

\* Original Article

## **Intellectual property and public health: the role of the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária - ANVISA) in pharmaceutical patenting in Brazil**

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### **Summary**

This article aims to present results of a study on the examination of pharmaceutical patent applications held by the National Health Surveillance Agency (Anvisa), known as prior informed consent. The implementation of patent examination within the Anvisa - health regulatory agency in the country - is an example of using adapting devices of the TRIPS Agreements of the World Trade Organization (WTO) and instrument of promotion of the right to health. With adherence to the TRIPS Agreement, Brazil was taken to recognize patents for pharmaceutical products and processes, which resulted in the enactment of the Industrial Property law (Law 9,279 of 1996). The temporary monopoly created by patentability interferes with access to medicines and health policies, in particular in the pharmaceutical area. To reduce this interference, Brazil implemented, starting in 1999 (with the creation of prior informed consent), a specific procedure for the examination of pharmaceutical patents, done in two steps: in the Industrial Property National Institute (INPI) and the Coordination of Intellectual Property of Anvisa (Coopi-Anvisa). The practice resulting from this measure is permeated today by numerous conflicts and tensions involving different sectors of Brazilian society. The study of this experience was based on specialized literature, on press material examination, patent applications, laws and decrees relating to medicines and intellectual property and in interviews with those responsible for the operation of the prior informed consent.

**Keywords:** patents; intellectual property; access to health; Anvisa

## Introduction

In 1996, the Brazilian National Congress approved a new Brazilian Industrial Property Law (IPL) - Law no. 9,279 of May 14, 1996, which became effective in 1997 and expanded the scope of goods subject to patent protection. A patent is the exclusive right of use granted by the State to the holder of an invention. At the end of the protection period, the invention falls into the public domain and others may exploit it. According to the IPL, certain basic technical requirements must be met in order for a patent application to be granted: the invention must be novel (that is, it must never have been made public before the filing date of the patent application), it must be the result of inventive activity (the product or process must result from an inventive effort and not just be the obvious consequence of a technical process for a technician in a given field of knowledge) and it must have industrial applicability (it must be proven that the invention can be used or produced).

In 2001, the new IPL was modified to require *prior* legal approval for patent applications in the pharmaceutical field. Until then, applications for patents in all fields of knowledge were only reviewed by the National Institute of Industrial Property (Instituto Nacional da Propriedade Industrial - INPI), which is an organization attached to the Ministry of Development, Industry and Foreign Trade.<sup>1</sup> From 2001 onward, the granting of patents involving pharmaceutical products and processes also depends on prior approval from The National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária - Anvisa) under the Ministry of Health. In other words, patent applications in the pharmaceutical field would still be evaluated by INPI, but the final decision would be given after a newly mandated technical examination was conducted by Anvisa's Office of Coordination of Intellectual Property (Coordenação de Propriedade Intelectual da Anvisa - Coopi-Anvisa), which had been created for this purpose.

This important innovation in the regulation of intellectual property for pharmaceutical products in Brazil was immediately mired in controversy. One might say that the work of Coopi-Anvisa is unprecedented in the history of intellectual property regulation in Brazil, not only because it is an evaluation conducted within the ambit of a health sector agency but mainly because this evaluation considers public health issues. However, both Coopi-Anvisa and INPI use the same criteria for the technical evaluation of patents.

To allow Anvisa to take on this new function, patent examiners were trained within the Ministry of Health. Sixteen professionals (chemists, chemical engineers, pharmacists and biologists) were selected by Anvisa in 2001 and took courses on intellectual property held at institutions within the Ministry of Health. This setup was maintained until 2005, when patent examiners and other employees were hired via public tender to work permanently for Coopi-Anvisa.

Recently, we analyzed the experience of Coopi-Anvisa in conducting evaluations of pharmaceutical patents (GUIMARÃES, 2008; CORRÊA et al., 2007). Underpinned by theoretical and methodological perspectives on health, innovation and rights sociology, that study identified the controversies involving medicine-related intellectual property in Brazil and the main actors involved in these debates. In the present paper, we examine the controversies identified in our previous research. The first section explores changes brought about by the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement in the pharmaceutical

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<sup>1</sup> INPI is a federal agency that grants trademarks and patents, formalizes technology transfer contracts and performs other duties related to these purposes.

sector in Brazil and the controversies surrounding the patentability of drugs. We then go on to examine how Coopi-Anvisa implements a unique approach in the technical field of patent application evaluations and discuss the main findings. The third section addresses the intensification of challenges to prior approval, which resulted in the intervention of the Federal Attorney General in the issue of Anvisa's patent evaluations. The various reactions and controversies raised in the 10-year conflict surrounding prior approval will also be discussed. Finally, the conclusion will summarize the general themes of the paper and highlight the importance of the debate on prior approval in Brazil.

### **Patents in the pharmaceutical field: impasses in the debate over the limits of intellectual property rights**

The tension between public health issues and intellectual property rights in the pharmaceutical arena is not new. Since the enactment of the new IPL, there has been ongoing debate on the balance between the right of the population to health and Government public health policies on one hand and the ownership of inventions on the other. Historical examples of similar controversies include the parliamentary debates regarding the possibility of excluding medicines from the scope of patentable materials that occurred between 1843 and 1844 in France, a country with many biomedical institutions and high patent rates in the present day. During this historic debate, the following important arguments were cited in favor of patents: (i) the positive impact of patents on the development of the pharmaceutical market, (ii) the natural right of the inventor over his creation and (iii) the benefits that patents generate for public health in terms of incentives for industrial innovation within the sector. Those who were opposed to the patenting of pharmaceutical products and processes emphasized (i) the public health interest, (ii) the essential character of these goods for the welfare of the population and (iii) the possibility of implementing alternative incentive systems for inventors (CASSIER, 2004).

These tensions are inevitable to the extent that the whole intellectual property system must serve a dual purpose in the pharmaceutical field. On one hand, it seeks to encourage inventors, promoting the cumulative progress of inventions through patents. On the other hand, there should be mechanisms of limitation, correction and the suspension of property rights when the right to health is threatened. Industrial property rights must therefore include the interests of both the producers and the consumers of pharmaceutical products (CASSIER, 2004).

It is also important to note that companies in the chemical pharmaceutical industry are among those that depend most upon patent protection: a comparison of the innovative products of this industry with those of other fields suggests that pharmaceuticals are difficult to develop in secrecy and are easily copied (SCHERER et al., 2001). The fact that most organic chemistry methods are widely available in the literature only makes copying easier. Maintaining secrecy during pharmaceutical production is difficult because drugs are molecular entities whose value derives essentially from their effects on humans; therefore, all of the preclinical testing and clinical trials (phases 1, 2 and 3) that are required for the approval of a new pharmaceutical product make the trade secrets involved public to some extent. Without patent protection or other forms of assurance of market exclusivity, a copycat company would therefore be able to invest less money and time by copying an original product (REIS et al., 2004). Therefore,

patenting in the pharmaceutical field becomes a key mechanism by which the entry of competitors is limited, offering further relevant conditions so that the holder of the temporary monopoly can establish higher prices.<sup>2</sup>

In the last round of the *General Agreement on Tariffs and Trade* (GATT) in 1994 in Uruguay, the World Trade Organization (WTO) was created and, in addition to other multilateral agreements, the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement was signed. Since then, the *patenting/public health* tension has taken a new form. The TRIPs agreement established that each member country should recognize and effectively protect the intellectual property rights (patents, trademarks, trade secrets, etc.) of the other member nations. It was created as a compromise that aimed to reduce the barriers to international free trade and stimulate economic and technological development. Consequently, minimum standards of protection were established for each subarea of intellectual property and the particulars of administrative procedures to be incorporated into the national legislation—which could then be used by the holder of a patent in the event of a dispute—were developed (Art. 41-61).

Until 1995, most member countries of the WTO did not recognize patents for pharmaceutical products and processes. This situation changed dramatically with the inception of the TRIPs Agreement and the consequent reformulation of national intellectual property laws, which was accompanied by the emergence of serious impasses in health initiatives, especially in less developed countries. Indeed, for reasons of national strategic interest, even developed countries did not allow the patenting of pharmaceutical products until the second half of the twentieth century (Switzerland did not until 1977, Germany until 1968, Finland until 1995, Norway and Spain until 1992). In Italy for example, a Mussolini government decree in 1939 prohibited patenting in the pharmaceutical field to promote scientific and technological development of the national chemical pharmaceutical industry. Italy therefore began copying original pharmaceutical materials from innovative companies and exported them at prices below those charged by the innovative transnational industries of several countries, including Brazil. The combination of local industrial capacity and a lack of patents in the chemical pharmaceutical field led Italy to become a major supplier of drugs during the 1960s and 1970s. However, the Italian Supreme Court decided in 1976 that the exceptional treatment of the pharmaceutical industry by the intellectual property system was unconstitutional and recommended changes in legislation (TACHINARDI, 1993).

The advent of the TRIPs Agreement brought with it challenges to the relationship between intellectual property rights and the stimulation of innovation in the pharmaceutical industry, which was no longer seen as direct or automatic. A study conducted by the *National Institute for Health Care Management* (NIHCM FOUNDATION, 2002) indicated that the number of patents protecting incremental innovations had grown since the late 1990s in the United States, especially since 1995, the first milestone in the TRIPs Agreement era. Between 1989 and 2000, only 15% of all medicines approved in the United States offered a significant clinical innovation. In Europe, a Sectoral Survey of the pharmaceutical field prepared by the European

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<sup>2</sup> The use of the term *relevant conditions* is deliberate because, as noted by Combe et al. (2003) and by Reis et al. (2004), the possibility of imposing a certain price on a drug depends on several factors (consumer marketing strategies and the market profile, among others). However, the temporary monopoly on the marketing and use of a pharmaceutical product or procurement process represents a powerful weapon in plans to impose prices, as, in any price negotiation between government institutions and pharmaceutical firms, the patent gives the former important bargaining power.

Commission in November 2008 examined data from 2000-2007 and considered a sample of 219 medicines. The authors reported extreme concern regarding the strategies that large laboratories were using in the field of intellectual property to delay the introduction of generic drugs onto the market. The reports are absolutely stunning, including one in which a single medicine had approximately 1,300 valid patents in Europe. The permissiveness of the European Patent Office has generated a scenario of legal uncertainty, resulting in numerous disputes with generic manufacturers. The cost of delays in the introduction of generic drugs in the European market may be as high as 3 billion Euros (EUROPEAN COMMISSION, 2008).

Similarly, a report from the *UK Commission on Intellectual Property Rights* argued that the positive relationship between *intellectual property rights and innovation* should be interpreted with caution. Furthermore, in low-income countries, the level of intellectual property protection recommended by the TRIPs Agreement would not be a determining variable of growth. Rather, rapid growth in these countries is often linked to weaker levels of intellectual property protection. In developing countries, the system of patent protection only becomes relevant after reaching a certain stage of growth and, even then, only if a country falls clearly into the average-income category (CDPI, 2003, p. 22).

Correa (2004) notes that the production of truly innovative knowledge in the pharmaceutical arena is not the predominant trend. Instead, large companies in the industry skillfully exploit the patent system to implement aggressive strategies—notably through the patenting of so-called incremental innovations—to block potential competitors. Incremental innovations do not transform the fundamental features of existing technologies and therefore differ from radical innovations, which are products and processes with characteristics or uses that are significantly different from other existing products and processes (MOREIRA, 2010).<sup>3</sup> Most of these patents are filed to protect minor technical improvements for existing medicines under the premise that making such incremental innovations will extend the commercial benefits of already available pharmaceutical products. Consequently, new patent applications are filed just as the original patents are expiring; this strategy prevents the molecule from falling into the public domain and blocks generic drug-producing competitors from entering the market.

In addition to issues surrounding economic development and innovation in the pharmaceutical field, the TRIPs Agreement creates bottlenecks in access to healthcare. Several studies have argued that the guidelines contained in this Agreement inflate the prices of medicines and vaccines, posing a serious threat to the sustainability of national public health programs in many countries (WORLD BANK, 2002, p. 130; CDPI, 2003, p. 36-37; NOGUÉS, 1993, p. 37). In the case of the National STD and AIDS Program (Programa Nacional de DST-Aids) in Brazil, during the year of implementation of the IPL, the average cost of antiretroviral therapy rose from U.S. \$3,810 to U.S. \$4,860 per patient/year (TEIXEIRA et al., 2003).

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<sup>3</sup> There is no consensus in the debate on frivolous, incremental or trivial patents, which is a central aspect in the discussion on the impact of TRIPs in Brazil. Some authors make a distinction between so-called trivial or frivolous patents and incremental patents. As noted by Reis (2012), frivolous or trivial patents are harmful to society because they add little or nothing to existing therapies and avoid competition by placing a legal shield around the original product. In turn, incremental claims are seen by many countries as patentable because they sometimes resolve important technical impasses; for example, the creation of a new pediatric formulation can make a medicine that needed to be refrigerated stable at room temperature (allowing for a wider distribution). However, in a context in which protection is intensely sought for innovations to ensure the highest possible profitability for each molecule or compound, clearly distinguishing between a trivial or incremental patent is an arduous task for a patent examiner (REIS, 2012).

It is important to stress that access to health depends upon several variables, including behavioral, socio-demographic, symbolic and organizational factors. For example, issues related to treatment adherence, stigma and other factors must always be considered when analyzing access to health (GIOVANELLA et al., 1996). Analysis of some of the dimensions to be considered when studying access to medicines (availability, affordability, geographical accessibility, acceptability, quality of products and services) suggests that the affordability of medicines for governments—and consequently, their availability to citizens—may be adversely affected by the intellectual property rights of pharmaceutical products and processes due to price increases during the period of temporary monopoly granted by patents (LUIZA, 2003; REIS et al., 2004, p. 99).

The dilemmas generated by the international dissemination of the TRIPs Agreement became so acute that the Doha Declaration was enacted in 2001. This declaration had a considerable impact on the international debate on social justice and trade because it established that signatory countries must interpret the TRIPs Agreement in a way that protects public health and that the Appellate Body and WTO panels should review the rules of the treaty and adjudicate disputes arising from it, taking into consideration the public health needs of each of the parties involved (CORREA, 2002).

It is within this context that we must analyze the impact of the TRIPs Agreement in Brazil. Drafted in accordance with the dictates of the WTO, this new IPL was especially important to healthcare because Brazil had not granted patents on pharmaceutical products since 1945 nor on their manufacturing processes since 1969 (CARVALHO, 2005). Moreover, Brazil could have postponed the changes introduced by the TRIPs Agreement for five years but chose not to make use of this mechanism. Consequently, it is estimated that the immediate recognition of patents resulted in both the closure of 1,096 production units and the cancellation of 355 projects in the field of fine chemicals (raw materials for medicines) (VIEIRA, 2010).

Therefore, the establishment of patents for pharmaceutical products and processes also exerted an impact on Brazilian industrial policy. According to Cassier et al. (2003, 2007), the decision to make medicines non-patentable, made under President Getúlio Vargas in 1945, aimed to boost the creation of a local pharmaceutical industry and the knowledge transfer of inventions that were protected abroad. This decision was legally sound under the Paris Convention,<sup>4</sup> as it reflected the strategy adopted by countries such as Italy, as mentioned above (TACHINARDI, 1993). The strategy was reaffirmed during the 1970s, when the Industrial Property Code (Código da Propriedade Industrial) (Law no. 5,772/71) decreed that the process of obtaining pharmaceuticals was not patentable. In addition to protecting public health, the goal was to promote industrial technology transfer for local laboratories. As a core component of this proposal, the Ministry of Health, through the Central Medicines Office (Central de Medicinos - CEME),<sup>5</sup> maintained several contracts with the Technological Development Company (Companhia de Desenvolvimento Tecnológico - CODETEC) throughout

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<sup>4</sup> The international regime of intellectual property was created at the end of the nineteenth century with the signing of the Paris Convention (PC). It is still in force. This was the first far-reaching international treaty on the issue that sought to establish minimum guarantees of legal protection for inventors who wanted to make their inventions public. The PC entered into force in 1884 and had ten contracting countries: Brazil, Belgium, France, Spain, Italy, Netherlands, Portugal, the UK, Tunisia and Switzerland. Three years later, Sweden, Norway and the United States adhered to the Convention.

<sup>5</sup> CEME was created to regulate the production and distribution of pharmaceutical drugs in association with or under the aegis of Brazilian ministries (CASSIER et al., 2008; SANTANA et al., 2004).

the 1980s.<sup>6</sup> As a result, Brazilian businessmen and university researchers became involved in the production of raw materials for pharmaceuticals of public health interest. National laboratories received funds to use reverse engineering to copy medicines that were considered essential, many of which had valid patents abroad (CASSIER et al., 2008). The adoption of intellectual property rights in the pharmaceutical field makes the copying of new molecules much more complicated, as they are now patented. This situation is very different from that which previously prevailed in Brazilian public and private sector laboratories.

Even within the new framework of patent protection, many argue that despite its protection of intellectual property rights and their relationship to international trade, the TRIPs Agreement represents not only the rights of the patent holder but also the notion of balance between the rights and obligations of all of the involved parties (BASSO, 2000). After all, the treaty allows each country a certain degree of freedom in defining its own understanding of the technical requirements for protection, and countries can adopt measures to promote the economic and social welfare of their population (Article 7); to protect public health, nutrition and public interest in areas of great socioeconomic importance (Article 8.1); and to prevent the abuse of intellectual property rights by holders (Article 8.2). Finally, it establishes that countries may exclude from patentability some inventions, such as diagnostic, therapeutic and surgical treatment methods for humans and animals and inventions that threaten public order and the moral foundations of society. In this light, the prior approval mechanism must be understood as the means granted to the Brazilian government to regulate intellectual property rights on medicines within the margins of freedom provided by the TRIPs Agreement.

Although on one hand, the patent can be seen as a fundamental legal artifice for the scientific and technological development of a society, on the other hand, depending on the economic and political situation of a country, the establishment of wide-ranging intellectual property rights can have negative consequences. In Brazil, government sectors, NGOs, associations, experts, etc. have all debated and taken direct action on the issue of intellectual property rights for medicines since the beginning of negotiations for the establishment of the new IPL (TACHINARDI, 1993). In the midst of these debates on the application of the IPL and even on whether some of its articles should be changed in light of the problem of access to medicines in Brazil, the question of Coopi-Anvisa's role in prior approval has emerged as a central theme.

## **Debates and conclusions in the controversies relating to the Anvisa patent evaluation process**

Throughout its 10 years of existence, the supporters of the prior approval process have always defended it by arguing that it allows for a more rigorous evaluation of relevant patents, only allowing the patenting of substantive innovations in the pharmaceutical field. This historical position leads us to a debate on the quality of patents.

Remi Lallement, a researcher at the Center for Strategic Analysis of the French government, defines "a poor quality patent" as one that should not have been granted because it does not meet patentability requirements, is ill-defined in relation to other already existing patents, is not described properly or leaves a gap between the protection area claimed by the depositor and the technical contribution of his invention. Lallement indicates that the use of "strategic

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<sup>6</sup> CODETEC was a Brazilian technology company that was directly involved in the policies of CEME and the Ministry of Health.

patenting"—that is, the accumulation of patents as a strategy to block competitors—is becoming common practice in Europe (LALLEMENT, 2008). Currently, public demonstrations are occurring across Europe to demand that governments focus on this issue to establish a healthier intellectual property regime for the continent. For example, a report from the *Union Syndicale de l'Office Europeen des Brevets* (USOEB, 2002) argues that the overall balance of the patent system is only economically beneficial when the rights granted to the patentee are commensurate with his technical contributions. The role of the patent application evaluation is therefore to ensure an adequate level of quality of patents so that society as a whole is protected. The evaluation process must therefore encourage a *real culture of quality* within national patent offices.

Although the TRIPs Agreement allows each country to define the degree of inventiveness in its system—permitting each country to define a minimum quality standard for the patents that it grants—the extent of the controversy generated by the prior approval process is readily apparent in the media, institutional documents, international reports and arguments presented in legal proceedings involving Coopi-Anvisa.

The first and strongest criticism directed at Anvisa's role in the prior approval process came from the Brazilian Association for Intellectual Property (Associação Brasileira de Propriedade Intelectual - ABPI), which has over 400 members, including representatives of national and multinational companies and the most important Brazilian intellectual and industrial property offices. Just a month after approval of the interim measure that established Anvisa's prior approval role, the ABPI issued an internal resolution containing harsh reviews of article 229-C, mainly questioning its legality.

Another high-profile group that protested the new law was the Pharmaceutical Research Industry Association (Associação da Indústria Farmacêutica de Pesquisa - Interfarma), which comprises more than 30 laboratories and represents approximately 54% of the Brazilian medicine market. Interfarma estimates that the groups associated with it have approximately 15,000 patent applications in Brazil (LICKS, 2002). According to Interfarma, Coopi-Anvisa discourages direct investment in high technology for other countries, such as Chile and Mexico, and creates longer delays in the patent granting process (LICKS, 2002).

Contributions to this debate have not been restricted to national bodies. The *United States Trade Representative* (USTR), which addresses matters relating to U.S. foreign trade, the *Pharmaceutical Research and Manufacturers of America* (PhRMA)<sup>7</sup> and the *European Federation of Pharmaceutical Industries and Associations* (EFPIA) have all at various times voiced major concerns regarding prior approval.<sup>8</sup>

Despite this pressure, Coopi-Anvisa has continued to develop their patent evaluation process. Several sections of the Ministry of Health are now involved in patent evaluation, and the group is working to formulate its interpretation of the laws while exercising flexibility in the application of intellectual property rights in the interest of public health.

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<sup>7</sup> PhRMA represents the leading companies in the biotechnology and pharmaceutical arenas and works within governments and other sectors to advocate for policies that promote technological development in the industries of its members.

<sup>8</sup> EFPIA represents the pharmaceutical industries operating in Europe. It currently includes 32 European pharmaceutical industry associations and 44 companies working in the research, manufacture and development of medicinal products for human use on the continent.

This dimension of the efforts surrounding prior approval can be understood, for example, by considering the controversial case of patents involving new polymorphic forms of a previously known molecule. Polymorphism refers to the ability of a molecule to crystallize into two or more forms. Although the chemical properties of different crystalline forms of the same substance are identical, their solubility, stability and melting point, as well as other characteristics, may vary significantly. Consequently, the presence of different crystalline structures of an active ingredient can alter the execution of various procedures during the development of a medicine (SOARES et al., 2010). Furthermore, because polymorphism is a natural property resulting from the specific conditions under which a compound is obtained, any chemical compound that presents polymorphic abilities will naturally crystallize in its most stable form even without any human intervention. Many experts believe that because this is a natural property of the compound, one should not grant patents for polymorphs (CORREA, 2007). Moreover, there is debate regarding the frequent use of such claims to obtain extensions on the monopoly for the original invention; for example, the firm Smithkline filed a patent on a polymorphic form of cimetidine five years after the original patent letter was issued (JANNUZZI et al. 2008; AGUIAR et al. 1999).

For years, INPI deemed this type of claim patentable, whereas Anvisa began to deny patents for this reason. In 2008, the Interministerial Intellectual Property Group (Grupo Interministerial de Propriedade Intelectual - GIPI)<sup>9</sup> met to discuss the protection of patents involving new polymorphic forms with representatives from Coopi-Anvisa and INPI (BRAZIL, 2008). After a long session of listening to arguments from both institutions, eight of the eleven agencies of the Federal Public Administration voted in favor of the position adopted by Anvisa: patents for new polymorphic forms would be contrary to the goals of public health policies, were contrary to the development of the Brazilian health industry, would extend Brazilian obligations established within the TRIPs Agreement and would prevent the local production of generic medicines (SOARES, 2011).

Another notable example is the case of second medical use patents, i.e., medicines in which the active ingredient—the substance in the composition responsible for its therapeutic effect—is a previously known molecule but one for which a new therapeutic use is introduced. Although allowed in some countries, the patentability of such drugs is not expressly required by the TRIPs Agreement, which only requires the granting of patents on products and processes. Some experts argue that second medical use claims are inconsistent with the requirements of novelty. Because both the process to prepare the medicine and the medicine itself are already known and have industrial applications, the novelty would consist of an identified effect on the human body rather the product itself or its manufacturing method. Furthermore, these are simple discoveries related to a product that is already known and the mere disclosure of a feature of the product.<sup>10</sup> However, some experts have argued that

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<sup>9</sup> GIPI was initially conceived in the mid-1980s, when the then government was faced with the need to coordinate its position to participate in negotiations on intellectual property within the GATT Uruguay Round. At that time, the activities of the group were mostly informal. However, the Interministerial Ordinance n<sup>o</sup> 346 of July 1990 led to the creation of a commission to draft a government bill that would change the old industrial property code. The ministries of Economy, Health and Foreign Affairs participated in this commission. Today, GIPI also has members from the Ministry of Agriculture, Livestock and Supply; the Ministry of Science and Technology; the Ministry of Development, Industry and Foreign Trade; and the Ministry of Justice, among others (BRAZIL, 2011a).

<sup>10</sup> Invention differs from discovery in that it features novelty, inventive activity and industrial application. The patenting of discoveries is universally prohibited in the intellectual property system.

applications involving new uses are not discovered at random, but rather as the result of research, analysis and investment that therefore represent patentable inventive steps (CORREA, 2007).

Consequently, INPI decided to accept this type of claim. Anvisa, however, issued a resolution in 2004 on the scope of patentability of medicines that was contrary to INPI's decision. One of the items of that resolution stated the following:

IV - Regarding applications that claim the 'new use' of substances - The Board at its meeting held on November 26, 2003 decided the following: 'The Board deemed that the practice is harmful to public health and the scientific and technological development of the country and may hinder the population's access to medicines. In light of this, it decided not to grant prior approval in second use patent cases.' (ANVISA, 2004)

This decision generated much debate and the then coordinator of Coopi- Anvisa argued that many medicines were sold in a monopoly in the domestic market by patent holders and that the new use of existing drugs is just a discovery, often the result of side effects or adverse reactions encountered in the routine use of the product in medical practice. He also said that a patented medicine already has its own protected use(s) and so claiming new uses appeared to be a tactic to extend the term of patent protection (LIMA, 2004).

In 2007, following widespread controversy, INPI organized a Series of Technical Discussions (Ciclo de Discussões Técnicas) to gather information to improve and develop new guidelines for patent evaluation. Meetings were devoted to discussing second medical use claims among the major national bodies: INPI, Anvisa, the National Association of Pharmaceutical Laboratories (Associação dos Laboratórios Farmacêuticos Nacionais - Alanac), the public laboratory of the Farmanguinhos-Fiocruz Ministry of Health and Interfarma, among others (INPI, 2007). In the same year, Bill 2511\_07 was introduced by the Brazilian National Congress to change the IPL by making new therapeutic indications for pharmaceutical products and processes unpatentable. The proposal was widely supported by NGOs operating in Brazil, including Doctors Without Borders; the coordinator of their Campaign for Access to Essential Medicines argued that the renewal of authorization for exclusive production of medicines harms the ability for patients to access drugs for the treatment of various diseases, especially in poorer countries (GOVERNO..., 2009).

With regard to the impact of prior approval on the granting of pharmaceutical patents, the last official report of Anvisa (which evaluates the period from 2001-2008) stated that an official decision had been made on 1,047 patent applications that went through Coopi. 89.4% of these requests were granted and 10.6% were rejected. However, it should be noted that, as the INPI evaluation precedes that of Anvisa (in other words, Anvisa only evaluates requests that have already been evaluated and granted by INPI), these figures indicate a rate of almost 11% clear disagreement between the two bodies. Moreover, other extremely important data indicate that, even among the requests granted by Anvisa, 36.6% underwent changes to the initial request that had been granted by INPI. In other words, more than one third of patent applications for pharmaceutical products and processes accepted by INPI had corrections made or their scope much reduced after evaluation by the Ministry of Health (ANVISA, 2011).

## **The intervention of the Office of the Attorney General in the patent granting process**

All of the decisions made while processing patent applications must be published in the Industrial Property Journal (Revista da Propriedade Industrial - RPI), the official journal of INPI; this publication allows all of the interested parties to track the status of requests. As one might guess, throughout the institutional relationship between INPI and Anvisa, disputes have arisen regarding the publication of rejections issued by Coopi-Anvisa. The attorney for the Brazilian Interdisciplinary AIDS Association (Associação Brasileira Interdisciplinar de Aids), Renata Reis, reported in 2007 that INPI had not published decisions of non-approval issued by Coopi-Anvisa. Without the publication of such judgments, the decisions made by Anvisa had no practical effect. At the time, Reis brought up the example of U.S. application PI9710693-3 (seeking the protection of a compound useful for the treatment of neuropathies, Alzheimer's and Parkinson's, among other conditions), which, despite having been sent to INPI in mid-2004 with a non-approval decision, had still not been reported in the RPI in August 2007 (REIS, 2007). The worsening disagreements and standoffs between the two institutions led Anvisa to issue a resolution in 2008: Board Resolution (Resolução da Diretoria Colegiada - RDC) 45, stating that the decisions of Coopi-Anvisa on its evaluation of pharmaceutical patents would now be disclosed in the Official Union Gazette (Diário Oficial da União) and no longer in the RPI.

In one of two public hearings of the National Congress on the prior approval role granted to Anvisa, the president of INPI argued that because Anvisa only became involved at the end of the technical evaluation, with the official position of INPI having already been issued, differences between the two bodies were inevitable. He claimed that one public entity could not correct problems or diverge from the official decisions of another authority. He therefore argued that Anvisa should only contribute information about public health risks in the light of clinical trials and that the evaluation of pharmaceutical patent applications should be withdrawn from the legal ambit of the agency (BRAZIL, 2009a).

The continuing alleged "conflict of duties" between INPI and Coopi-Anvisa caused the Federal Attorney General to intervene in 2009. In August of that year, Federal Attorney Estanislau Viana de Almeida issued a determination (Determination no. 210/PGF/AE/2009) on the subject. Initially, he claimed that state entities cannot abandon, alter or modify the institutional objectives for which they were founded and, in analyzing the legal texts stipulating the legally established institutional purposes for each, he found that Anvisa was operating outside of its own administrative remit, breaking the principle of legality. Consequently, the Attorney General determined that Anvisa could not reevaluate patentability requirements, except when (i) the new invention could cause harm to population health and (ii) it found that the effectiveness of the invention was questionable (BRAZIL, 2009b).

Shortly thereafter, the CEO of Anvisa requested reconsideration of the decision. He argued that the Attorney General's determination confused two of Anvisa's separate legal institutions with different aims: prior approval of patent applications for pharmaceutical products and processes on one hand and the sanitary registration of medicines on the other. The Attorney General had therefore argued for a settlement proposal that could not be carried out, because, as INPI was not able to study the safety and therapeutic efficiency of pharmaceutical products and processes, it would not be able to carry out the activities proposed by Federal Attorney

Estanislau de Almeida. Moreover, as patent applications are generally designed to protect just chemical substances—without knowing beforehand whether they will be developed into new medicines and produced and marketed—the proposal would be innocuous. Finally, Anvisa argued that because medicines are goods of a paramount social interest, the political and legislative choice of prior approval demonstrated that the government wanted Anvisa, an agency of the health sector, to review the requirements for patentability with a more systematic focus that took public health, constitutional law and access to medicines into consideration. This care is particularly necessary in the field of intellectual property because, as patentability requirements such as novelty and inventive activity are not clearly defined, there is always ample scope for subjectivity in the interpretation of such requirements in the review of patent applications.

This component of the Anvisa argument is particularly interesting because, in addition to defending the interests of public health and constitutional law, it brought into question the issue of the malleability of normative devices governing intellectual property (in this case, the requirements for patentability established by the IPL). This argument is surprisingly reflective of the work on patents done by humanities scholars (CAMBROSIO et al., 1996; PECKER et al., 1995; TEITELBAUM et al., 2007), whose findings suggest that patentability requirements possess a strong degree of interpretability and subjectivity because they contain philosophical, economic and legal justifications and even common sense arguments.

In addition to the arguments put forward by Anvisa, a group of Brazilian NGOs published a position paper on the findings presented by the Federal Attorney General on the role of Anvisa in the prior approval process. In this paper, a series of criticisms of the findings presented by the Attorney General were presented: (i) careful evaluation of patent applications to avoid undue concessions could be understood as a component of indirect price regulation, the legal responsibility assigned to Anvisa; (ii) the promotion of public health, the institutional purpose of Anvisa, is not restricted to the particular characteristics of health products (their effects on the human body) but also includes the consequences of releasing them onto the market; (iii) the possible association of patent application review with sanitary registration contravenes the TRIPs Agreement to the extent that a fourth requirement of patentability would thus be created; and (iv) the safety and efficacy of a drug cannot be analyzed during the patenting process because, as many applications are in early stages of development, this would be a long-term task in terms of pharmacosurveillance strategies (Rebrip-GTPI, 2011a).

The then chief executive of the Brazilian Association of Generic Medicines Industries (Associação Brasileira das Indústrias de Medicamentos Genéricos - PróGenéricos) lamented the decision of the Attorney General, arguing that the work of Anvisa prevented laboratories, especially those of large transnational pharmaceutical industries, from using the intellectual property system to enact strategies aiming to extend patents and delay the entry of generic competitors (PRATEANO, 2011).

In January 2011, the Federal Attorney General Marcelo de Siqueira Freitas approved a new determination, complementing the first, stating that although Anvisa could not deny approval of a patent application based on patentability requirements, nothing would prevent Coopi-Anvisa from formally presenting its considerations to INPI regarding a particular patent application, as provided in Article 31 of the Industrial Property Law, which institutionalizes the

legal allowance of the technical evaluation. In other words, the position that Anvisa should not be able to conduct patent evaluations was upheld (BRAZIL, 2011b).

Angry with the decision, Brazilian NGOs sent a complaint against the Brazilian government to the then UN *Special Rapporteur* on the right to health, arguing that the main consequence of the decision would be a violation of the right to health, defined as a fundamental right of the individual in Brazil (Rebrip-GTPI, 2011b).

In terms of everyday legal practice, the decision of the Attorney General had immediate effects: days after the promulgation of the decision, the 7th Federal Jurisdiction of the Judicial Section of the Federal District subpoenaed the president of Anvisa to annul the non-approval of PI1100756-7, submitted by the Takeda Pharmaceutical Company, Ltd. At the time, Coopi-Anvisa had issued a determination following the guidelines of the Attorney General, indicating that the request had not—and could not have—included all the information necessary to assess the quality, safety or efficacy of the claimed object. However, the federal judge concluded that Anvisa purposefully combined the patenting requirements with those of sanitary registration to deny the patent (DISTRITO FEDERAL, 2011).

## **Conclusions**

According to Kostecky's (2006) study of *Technical assistance services related to intellectual property* (TASIP; which is offered to governments, national industrial property offices and civil societies, among others), many of the activities related to TASIP do not consider the specific interests of developing countries: a) they generally hold high standards of intellectual property protection that operate in the interest of developed countries, rather than more flexible standards; b) the literature used in the creation of these services originates from industrial fields of interest to developed countries; c) "dissident views" tend to be discouraged; and d) those who benefit from the low standards of intellectual property protection (informal industry producers, consumers, mid- and small-size businesses) tend not to be consulted.

López (2009) also highlights this problem and notes that the few available studies that take into account the context of developing countries and tend to regard them as a uniform set, ignoring the fact that the term "developing countries" encompasses a wide variety of nations at various stages of economic development and technological capability. Therefore, micro-studies that identify the individual contexts of these countries should be carried out to clearly determine the policies and the levels of protection of intellectual property rights appropriate to each environment.

Returning to the controversy over prior approval in Brazil, there is clear tension in the debate on the exceptionality—or lack thereof—of pharmaceutical patents; the question centers around whether there is a need to treat pharmaceutical patents differently, as the temporary monopolies generated by intellectual property rights have an impact on goods that could be essential to health and life.

Those opposed to the role of Anvisa in the patent granting process tend to argue that prior approval discourages companies and researchers, causing a loss of private investment in the sector. Critics who conceive of the patent as a central instrument for the development of new medicines argue that the creation of a new stage in the review of pharmaceutical patents is illegal, especially in the face of international commitments made by the Brazilian government,

and it would be at odds with the IPL. This notion of the role of the intellectual property system, stressing the importance of pharmaceutical patents in the economic sector, becomes clearer when one notes that two important international associations focused on the interests of the industrial sector—the *United States Trade Representative* and the *European Federation of Pharmaceutical Industries and Associations*—officially censured the work of Coopi-Anvisa based on arguments centering around losses incurred by investors in their field.<sup>11</sup>

Those in favor of the participation of Anvisa tend to argue that the role of prior approval is to protect the welfare of the population, public health (ensuring access to medicines), social interest and the guarantee of life. Defenders of the legality of prior approval appeal to national legislation (the Federal Constitution establishes that the economic order must meet the social function of property) and to international legislation (the TRIPs Agreement provides safeguards and flexibility for developing countries and the Doha Declaration states that an intellectual property regime cannot ignore the need to protect public health). Moreover, they note that Article 229-C, which enacted the prior approval role of Anvisa, was lawfully created by a Provisional Measure.

These conflicting perceptions on the limits of the intellectual property system lead us back to the tensions surrounding the dual purpose that should be fulfilled by the system of appropriation of pharmaceutical products and processes: to ensure access to health and to foster industrial innovation in the sector (CASSIER, 2004). Furthermore, the heterogeneity of actors involved in the debate on prior approval deserves to be highlighted, as the issue concerns not only people linked to the Ministry of Health and INPI but also lawyers, industrial estate agents, class associations linked to the industrial sector, international organizations and even national and international NGOs.

The analysis proposed here illustrates that the patenting of medicines and health products is a topic that interests various sectors of society. Moreover, it shows that the social and private interests involved in patenting—the fair remuneration of inventive effort, the legal and economic security of investments into new treatments, the dissemination of scientific knowledge and impact of monopolies, among others—are not matters of consensus between experts but within society in general. In the case of the controversy over prior approval, the argument is not whether patent rights for pharmaceutical products and processes should exist, but what the legal limits should be and what the technical justifications are for such limits. In Brazil, this controversy takes a very specific form, as the state is constitutionally responsible for ensuring universal, free and equal access to health services.

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<sup>11</sup> The recently released annual report of the *United States Trade Representative - the 2012 Special 301 Report* - warned that Brazil was still on its *Watch List* due to the prior approval process, among many other reasons. Therefore, the North American government officially voiced its support of the decision of the Attorney General and encouraged Brazil to formalize the decision (USTR, 2012).

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