Thurakit*\(^\text{17}\), the CL campaign was another significant development step in the fight for access to medicines, consisting of various stakeholders and actors, including:

**The State:** through the Ministry of Public Health, National Health Security Office, Government Pharmaceutical Organization, Food and Drug Administration, Department of Intellectual Property, and Council of State;

**Public stakeholders:** The TNP+ had the longest experiences in insisting and demanding that commercial interests take into account patients’ benefits and physical health promotion, which underpinned national and economic development. This fight for CL rights is leading

\(^{17}\) Thai newspaper
to the emergence of new networks consisting of patients with chronic kidney disease, heart disease and cancer.

**Civil society:** comprising the medical, pharmaceutical and law academics that have ceaselessly monitored this issue since 1985 such as the Drug Study Group, Social Pharmacy Action Research Unit, Chulalongkorn University’s Consumers’ Health Protection Programme, Rural Pharmacists Foundation, Rural Doctors Foundation, Law Society of Thailand, NGOs working on AIDS and consumers’ rights, AIDS ACCESS Foundation, Centre for AIDS Rights, Thai NGO Coalition on AIDS, Foundation for Consumers and Health and Development Foundation, as well as the FTA Watch group monitoring free trade negotiations.

These three groups, furthermore, coordinated with their foreign counterparts. For example, relationships were made between the Thai and Brazilian Ministries of Public Health and the Thai Government Pharmaceutical Organization and the Indian generic drug industry. The medical, pharmaceutical and law academics had networks in many countries, as did the international NGOs, such as Médecins Sans Frontières-Belgium (Thailand), Oxfam, Focus on the Global South, the US-based Knowledge Ecology International, Third World Network, Health Gap, and Essential Action. Meanwhile, the work of local networks of people’s organizations and NGOs was connected with the TNP+, foreign NGOs and movements of university students.

Another significant component in the CL campaign was the effort to further educate the Thai public about this important issue by the mass media. Some in the mass media did not appear to fully support the issuance of the first CLs in late 2006, because of the complexity of the issue and the mass media’s discontent with the government’s ban on alcoholic drink advertisements. But after witnessing the intense pressure put on the Thai government by the multinational drug industry and the US administration, the mass media took an active role in promoting public education of the issue by presenting news reports, articles, special reports, regular columns, and editorials through the printed media, radio, television and online media. This concerted campaign brought about an unprecedented united front among the wider Thai society in the fight for
drug access. Essentially, CLs have become a watchword to the public, as the public’s education about them has grown over the past few years thanks to the partnership developed between Thai civil society and media. Prachachat Thurakit concluded its reporting of the Tripartite Fight for Patients’ Rights (with tremendous support from the local and international mass media) with the following statement.

“The campaign tried to tell Thai society and the global community that in the world of trade, whose aim is to make monetary gains, there is also a world that has to take into account the value of life and healthcare, whereby medicines are a fundamental factor relevant to everybody’s well-being.”

“Thus, the movement of these people will continue in spite of the vigorous attacks from the multinational pharmaceutical industry and those who will lose their benefits because of this campaign.”

III. PRODUCTION OF ANTIRETROVIRALS (ARVs) IN THAILAND

A. Profile of Local Production of ARVs

Although Thailand has a significant generic pharmaceutical industry, only the Government Pharmaceutical Organization (GPO) has carried out R&D and production of ARV on a large scale, beginning in 1992 when the Research and Development Institute of the GPO produced its first generic ARV drug (zidovudine capsule 100 mg). In 2002, the Research and Development Institute developed and manufactured GPO-VIR S®. GPO-VIR S®, a fixed-dose combination tablet of stavudine, lamivudine and nevirapine, on an industrial scale. This fixed dose combination tablet, which is at the heart of the national treatment programme, has good efficacy and costs 1,200 baht per month compared with 20,000 baht per month for the equivalent brand name medicines.

To date, the GPO manufactures 16 adult ARV medicines and 8 paediatric ARV medicines, including second line drugs. A list of these ARVs is shown in Table 1.
<table>
<thead>
<tr>
<th>Item</th>
<th>Packing unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Didanosine chewable buffered tablets 25 mg (DIVIR®)</td>
<td>60’s</td>
</tr>
<tr>
<td>2. Didanosine chewable buffered tablets 125 mg (DIVIR®)</td>
<td>60’s</td>
</tr>
<tr>
<td>3. Didanosine chewable buffered tablets 200 mg (DIVIR®)</td>
<td>60’s</td>
</tr>
<tr>
<td>4. Indinavir capsules 200 mg (INAVIR®)</td>
<td>360’s</td>
</tr>
<tr>
<td>5. Indinavir capsules 400 mg (INAVIR®)</td>
<td>180’s</td>
</tr>
<tr>
<td>6. Lamivudine tablets 150 mg (LAMIVIR®)</td>
<td>60’s</td>
</tr>
<tr>
<td>7. Lamivudine tablets 300 mg (LAMIVIR®)</td>
<td>30’s</td>
</tr>
<tr>
<td>8. Lamivudine syrup 10 mg/ml (LAMIVIR®)</td>
<td>60 ml</td>
</tr>
<tr>
<td>9. Lamivudine 150 mg + Stavudine 30 mg tablets (LASTAVIR®)</td>
<td>60’s</td>
</tr>
<tr>
<td>10. Nelfinavir mesylate tablets 250 mg (NAFAVIR®)</td>
<td>270’s</td>
</tr>
<tr>
<td>11. Nevirapine for oral suspension 10 mg/ml (NERAVIR®)</td>
<td>60 ml</td>
</tr>
<tr>
<td>12. Nevirapine tablets 200 mg (NERAVIR®)</td>
<td>60’s</td>
</tr>
<tr>
<td>13. Nevirapine 200 mg + Lamivudine 150 mg + Stavudine 30 mg tablets (GPO-VIR S30®)</td>
<td>60’s</td>
</tr>
<tr>
<td>14. Nevirapine 200 mg + Lamivudine 150 mg + Stavudine 40 mg tablets (GPO-VIR S40®)</td>
<td>60’s</td>
</tr>
<tr>
<td>15. Nevirapine 200 mg + Lamivudine 150 mg + Zidovudine 250 mg tablets (GPO-VIR Z250®)</td>
<td>60’s</td>
</tr>
<tr>
<td>16. Ritonavir oral solution 80 mg/ml (RINAVIR®)</td>
<td>60 ml</td>
</tr>
<tr>
<td>17. Stavudine capsules 15 mg (STAVIR®)</td>
<td>60’s</td>
</tr>
<tr>
<td>18. Stavudine capsules 20 mg (STAVIR®)</td>
<td>60’s</td>
</tr>
<tr>
<td>19. Stavudine capsules 30 mg (STAVIR®)</td>
<td>60’s</td>
</tr>
<tr>
<td>20. Stavudine for oral solution 5 mg/ml (STAVIR®)</td>
<td>60 ml</td>
</tr>
<tr>
<td>21. Zidovudine 300 mg + Lamivudine 150 mg tablets (ZILARVIR®)</td>
<td></td>
</tr>
<tr>
<td>22. Zidovudine capsules 100 mg (ANTIVIR®)</td>
<td>100’s</td>
</tr>
<tr>
<td>23. Zidovudine capsules 300 mg (ANTIVIR®)</td>
<td>100’s</td>
</tr>
<tr>
<td>24. Zidovudine syrup 10 mg/ml (ANTIVIR®)</td>
<td>60 ml</td>
</tr>
</tbody>
</table>
B. Influence of Local Production of ARV in the Level of Access to Medicines

Prior to local generic production of ARV medicines, only 5% of the estimated 100,000 PLWHA needing treatment were able to access the required medicines due to the high cost of the imported brand-name drugs. A month’s treatment using these imported brand-name drugs cost US$136, while the average salary of an office worker was US$120 per month.

In 2002, the launch of a locally produced generic fixed drug combination of GPO-VIR S® reduced the cost of treatment more than 15 times from 650 to 40 Baht daily. This cost reduction enabled the Thai government, under the National Access to Antiretroviral Program for PHA (NAPHA), to provide an estimated 800 million Baht to purchase ARV medicine from the GPO and distribute to patients free of charge (covering approximately 50,000 cases). At the same time, Global Fund money has provided approximately 200 million Baht to purchase ARV medicines for 10,000 cases. In 2006, the Thai government launched a universal access scheme for all HIV/AIDS patients that assured constant access to all antiretroviral medicines, while the Social Security Office (SSO) gives free antiretroviral treatment to more than 10,000 employees. Again, none of this would have been possible without the use of low-cost generics and civil society advocacy.

IV. IMPACT OF TRANSNATIONAL PHARMACEUTICAL COMPANIES ON ACCESS TO ARV TREATMENT IN THAILAND

A. Transnational Pharmaceutical Companies Monopolize the Drug Market via Patent System

Transnational pharmaceutical companies (TNCs) are a highly profitable business—their 21.2-58.6% profit margin is much higher than most other businesses. The average research and development cost is only 13.9% of sales as illustrated in Table 2.
Table 2  **Structural cost of Transnational Pharmaceutical Companies (TNCs) in 2005**

<table>
<thead>
<tr>
<th>TNCs</th>
<th>R&amp;D (%)</th>
<th>Marketing (%)</th>
<th>Profit (%)</th>
<th>Total Sale (m$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer, Inc</td>
<td>14.5</td>
<td>33.1</td>
<td>15.8</td>
<td>$51,298</td>
</tr>
<tr>
<td>Johnson and Johnson</td>
<td>12.5</td>
<td>33.4</td>
<td>20.6</td>
<td>$50,514</td>
</tr>
<tr>
<td>Abbott</td>
<td>8.2</td>
<td>24.6</td>
<td>15.1</td>
<td>$22,338</td>
</tr>
<tr>
<td>Merck &amp; Co.</td>
<td>17.5</td>
<td>32.5</td>
<td>21.0</td>
<td>$22,012</td>
</tr>
<tr>
<td>Bristol-Myers Squibb</td>
<td>12.9</td>
<td>33.2</td>
<td>12.3</td>
<td>$19,380</td>
</tr>
<tr>
<td>Wyeth</td>
<td>14.7</td>
<td>32.6</td>
<td>19.5</td>
<td>$18,756</td>
</tr>
<tr>
<td>Eli Lilly</td>
<td>20.7</td>
<td>30.7</td>
<td>13.5</td>
<td>$14,645</td>
</tr>
<tr>
<td><strong>Average</strong></td>
<td><strong>13.9</strong></td>
<td><strong>32.0</strong></td>
<td><strong>17.4</strong></td>
<td><strong>$198,943</strong></td>
</tr>
<tr>
<td><strong>Total (m$)</strong></td>
<td><strong>$27,715</strong></td>
<td><strong>$63,568</strong></td>
<td><strong>$34,523</strong></td>
<td><strong>$198,943</strong></td>
</tr>
</tbody>
</table>

Source: stock market report 2005

The TNCs based in Thailand only import the finished products, neither investing in the manufacturing nor the research and development of the products domestically. Since Thailand, under US trade pressure, amended the Patent Act in 1992 to include an extension of the patent life from 15 to 20 years coupled with the introduction of pharmaceutical product patent, the window of opportunity for local manufacturing of new generic drugs was closed nearly 13 years. The data in Table 3 illustrates the decreasing number of local pharmaceutical plants compared to the increasing number of imports. Table 3 also details the increase in the high percent growth of imported drugs when compared to locally produced drugs over time. The market share of local drug manufacturing is decreasing over time as shown in Table 4.

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Table 3 The number of pharmaceutical plants and importers, and the value of locally produced and imported drugs, varied by time from 1996–2006.

<table>
<thead>
<tr>
<th>Year</th>
<th>No. Of Industries</th>
<th>No. Of Importers</th>
<th>Locally produced drugs</th>
<th>Imported drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Million Baht</td>
<td>% Growth</td>
</tr>
<tr>
<td>1996</td>
<td>175</td>
<td>480</td>
<td>18,174.40</td>
<td>N/A</td>
</tr>
<tr>
<td>1997</td>
<td>175</td>
<td>449</td>
<td>19,591.60</td>
<td>7.80</td>
</tr>
<tr>
<td>1998</td>
<td>176</td>
<td>485</td>
<td>16,726.10</td>
<td>-14.63</td>
</tr>
<tr>
<td>1999</td>
<td>178</td>
<td>590</td>
<td>19,033.90</td>
<td>13.80</td>
</tr>
<tr>
<td>2000</td>
<td>174</td>
<td>510</td>
<td>20,995.90</td>
<td>10.31</td>
</tr>
<tr>
<td>2001</td>
<td>175</td>
<td>521</td>
<td>23,087.90</td>
<td>9.96</td>
</tr>
<tr>
<td>2002</td>
<td>174</td>
<td>523</td>
<td>24,686.80</td>
<td>6.93</td>
</tr>
<tr>
<td>2003</td>
<td>174</td>
<td>527</td>
<td>27,563.30</td>
<td>11.65</td>
</tr>
<tr>
<td>2004</td>
<td>171</td>
<td>579</td>
<td>32,639.50</td>
<td>18.42</td>
</tr>
<tr>
<td>2005</td>
<td>166</td>
<td>600</td>
<td>31,130.60</td>
<td>-4.62</td>
</tr>
<tr>
<td>2006</td>
<td>141</td>
<td>600</td>
<td>32,745.10</td>
<td>5.19</td>
</tr>
</tbody>
</table>

Source: Food and Drug Administration, Thailand, 2006.

Table 4 The percentage of market share of locally produced and imported drugs, varied by time from 1996–2006.

<table>
<thead>
<tr>
<th>Year</th>
<th>Locally produced drugs (mBaht)</th>
<th>Imported drugs (mBaht)</th>
<th>Total market value (mBaht)</th>
<th>Locally produced drugs (% market share)</th>
<th>Imported drugs (% market share)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996</td>
<td>18,174.40</td>
<td>10,435.30</td>
<td>28,609.70</td>
<td>63.53</td>
<td>36.47</td>
</tr>
<tr>
<td>1997</td>
<td>19,591.60</td>
<td>13,375.60</td>
<td>32,967.20</td>
<td>59.43</td>
<td>40.57</td>
</tr>
<tr>
<td>1998</td>
<td>16,726.10</td>
<td>9,739.10</td>
<td>26,465.20</td>
<td>63.20</td>
<td>36.80</td>
</tr>
<tr>
<td>1999</td>
<td>19,033.90</td>
<td>14,232.30</td>
<td>33,266.20</td>
<td>57.22</td>
<td>42.78</td>
</tr>
<tr>
<td>2000</td>
<td>20,995.90</td>
<td>16,700.30</td>
<td>37,696.20</td>
<td>55.70</td>
<td>44.30</td>
</tr>
<tr>
<td>2001</td>
<td>23,087.90</td>
<td>19,967.60</td>
<td>43,055.50</td>
<td>53.62</td>
<td>46.38</td>
</tr>
<tr>
<td>2002</td>
<td>24,686.80</td>
<td>22,769.80</td>
<td>47,456.60</td>
<td>52.02</td>
<td>47.98</td>
</tr>
<tr>
<td>2003</td>
<td>27,563.30</td>
<td>29,588.10</td>
<td>57,151.40</td>
<td>48.23</td>
<td>51.77</td>
</tr>
<tr>
<td>2004</td>
<td>32,639.50</td>
<td>33,647.10</td>
<td>66,286.60</td>
<td>49.24</td>
<td>50.76</td>
</tr>
<tr>
<td>2005</td>
<td>31,130.60</td>
<td>41,630.90</td>
<td>72,761.50</td>
<td>42.78</td>
<td>57.22</td>
</tr>
<tr>
<td>2006</td>
<td>32,745.10</td>
<td>48,589.10</td>
<td>81,334.20</td>
<td>40.26</td>
<td>59.74</td>
</tr>
</tbody>
</table>

Source: Food and Drug Administration, Thailand, 2006.
Most of the local pharmaceutical producers in Thailand are new generic drug producers—they incorporate research and development into active pharmaceutical ingredients or new drugs. For domestic generic drug producers, R&D is aimed at using less costly production processes to produce bioequivalent generic products; whereas for the original producers, R&D aims to find new chemical entity (NCE) or new products, new use, and new drug delivery systems. The estimated global health R&D in the report of CIPIH\textsuperscript{19} indicated that high income countries spent 96\% of global R&D budget of which about half come from the private, for-profit sector (Table 5). Thailand spent only 0.22 percent of GDP on R&D\textsuperscript{20}, only one–tenth of the R&D spent by the newly industrialized countries.

<table>
<thead>
<tr>
<th>Table 5 Estimated Global Health R&amp;D Funding, 2001 (In Current Us$ Billion)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
</tr>
<tr>
<td>Total public sector</td>
</tr>
<tr>
<td>Total private sector</td>
</tr>
<tr>
<td>Total private for-profit</td>
</tr>
<tr>
<td>Total private not-for-profit</td>
</tr>
<tr>
<td><strong>High income countries</strong></td>
</tr>
<tr>
<td>Public sector</td>
</tr>
<tr>
<td>Private for-profit</td>
</tr>
<tr>
<td>Private not-for-profit</td>
</tr>
<tr>
<td><strong>Total high income countries</strong></td>
</tr>
<tr>
<td><strong>Lower middle income countries</strong></td>
</tr>
<tr>
<td>Public sector</td>
</tr>
<tr>
<td>Private for-profit sector</td>
</tr>
<tr>
<td><strong>Total lower middle income countries</strong></td>
</tr>
</tbody>
</table>


\textsuperscript{20} IMD World Competitiveness Yearbook 2004.
The lack of new drug R&D in the Thai pharmaceutical field is also reflected in the number of patent applications filed in the Thai Department of Intellectual Property. The patent applications with the International Patent Code (IPC) of A61K — the international patent code on pharmaceutical products — filed during 1992–2002, were 2,444 applications. Only 1.31 percent of these patent applications were Thai applicants.

The financial data analysis on the Thai pharmaceutical industries was compared to the global pharmaceutical industries — by return on assets (ROA), the profit margin and total assets turnover ratio as shown in Table 3. The range data from Pfizer, Merck, GlaxoSmithKline, AstraZeneca, Sanofi-Aventis and Takeda on ROA, profit margin, and total assets turnover ratio are 10.47–19.30 percent, 8.47–25.13 percent, and 0.52–0.96 respectively. Whereas the average value for Thai pharmaceutical companies are 5.03 percent, 3.2 percent and 1.1 percent respectively. These data illustrate that the Thai pharmaceutical industries’ profits are quite low compared to the TNCs (Table 6).

<table>
<thead>
<tr>
<th>Table 6 Profitability analysis of the Thai pharmaceutical industry and TNCs pharmaceutical industries average for 3 years (2002–2004).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thai drug industry(^{22}) (average)</td>
</tr>
<tr>
<td>Return on Total Assets (%)</td>
</tr>
<tr>
<td>Profit margin</td>
</tr>
<tr>
<td>Total Asset Turnover Ratio</td>
</tr>
</tbody>
</table>

Of the 141 local pharmaceutical industries in Thailand, 75.2% are classified as a small business, 20.6% are classified as a medium business, and only 4.2% are classified as a big business\(^ {24}\). Since most of Thai local


\(^{24}\) Jiraporn Limpananont, et al, "Impact of Thai–US FTA on the Local Pharmaceutical Industries in Thailand"
industries are small businesses with low profit margins, it is impossible for them to invest in R&D for new drug development. The R&D challenges for these companies are drug formulation and bioequivalence study of drugs recently off-patent. According to the Thai Patent Act and the Bolar exception in TRIPS, research using currently patented subject matter is permitted when developing generic versions of drugs about to go off-patent. However, the introduction of new generics in the Thai market is very slow — more than 5 years after the termination of patent. The crucial obstacle to reducing this delay is the inefficiency and inaccessibility of Thai patent database in searching for patent status of new drugs. Without improving access to this information, generic companies will continue to produce drugs that they are unable to market after receiving notification of patent infringement from the patent owner.

Table 7 The daily cost of ARV regimens comparing original and generic ARV.

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>s30</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>1200</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d4T+3TC+NVP</td>
<td>465.22</td>
<td>156</td>
<td>435.86</td>
<td>57</td>
<td>437.64</td>
<td>57</td>
</tr>
<tr>
<td>GPO-Z (AZT+3TC+NVP)</td>
<td>48</td>
<td>1440</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AZT+3TC+NVP</td>
<td>470.14</td>
<td>176</td>
<td>440.78</td>
<td>78</td>
<td>442.56</td>
<td>74</td>
</tr>
<tr>
<td>d4T+3TC+EFV</td>
<td>489.04</td>
<td>212.68</td>
<td>489.04</td>
<td>126.68</td>
<td>492.94</td>
<td>137.58</td>
</tr>
<tr>
<td>AZT+3TC+EFV</td>
<td>493.96</td>
<td>232.68</td>
<td>493.96</td>
<td>154.68</td>
<td>497.86</td>
<td>154.58</td>
</tr>
<tr>
<td>AZT+3TC+RTV+IDV</td>
<td>524.8</td>
<td>263.52</td>
<td>524.8</td>
<td>185.52</td>
<td>535.2</td>
<td>191.92</td>
</tr>
<tr>
<td>d4T+3TC+RTV+IDV</td>
<td>519.88</td>
<td>243.52</td>
<td>519.88</td>
<td>164.52</td>
<td>530.28</td>
<td>174.92</td>
</tr>
<tr>
<td>Combid+NVP</td>
<td>361.06</td>
<td>100</td>
<td>331.7</td>
<td>80</td>
<td>333.48</td>
<td>80</td>
</tr>
<tr>
<td>d4T+ddI+NVP</td>
<td>374.81</td>
<td>128</td>
<td>345.45</td>
<td>85</td>
<td>347.23</td>
<td>85</td>
</tr>
<tr>
<td>Combid+IDV</td>
<td>328.6</td>
<td>100.4</td>
<td>328.6</td>
<td>100.4</td>
<td>328.6</td>
<td>100.4</td>
</tr>
<tr>
<td>AZT+ddI+RTV+IDV</td>
<td>434.39</td>
<td>235.52</td>
<td>434.39</td>
<td>213.52</td>
<td>444.79</td>
<td>219.92</td>
</tr>
<tr>
<td>AZT+3TC+RTV+SQV</td>
<td>780.8</td>
<td>519.52</td>
<td>780.8</td>
<td>441.52</td>
<td>791.2</td>
<td>447.92</td>
</tr>
<tr>
<td>IDV+Kaletra</td>
<td>655.68</td>
<td>655.68</td>
<td>19670.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SQV+Kaletra</td>
<td>966.22</td>
<td>966.22</td>
<td>886.48</td>
<td>886.48</td>
<td>26594.4</td>
<td></td>
</tr>
</tbody>
</table>
B. Transnational Pharmaceutical Companies Strengthen Themselves as Pharmaceutical Research and Manufacturers Association (PReMA)

In 1970, 35 Thai pharmaceutical companies banded together to form the original Pharmaceutical Producers Association (PPA) before PReMA inaugurated its new name and identity on 29 September 2004. The Association was founded as a non-profit, non-government organization to represent Thailand’s pharmaceutical manufacturers and associated companies. The objective was to create a means of cooperating with the government in the implementation of laws and dealing with other issues that arise in the pharmaceutical industry. Today, PReMA has 43 members, which employ nearly 12,000 staff\textsuperscript{25}.

C. The Strategies of TNCs and PReMA Affecting Access to Medicines

1. Lobby the government officers and politicians to strengthen the higher standard of IPRs through Patent Act amendment and FTA

Since 1985, the PhRMA (Pharmaceutical Research and Manufacturers of America) claims to have lost US$ 165 million export revenue from Thailand due to weak patent protection on pharmaceuticals. This claim led the USTR to put trade pressure on Thailand to introduce a high level of patent protection. In response to this pressure, Thailand amended the Patent Act in 1992.

In July 2002, the Thai Trade Secrets Act was enacted to comply with article 39.3 of the TRIPS agreement dealing with data protection. Under this law, the authorized market approval agencies require, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products that use new chemical entities, the submission of undisclosed

\textsuperscript{25} http://www.prema.or.th (accessed on July 2, 2008)
test or other data. The data submitted to agencies for market approval is protected against unfair disclosures.

The United States trade agenda involves working to open markets globally (WTO negotiations), regionally (Enterprise for ASEAN Initiative, EAI), and bilaterally (Free Trade Agreement, FTA). The fact sheet released from the White House in October 2002\(^26\) stated the roadmap to FTAs between the U.S. and individual ASEAN countries would be based on the high standards set in the U.S.–Singapore FTA. The USTR notified Congress of its intent to initiate FTA negotiations with Thailand on February 12, 2004\(^27\). The U.S.-Thailand FTA started the negotiation in Hawaii on June, 28, 2004. The negotiation text, however, was kept secret even after Thai civil society requested it. The coalition of Thai NGOs working on this area formed an “FTA watch”. This coalition published the study entitled “Sovereignty not for Sale”\(^28\), detailing the impact of U.S.-Thailand FTA in several areas, including agriculture, investment, and intellectual property rights.

The high level of Intellectual Property Rights (IPR) Protection or TRIPS-plus provisions in the text of the sixth round of negotiations of the Thai-US FTA was disclosed on the website of bilaterals.org\(^29\) as follows:

- **Data Exclusivity (DE) Protection**: test data and trade secrets submitted to a government for the purposes of product approval will be protected for 5 years for pharmaceuticals and 10 years for agricultural chemicals. Consequently, no new generic drugs can registered in this period, and government use or CL can not be applied during DE.

- **Patent term can be extended to compensate for up-front administrative or regulatory delays in granting the original patent, consistent with U.S. practice.**

- **Linkage between drug registration and patent status**: ensures that government marketing-approval agencies will not grant approval to patent-violating products. This turns the FDA officials into the patent police.

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\(^{27}\) http://www.ustr.gov


\(^{29}\) http://www.bilaterals.org/article.php3?id_article=3677 (accessed on July 14, 2008)
Grounds for revoking a patent are limited to the same grounds required to originally refuse a patent; thus protecting against arbitrary revocation.

Provides protection for patents covering biotech plants and animals.

Protects against imports of pharmaceutical products without patent-holder’s consent by allowing lawsuits when contracts are breached.

Criminal penalties for companies that make pirated copies from legitimate products.

2. Lobbying Efforts to Argue Against the Use of CLs

The president of PReMA interviewed in several newspapers, radio programs and television programs argued against the use of CLs in Thailand. They tried to convince the public that 1) the military government issued the CLs in order to transfer the savings this created in the health budget to the military budget; 2) the CLs did not comply with TRIPS and non-transparency principles; 3) the CL in Thailand is illegitimate because the government did not inform the patent holders that it was going to issue a CL and did not ask for their consent; 4) the consequences of the CL will destroy the foreign investment in Thailand; and 5) the import products from CL are low quality generics. The USA for Innovation30 and the TNCs’ academics discredited Thailand after it issues its CLs by distributing distorted and misleading information through the media. Only through the tireless work of Thai civil society advocates, were members of the media and the Thai public able to receive unbiased information about the CLs (See Section II.B.3). Finally, PreMA’s staff tried to lobby high rank officials in the Ministry of Public Health (MOPH) to convince them to cancel the use of CLs and introduce the public-private partnership strategy to improve Thailand’s healthcare system.

3. Retaliatory withdrawal of the new drug registration dossiers by Abbott

On January 24, 2007, the Thai government announced a CL for Ritonavir+Lopinavir. Abbott, the patent owner of this drug, retaliated

against this CL issuance on March 2007 by secretly withdrawing the 7 new drug registration dossiers it had pending with the Thai FDA. As a result, the Foundation for Consumers sued Abbott under the Thai Competition Law, arguing that its retaliation constituted illegal anti-competitive practice; thus, it was illegal for Abbott to withdraw its seven pending new drug dossiers from the Thai FDA.31

<table>
<thead>
<tr>
<th>Trade name</th>
<th>Generic name</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Aluvia</td>
<td>Lopinavir-Ritonavir</td>
<td>HIV infection</td>
</tr>
<tr>
<td>2. Humira</td>
<td>Adalimumab 40 mg/0.8ml</td>
<td>Osteoarthritis, rheumatoid arthritis</td>
</tr>
<tr>
<td>3. Clivarine</td>
<td>Reviparin sodium</td>
<td>Thrombosis, thrombo-embolism, anti-platelet aggregation</td>
</tr>
<tr>
<td>4. Tarka</td>
<td>Trandolapril-Verapamil</td>
<td>Idiopathic hypertension</td>
</tr>
<tr>
<td>5. Zemplar</td>
<td>Paricalcitol</td>
<td>Hyperparathyroidism in chronic renal disorders</td>
</tr>
<tr>
<td>6. Brufen</td>
<td>Ibuprofen (suspension)</td>
<td>Fever and pain</td>
</tr>
<tr>
<td>7. Abbotic</td>
<td>Clarithromycin (granule for oral suspension)</td>
<td>Upper and lower respiratory tract infections; acute otitis media; cellulitis; folliculitis</td>
</tr>
</tbody>
</table>

Source: Food and Drug Administration, Thailand

4. Request to the USTR to place Thailand on the Priority Foreign Country (PFC) under US trade law

In 2007, USTR placed Thailand on the Priority Watch List (PWL) for the following stated reasons32:

“While the United States acknowledges a country’s ability to issue such licenses in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern. These actions have compounded previously expressed concerns such as delay in the granting of

31. A decision on this case is still pending.

While it is clear that Thailand is TRIPS compliant, PhRMA in 2008 still threatened Thailand by sending the Special 301 submission 2008 to the USTR, requesting that the USTR change Thailand’s trade status from PWL to Priority Foreign Countries (PFC). PhRMA requested this change to retaliate against Thailand’s issuance of CLs:

“However, in view of the recent decisions to expand the compulsory licensing policy in Thailand, the innovative pharmaceutical industry calls on the US Government to designate Thailand as a **Priority Foreign Country** under Section 182 of the Trade Act of 1974 (as amended)”.

### V. Attempts to Impose TRIPS-Plus Provisions in the US-Thailand FTA

Despite these significant increases in intellectual property protections, the US government and multinational pharmaceutical industries are still not satisfied, demonstrated by proposals to increase the already high levels of protections in the Thai-US Free Trade Agreement negotiations. The US and Thailand started negotiations on a comprehensive bilateral free trade agreement in June 2004. Like other recent bilateral free trade agreements with the US, the US-Thailand FTA will cover investment, services, government procurement, intellectual property, as well as agriculture. Many expect it to be modeled on the US-Singapore FTA.

The negotiations have attracted strong opposition and concern among many Thai civil social movements. A broad civil society coalition, FTA Watch, was formed at the outset to closely monitor the process from a public interest perspective. Under the banner of “sovereignty not for sale!”, key issues of popular concern include access to medicine, GMOs in agriculture and patents on life.

33. [http://international.phrma.org/content/download/1414/8174/file/PhRMA%20Special%20301%20Submission%202008.pdf](http://international.phrma.org/content/download/1414/8174/file/PhRMA%20Special%20301%20Submission%202008.pdf) (accessed on July 14, 2008)
The last round (6th round) of talks took place in Chiang Mai in January 2006. The issue of intellectual property was raised in this round. As expected, all TRIPS-plus provisions were included in the negotiation text. A huge demonstration of 10,000 protestors in the streets disrupted the meeting, resulting in no conclusion being reached from this round. In addition to the extension of the patent term, demands for expanded patent protections of medical information monopoly rights would have prevented generic drugs from being marketed for a further five years. Furthermore, the demands included further restrictions on the use of compulsory licensing, the dismantling of the process for challenging patents, and amendments that would make it easier to intervene in the approval of a patent. Although the negotiations have been halted since September 2006, there are attempts from various actors, such as the business sector, politicians and officers in the Ministries of Trade and Foreign, to revive the negotiations and implement what is demanded in the US proposal. The attempt to speed up the ratification of The Patent Cooperation Treaty (PCT) is one explicit example.

TNP+ along with NGOs and the academic community closely monitor Free Trade Agreement negotiations (and other bi/multilateral agreements) to ensure TRIPS+ provisions are not included in them. These activists also support and encourage the Thai government to use TRIPS flexibilities to ensure access to medicine for not only PLWHA, but everyone, especially those with other chronic disease such as renal failure, cancer and psychiatric diseases.

VI. ORGANISING PRINCIPLES FOR THE CONTINUED CAMPAIGN FOR ACCESS TO MEDICINES

Since access to medicines is an ongoing public interest issue in Thailand, a coalition of various organizations was organized to plan for the future strategies to continue working on this issue. The seven future strategies

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35. Health Consumer Protection Programme (HCP), Pharmacy Network for Health Promotion Programme (PNHP), Social Pharmacy Research Unit (SPR), Faculty of Pharmaceutical Sciences, Chulalongkorn University, Health and Development
were detailed in “Access to Medicine for All: Civil Society's Strategies”.  

The seven strategies are as follows:

1. Coordinating partner networks for access to drugs
2. Supporting patients to get access to drugs and participate in health care and health promotion
3. Promoting local drug prices that correspond with the local cost of living
4. Developing the local pharmaceutical industry
5. Making use of legal provisions and/or reducing barriers deriving thereof
6. Proper use of drugs
7. Research and development of new drugs.

**CONCLUSION**

The struggle to combat the spread of HIV/AIDS has been an ongoing battle for almost three decades. One of the biggest issues in this fight is the availability and affordability of ARVs, especially in developing countries hardest hit by the AIDS epidemic, like Thailand. Through the mobilisation of HIV/AIDS patients, advocacy groups, and other Thai civil society members as well as like minded civil servants, politicians, and international community organizations, Thailand has been a world leader in fighting for access to affordable quality medicines, including ARVs. While Thai civil society has won many advocacy battles that have increased the quality of life of Thai PLWHA, the battle is far from over. Thailand will continue the struggle for access to medicines and hopes it can serve as a model for other developing and less developed countries as they too fight for access to much needed ARVs and other essential medicines.

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Foundation (H&DF), AIDS Access Foundation, Foundation for Consumers (FFC), Drug Study Group (DSG), The Thai Network of People Living with HIV/AIDS (TNP+).

36. The complete, detailed list outlining all the organizing points under each strategy can be accessed at http://www.samatcha.org/node/180.