

### 3 A BRIEF NOTE CONCERNING PIPELINE PATENTS IN BRAZIL

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#### ABSTRACT

Until 1996, when Brazil changed its Industrial Property Law, there was no patent protection for pharmaceutical and food inventions and only process patents (and not product patents) existed for chemical inventions. To comply with the TRIPS Agreement, new Brazilian intellectual property laws extended patent protection to most areas of technology. A special and temporary provision was included in the law, the so-called pipeline system. By virtue of this provision, previously published inventions relating to pharmaceuticals and food were patentable in Brazil, provided that, *inter alia*, the resulting product had not entered the market. This controversial TRIPS-plus provision, which generated over 1,100 patents in Brazil, is now the subject of a constitutionality claim before the Brazilian Supreme Federal Court filed by the Attorney General.

*Keywords:* Brazilian pipeline patents, access to health, unconstitutionality

#### I. INTRODUCTION

This paper focuses on the controversial system of pipeline patents in Brazil and reviews the relevant provisions of the Industrial Property Law in force. Before proceeding with an analysis of the pipeline system, however, it provides a short historical overview of Brazilian industrial property laws. It further notes the mandatory changes in Brazilian Law standards in order to comply with international obligations. One of the innovations contemplated in the 1996 Industrial Property Law revoking the former Brazilian 1971 Industrial Property Code (Law 5772/71) was the establishment of the pipeline system.

As this paper demonstrates, the escalating costs of purchasing pharmaceutical drugs negatively impacted on the country's health budget. The costs of these drugs had risen because the subject matter of most pipeline patents was pharmaceutical products. Furthermore, this paper also explores the standpoint of competitors and consumers on the pipeline system; the competitors have a legitimate expectation of exploring the public domain technology market, and the consumers have the possibility of buying newly patented medicines at a lower price.

Amid the social conflicts of interests among competitors, consumers and private right holders stemming from the pipeline system, especially those concerning the effects of the binding provisions of the Brazilian Constitution, in 2009 the Federal Attorney General filed a constitutionality claim against the pertinent provision of the 1996 Industrial Property Law before the Brazilian Supreme Federal Court. For the purposes of this paper, the main arguments used by the plaintiff and the *amici curiae* briefs filed are described.

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In the concluding sections of this paper, a summary of the arguments developed in the previous sections are presented, demonstrating the unconstitutionality of the pipeline system in Brazil and its failure to fulfil principles mandatory to the public interests.

## II. A SHORT HISTORICAL OVERVIEW OF BRAZILIAN INDUSTRIAL PROPERTY LAW

Brazil has a longstanding tradition of intellectual property protection. In fact, the first pertinent national law was enacted in 1809 (the so called *Alvará*) by the King of Portugal and Brazil, King D. John VI. Its purpose was to regulate external trade, especially with the British, to stimulate foreign investments in Brazil, and to grant patents to subject matter that succeeded in proving local innovation.

Notwithstanding the contemporaneous view of international novelty standards, intellectual property protection in Brazil evolved more as a means of attracting industries to the country, rather than promoting the invention of novel subject matter. A new invention not previously worked in the country, even though the respective invention was already known or worked elsewhere, was deemed novel under Brazilian law.

Fifteen years later, the 1824 Constitution<sup>1</sup> included a patent protection norm in its Bill of Rights list; some provisions to that end remained in all the following six Constitutions (1891<sup>2</sup>, 1934<sup>3</sup>, 1946<sup>4</sup>, 1967<sup>5</sup> and 1969<sup>6</sup>) and are still mentioned in the fundamental rights embodied in the 1988 Constitution, which is still in effect.<sup>7</sup> Even though the wording regarding patent protection varied in the provisions of these Constitutions, there was always a property approach towards technological intangible assets.<sup>8</sup>

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<sup>1</sup> Article 179, XXVI. Available online at:

<[http://www.planalto.gov.br/ccivil\\_03/constituicao/constituicao24.htm](http://www.planalto.gov.br/ccivil_03/constituicao/constituicao24.htm)> accessed 18 June 2012.

<sup>2</sup> Article 72, §25. Available online at:

<[http://www.planalto.gov.br/ccivil\\_03/constituicao/constituicao91.htm](http://www.planalto.gov.br/ccivil_03/constituicao/constituicao91.htm)> accessed 19 June 2012.

<sup>3</sup> Article 113, §18. Available online at:

<[http://www.planalto.gov.br/ccivil\\_03/constituicao/constituicao34.htm](http://www.planalto.gov.br/ccivil_03/constituicao/constituicao34.htm)> accessed 19 June 2012.

<sup>4</sup> Article 141, §17. Available online at:

<[http://www.planalto.gov.br/ccivil\\_03/constituicao/constitui%C3%A7ao46.htm](http://www.planalto.gov.br/ccivil_03/constituicao/constitui%C3%A7ao46.htm)> accessed 19 June 2012.

<sup>5</sup> Article 150, §24. Available online at:

<[http://www.planalto.gov.br/ccivil\\_03/constituicao/Constitui%C3%A7ao67.htm](http://www.planalto.gov.br/ccivil_03/constituicao/Constitui%C3%A7ao67.htm)> accessed 19 June 2012.

<sup>6</sup> Article 153, §24 has the same law text as the previous 1967 Constitution. Available online at:

<[http://www.planalto.gov.br/ccivil\\_03/constituicao/emendas/emc\\_anterior1988/emc01-69.htm](http://www.planalto.gov.br/ccivil_03/constituicao/emendas/emc_anterior1988/emc01-69.htm)> accessed 9 June 2012.

<sup>7</sup> Free translation of former Article 5, XXIX: 'The Law will guarantee to the authors of industrial inventions the temporary privilege for its use, as well as the protection to the industrial creation, the property of trademarks, the trade names and other distinctive signs, considering the social interest and the technological and economic development of the Country'.

<[http://www.planalto.gov.br/ccivil\\_03/constituicao/constitui%C3%A7ao.htm](http://www.planalto.gov.br/ccivil_03/constituicao/constitui%C3%A7ao.htm)> accessed 19 June 2012.

<sup>8</sup> 'Not only goods, or tangible assets, but also intangible assets can be classified as being of the nature of [property], for example: the commercial point, the copyright or the rights of the owner of an invention. On this view, property is conceived of as an extension and variety of aspects that could not correspond to those of Roman Law; in other words, there is no longer [the notion of] property, but *properties*, because each category of goods will support a private form of appropriation: the plasticity of property law in infinite', translated from Oscar Barreto Filho, *Teoria do Estabelecimento Comercial – Fundo do Comércio ou Fazenda Mercantil* (Saraiva 1988).

Brazil was a founding member and active contributor to portions of the Paris Convention of 1883<sup>9</sup>, which was elaborated on international standards of intellectual property law. Furthermore, Brazil acceded to the Berne Convention on 6 February 1922<sup>10</sup>, signed the Patent Cooperation Treaty on 19 June 1970, and became a Member of the World Trade Organization on 1 January 1995.<sup>11</sup>

Although Brazil has always fully recognized the intellectual property system, in light of the social impact of exclusive patent rights, it excluded from 1945 some fields of technology from patent protection protected in most OECD countries at the time. In fact, the Brazilian Industrial Property Code of 1945 (and the ensuing Laws up to 1996) banned the issuance of all food and pharmaceutical patents, along with chemical product patents; this exclusion was entirely compatible with the treaties then in force.<sup>12</sup>

Therefore, publications of a patent specification, for instance made abroad or in Brazil, for food and pharmaceutical inventions, turned the pertinent teachings into a part of the Brazilian public domain. The purpose of Brazil's public policy was to protect its undeveloped industries from international competition, and to avoid the establishment of artificial barriers that could minimize access to products or services deemed necessary for the development of the Brazilian economy and society.

The refusal to grant patent protection in health and food-sensitive areas, in addition to being compatible with the international treaties in force, was also deemed compliant with the Brazilian Constitution<sup>13</sup> (and its internal technological development purposes), which guarantees minimum standards of State protection of fundamental rights.

To conclude, it is necessary to consider the historical efforts of patent protection from both a national and international perspective. Such protection has acted as an instrument to promote innovation in Brazilian law, since it simultaneously complies with the social, technological and economic development targets of the Constitution.

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<sup>9</sup>Information available online at:  
<[http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty\\_id=2](http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2)>  
accessed 18 June 2012.

<sup>10</sup>Information available online at:  
<[http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty\\_id=15](http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=15)>  
accessed 18 June 2012.

<sup>11</sup>Information available online at:  
<[http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm)> accessed 19 June 2012.

<sup>12</sup> Regarding the obligations concerning the Paris Convention (Article 2(1)), as Brazil accorded equal treatment to both nationals and foreigners concerning the prohibition of patent granting in those niches, there was no violation in the adoption of the aforementioned public policy.

<sup>13</sup> Free translation of Article 196 of the Constitution in force: 'Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic politics aimed at reducing the risk of illness and at universal and equal access to actions and services for its promotion, protection and recovery'. Even under the previous 1967 Constitution, the Supreme Court declared constitutional the refusal of pharmaceutical patents (Decision of April 13, 1982, RE 94.468-1-RJ).

### III. THE TRIPS AGREEMENT AND THE NEW INTELLECTUAL PROPERTY LAW IN BRAZIL

As usually noted by legal commentators, most developing countries had a lower level of intellectual property protection before the entry into force of the WTO Agreement, most probably because of their own internal political welfare standards. These economically underprivileged countries agreed to expand intellectual property rights in their struggling economies. Bilateral and regional trade agreements, in which other parties subjected less powerful governments to significant political and financial pressure, further enhanced intellectual property protection after the WTO Agreement entered into force.

According to developed countries, in what could be deemed a self-centered view of innovation and intellectual property systems, the gap between the average level of intellectual property protection prevailing in the highest stage capitalist economies and the optimum level of protection for those countries still seeking to create a minimum national structure was incompatible with the promotion of what developed countries considered fair trade.

The huge consumer market of the developed countries was attractive to countries in other stages of economic development, which had an adequate productive scale ability (lower wages, cheaper materials, more basic assets quantity etc.). Developing countries wanted to guarantee reasonable tariffs on their exported goods. In the short term, it was argued that conceding to a level of intellectual property protection that could be deemed in excess of the optimal level of protection would result in greater access to the OECD markets.

Therefore, hard TRIPS Agreement negotiations were 'necessary' for the establishment of a multilateral system inclusive of a generally higher<sup>14</sup> standard of intellectual property protection<sup>15</sup> for developing and least developed countries. To achieve such a system, developed countries used increased access to their huge consumer markets as a bargaining tool.<sup>16</sup> A sad note in this context is that the design of the WTO multilateral trading system was perceived to avoid and dilute unilateral pressure, especially on developing countries.<sup>17</sup>

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<sup>14</sup> '[E]xperience shows that emerging economies are, in fact, greatly challenged by the costs and hardship associated with adjusting their development strategies to new legal realities and that successive rounds of negotiations tend to reduce the flexibilities available for nations to tailor intellectual property law to their own needs' in Jerome H. Reichman and Rochelle Cooper Dreyfuss, 'Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty' [2007] 57 Duke L J 85.

<sup>15</sup> 'Serving as key leaders of the in the developing world, both Brazil and India had been vocal about their opposition to the inclusion of new substantive intellectual property norms in the GATT'. in Peter K. Yu, 'The Objectives and Principles of the TRIPS Agreement' [2009] 46 Houston L Rev 79.

<sup>16</sup> 'Developing country Parties to the GATT, therefore, had not committed themselves to accept rules that expanded IP protection. What happened then between Punta del Este (1986) and Montreal, where the Mid-Term Review Decision was adopted, in 1989, and in which the mandate for negotiators to conclude an Agreement covering standards became also unequivocally mandatory? (...) The answer is that developing country Parties to GATT understood (or were led to understand) in the meantime that a future Agreement on TRIPS would protect them against unilateral sanctions by developed country partners because of their failure to protect the IP rights of developed countries' citizens' in Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* (Kluwer Law International 2002).

<sup>17</sup> 'The Understanding leaves no doubt that it is intended to strengthen the multilateral trading system. In an article clearly signalling this intent, entitled 'Strengthening of the Multilateral System', the ministers impose upon the member states a requirement to seek 'recourse to, and abide by, the rules and procedures of this Understanding', when seeking redress of a 'violation of obligations or other

The entry into force of the TRIPS Agreement with its new basic mandatory standards<sup>18</sup> obliged legislators throughout the globe to produce new internal norms. Owing to the natural need to treat unequal societies in a fair manner<sup>19</sup>, the TRIPS Agreement provided flexibilities for the application of the new rules, in particular for developing countries. One important example was time application differentiation.

Such flexibilities included a longer period of time for incorporating most TRIPS Agreement obligations: for developing country Members and those in transition, a period of five years until 1 January 2000; and for developed country Members, most of which had legislation already in accordance with the TRIPS Agreement, a one-year period. A ten-year deadline was also given for those developing countries that did not offer protection for specific areas of technology such as pharmaceuticals.

Therefore, although Brazil had the right to delay the implementation of the TRIPS Agreement up to 1 January 2000, and certain provisions (protection of pharmaceutical and agrochemical subject matter, pursuant to Articles 65.1, 65.2 and 65.4 of the TRIPS Agreement) until 2005, it voluntarily enacted the 1996 Industrial Property Law before the mandatory deadline. In anticipation, the Brazilian Government abdicated a substantial opportunity to invest in its local welfare, especially in the frailest technology sectors.

As a matter of fact, before 2000 (the general deadline for developing countries to implement the TRIPS Agreement), Brazil approved its plant varieties law (9.456/97), its software law (9.609/98), and its new provisions on authors' right (9.610/98). Just after the 2000 deadline, Brazil passed an unrequired data protection exclusivity law (10.503/2002) to complete its intellectual property adaptation 'package'.

Under the new 1996 Industrial Property Law, the pipeline system enabled a new claim by the right holder to an invention that included content in the public domain. The pipeline system was therefore a voluntarily adopted TRIPS-plus legal device that significantly affected public access to technology.

The pipeline provision (thereafter accepted unilaterally by Mexico)<sup>20</sup> was proposed by the United States during the TRIPS Agreement negotiations and formally refused by negotiating

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nullification or impairment of benefits' under the covered agreements. Article 23 goes on to specify that the members 'shall (...) not make a determination to the effect that a violation has occurred (...) except through recourse to dispute settlement in accordance with the rules and procedures of this Understanding. ... 'In short, the Understanding leaves no doubt that freelance, unilateral, or even unauthorized bilateral dispute resolution is not acceptable'. Michael Young, 'Dispute Resolution in the Uruguayan Round - Lawyers Triumph over Diplomats' [1995] 29 Intl Lawyer 389 (1995).

<sup>18</sup> See Denis Borges Barbosa, 'Minimum Standards v Harmonization in the TRIPS Context: the Nature of Obligations under TRIPS and Modes of Implementation at the National Level in Monist and Dualist systems' in Carlos M. Correa, *Research Handbook on the Interpretation and Enforcement of Intellectual Property Under WTO Rules* (Edward Elgar Publishing Ltd 2010).

<sup>19</sup> Free translation. 'because, people being unequal, they should not have an equal portion' in Aristotle, *Ética a Nicômaco*. Tradução, textos adicionais e notas: Edson Bini (Editora Edipro 2007).

<sup>20</sup> Article 12 of the Mexican Law of Industrial Property, in force as of 28 June 1991 'all applications covering inventions that were not patentable under the prior law and that had been filed in a member country of the Patent Cooperation Treaty (PCT), prior to the date of enactment of the new law, could be subject to the filing of a valid patent application in Mexico, with recognition of convention

parties.<sup>21</sup> As demonstrated in Section IV, the basic premise of the pipeline system was to revoke public domain subject matter, and to base a local patent on a grant made abroad.

On the contrary, the TRIPS Agreement expressly exempted from protection acts which occurred before the date of application of the Agreement for the Member in question. Furthermore, it did not create an obligation to restore protection to subject matter which, on the date of application of the Agreement for the Member in question, fell into the public domain, as mentioned in Articles 70.1<sup>22</sup> and 70.3.<sup>23</sup>

Thus Brazil made a fast-track effort to adapt its internal intellectual property laws to the international standards set by the multilateral WTO Agreements, irrespective of whether the standards focused on promoting internal welfare. Brazil's preferred external policy of resisting most of the changes proposed by the developed countries and its voluntary acceptance of a TRIPS-plus device showed lack of a coherent position.<sup>24</sup>

#### IV. THE PIPELINE SYSTEM AND CONFLICTS IN ACCESS TO HEALTH

Under the pipeline system, the Brazilian Patent and Trademark Office (PTO) automatically dispensed with the examination of the patentability requirements of novelty, inventive step and industrial application for patents granted in another country. In many cases, this led to the issuance of a revalidation patent. Even the foreign filings already published (and therefore in the Brazilian public domain) concerning subject matter excluded from patentability at the time of filing in Brazil were considered by the Brazilian PTO. The only inventions essentially excluded from protection under the pipeline system were those already introduced in the market (anywhere in the world) at the date of the revalidation filing in Brazil.

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priority on the first application filed in any one of said countries and regardless of prior disclosure, provided that the following conditions, disclosed in Article 12 transitional, were met: - The corresponding Mexican patent application was filed within 12 months of the enactment of the law; the application should be filed by the first applicant of the corresponding foreign application or by the assignee thereof; - The applicant could prove to have filed the application in any of the member countries of the PCT or could prove to have obtained the corresponding patent; and - The exploitation of the invention, or the import on a commercial scale of the patented product or of the product obtained by the patented process, had not been initiated by any person in Mexico, prior to the filing of the application in Mexico'. Amalia Bagües, *The End of Pipeline Patents in Mexico* available online at: <<http://bcb.com.mx/Publicaciones/2010/WIPR/WIPRMayJune2010.pdf>> accessed 5 November 2012.

<sup>21</sup> UNCTAD-ICTSD, *Resource Book on Trips and Development* (2005).

<sup>22</sup> TRIPS Article 70.1: 'This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question'.

<sup>23</sup> TRIPS Article 70.3: 'There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain'.

<sup>24</sup> This can be established as a clear conflict of interests between foreign politics and national lobbies in Congress. For details concerning the interests at play at the time, see Garcia and Mendes di Blasi, *A Propriedade Industrial* (Forense 2000).

Accordingly, Article 230 of Law 9.279/96 provides:

A patent application may be filed relating to substances, matters or products obtained by chemical means or processes, food and chemical-pharmaceutical substances, matters, mixtures or products, and medicaments of any kind, as well as the respective processes of obtaining or modifying them, by any person entitled to protection under a treaty or convention in force in Brazil, and the date of the first filing abroad shall be recognized, provided that subject matter has not been placed on any market by direct initiative of the proprietor or by third parties with his consent, nor have third parties carried out, in this country, serious and effective preparations for exploiting the subject matter of the application or patent.

Patent revalidation was not an original<sup>25</sup> binding provision in Brazil<sup>26</sup> or abroad<sup>27</sup>, as the principle of the independence of patents in the Paris Convention (Article 4*bis*) enabled full discretion to each patent and trademark office to establish its own examination criteria.

Nevertheless, under the pipeline system more than 1,100 pipeline applications were filed concerning subject matter that was in the public domain in Brazil. Many blockbuster pharmaceutical right holders benefited<sup>28</sup> under the pipeline system, with protection being granted for medicines to treat diseases such as cholesterol (Lipitor)<sup>29</sup>, thrombosis (Plavix)<sup>30</sup>, aids (Kaletra)<sup>31</sup>, cancer (Zyprexa)<sup>32</sup>, schizophrenia (Seroquel)<sup>33</sup>, and erectile dysfunction (Viagra).<sup>34</sup>

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<sup>25</sup> Free translation: 'Men walk, almost every time, by paths built by others and act by imitation' in Nicolau Machiavelli, *O Príncipe* (Editora Centauro 2001).

<sup>26</sup> As stated, the 1809 Brazilian Alvará protected the importation of an already known technology, however the Brazilian law up to 1883 did not assure exclusive rights to foreign inventors who did not work their inventions in Brazil.

<sup>27</sup> '[T]he duration of the patent of importation may be made dependent on the duration of a foreign patent which is the basis of the grant of the patent of importation'. G H Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property* (United International Bureaux for The Protection of Intellectual Property - BIRPI 1968) p 62.

<sup>28</sup> 'Inventions are Patentable Despite a Lack of Perceptible Public Benefit'. David Vaver, *Intellectual Property Law* (2nd edn Irwin Law 2011).

<sup>29</sup> Patent number PI 1100079-1. This patent was also the object of a deadline postpone litigation between the right holder Warner-Lambert and the Brazilian PTO, filed before the Second Circuit Federal Region Court (TRF-2) under the docket 00233326119994025101 (originally before the 14<sup>th</sup> first instance Federal Trial Court).

<sup>30</sup> Patent numbers PI 1100113-5 and PI 1100111-9. These patents were also the object of a deadline postpone litigation between the right holder, Sanofi-Synthelabo, and the Brazilian PTO, filed before the Second Circuit Federal Region Court (TRF-2) under the docket 05243877720054025101 (originally before the 37<sup>th</sup> (13<sup>th</sup>) first instance Federal Trial Court).

<sup>31</sup> Patent number PI 1100397-9. This patent was also the object of a invalidation claim litigation between a national pharmaceutical company, Cristalia, against the right holder, Abbott and the Brazilian PTO, filed before the Second Circuit Federal Region Court (TRF-2) under the docket 08083895420094025101 (originally before the 39<sup>th</sup> (9<sup>th</sup>) first instance Federal Trial Court).

<sup>32</sup> Patent number PI 1100012-0. This patent was also the object of a deadline postpone litigation between the right holder, Eli Lilly, and the Brazilian PTO, filed before the Second Circuit Federal Region Court (TRF-2) under the docket 05345626720044025101 (originally before the 37<sup>th</sup> (13<sup>th</sup>) first instance Federal Trial Court).

While mentioned as a fundamental right in the Brazilian Constitution, whether technologies may be protected by patents depends on their ability to fulfil the concept of 'invention'. Since the idea of an 'invention' stems from the novelty<sup>35</sup> requirement and is intimately linked to the concept of *ordre public* under the Brazilian system, the first constitutional infringement perpetrated by the pipeline system concerns the novelty criteria.

In fact, although the 1996 Industrial Property Law allowed for the revalidation of technologies that were not considered new, it is argued that the Brazilian Congress does not have the power to edit legislation that is contrary to the national Bill of Rights.<sup>36</sup> As the Brazilian democratic system is based on the supremacy of the Bill of Rights over any other binding norm, a law contrary to the Constitution is void as unconstitutional.

As noted by legal commentators<sup>37</sup>, the novelty requirement imposes a balance between the society, the State and the right holder, since the latter will benefit from an exclusive right

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<sup>33</sup> Patent number PI 1100099-6. This patent was also object of a deadline postpone litigation between the right holder Zeneca and the Brazilian PTO, filed before the Second Circuit Federal Region Court (TRF-2) under the docket 200651015003322 (originally before the 38th (31st) first instance Federal Trial Court).

<sup>34</sup> Patent numbers PI 1100088-0 and PI 1100028-7. These patents were also the object of a deadline postpone litigation between the right holder, Pfizer, and the Brazilian PTO, filed before the Second Circuit Federal Region Court (TRF-2) under the docket 00257682719984025101 (originally before the 23rd first instance Federal Trial Court).

<sup>35</sup> [P]articularly where the prior art and the invention are identical or the prior art leads directly to the patented invention, it will be relatively easy to determine whether an invention has been made available to the public' in Lionel Bently and Brad Sherman, *Intellectual Property Law* (2nd edn Oxford Press 2004).

<sup>36</sup> *Graham v John Deere Co* 383 U.S. 1 (1966) ('Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available. Innovation, advancement, and things which add to the sum of the useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of (...) the useful Arts'. This is the standard expressed in the Constitution and it may not be ignored. And it is in this light that patent 'validity requires reference to a standard written into the Constitution'.

<sup>37</sup> From the second point of view, the novelty requirement finds its justification in the harsh effect of the exclusivity right in respect of inventions and utility models, and therefore demands a normative publicity. Exclusivity, in fact, is not coordinated with the promotion of technical development, but focuses on publishing the inventions during the patent administrative procedure. So the focus on the public utility of the invention is fulfilled when it may be used by everyone, because the exclusivity effect must be coordinated with the possibility of the society benefiting from the technological content once the patent has expired (...). The publication of the invention by the inventor extinguishes the patentability and, therefore, puts an end to the possibility of acquiring an exclusivity right in the technology invented, since it terminates the possibility to constitute an exclusivity asset. The publicity – before the exclusivity request – extinguishes the right because it cannot any longer fulfil the function of stimulation and inducement which, in other circumstances, would be a consequence of the invention and of the possibility (in terms of the publicity connected with the patent and the limitation of the exclusivity rights period) of general use (...). The examination of novelty finds its justification, first in a guarantee of a serious patenting procedure, and in the protection of the society's interest against the establishment of a patent when a new technology is not present'in Tullio Ascarelli, *Teoria della concorrenza e dei beni immateriali* (Dott A. Giuffrè 1960).



which results in loss to others. Therefore, the novelty requirement functions as an equitable means to justify monopoly rights.<sup>38</sup>

The other issues criticized by many legal authors<sup>39</sup> concern the paradox that the pipeline system achieves Brazilian constitutional goals, including (a) culture;<sup>40</sup> (b) competition; (c) public funding welfare; (d) health; and (e) public domain as a universal freedom (including consumers' choice). While one purpose of intellectual property rights is supposedly to diffuse knowledge, culture and science, this premise is built on the necessity of exchanging exclusivity for technical or expressive innovation. If there is no innovation, there is no point in property rights preventing societies from accessing cultural or technical goods.

Indeed, with the introduction of a retrospective property system taking information out of the public domain, pharmaceutical prices rose sharply once competition (potential players that could enter those technological markets) was excluded. However, the exclusion of competitors as a result of the pipeline system was not the only harmful effect: concentrated offer market directly impacts consumers.

Considering the competitive loss resulting from the advent of the pipeline system, some 1,400 chemical and pharmaceutical industrial plants closed down or discontinued production within five years of the introduction of the pipeline system in Brazil.<sup>41</sup> Manufacturing of pharmaceutical active ingredients was entirely discontinued, and nearly all products protected by the pipeline system entered the Brazilian markets through importation.

Nonetheless, Brazil has a universal health access system that obliges the national Government to provide some designated pharmaceuticals for those that cannot afford them. Therefore, although the factual monopsony could empower the government to a stronger position to negotiate costs, right holders (enforcing their exclusive rights) were able to fix prices that far exceeded the Brazilian health budget. Considering the essential public demand of almost 200 million people, the pipeline patent holders stood to gain billions of dollars from the

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<sup>38</sup> English Statute of Monopolies (1621) Article 6(a) ('Provided also, that any declaration before mentioned shall not extend to any letters patents (b) and grants of privilege for the term of fourteen years or under, hereafter to be made, of the sole working or making of any manner of new manufactures within this realm (c) to the true and first inventor (d) and inventors of such manufactures, which others at the time of making such letters patents and grants shall not use (e), so as also they be not contrary to the law nor mischievous to the state by raising prices of commodities at home, or hurt of trade, or generally inconvenient (...)').

<sup>39</sup> Denis Borges Barbosa, *A Inconstitucionalidade das Patentes Pipeline* (2006). Available online at: <<http://denisbarbosa.addr.com/pipeline.pdf>> accessed 3 November 2012; Pedro Marcos Barbosa, 'Patentes Pipeline: Uma Análise sobre os Dispositivos Pertinentes da Lei 9.279/96' [2012] 16 2nd Federal Circuit Magazine (TRF-2). Available online at: <<http://www.trf2.gov.br/emarf/documents/revistaemarfvoll6.zip>> accessed 3 November 2012.

<sup>40</sup> 'Between the secret and the information, Laws focused to promote an 'Estate of Culture' should choose in favour of information and for its free circulation: in a way that a secret only is justified by reasonable reasons (...)' Pietro Perlingieri, *O Direito Civil Na Legalidade Constitucional* (Renovar 2008).

<sup>41</sup> Data provided by ABIFINA (generic and similar pharmaceutical and agrochemical association in Brazil).

sale of technologies already in the public domain at the time of filing of the patents in Brazil by essentially selling to the Ministry of Health.<sup>42</sup>

Another issue with the pipeline system concerns the Bill of Rights provision that only protects intellectual property provided it is used for the promotion of internal welfare and economic or technological development<sup>43</sup> (Article 5, XXIX). Since most players in the economy that benefited from the pipeline system were foreign companies (which, as it happened, did not provide employment, restrained industrial investment in Brazil and in essence sent royalties abroad), it may be said that beyond other violations, the functioning of the pipeline system was inconsistent with the intellectual property protection goals embodied in the Constitution. Therefore, those parameters demonstrate its inherent and abstract lack of constitutional status.<sup>44</sup>

The provision not only directly adversely impacted health and social rights, but it also had political implications. Brazil became the subject of international criticism originating from the first national compulsory licence in the Efavirenz case, which was a pipeline patent. The right holder was eager to create an unfavourable environment for the Brazilian Government, accusing the Ministry of Health of abuse. After a long period of negotiation, the Brazilian Government chose to utilize the TRIPS Agreement flexibility in Article 31. Rather than burning political ammunition to enable a compulsory licence, Brazil should have designed a patent system that excluded from patentability technology in the public domain.

In April 2009, the Brazilian General Public Attorney filed a constitutionality claim (docket 4234) before the Brazilian Supreme Court, which has not been adjudicated upon. The plaintiff and amici curiae argued relevant issues such as: (1) lack of novelty would offend Brazilian *ordre public*; (2) revocation of public domain without compensation violates the constitutional provision on expropriation measures; (3) Brazilian sovereignty is offended by a revalidation of a foreign patent office analysis that binds the Brazilian PTO; (4) Congress is not entitled to remove technologies from the public domain by simply editing federal law (to which constitutional provisions are superior); (5) public (free, capitalist) market<sup>45</sup> competition was avoided concerning technologies in the public domain, which violated the Brazilian Constitution (Article 170, IV); (6) major changes to consumer law to the detriment of consumer protection

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<sup>42</sup> Examples of pharmaceuticals from the pipeline provisions that induced high costs to the Health Budgets include pipeline patents for Lung Cancer (Alimta) – Box 50ml – US\$3,800.00; (HAP/LHP) Arterial and Lung Hypertension (Tracleer) – Box 60 pills – US\$8,800.00; and Aids (Kaletra) – Box 120 pills – US\$800.00. The current minimum wage in Brazil is US\$350.

<sup>43</sup> Concerning the TRIPS Agreement provisions: 'IPRs should work 'in a manner conducive to social and economic welfare'. This means that the recognition and enforcement of intellectual property rights are subject to higher social values (...)'. Carlos Maria Correa, *Trade-Related Aspects of Intellectual Property Rights* (Oxford University Press 2007).

<sup>44</sup> Free translation: 'All unjust dispositions, all evil institutions, such as recognized by the people, imply an attack on the Law spirit of the nation and, by consequence, on the national power' in Rudolf Von Jhering, *A Luta Pelo Direito* (Forense 1972).

<sup>45</sup> Free translation: 'The market is not a natural creation or a spontaneous result of a developing process, but a political choice, always demanding the State's intervention, tracing its limits' in Eroulth Junior Cortiano, *O Discurso Jurídico da Propriedade seus Rupturas: Uma Análise do Ensino do Direito de Propriedade* (Renovar 2002).

and access<sup>46</sup> to health; (7) violation of the principle of the independence of patents in the Paris Convention (Article 4*bis*); and (8) since most of the right holders were foreign companies, and the law essentially was detrimental to Brazilian citizens and Brazil's economy, it also violated the equal rights<sup>47</sup> clause in the Bill of Rights.

Even though the Supreme Court has yet to issue its decision on this constitutional claim, the Ninth Federal Trial Court of the Second Federal Circuit<sup>48</sup> ruled the pipeline system unconstitutional, declaring an HIV Pharmaceutical Patent (Kaletra) void. As rulings declaring incidentally a law unconstitutional do not have an *erga omnes* effect (Supreme Court decisions in a direct constitutional claim render the law itself void), and as the right holder appealed to the Appellate Court of the Second Federal Circuit, the final decision of this individual dispute is unpredictable.

## V. CONCLUSION

Despite the enormous public, economic, competition and health concerns at stake, the Supreme Court is not expected to issue a decision before 2013 or 2014, and even though all of the pipeline patents issued will fall into the public domain by 2017, they still consistently affect the health budget.

The ruling will impact future legislative elaboration and immediately affect the royalties sent abroad from the patents, since the Supreme Court's decisions considering unconstitutional claims may result in an *ex tunc* effect.

While the WTO Agreement has actually helped Brazil correct its irrational acceptance of TRIPS-plus commitments, the pipeline system has arguably failed to comply with the Bill of Rights clause allowing for the protection of intellectual property only to the extent it pursues the social interests and provides for Brazil's economic and technological development.

The contention, therefore, is that the pipeline system included in the 1996 Industrial Property Law is unconstitutional, as it ultimately benefited a restricted number<sup>49</sup> of non-local economic players to the exclusion and detriment of millions of Brazilians and their Government. The pipeline system was essentially forged on an abstract model. It is also contrary to the goals established by the Bill of Rights. In conclusion, the implementation of the pipeline system

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<sup>46</sup> Free translation: 'In this connection, it could be said that this subjective right must focus on the society as a whole, in such a way that the property right can be understood as also involving access to the property right' in Luiz Edson Fachin, *Teoria Crítica do Direito Civil* (Renovar 2003).

<sup>47</sup> Free translation: 'It is also forbidden to create benefits restricted to foreign groups, to the detriment of nationals, especially if the former enjoy the benefit, as a specific prerogative, of high-level technologies, since this would deny the first principle of an independent State, which is the protection of its nationals, apart from running counter to the idea of authentic national development' in Celso Antônio Bandeira de Mello, *O Conteúdo Jurídico do Princípio da Igualdade* (Malheiros 2010).

<sup>48</sup> Patent number PI 1100397-9. This patent was also the object of an invalidation claim litigation between a national pharmaceutical company, Cristalia, against the right holder, Abbott, and the Brazilian PTO, filed before the Second Circuit Federal Region Court (TRF-2) under the docket 08083895420094025101 (originally before the 39th (9th) first instance Federal Trial Court).

<sup>49</sup> 'If the power cannot be trusted to all members of the social body, it should, in any hypothesis, be applied in the benefit of all, and not only for some; nonetheless in the exclusive profit of the powerful' in Fábio Konder Comparato, 'O Poder de Controle na Sociedade Anônima' (Revista dos Tribunais 1976).

failed to comply with the minimum requirement of balance of interests with a view to development as provided in the TRIPS Agreement.<sup>50</sup>

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<sup>50</sup> TRIPS still relied heavily on national political processes to ensure appropriate balance. If one is to find balance embedded in the TRIPS context, it can only be found by recognizing that in return for accepting restrictions on national autonomy to maintain unduly low levels of intellectual property protection, developing countries secured benefits in terms of market access and technology transfer. That is, the balance embodied in the 1994 WTO agreements was not a balance intrinsic to intellectual property law, which we find in the domestic political context, nor even a balance that also figured in the right mix of universal standards versus national autonomy, which we find in the classical international intellectual property. Rather, TRIPS added a third vector: policy objectives secured by a balance of intellectual property rights and other tools of economic development'. Graeme B Dinwoodie, 'The Global Politics of Intellectual Property' (unpublished manuscript 2006, on file with the author).

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