

**PATENT RIGHTS OVER PHARMACEUTICAL PRODUCTS
AND PROCESSES *VERSUS* ACCESS TO DRUGS:
AN EMERGING ISSUE IN BRAZIL**

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PATENT RIGHTS OVER PHARMACEUTICAL PRODUCTS AND PROCESSES VERSUS ACCESS TO DRUGS: AN EMERGING ISSUE IN BRAZIL

Abstract

This article seeks to level the current controversy of pharmaceutical patents and public health to the constitutional field, to show that only through a rational and fair balancing between those rights the public interest will be satisfied. Promoting drug innovation and access to drugs are equally important, and both converge to the same target: social interest. The fact that a temporary privilege grants to its holder the advantage of exploiting the subject matter of the patent is not an obstacle for enforcing the constitutional rights of access to health. Rather, a temporary privilege seeks to foster a progressive development of new therapies, which also meet public interest. In Brazil, a certain prejudice against patents in general, and specially pharmaceutical patents, adds a non-legal or fair component to said controversy, which ends up being detrimental to patent holders and to society in the long run.

I

INTRODUCTION: DIVERGENCE OR CONVERGENCE?

The values of *being healthy, benefiting from scientific developments and enjoying protection over its scientific productions* are classified, among others, as human rights. In fact, the rights to (i) "a standard living adequate for the health [...] including [...] medical care"; (ii) "to share in scientific advancement and its benefits"; and (iii) "to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author" are equally stated in the Universal Declaration of Human Rights (articles 25 and 27).

Notwithstanding the above, a controversy regarding pharmaceutical patents *versus* public access to drugs has progressively gained international implications, which were in great part motivated by the HIV pandemic throughout the world. The WTO Doha Declaration on Public Health and Access to Drugs is the most recent corollary of the attempt of harmonizing the two apparent opposing sides¹.

¹ For more information, check <https://www.wto.org/english/tratop_e/dda_e/dda_e.html>

Generically stated, two important values are at stake: public health and private rights over a patent of invention. The question that arises from this discussion, that needs to be taken into consideration by the authorities and the opinion leaders who oppose to pharmaceutical patents, resides in the real divergence between those values. In other words, the two-pronged values inherent to a patent of invention (temporary *private right* and *access to an innovative drug* that will benefit the public) seem to be overlooked when it comes to access to drugs *per se*².

The most realistic approach, quoting Dworkin, is to admit that "there is no right answer" to the apparent conflict. *The proper balance between the two values can only be reached in a concrete situation*³.

However, generalizing the long-standing prejudice against patents of invention seems to be common sense, and shifts the focus of public health concerns to innovative pharmaceutical products, as if patent protection was the only obstacle for promoting public health⁴.

In Brazil the controversy started in 1996, when pharmaceutical products became statutory patentable subject matter with the implementation of the new Industrial Property Act and the WTO-TRIPs Agreement⁵. Since then, the research-based industry is experiencing a massive political pressure against its patents, which now reached the Judiciary Power.

By leveling the discussion to the public law perspective, this article aims at showing how the so-called controversy between pharmaceutical patents and access to drugs is being treated by the Brazilian Executive and Judiciary Powers. Finally, the article intends to bring the discussion to the constitutional level, by analyzing both public health and patent rights under the Brazilian Lex Mater, and showing how the proper balance between those rights may reach the government's intent of fostering access to drugs. Indeed, public health would be benefited with the access to drugs. However, suppressing patent rights on pharmaceutical products and processes, instead of promoting public health, would rather—in the end—be detrimental thereto.

II

THE BRAZILIAN FEDERAL CONSTITUTION OF 1988

After the long period of military dictatorship in Brazil, started in 1964 up until 1985, the Federal Constitution of 1988 is a landmark in the process of turning the State towards a democracy system. The Constitution of '88 is known in Brazil as the *Citizen Constitution*, to the extent that it ensures "the exercise of social and

² In this connection, see Oswald, Maria Cecilia and Leonardos, Luiz. *Direito de Patentes: Uma proposta de filtragem constitucional*. Revista da ABPI, No. 86, Jan/Feb 2007.

³ Dworkin, Ronald. *Levando os direitos a sério*, São Paulo: Martins Fontes, 2002.

⁴ In what concerns the general and long-standing criticism against patent rights, see MACHLUP, Fritz; PENROSE, Edith. *The Patent Controversy in the Nineteenth Century*. The Journal of Economic History, vol. X, n. 1, mai. 1950.

⁵ See Mayer, Christopher S., *The Brazilian pharmaceutical industry goes walking from Ipanema to prosperity: will the new intellectual property law spur domestic investment?*, HeinOnline, 12 Temp. Int'l & Comp. L.J. 377 1998.

individual rights, liberty, security, well-being, development, equality and justice as supreme values of a fraternal, pluralist and unprejudiced society", as stated in its Preamble.

The fundamental objectives of the Constitution are, according to its article 3, to:

- I. to build a free, fair and solidary society;
- II. to guarantee national development;
- III. to eradicate poverty and substandard living conditions and to reduce social and regional inequalities;
- IV. to promote the well-being of all, without prejudice as to origin, race, sex, colour, age and any other forms of discrimination.

As a milestone in the then new democratic State, the "sole paragraph" of article 1 of the Constitution states that "[a]ll power emanates from the people, who exercise it by means of elected representatives or directly, as provided by this Constitution". In other words, the values and targets contained in the Constitution are those that were brought by the people, through its elected representatives in the Constitutional Assembly.

Each and every statute has to be edited in light of the Constitution. The same holds true for court decisions, which have to be aligned with the constitutional principles and rules. The Constitution of '88 sets the standards and values that have to be respected in all acts rendered by the Executive, Legislative and Judiciary Powers.

Either "public access to health" and protection to patent rights as a means of fostering development are foreseen in the Constitution as two important values towards a free, fair, and fraternal society.

II.1. *Public Health under the Brazilian Constitution*

Inspired by the Universal Declaration of Human Rights, the Brazilian Constitution establishes in its article 5 that "*all persons are equal before the law*, without any distinction whatsoever, Brazilians and foreigners residing in the country *being ensured of inviolability of the right to life*, to liberty, to equality, to security and to property." "Life" within the meaning of article 5 indirectly reflects the right to health, which, according to article 6 of the Constitution, is considered as a social right, together with education, work, leisure, security, social security and the like.

Specifically regarding access to health, article 196 of the Constitution establishes that:

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

It is *upon the State* to ensure public health to all as a means of reducing the risk of disease and other hazards through *public policies*, which encompass the acts of endowing the society with public hospitals to supply in the municipal, state and federal levels, free distribution of essential drugs, and providing free healthcare for the whole population.

Those acts, according to the Constitution, constitute a *single system*, reason why article 198 established the "Unified Healthcare System" (known in Brazil by the acronym "SUS"). Such provision determines that "[h]ealth actions and public services integrate a regionalized and hierarchical network and constitute a single system". The "SUS" is financed with the social welfare budget of the federal government, the states and the municipalities, and was later on ruled by Law #8,080, of 19 September 1990, being statutorily defined as comprising: "health activities and services, provided by public and federal entities and institutions, both by states and municipalities, of the direct and indirect administration and of the foundations maintained by the government". "SUS" relies on government-owned facilities, such as hospitals, and hires private contractors through public bids for specific needs.

As shown above, the rule of article 196 of the Constitution is essentially fulfilled by the actions of "SUS", which is also responsible for the distribution of free medicines to the public as a means of conferring efficacy to the constitutional provision.

Under the Constitutional Law perspective, article 196 is a "programmatic rule", insofar as it is complied with through the actions of the State, either positive or negative. On the other hand, the direct enforceability of article 196 towards individuals in need is accepted by the Judiciary⁶. There are several court precedents confirming that individuals may request and obtain through courts a certain medicine not listed in the "SUS Essential drugs", which are freely distributed thereby.

II.2. *Patents of invention under the Brazilian Constitution*

Article 5 of the Constitution establishes the fundamental and individual rights and guarantees, which cannot be amended or abolished, under article 60, paragraph 4 of the Constitution.

In its item XXIX, article 5 rules that "[t]he law shall ensure the authors of industrial inventions of a temporary privilege for their use, as well as protection of industrial creations, property of trademarks, names of companies and other distinctive signs, in view of the social interest and the technological and economic development of the country".

The provision encompasses two different values: the individual and temporary rights conferred upon inventors *and* the social interest and technological and economic development of the country. In other words, the provision is ambivalent inasmuch as it states that temporary privileges are justifiable and aligned with the social interest and the development of the country. It embraces simultaneously a private right and a public interest.

In fact, the rationale of patents of invention is to encourage new inventions, which will develop technology and economy, and, consequently, will benefit the society, which will be better-off having access to progressively better and more advanced devices.

Different from what is defended by some Brazilian jurists, the "*social interest and the technological and economic development of the country*" is not a limitation to the rights of inventors, but an *explanation* to it. The constitutional option of grant-

⁶ SARMENTO, Daniel. *Direitos fundamentais e relações privadas*. Rio de Janeiro, Ed. Lumen Juris, 2004.

ing temporary individual rights to inventors is necessary so as to reach the constitutional objectives of social interest and technological and economic development of the country.

The importance of granting temporary rights to inventors *as a means* of benefiting society and fostering the development in the country is perfectly summarized in item XXIX of article 5 of the Constitution.

III

PHARMACEUTICAL PATENTS IN BRAZIL

Since 1969, pharmaceutical products or processes were considered in Brazil as statutory non-patent eligible subject matter. The legislative choice was grounded on the intent to create a strong National pharmaceutical industry through R&D efforts that would be financed by the Government.

Unfortunately, history has oriented the Government's primary target towards piracy and the manufacture and sell of substandard drugs. In fact, rather than concentrating its efforts in R&D, the national industry turned out to manufacture copycats of foreign drugs developed by research-based industries.

With the implementation of the WTO-TRIPs Agreement, in 1994, the Brazilian Legislative Power amended its previous Patent Act so as to, among other changes, allow pharmaceutical patents. On May 14, 1996, the Brazilian Patent Act (Law #9,279/96) was promulgated, being put into force as of that date only the "transitory provisions" (which established the pipeline patents to ensure the transition from the prohibition of pharmaceutical patents to its allowance), and one year later all the other provisions.

Under the rule contained in article 5, item XXIX of the Constitution, article 2 of the Patent Act also asserts the convergence between the private rights of an inventor and the public interest, as follows:

"Article 2. The protection of rights relating to industrial property, *taking into account the interests of society and the technological and economic development of the country*, is effected by means of:

I - *the grant of patents of invention and utility model patents; [...]*"

Article 10 of the Patent Act lists the matters which are not patent-eligible, such as discoveries, scientific theories, mathematical methods, purely abstract concepts, operating or surgical techniques and therapeutic or diagnostic methods, for use on the human or animal body. Article 18 excludes from patentability subject matters (i) "contrary to morals good customs and public security, order and health; (ii) substances, matter, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes of obtaining or modifying them, when they result from the transformation of the atomic nucleus; and (iii) living beings, in whole or in part, except transgenic micro-organisms meeting the three patentability requirements—novelty, inventive activity and industrial application—provided for in article 8 and which are not mere discoveries."

Provided the subject matter of an invention does not fall within the prohibitions of articles 10 and 18, it is patentable if it complies with the statutory requirements of novelty, inventive step and industrial applicability (article 8).

The Brazilian Patent Office (hereinafter referred to as INPI) has the statutory authority of examining and granting each and every patent which fulfills the patentability requirements. The INPI is obliged to grant the patent, meaning that there are no flexibilities conferred upon the Office to deny a patent when it satisfies the statutory requirements for its grant. The administrative act is ministerial, and not discretionary.

IV

THE BURDENS POSED TO PHARMACEUTICAL PATENTS UNDER THE "PUBLIC HEALTH" PARADIGM

Pharmaceutical patents in Brazil are rather new and, for this reason, face a strong opposition by local pharmaceutical industries that were dedicated in the past to manufacturing and commercializing drug copycats.

The general prejudice against pharmaceutical patents is also expressed by the media and, to some extent, by the Federal Government, through the Ministry of Health. The approach taken by those voicing against pharmaceutical patents seem simplistic and far-fetched, since their main grounds are essentially that "public health" is a supreme right and, for this reason, should prevail over the private rights conferred to an inventor.

Some measures have been taken by the Executive Power as a means of hindering the grant of pharmaceutical patents under the "public health" argument, so as to weaken the constitutional rights granted to inventors.

In fact, amendments to the Patent Act and to the Decree which regulates the grant of compulsory licenses, as well as the threat of the grant compulsory licenses are some of the risks and challenges posed to the research-based pharmaceutical industry.

IV.1. *Amendment to the Brazilian IP Statute (229-c)*

On December 14, 1999, the Patent Act was amended through Provisional Measure #2,006⁷, which, among other changes, established that pharmaceutical patents can only be granted after obtaining a "prior approval" from the National Sanitary Surveillance Agency (ANVISA). The Provisional Measure was reissued several times un-

⁷ Provisional Measures are hierarchically equivalent to Statutes, but are approved under urgency by the Executive Power, according to article 62 of the Constitution, which establishes that: "In important and urgent cases, the President of the Republic may adopt provisional measures with the force of law and shall submit them to the National Congress immediately, and if Congress is in recess, a special session shall be called to meet within five days." According to the sole paragraph of the constitutional provision, provisional measures "shall lose effectiveness from the day of their issuance, if they are not converted into law within a period of thirty days as from their publication and the National Congress shall regulate the legal relations arising therefrom".

til it turned into Law #10,196, of February 14, 2001, finally amending and adding provisions to the Patent Act, and determining the grant of patents on pharmaceutical products and processes to be dependent on ANVISA's "prior approval", in the following terms:

"Article 229-C. The granting of patents on pharmaceutical products or processes shall depend on the prior approval of the Agência Nacional de Vigilância Sanitária (ANVISA)."

The initial controversy about article 229-C related to the role of ANVISA in the grant of patents, since the Agency's authority does not encompass the examination of patentability requirements, which is upon the sole statutory authority of the INPI. Neither the INPI or ANVISA were institutionally prepared for putting article 229-C into force. An uncertainty period as to ANVISA's role was the cause of concern and apprehension by the research-based industry, which worried about a double-examination of its patent applications through a biased and political view of the Ministry of Health, to which ANVISA is statutorily linked.

Initially, the role of ANVISA under the mandate of article 229-C was to make minor technical corrections to patent specifications and claim charts. At first, this did not seem to implicate any burdens to patent application holders, except for the delay in the prosecution of the patent, which, by itself, was already a burden.

However, by the beginning of 2004, ANVISA started to issue opinions under article 229-C using rather political and biased arguments to reject prior approval to pharmaceutical patents. Finally, on August 25, 2004, ANVISA issued a "Technical Warning", published in its website, stating that no prior approval would be granted to certain types of pharmaceutical patent claims (such as Swiss-type or selection inventions), grounded on the alleged fact that:

"such patents are harmful to public health, to the country's scientific and technological development, and that it may hinder access to drugs by the population."

Also, by means of a press release, ANVISA self-determined its role as regards article 229-C, by affirming in a statement named "Current Policy for Drug Regulation in Brazil, that:

"Pharmaceutical product and process patent applications since 1999 are subject to ANVISA's mandatory review through the 'prior approval' procedure. This approval is either granted or denied following product evaluation, taking into account, in addition to the formal examination aspects (technical examination of patentability requirements), *the specific public health aspects (access to drugs and technical evaluation of compounds)*."

As seen from the statement above, ANVISA actually understands that the statutory "prior approval" may also be used as a final administrative decision to reject pharmaceutical patents grounded on public health aspects, such as access to drugs.

Even though there are no legal provisions binding the INPI to ANVISA's rejection to pharmaceutical patents, currently both institutions issue a single opinion, combining technical examination of patentability statutory requirements tempered with the political perspective of public health concerns. It seems from some cases that the "technical examination" is conducted under a strong and negative interpretation of the Patent Act, as a *default* and formality to reject pharmaceutical patents under the hidden reasoning of public health concerns. In other words, the balancing of the values inserted in the Constitution is nullified by a *prima facie* rejection of the patent application through the strict and discretionary "examination" thereof to make one of the values (public health) prevail over the individual rights to obtain a temporary privilege for a pharmaceutical invention.

IV.2. *Amendment to Decree 3,201/99 (Compulsory license)*

By adopting the rationale of the WTO Doha Declaration on TRIPs and Public Health, Decree #3,201, of October 6, 1999 was amended by Decree #4,830, of September 4, 2003. Before explaining the mentioned Decrees, it must be noted that the Doha Declaration aims at providing flexibilities to patent rights, but not to suppress them *vis-à-vis* public health. In fact, while the Declaration reaffirms the rights of the members to grant compulsory licenses in view of public health concerns, it reaffirms the statutory mandate of article 71 of the Brazilian Industrial Property Act, which expressly determines that:

"Art. 71 - In cases of national emergency or public interest, declared by an act of the Executive Power, provided the patent holder or its licensee cannot supply such need, it may be granted, *ex officio*, a compulsory license, temporary and non-exclusive, for the exploitation of the patent, without prejudice to the rights of its respective holder."

The provision above is regulated by the above-mentioned Decree # 3.201/99, which provides for the granting, *ex officio*, of a compulsory license in cases of national emergency. The Decree was further amended by Decree #4.830, of September 4, 2003, in order to make it possible the importation of patent-protected products without the need that such products have been directly placed in the market by its holder or with its authorization, according to article 10 of the amended Decree #3,201/99, as follows:

"Article 10. In the cases where it is not possible to fulfill the national emergency and public interest situations with the product put in the internal market, or it shows unfeasible the production of the subject matter of the patent by a third party, or by the Government, the latter may be able to import the subject matter of the patent.

Sole Paragraph. In the cases set forth in this article, the Government shall preferentially acquire the product put in the internal market directly by the patent owner or with its consent, always when this procedure does not hinder the purposes of the license."

Decree #4,830/03 innovates in its provision which determines the taking without compensation of trade secrets relating to the data package on safety and efficacy of the compulsorily licensed drug, added to article 5 of Decree #3,201/99 as follows:

"Article 5. The act granting a compulsory license shall establish, among others, the following conditions:

§1^a. The act granting the compulsory license may also establish the obligation of the owner to transmit the necessary and sufficient information for the effective reproduction of the protected subject matter and other technical aspects applicable to the case, *being, if not transmitted such information, applicable article 24, of Title I, Chapter IV, of the Law #9,279, of May 16, 1996.*"

The Brazilian Constitution determines in its article 5, item XXIV, as a fundamental right, that "the Law shall establish the procedure for expropriation for public necessity or use; or for social interest, under fair and prior monetary compensation, except for cases set forth in this Constitution".

Compulsory license is duly provided for by the Patent Act and is a fair measure for limiting patent rights, in the situations described in articles 68, 70 and 71⁸. How-

⁸ Article 68. A patentee will be subject to have his patent licensed compulsorily if he exercises the rights resulting therefrom in an abusive manner or by means of it practices abuse of economic power that is proven under the terms of the law by an administrative or court decision.

§1 - The following may also result in a compulsory license:

I - the non-exploitation of the subject matter of the patent in the territory of Brazil, by lack of manufacture or incomplete manufacture of the product or, furthermore, by lack of complete use of a patented process, except in the case of non-exploitation due to economic inviability, when importation will be admitted; or

II - commercialization that does not meet the needs of the market.

§2 - The license can only be requested by a party with legitimate interest and that has the technical and economic capacity to carry out the efficient exploitation of the subject matter of the patent, that should be destined predominantly for the internal market, suppressing, in this case, the exception provided for in item I of the previous paragraph.

§3 - In the case that a compulsory license is granted due to abuse of economic power, a period of time, limited to that provided for in article 74, will be guaranteed to the licensee proposing to manufacture locally, to proceed with the importation of the subject matter of the license, provided it has been placed on the market directly by the patentee or with his consent

§4 - In the case of importation for exploitation of a patent and in the case of importation provided for in the previous paragraph, the importation by third parties of a product manufactured according to a process or product patent will equally be allowed, provided it has been placed on the market directly by the patentee or with his consent.

§5 - A compulsory license, to which § 1 relates, may only be requested after 3 (three) years from grant of the patent.

Article 70. A compulsory license will also be granted when the following hypotheses are shown to exist cumulatively:

I - a situation of dependency of one patent on another is characterized;

II - the subject matter of the dependent patent constitutes a substantial technical advance in relation to the earlier patent; and

III - the patentee does not come to an agreement with the patentee of the dependent patent for the exploitation of the earlier patent.

§1 - For the purposes of this article, a dependent patent is considered to be one the exploitation of which depends obligatorily on the use of the subject matter of the earlier patent.

ever, there are no constitutional or statutory grounds to declare a patent invalid for lack of enablement if the patent holder does not disclose its confidential data package for the reproduction of the drug whose patent has been compulsorily licensed.

The amendments made to Decree #3,201/99 may indicate that the Brazilian Government intends to pursue an industrial policy license through the granting of compulsory licenses as a means of strengthening the government-owned laboratories to manufacture and sell copies of patented drugs. The government's apparent intent goes in the opposite direction contained in the WTO's General Council chairperson Carlos Pérez del Castillo's statement on the decision contained in document IP/C/W/405 to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. The statement is clear when it affirms that:

"First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives."

The recent *ex officio* compulsory license granted by the Brazilian government to a patent covering an antiretroviral drug may be an example of a possible intent to develop local technology for working a patented drug. After some threats by the Brazilian Ministry of Health to Merck's efavirenz patent (covering Stocrin®) in order to lower its price, on April 24, 2007, the Ministry of Health declared through Ordinance #886, the public interest over the drug. According to article 3 of Decree #3,201/99, declaring the public interest over a patent is a preliminary requirement for the granting of a compulsory license.

Finally, on May 4, 2007, Decree #6,108 was enacted to grant the compulsory license over Merck's patent covering efavirenz, grounded on the public interest. According to the media releases regarding the compulsory license granted for Merck's patents covering efavirenz, Brazilian laboratories would furnish the drug to the government in a second moment of the license. The MoH announced that the government-owned laboratories LAFEPE and FarManguinhos would start to furnish efavirenz until the end of 2008.

The two laboratories were also nominated by the MoH as members of the "Technical Group" to monitor the production development process, by the Government of by contracted third parties, of the subject matters of the patents, totally or partially, regarding the compulsory license of the antiretroviral efavirenz, for public and non-commercial use, to be coordinated by the Secretary of Science, Technology and Strate-

§2 - For the purposes of this article, a process patent may be considered as dependent on a patent for the respective product, as also a product patent may be dependent upon a process patent.

§3 - The proprietor of a patent licensed under the terms of this article will have the right to a compulsory cross license under the dependent patent.

Article 71. In cases of national emergency or public interest, declared in an act of the Federal Executive Authorities, insofar as the patentee or his licensee does not meet such necessity, a temporary *ex officio* non-exclusive compulsory license for the exploitation of the patent may be granted, without prejudice to the rights of the respective patentee.

Sole Paragraph - The act of grant of the license will establish its term of validity and the possibility of extension.

gic Inputs of the Ministry of Health. Such group was established by means of the MoH's Ordinance #1415, published in the Official Gazette of June 15, 2007.

The government's target of developing its own laboratories with patented technology may evidence that the license will be used to pursue an industrial policy.

It should also be pointed out that the only ground for granting the compulsory license was the allegedly "high price" charged by Merck for its drug Stocrin®. The negotiations held with Merck did not end up in the price the MoH intended to pay for the drug in order to freely distribute to HIV-patients through SUS.

Brazil, like several countries, provides for mechanisms of drug price regulation⁹. Prior to their launch in the market, drugs have to obtain price approval from the Pharmaceutical Market Regulation Chamber (CMED), which is composed of representatives from the Ministries of Health, Justice, Economy, Development Industry and Foreign Trade and State Department¹⁰. Among other requirements set in administrative rules of CMED, patents are one of the issues that are taken for consideration during price approval procedure¹¹.

Therefore, there is no reason to put into question the drug price that was approved by CMED, which also includes a representative from the Ministry of Health. It seems, taken the above for granted, that the MoH's primary purpose was to pay less for the drug, and justified the lower price need with the generic argument of "public health" to reach its objective.

Currently, a different approach is being taken by the MoH in order to avoid the grant of pharmaceutical patents whose subject-matter are strategic to public health policies, such as antiretrovirals. On April 9, 2008, the MoH declared, through Ordinance #681, the public interest over Gilead's patent application PI 9811045, covering Tenofovir (Viread®). The Ordinance seeks the priority examination of such patent application in view of its rejection by the USPTO for lack of nonobviousness (US 5,935,946).

The examples above, added to the intervention of the MoH, through ANVISA, in the examination of patent applications covering pharmaceutical products and processes clearly show that the "public health" approach is in fact posing a threat to the research-based industry.

As further discussed below, such intervention applies a *prima facie* prejudice against patent rights, rather than applying the proper balance between IP rights and access to health rights.

⁹ For more information, see Lanjouw, Jean O. Patents, price controls and access to new drugs: how policy affects global market entry. 2005. NBER Working Paper Series. Cambridge: National Bureau of Economic Research (available at <<http://www.nber.org/papers/w11321>>).

¹⁰ CMED was created by Law # 10,741, of 10/06/03, which also defines the general criteria for price approval in the pharmaceutical market, further detailed by administrative rules enacted by CMED.

¹¹ Article 4 of CMED's Administrative Rule # 2 of March 5, 2004 lists the information to be submitted by the company applying for price approval. Amongst the required information, item XI of the provision determines that the applicant should submit the following information:

- (a) number of the first international patent application, filing date and country where it was filed;
- (b) number of the patent application before the Brazilian Patent Office; and
- (c) innovation presented by the product in which the patent application was based.

V

COURT DECISIONS GUIDED TOWARDS PUBLIC HEALTH IN DETRIMENT
TO PHARMACEUTICAL PATENTS

Pharmaceutical patents are a new issue to the Brazilian Judiciary Power in view of the recent introduction of the patentability of pharmaceutical products and processes in the Brazilian body of laws.

Some court decisions, however, are starting to reveal a "public health" approach without conducting a proper balance between the two rights at stake. This approach is further facilitated with a court appeal (a kind of political appeal) which allows government agencies to revert court decisions ruling against them and "causing serious risk of damage to health and public order"¹².

In a decision rendered on May 5, 2005, the Court of Appeals for the Federal Circuit of Rio de Janeiro stayed the effects of the lower court decision, which ruled against ANVISA and INPI, establishing that the patent application at issue fulfilled the statutory requirements of novelty, inventive step and industrial applicability and, therefore, had to be granted despite ANVISA's denial of prior approval.

The appellate court decision took into consideration the fact that the patent application covered an antiretroviral drug. For this reason, ANVISA filed a political appeal asserting that the grant of the patent would cause severe damage to public health. The Court of Appeals reversed the court decision attacked in ANVISA's appeal, by deciding that:

"there was indeed a public health concern in the grant of the patent and that the public interest related to the case was clear in order to protect the citizens who need or will need the drug against the unbalance provoked in the market by the undue granting of a patent, for the irreversible harm to public health and economy, understood as the fight against diseases, ensuring the population the access to indispensable drugs¹³."

In an appellate court decision over the same drug, the panel of the Court of Appeals for the Federal Circuit of Rio de Janeiro also pointed out the public interest represented by the existence of collective legal interests, whose ownership spreads through the whole collectivity (public health and public economy). The decision, which was unanimous, stated that, "in the case at issue, the pharmaceutical product is an antiretroviral drug, of fundamental importance for the health public policies related to the treatment of citizens suffering from HIV¹⁴."

¹² Law #8,437, of June 30, 1992, determines in its article 4 that "It is of the court's president's authority [...] to stay, through a grounded decision, the enforcement of the decision in lawsuits filed against the public administration or its agents, by request of the public prosecutor's office or the public administration's representative in cases of evident public interest [...] to avoid serious damage to public order, health, security and economy".

¹³ AGTPT 2004.02.01.013399-0. Special Court, Vice President of TRF 2, Decision published on February 20, 2006.

¹⁴ Pet. 2008.02.01.000467-7, TRF 2, Decision rendered on April 25, 2008.

The public health assessment used by Brazilian judges is also applied to justify the admission of third parties in patent invalidity lawsuits. Public health is raised as an important issue that would apparently prevail over the patent holder's rights. An appellate court decision rendered on June 27, 2007 reveals this approach, as follows:

"It should be stressed that the Federal Constitution ensures to inventors of patents the temporary privilege for its use, in view of the social interest and the technological and economic development of the country (article 5, item XXIX), but the same *Lex Mater* also determines that the property shall observe its social function (article 5, item XXIII). It happens that the right to access to health, constitutionally ensured in the terms of article 196—since it leads with social rights, foreseen in article 6 of the Constitution—shall be equally observed in the present case. Considering that the drug which, by means of the initial lawsuit, is intended not to be patented, refers to the treatment of cancer, the alleged mistaken grant of the patent may cause serious damage to public health and public economy, specially in view of the fact that the monopoly of its manufacture would allow the abusive increase in its prices, with which the public interest is demonstrated as of being of utmost relevance¹⁵."

Courts are also applying the general principle of access to drugs as a means of denying the statutory right ensured to pipeline patents' holders to have their patents granted for the remainder of the term of their original foreign patents¹⁶. The majority of court precedents on the correction of pipeline patent terms are a clear evidence that judges usually deny the enforcement of the specific and express right contained in the Patent Act under the allegation that the "extension" of a pipeline patent term will be detrimental to public access to the patented drug.

The reasoning inserted in court decisions show that courts enforce a strict scrutiny over pharmaceutical patents, and most of the decisions tend to be harder to pharmaceutical patents' holders as compared with decisions ruling on patents covering other types of technology.

¹⁵ AI 2006.02.01.008434-2. TRF2 – 1.^a Turma Especializada, Reporting Judge Márcia Helena Nunes. Date of judgment: June 27, 2007.

¹⁶ §4 of article 230, of the Patent Act, establishes that pipeline patents "will be guaranteed the remainder of the term of protection in the country where the first application was filed, counted from the date of filing in Brazil and limited to the term defined in article 40".

Notwithstanding the provision, which is clear and express in what concerns pipeline patent terms, the INPI understands that pipeline patents must be granted for 20 years from the filing date of the first foreign application. Courts have been adopting the same understanding, by adding to their interpretation the known prejudice against pharmaceutical patents and tempering the decisions with public health and access to drugs to deny the correction of pipeline patent terms.

VI

BALANCING IP RIGHTS WITH PUBLIC ACCESS
TO INNOVATIVE DRUGS

Whenever a government act or court decision is rendered, the rights under discussion must be balanced, in accordance with the rules of constitutional interpretation. A proper balance does not consist of suppressing one of the constitutional rights by the other.

The axiomatic rule, which is not written anywhere in the Brazilian body of laws, determines that "the public interest must always prevail over the individual one". This rule is applied in most of the court decisions to justify the prevalence of public health rights over patent rights. However, in view of the two-pronged constitutional rights over an invention, the application of this axiomatic rule does not reflect a rational enforcement of the constitutional values at issue. Instead, the rule is applied as a means to treating the apparent conflict of constitutional rights as if they were diverging; while they are converging to the same end: public interest.

Specifically concerning patent rights, the balance to be conducted must also ponder the fact that the "temporary privilege" granted to an inventor is also convergent with the "public interest", inasmuch as it fosters the development of economy and technology, which benefits society with the promotion of more modern products.

The incentive to innovation is also one of the goals to be pursued by the State, in parallel to promoting the equal access to drugs to the population. However, as pointed out by Nuno Pires de Carvalho, with no protection to pharmaceutical patents that do not yet exist, or will never exist in view of the lack of incentive to innovation, there will be either no access to drugs¹⁷.

The proper balancing of rights must not include ungrounded prejudice against pharmaceutical patents, but must give the maximum enforceability to each of the rights at stake in order to reach a fair and rational decision¹⁸.

VII

CONCLUSION

Under the Brazilian Constitution, access to drugs and patent rights are equally guaranteed and respectively substantiated through public health policies and the

¹⁷ CARVALHO, Nuno Pires. *The TRIPS regime of patent rights*. The Netherlands. Kluwer Law International, 2005. p. 146-7.

¹⁸ BARCELLOS, Ana Paula de. *Ponderação, Racionalidade e Atividade Constitucional*. Rio de Janeiro: Renovar, 2005.

ÁVILA, Humberto. *Teoria dos Princípios: da definição à aplicação dos princípios jurídicos*. São Paulo, Malheiros, 2005, p. 96.

PEREIRA, Jane Reis Gonçalves. *Interpretação Constitucional e Direitos Fundamentais*. Rio de Janeiro: Renovar, 2006.

granting of patents, provided the statutory requirements are met (novelty, inventive step and industrial applicability).

Simply and generically stated, two values are at stake: human health and intellectual property rights. However, only apparently those two values are conflicting. Rather, the values are mostly convergent to the same target, i.e., to promote public health through the access to innovative drugs, which will foster research and development, in a growing technology advancement that will progressively benefit society.

The situations of conflict between patents of invention and access to public health are very restrict, and the Patent Act sets forth a legal remedy for each act of a patent holder which eventually hinders the access to a strategic drug. In other words, the Brazilian Patent Act provides for all the flexibilities set forth in the WTO Doha Declaration on TRIPS and Public Health.

One of the arguments contrary to pharmaceutical patents refer to the prices charged by its holders. However, besides the fact that drug prices are regulated by the Brazilian government, in case it is understood the patent holder is exercising its rights in an abusive manner, the patent may be subject to a compulsory license under article 68 of the Patent Act.

When two constitutional provisions are in apparent conflict, a decision, either administrative or judicial, must conduct a fair and equal balance between the values at issue in order to reach a rational outcome. Currently this does not seem to hold true in Brazil when it comes to pharmaceutical patents and public health, since the proper balancing is most of the times replaced by the enforcement of the axiomatic rule of "public interest over individual one" to justify the prevalence of public health over patent rights, as if they were divergent, instead of convergent, in accordance to article 5, item XXIX, of the Constitution.

A *prima facie* interpretation of the Brazilian constitutional provision ensuring public health (article 196) may lead to the wrong balancing between public health *vis-à-vis* the rights inserted in article 5, XXIX of the Constitution, which grants to inventors the right of obtaining the temporary protection to his/her invention.

Despite the fact that article 196 is not, essentially, a programmatic rule, since it foresees a *guarantee* to the right of health, such right is accomplished through the actions and services of the State, substantiated in social and economic policies seeking the lessening of risk of disease and other hazards. Therefore, article 196 poses an obligation to the State, and also raises a subjective negative right to request to the State to abstain from conducting acts which are not compatible with the constitutional provision¹⁹.

The right of access to health, therefore, encompasses several measures, positive and negative, which are the duty of the State, in order to confer efficacy to article 196.

Article 5, XXIX, on its turn, determines that the social interest is one of the goals of the patents of invention. Thus, the social interest is also accomplished by *the access to innovative drugs*, which promote the well-being of a society and, sometimes, provide the chance of survival of some patients. The guarantees stated through a

¹⁹ BARROSO, Luis Roberto. O Direito Constitucional e a efetividade de suas normas. Rio de Janeiro: Renovar, 2006.

patent of invention foster the unceasing research and development of new therapies for the treatment of maladies.

In light of the above, it is certain that the "access to drugs" contained in article 196 goes to the same direction of the objective sought by article 5, XXIX, to the extent that the access to innovative drugs benefits public health. The public perspective of article 5, XXIX converges to the same goal foreseen in article 196.