

We all know that medicines are important in our lives. Furthermore, we know that the price of medicines is an important barrier to its access. One of the primary reasons for the hike in prices of medicines is that they are patented. It is, therefore, very important to know not only which medicines are protected by patents in Brazil, but the form of such protection.

This pamphlet brings to light the controversial issue of the so-called pipeline patents. Due to the pressure of organized civil society, these patents are being questioned in the Brazilian Supreme Court. They permit the exclusivity of exploration of hundreds of important medicines — even of those that do not fulfill the requirements of the Law and, thus, brushes aside the Federal Constitution.

You need to know why this is relevant to you. Some essential medications have high prices in Brazil because the pipeline patents exist. This pamphlet will explain how, why and what medicines are expensive due to this mechanism.

QUESTIONS & ANSWERS ABOUT

# PIPELINE PATENTS

How do they affect your health?

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**QUESTIONS & ANSWERS ABOUT**

**PIPELINE**

**PATENTS**

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## 1. What is a patent?

Patents are a form of intellectual property protection that are granted by States through temporary rights which allow the owner(s) of an invention to be the sole exploiter of the invention. An invention may only be patented when it fulfils the patentability requirements: novelty, inventive step and industrial application. An invention is recognized as being novel when it has not yet been disclosed and made available to the public. It is recognized for its inventiveness when it is not considered obvious by a specialized technician. The industrial application occurs when the invention may be produced or used by any type of industry. The international agreement on intellectual property (Trade Related Aspects of Intellectual Property Rights, also known as TRIPS) of the World Trade Organization (WTO) allows its members some degree of autonomy to interpret the requirements for patentability.

There are two principles that guide the international system of intellectual property: territoriality and patent independence. The first refers to the protection of the invention being restricted to a national territory. If a patent is granted in a country, its validity is solely national. The latter refers to the independence in granting patents; a country is not obliged to grant a specific patent simply because it was granted in another country. Therefore, the countries have the autonomy to interpret the patentability requirements according to their own criteria and interests.

## 2. Why patents are considered an incentive for innovation?

Patents may be understood as an exchange between public and private spheres. The investor in Research and Development (R&D) which developed a new and successful technology (be it a phone device, or a new medication) will have exclusive rights to its commercialization, allowing there to be a reimbursement for initial investments. On the other hand, the patent holder is obliged to disclose the technological knowledge in a patent document, which would be made available to

the general public. In Brazil, exclusive rights can **only** be granted if the invention fulfills the patentability requirements and meets the constitutional principles of protection to industrial assets, established in the 5<sup>th</sup> article, item XXIX of the Brazilian Federal Constitution. **Thus, protection will only be granted if the patent subordinates itself to the social interest and the technologic and economic development of Brazil.**

### 3. What are pipeline patents?

Pipeline patents (or revalidation patents) are regulated by articles 230 and 231 of law 9.279/96 – the Brazilian Industrial Property Law. These articles allowed patent applications for technological fields that Brazil did not recognize during the previous legislation (primarily medication<sup>1</sup> and foods). It has always been a controversial mechanism, even during the formation of the new Brazilian Industrial Property Law.

Pipeline patent applications were processed differently from other patent applications in Brazil. They were accepted for a year, from May 1996 to May 1997, and the patent office “revalidated” patents for medication, foods and chemical-pharmaceutical products and processes granted in other countries. These applications were formally analyzed once and followed the patent term granted in foreign countries. They were not submitted to the technical examination of the patentability requirements in the Brazilian patent office, the National Institute of Industrial Property (INPI, acronym in Portuguese).

As consequence of already having patents in other countries, the products’ information had already been published in industrial property magazines and other media. When such patent applications were filed in Brazil, they no longer fulfilled the novelty requirement, since the information has already been in public domain.

<sup>1</sup> Substances, materials or products obtained through chemical means or processes, and the substances, materials, mixtures or food products, chemical pharmaceutical and medications of any sort, as well as their respective processes for yield or modification.

Brazil adopts the absolute novelty principle (article 11, §1º of the Brazilian Industrial Property Law), which means Brazil cannot grant a patent for an application filed for a technology that has already been made public in another country.

Below, we present a summary of the differences between the patents granted by conventional procedures and those granted by the pipeline mechanism.

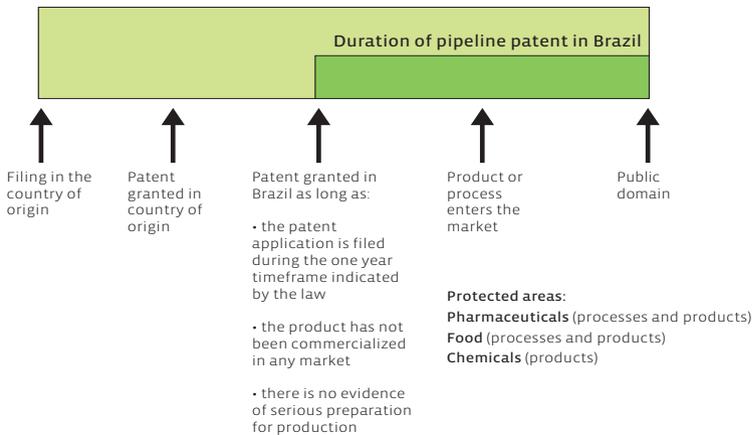
<b>PATENTS</b>	<b>PIPELINE PATENTS</b>
The analysis of the patentability requirements – novelty, inventive step and industrial application – is made based on nationally established criteria.	There was no analysis of the patentability requirements in Brazil. The revalidation of these patents in Brazil depended solely on the country where the patent was first granted.
Brazil adopts the absolute novelty principle, which determines that if an invention were to be protected by a patent, the patent could not be published elsewhere. Therefore, patents in Brazil may only be granted when the technology is new.	The novelty principle was not fulfilled, since the invention was already made public in foreign countries through the disclosure of the invention in industrial property magazines and other media.
Conventional patent applications may be deposited at any time. The INPI will then evaluate if the application will be granted after a formal and technical exam.	Pipeline patent applications could only be deposited during a one-year-period, from May 1996 to 1997, going through only one formal analysis.

The picture below summarizes the pipeline mechanism.

PICTURE 1

### Pipeline mechanism:

Duration of patent: 20 years



Source: SCHOLZE. Simone H. Cossotin - Patentes, Transgênicos e Clonagem. Brasília: UNB. 2002.

In total, 1,182 patent applications were filed through the pipeline mechanism. They consisted of 45% coming from the USA, 13% from the United Kingdom, 10% from Germany, 9.6% from Japan and 7.7% from France. This represented, in practical terms, at least 340 medications that were protected in Brazil that would not have been protected if the pipeline mechanism were not adopted.

#### 4. What were the necessary requirements for granting patents through the pipeline mechanism?

For a patent to be granted through the pipeline mechanism, the following requirements should be observed (articles 230 and 231 of the Brazilian Industrial Property Law):

- i) the object of the patent application should not have been commercialized in any market;
- ii) there must be the absence of serious and effective preparation for the exploitation of the object to be patented in Brazil;
- iii) the application must be filed during a timeframe of year, as indicated by the Brazilian Industrial Property Law;
- iv) the application may not infringe on articles 10 and 18 of the Brazilian Industrial Property Law (**article 10 defines what is not considered an invention in Brazil and article 18 defines the inventions that are not patentable**).

The criteria for granting pipeline patents was only a formal analysis made by the INPI. Despite of a few applications made by national companies, there was no technical analysis of the patentability criteria established by article 8 of the Brazilian Industrial Property Law. INPI's analysis was limited to accepting the decision of the foreign patent offices, where the applications were first filed. This situation has caused serious distortions in the system because some countries do not have a technical exam for patents. Furthermore, Brazil gave up the liberty to interpret the patentability requirements according to its own criteria and interests.

## **5. Was it necessary for Brazil to include the pipeline mechanism in its legislation, having signed the TRIPS Agreement?**

No. The TRIPS Agreement established a **much more rigid minimum** standard for protection than previous international IP agreements. The minimum regulations made by TRIPS can be strengthened through other mechanisms, especially through the national legislation of each country and through bilateral and regional free trade agreements. These and other mechanisms that surpass the minimum standards of TRIPS are called TRIPS-plus. WTO<sup>2</sup> has already declared that TRIPS does not require the patents from the pipeline mechanism.

<sup>2</sup> OMC, [http://www.wto.org/english/tratop\\_e/trips\\_e/pharma\\_ato186\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm), Access in November 14th 2007.

In other words, the adoption of the pipeline mechanism was a decision made by the Brazilian legislative authorities, going beyond the obligations assumed by international agreements.

## **6. Some countries have incorporated mechanism known as mailbox. What is the difference between the mailbox and pipeline mechanisms?**

Despite much confusion, the pipeline mechanism is not equivalent to the mailbox mechanism, which is outlined in the TRIPS Agreement. The following concepts will assist in clarifying this difference.

**TRANSITION PERIOD:** The TRIPS Agreement established some phase-in periods for countries to adapt themselves to the new worldwide intellectual property regime according to their levels of development. TRIPS granted a ten-year deadline for countries that had not protected all technological sectors. This was the case of pharmaceutical patents in Brazil and India.

**MAILBOX MECHANISM:** TRIPS established that the countries that used this transition period should accept patent applications from these sectors, only if they were filed after January 1<sup>st</sup>, 1995, when the agreement was put into force. These applications would only be analyzed in the country after the transition period. Thus, the countries that had made use of this period (as was the case in India when in 2005 modified its patent law) received the patent applications for medication and put them in a “box”, which was to be opened and analyzed when the country altered its law (up to 10 years after the implementation of TRIPS).

### **DIFFERENCES BETWEEN PIPELINE AND MAILBOX:**

a) Analysis of the patent application: the mailbox mechanism established that the patent application could be evaluated after the transition period. Such an analysis would lead to the

established criteria by the new law, but would be done by the patent office where the patent application was first filed. In the case of the pipeline mechanism, there is no technical exam for the patent granting process for patents that had not been protected before the incorporation of TRIPS. In other words, the countries that adopted the mailbox system could reject patents that did not fulfill the requirements of patentability. Brazil revalidated patents granted abroad, even if they did not fulfill the Brazilian requirements of patentability.

b) Date of applications in the country of origin: While the mailbox system would only accept patent applications made by the country of origin starting on January 1<sup>st</sup>, 1995 (“moment zero” of TRIPS), applications granted in the country of origin before the “moment zero” of TRIPS would be accepted. The pipeline mechanism allowed for patents that were granted abroad from the 1980s and the early 1990s to be also granted in Brazil.

## **7. Can pipeline patents be considered an incentive for innovation?**

**No.** By protecting inventions that are already in public domain, a concession of pipeline patents violates an exchange between public and private, which is a fundamental principle that justifies the existence of a patent protection system. It further violates the patent system because a monopoly is obtained without the need for demonstrating the good’s technical novelty.

In the pharmaceutical sector, society has paid a high price, since the patent holder’s right of exclusivity allowed the practice of abusive pricing and prevented the acquisition of cheaper versions that are available on the international market and used by several other countries and organizations.

## 8. How did the pipeline patents impact the public health system in Brazil?

By allowing for exclusive exploitation of a product (with the legal authority of a patent), the system of patent protection puts itself at odds with the principle of free competition. The decrease of competition, demonstrated in scientific literature, directly impacts the prices and access to medication.

In this case, research proves that the drastic reduction in price of a product as soon as its patent expires is due to the competition of generic<sup>3</sup> products that become available on the market<sup>4</sup>. A study<sup>5</sup> conducted in the United States verified that, on average, the price of generic medication was equivalent to 43% of the price of the reference medication during the patent duration.

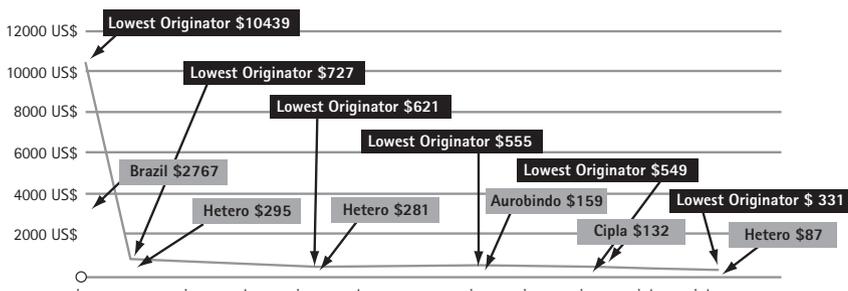
In the case of the treatment of AIDS, for example, the price of the triple first line therapy (stavudine, lamivudine and nevirapine) decreased from US\$10,439 per patient per year in 2000 (lowest original price) to US\$87 per patient per year (lowest international generic price)(see graph below). In other words, this was a reduction of more that 99% in treatment price. This was made possible due to the fact that these medications are not protected by patents in certain countries, permitting the production of a generic version.

<sup>3</sup> Generic medication: medication that is similar to a brand medication. It can be used interchangeably with the brand medication. It is generally produced after the patent term or the revocation of patent protection or other exclusive rights. For more information on the efficiency, safety and quality. Definition translated from Portuguese of: <http://www.anvisa.gov.br/medicamentos/conceito.htm#2.4>

<sup>4</sup> Other examples in "Integrating intellectual property rights and developing policy", Report of the Commission on intellectual property rights, London, 2002, p. 29-56.

<sup>5</sup> REIFFEN, D. e WARD, M. "Generic drug industry dynamics". US Federal Trade Commission Working Paper 248, 2002. Available at: [www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf](http://www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf), Access in April 23th 2009

GRAPH 1: COMPETITION AS THE CATALYST FOR MEDICINE PRICE REDUCTION



Source: Médecins sans Frontiers, 2008.

In Brazil, the federal constitution only allows for intellectual property protection to be applied to a determined invention if—and only if—there is an expectation that public and social interests will be promoted through access, research, development and technological innovation in Brazil. Currently, the capacity of the system of intellectual property to realize these objectives through patent grants is being scrutinized.

There are strong indicators that the system of intellectual property protection has not fulfilled its objectives even in the cases that protected inventions have met patent requirements. In the case of pipeline patents, this is evident. In fact, pipeline patents facilitate the practice of price abuse in situations where there are no motives for the granting the patent, given that the patent was already in Brazil’s public domain. Thus, no additional socioeconomic benefit was generated for Brazil.

The following examples of medications protected by pipeline patents illustrate their negative effects on access to medication policies in Brazil:

## **Efavirenz:**

The medicine Efavirenz is used currently by 87,000 of the 190,000 patients being treated for HIV/AIDS in Brazil<sup>6</sup> and was protected by a pipeline patent. In 2007, after various negotiations since 2003, Merck only offered a reduction of 2% of the price for therapy, which was US\$580 for patient/year. In April of 2007, the medication was declared of public interest and the following month the government issued a compulsory license for Efavirenz. The Brazilian government commenced buying the generic version at US\$190 per patient per year and did so until local production of the drug began in February 2009.

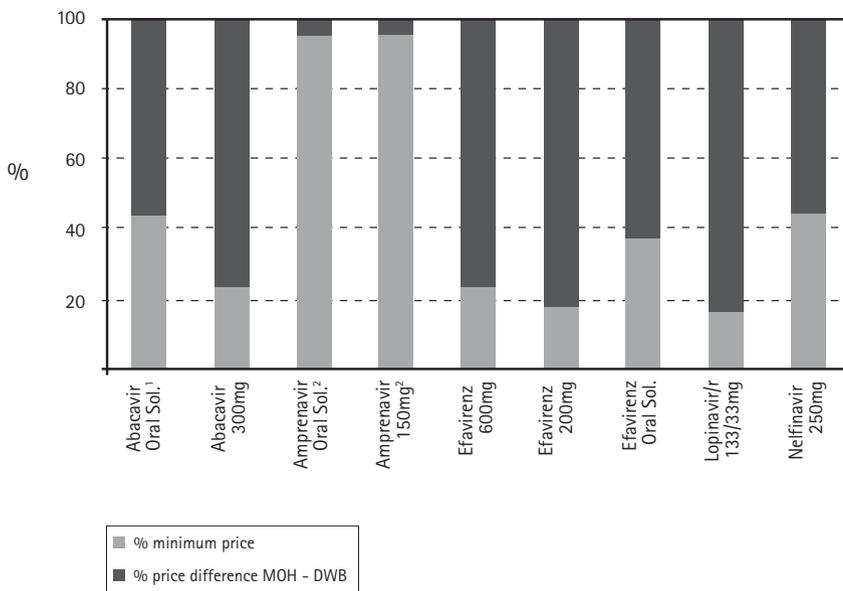
Other than Efavirenz, other medications used for the treatment of AIDS were also protected by the pipeline mechanism (abacavir, amprenavir, lopinavir, lopinavir/ritonavir e nelfinavir). These drugs cost the public health system excessively because they prohibited the procurement of cheaper generic versions available on the international market or to produce them locally at more affordable prices.

A technical study, fruit of development research under the coordination of Dr. Lia Hasenclever<sup>7</sup>, of the Institute of Economy at Federal University of Rio de Janeiro, estimated the damage caused by the adoption of the pipeline mechanism in Brazil in the case of government purchases of five ARV medications from 2001 to 2007. The facts revealed that Brazil spent between US\$420 million (World Health Organization) and US\$ 519 million (Doctors without Borders) during this period.

<sup>6</sup> Data from the National Program of HIV/STD. Ministry of Health. Information of May 2009.

<sup>7</sup> Lia Hasenclever – Economist, Master in Industrial Economy and doctor in Production Engineering of the Federal University of Rio de Janeiro.

GRAPH 2: MONETARY DAMAGE CAUSED BY PIPELINE PATENTS: DIFFERENCE PAID FOR THE PRICE OF GENERIC AND THE PRICE OF THE PRODUCT UNDER THE PIPELINE PATENT DWB, 2001-2007 (%)



**Obs.:** a – For the medication without a price quote for the WHO and/or DWB, in this case 5% royalties were used to calculate the cost of the pipeline patent mechanism; b – Conversion based on the real's average exchange rate against the dollar in 2006 (\$1.00 = R\$2,18); c – Calculation made based on the cheapest price reached in June 2006 by the WHO.

1 – Medication with price quote until 2005; 2 – Medications without price quote for WHO, in this case royalties of 5% were used to calculate the cost of the institute of pipeline patents.

Source: HASENCLEVER, L. e MINEIRO, A. Technical report about the negative aspects of the pipeline mechanism on the economy of health , 2007.

Considering that the patents granted by the pipeline mechanism are close to 1,200 and that the term of the patent goes further than the time period of the study (seven years), it is almost impossible to measure

the real monetary damage caused by the granting of pipeline patents. Economists have estimated this figure to be in the order of billions of American dollars.

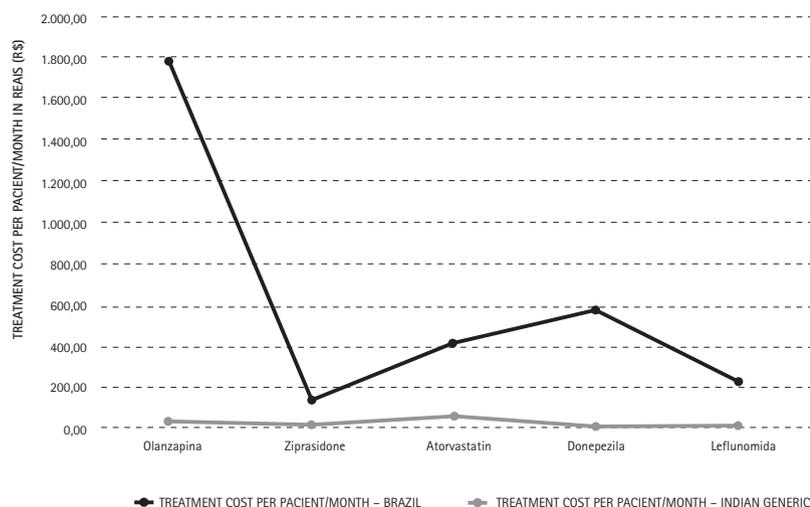
## 9. Besides AIDS medication, are there any other medications protected by these patents?

Yes, other than antiretrovirals, diverse medications are protected by the pipeline mechanism, among which are medications for cancer, Alzheimers, Parkinson's and mental diseases. The Ministry of Health has a list of medications called "exceptional." These medications either possess an elevated unitary value or become excessively expensive to be affordable for the population. Some of these protected medications by pipeline patents are included in the Program of Exceptional Medications, financed by the Ministry of Health and administered by the State or Municipal Secretaries of Assistance to Health.

Among the patented medication by the pipeline mechanism, 18 were identified constantly on the list of exceptional medicines of SUS<sup>8</sup>. In order to illustrate the impact of these patents, we compared prices paid by the Brazilian government for a selection of exceptional medication with the price paid on the Indian market of generics (see graph below).

<sup>8</sup>The following 18 medicines were analyzed in the research: Dutasteride (prostate cancer), Certican (prophylaxis of organ rejection), Raloxifeno (breast cancer), Micofenolato mofetil, Ácido micofenólico (prophylaxis), Leflunomida (rheumatoid arthritis), Etanercept (arthritis), Levodopa/Carbidopa, Tolcapone, Donepezila (parkinson's disease), Rivastigmina tartrate (parkinson's/alzheimers), Desmopressina (antidiuretic), Etanercept (treatment of autoimmune diseases), Mesilato de Imatiniba (chronic myeloid leukemia), Acetato de Octreotida (hormone inhibitor), Quetiapina, Ziprasidone, Olanzapina (schizophrenia), Atorvastatin (cholesterol control).

**GRAPH 3<sup>9</sup> – COMPARISON OF EXCEPTIONAL MEDICATION PRICES PAID BY SUS AND PRACTICED BY GENERIC INDIAN COMPANIES – PATIENT/MONTH IN REAIS.**

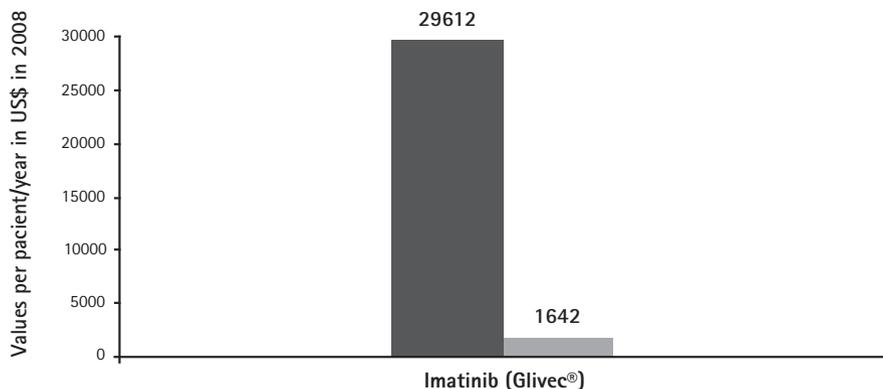


The impact of the exploitation of a product in situation of monopoly can be clearly demonstrated by observing the graph above. The case of Olanzapine (anti-psychotic medication) demonstrates the gravity of the matter: treatment financed with SUS resources cost 60 times more than the generic version produced by Indian companies.

The case of the medication Mesilato de Imatinib (Glivec ®) of the Novartis Company, which is used to treat chronic myeloid leukemia, is another example of exorbitant costs paid by the Ministry of Health for the acquisition of this treatment (see graph below). Even though generic versions are much cheaper on the international market, the Brazilian government is not permitted to buy cheaper versions because this medication is protected by a pipeline patent.

<sup>9</sup>Brazilian prices obtained in the Database of Prices in Health from the Ministry of Health (DATASUS). Indian prices practiced by generic pharmaceutical companies as informed by specialists.

GRAPH 4<sup>30</sup> – COST IN DOLLARS PER PATIENT PER YEAR ON THE MEDICATION GILVEC®, PAID BY SUS IN COMPARISON WITH THE PRICE FOR GENERIC VERSIONS



## 10. Why are pipeline patents unconstitutional?

Pipeline patents violate the objectives of the patent system established in article 5, item XXIX of the Federal Constitution, because they do not attend to social interests, technological and economic development of the country.

Pipeline patents do not respond to **social interests** of the country because, when you grant a company the commercial monopoly of a medication or pharmaceutical process that was already in public domain, it unnecessarily increases the expenses of medication. This impacts both patients' and government budgets.

Moreover, pipeline patents violate the **substantive legal process principle**, represented in the **reasonability and proportionality**, by allowing patent protection without the analysis of material requirements and in spite of the constitutional principles that determine the social function of property.

<sup>30</sup> Brazilian prices obtained in the Database of Prices in Health from the Ministry of Health (DATASUS). Indian prices practiced by generic pharmaceutical companies as informed by specialists.

It also goes against the **principle of equality**, allowing differentiated treatment between national and foreign products. A patent application of a national inventor must go through the patent requirements established by national law (article 8<sup>th</sup>, law 9.279/96), while under the pipeline mechanism foreign application were submitted only to their originating countries. In many cases, the requirements for securing a patent are different from those held in Brazil. This, therefore, allows the Brazilian government to grant a patent for a product that doesn't fulfill Brazil's patent requirements. **This situation brings grave distortions to the system, since many countries don't even have their patent application go through a technical exam.**

Lastly, granting pipeline patents violates the principle of non-withdrawal of what is of public domain, **violating the acquired collective right of the people**. Any knowledge after becoming of public domain may not be removed. When an asset becomes of public domain, it becomes something common to all and society acquires the collective right to maintain it available, preventing any individual attempts of appropriation<sup>11</sup>.

## **11. What is civil society's role and what is being done in relation to pipeline patents?**

Civil society has the obligation to monitor and analyze the negative impacts of adopting national and international laws and practices that could create obstacles for the populations to access medication. It, furthermore, must educate the public of its observations.

Due to the great impact caused by pipeline patents in Brazil, the Working Group on Intellectual Property of the Brazilian Network of the Integration of Peoples (GTPI/REBRIP) resolved to contest judicially this patent mechanism. On November 28, 2007, the National Federation of Pharmacists (FENAFAR in Portuguese), representing REBRIP, presented

<sup>11</sup> BARBOSA, Denis B. Pipeline: uma inconstitucionalidade patente. Available at <<http://denisbarbosa.addr.com/27.rtf>>, access in December 3rd 2007.

the Prosecutor General of the Republic a petition to consider the constitutionality of the pipeline patents. This resulted in a Direct Action of Unconstitutionality (ADI/4234), which seeks to eliminate the pipeline mechanism. The ADI is currently making its way through the Supreme Court (STF in Portuguese).

## **12. Why is it important for the STF to rule swiftly on this case?**

It is important that the STF judges this case quickly because once the pipeline mechanism is declared unconstitutional, generic versions of medication protected by pipeline patents can be acquired by the health system at affordable prices. This would be the case if the medications were made available by the international market or produced locally.

Moreover, the issue of this ADI is of utmost importance and urgency, as that it can alter a measure that is greatly responsible for the current situation.

## **13. What can you do about it?**

As a citizen, and probably a patient being treated by medication protected by a pipeline patent, it is important that you help by spreading information about the **substantial damage brought about by these patents to the public health system** and to the population's access to important medication. Moreover, it is important that the STF's decisions regarding the ADI be monitored so that pipeline patents may be quickly declared unconstitutional. The pressure of society and social organizations are fundamental in order to accelerate a decision by the STF, so that it is a favorable decision for public health and the access to medications.

## 14. Once pipeline patents are annulled, how will the supply of medication be made in Brazil? Will the quality of treatment be affected?

After the annulment of pipeline patents, the medication once protected by this institution will be available to be produced by generic pharmaceutical laboratories or imported from international generic companies and will be accessible at more affordable prices than the patented medication. Generic medication contains the same active ingredient, pharmaceutical formula, dosage and therapeutic indication as that of the branded medication, which served as a reference for the presentation of the same level of quality.

Moreover, Brazil and the Brazilian Ministry of Health (SUS acronym in Portuguese) represent an important market for transnational pharmaceutical companies, due to the size of its population and the security of governmental procurement. The promotion of competition will certainly contribute to the price reduction of medications that are currently being monopolized. That is to say, without pipeline patents, it will have cheaper generics and it will force the price reduction of brand medications.

For more information about the quality of medications, read the document in Portuguese and Spanish “**Medicamentos: falando de qualidade,**” which is available at: [http://www.abiaids.org.br/\\_img/media/Cartilha\\_Medicamentos.pdf](http://www.abiaids.org.br/_img/media/Cartilha_Medicamentos.pdf)

If you want to know more about medications patented through the pipeline mechanism that may have generic and cheaper versions if STF declares the institute unconstitutional, access the following website:

[http://www.abiaids.org.br/\\_img/media/ID\\_pipeline.xls](http://www.abiaids.org.br/_img/media/ID_pipeline.xls)