Social cost of pending the patent examination in Brazil: An analysis of the deleteric effects of the sole paragraph of Art. 40 of law No. 9.279/96 in the post-patent segment

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Abstract

In Brazil, the general rule is that the invention patent has a duration of 20 years and that of a utility model, 15 years, counted from the filing date of the patent application. However, if the examination of a patent of invention or utility model is not completed within 10 or 8 years, respectively, the sole paragraph of art. 40 of Law nº 9,279/96 - Industrial Property Law (LPI) determines a differentiated methodology for the calculation of the validity of the right. The standard in question provides that, in this case, the patent will be valid for at least ten years in the case of IP and seven years in the case of MU, counting from the date of the granting of patent (and not the file). The present paper deals with the problematic involved in the extension of the term of validity of patent in the hypothesis of administrative slowness of Brazilian Office

(INPI) in the appraisal of the application. As the vast majority of patents are granted using the benefit provided in the sole paragraph of art. 40 of the LPI, it will be analyzed the social cost of the automatic extension of the term of validity of the patent in the post-patent segment (pharmaceuticals and agricultural pesticides). It was found that the accumulated loss of the public coffers only taking into account nine medicines purchased by public health system (SUS) in regular centralized purchases up to January 2016 was over R$ 2 billion. As for agricultural pesticides, there was an annual cost of approximately R$ 318 million for the group of eight patents that were extended with the application of the legal safeguard.

Keywords: backlog; patent; social cost; Brazil

1. Introduction

The system of intellectual protection of a country is created to guarantee exclusivity in the exploitation of the object of intellectual activity in the industrial, scientific, artistic and literary fields. Within this system, patents are presented as a property title temporarily granted by the State, within its territory, which grants the owner the right of exclusivity, protecting the holder from any unauthorized economic exploitation carried out by third parties.

With the granting of a temporary monopoly, it is sought to protect the invention against the threat of unfair competition, so that, within the term of the patent, its holder may exclusively obtain extraordinary profits that reward it for the investments made for the invention. and the state, in turn, will benefit from the fruits of innovation and the revelation of its content.

The fact is that the State alone does not have the economic capacity to promote its scientific and technological development and has chosen the regime of incentive to the private sector through the protection of immaterial property, on the condition that the invention, after a certain time of the right of exclusivity by its owner, can be used by the collectivity, with a view to promoting national development.

Within this framework, the smooth functioning of a country's patent system and the intensification of the interaction between industrial and technological policy, productive sector and intellectual property constitute a key mechanism for innovation and competitiveness of companies. In turn, when the management of a nation's patent system operates poorly, its effects tend to hamper technological developments and market competition, reducing the incentive for innovation and the provision of new products and services to society.

In order to achieve its institutional objective of becoming an effective and efficient intellectual property system, the National Institute of Industrial Property (INPI) should, inter alia, be able to meet the demand in terms of patent analysis and the agility and quality demanded by society.

In Garcez Júnior and Moreira (2017), it was discussed the accumulation of patent applications pending the decision of the INPI and the slowness with which that authority has processed the examination work. It was verified that the time of granting patents in Brazil has increased in a worrying way, leaping from 6.81 years in 2003 to 10.8 years in 2013 and that, despite the efforts of the Brazilian office in the fight

against backlog, including it in its priority trouble list, INPI has not been able to find a sustainable solution to the problem.

It should be noted that globalization and technological progress have led to an increase in patent activity and an increasing number of patent application around the world, so the patent backlog is not a particular problem of INPI, affecting offices in other countries. The big problem in Brazil is that the Brazilian office, although presenting a low number of pending patent applications compared to other offices, such as the American and the European, cannot keep pace with the granting of the main patent centers. To get an idea, in 2003, INPI's backlog was approximately 7 years, and a decade later, it reached 11 years, with 166,181 applications pending in 2013. In turn, in the same year, although the US office had 595,391 applications the European Union, 377,994 and the Japanese, 196,732, each of them granted their patents in the average term of 2.4 years, 3.0 years and 1.95 years, respectively (GARCEZ JÚNIOR; MOREIRA, 2017).

In fact, an inefficient and bureaucratic system, which, only after eleven years from the date of filing, grants the patent, is an insurmountable obstacle to inventive activity and social interest. This too long delay in the analysis of patent applications in Brazil is highly detrimental to competitors and consumers of patent-pending technology, as it also extends the status of near-monopoly[1]for non-patentable inventions, alienating potential competitors from the extends the term of validity of the granted privilege with excessive delay, indicating that the patent applicant will not always be interested in the expeditious analysis of his request.

The general rule is that the invention patent has a duration of 20 years and that of a utility model, 15 years, counted from the filing date of the patent application[2]. However, if the examination of a patent of invention or utility model is not completed within 10 or 8 years, respectively, the standard in question determines a differentiated methodology for the calculation of the validity of the right. The determination inscribed in the sole paragraph of art. 40 of the Industrial Property Law (LPI) provides that, in this case, the patent will be valid for at least ten years in the case of IP and seven years in the case of MU, counting from the date of the granting of patent (and not the file).

The present paper deals with the problematic involved in the extension of the term of validity of patent in the hypothesis of administrative slowness in the appraisal of the application. As the vast majority of patents are granted using the benefit provided in the sole paragraph of art. 40 of the LPI, the question is asked about the social cost resulting from this INPI delay in granting the privilege.

A *London Economics* study, commissioned by the UK Patent Office (UKIPO), estimates that each year of pendency at Trilateral Patent Office[3] has a negative impact on the global economy of approximately £ 7.6 billion, of which £ 6 billion is to reduce the incentive to innovation, £ 359 million as additional non-

[1] The status of near-monopoly or exclusivity does indeed occur because a patent application, creates an expectation of a right of protection, which, if implemented, authorizes the patentee to apply for compensation for the improper exploitation of its object by third parties from the date of publication of the application for a patent. (Article 30, paragraph 1, c/art. 44 of Law 9.279 /96), which, in theory, removes the production and sale by third parties of a product with pending patent application, in the face of the fear of be prosecuted in the future for the practice of counterfeiting.

[2]Article 40, caput, of Law 9.279/96 (BRASIL, 1996).

[3] The European Patent Office (EPO), the United States Patent and Trademark Office (USPTO) and the Japanese Patent Office (JPO) are cited as the Trilateral Patent Office.

patentable requirements and £ 1.2 billion resulting from monopoly power for non-patentable applications (LONDON ECONOMICS, 2010).

In this line of thought, it will be analyzed the impact of the automatic extension of the term of validity of the patent in the Brazilian economy. In order to fulfill this need and as a way of delimiting the scope of this work, two important sectors impacted by the legal safeguard will be investigated[4]: drug market[5] and phytosanitary products (agricultural pesticides).

The competitive strategies of these two sectors are basically distinguished according to two business segments: products with patents or generics. In the first segment, we seek to create barriers to competition and the practice of monopoly prices, through the right of exclusivity. Here the extension period is seen with good eyes by the sector, since it will guarantee the maintenance of the price plus. On the other hand, considering that after the expiration of the monopoly, third parties may freely use the protected knowledge (post-patent segment), the delay in the examination and the automatic application of the extension term will mean damage to this sector and, consequently, a charge additional to society, prevented from consuming generic alternatives at a more affordable price.

The topic addressed in this study gravitates around the problem faced by the second business segment (generic products). At the outset, two solutions are seen for the issue: institutional strengthening of INPI to reduce the backlog, thus preventing the effectiveness of the authorization rule of automatic extension, with the adoption of various operational and structural actions, such as sharing search data and cooperation agreements with other offices, constant training, the development of electronic tools and the hiring of new examiners[6] or the suppression of the mechanism of extension of the legal order, either through its revocation or declaration of unconstitutionality, also discussed in this work.

2.Patent, economic development and technological progress

The system of protection of intellectual creation is directly related to the technological development of a country. Scudeler and Oliveira (2013) point out that the absence of an effective system of recognition and protection of creative activity leads to a loss of capacity for innovation and is considered one of the main factors of the economic stagnation of underdeveloped countries.

Brazil is one of the pioneer countries in patent legislation, although with some limitations to such as food, chemical and pharmaceutical products and drugs, especially considering the prohibition of patent protection contained in the Industrial Property Code, prior to the current Industrial Property Law - Law 9,279 / 96 (BRASIL, 1971, 1996).

Cerqueira (1982) points out that Brazil was the fourth country in the world to grant protection to the inventor's rights, with the Prince Regent´s Permit of 1809, behind France (1791), United States (1970) and England (1623). With the enactment of the current Industrial Property Law (LPI), Brazil has reinforced protection in technological areas not provided for in the previous legislation, as well as increased the term

[4] Legal safeguard or extension, term of extension are synonymous expressions used to the logo of this paper, all referring to the application of the sole paragraph of art. 40 of the LPI.

[5] From a technical point of view, drug and drug are distinct concepts: in a simplified way, the drug is the active principle, while the drug is the pharmaceutical product itself. However, in the context of this paper both will be used as synonymous expressions.

[6] Alternatives eligible for the decrease of INPI's backlog were discussed by Garcez Júnior and Moreira (2017).

of invention patents from 15 years to at least 20 years in compliance with most of the signatory countries of TRIPs (Trade-Related Aspects of Intellectual Property Rights) (BRASIL, 1996).

TRIPs aimed at completing the shortcomings of the WIPO (*World Intellectual Property Organization*) protection system and definitively linking intellectual property rights to international trade, reducing their distortions and obstacles, by imposing minimum standards for the protection of intellectual property member countries, which should put into force, in their domestic legal system, authorizing patent protection for all technological, product or process sectors.

When developing the TRIPs, member countries of the newly created World Trade Organization (WTO) agreed that the full implementation of their terms should take into account the level of development of participants. Thus, as a developing country, Brazil could wait until the year 2000 to implement the agreement, but did not do so (clauses 65.1 and 65.2 of the TRIPs Agreement). And it could, under clause 65.4, have waited until 2005 to initiate the patenting of pharmaceuticals, as it did in India[7](YUSUF; NABESHIMA; PERKINS, 2007; BRASIL, 1994).

Among the basic standards of protection imposed by the adjustment, the minimum level of validity of patents of invention in 20 years was established. In addition to having waived the transition period to comply with the agreement, Brazil went further and, in the interest of protection, even if there was no requirement at the international level, it allowed for the possibility of extending the validity of the patent in the event of administrative default of the INPI - a mechanism characterized by the doctrine as TRIPs-plus[8], that is, a norm that extends the scope of protection negotiated within the scope of the WTO.

The Gowers Report, published in 2006 and commissioned by the then Prime Minister of the United Kingdom, noted that even the minimum standards of intellectual property rights under the TRIPs Agreement "have proven to be very costly for some developing countries." Thus, TRIPs-plus clauses, which go beyond the minimum level of protection, are more onerous, as is the case of the legal safeguard discussed herein (GOWERS, 2006).

The protection strategy adopted by Brazil seemed to establish a sine qua non condition of existence of a strong patent system for the promotion of the technological development of the country. However, the literature points out that this simplistic relation of cause and effect does not always occur, and the level of development of each country must be taken into account.

According to Chang (2001), the historical experience of currently advanced countries indicates that a low level of protection of intellectual property rights (IPR) was a central factor in strengthening their productive capacities and research and development (R&D). In this sense, most would have adopted a fragile IPR system until they reached advanced stages of development, many of which would have violated IPRs in other countries.

[7] India stood out in the pharmaceutical segment with stimulus to the private productive sector and sophisticated technological capacity in the areas of chemistry, biology and chemical engineering, acquired before the legal protection of foreign patents for pharmaceutical products. In 2007, in terms of volume, the country was the fourth largest producer of drugs in the world, and in terms of production value, the thirteenth.

[8] "The term TRIPS-plus seems to have appeared in the late 1990s. It is not known, precisely, who would have used it for the first time, however, expressive number of NGOs have come to use this term - simultaneously - in their studies on developing countries. Likewise, governments, intellectual property experts, international organizations, market analysts and the media in general have passed on this expression as a known reality." (Basso, 2005).

The Netherlands, for example, decided to revoke its patent law for 47 years, from 1869 to 1910, so that the country could freely copy the chemical inventions of its neighboring country, Germany (BRASIL, 2013a). Switzerland, in turn, when it industrialized in the 1880s, chose not to adopt the patent system, allowing it to benefit from innovations developed in other countries. Ultimately, patents were introduced only under pressure from trading partners. Similarly, between 1960 and 1980, Asian economies emphasized the importance of reverse engineering and imitation. When South Korea adopted patent protection in 1961, its validity was limited to only 12 years and was not available for food, pharmaceutical or chemical products. Italy, in turn, surprisingly only introduced a patent system in 1978 (GOWERS, 2006).

Falvey et al. (2006) found that a strong intellectual property rights protection system can reap rewards in terms of national innovation and increased technological capacity in developing countries with sufficient capacity to innovate, but has little impact on innovation and technological capacity building in countries without this capability and may impose additional costs. Kim *et al*. (2012) pointed out that when a country's technological capacity is weak, a system that protects smaller inventions, so-called incremental innovations, is more conducive to economic development in that country.

Yu (2013) concluded that intellectual property protection is useful and efficient in attracting foreign direct investment (FDI) if two conditions are met. First, the country needs to have a strong ability to imitate foreign products and technologies, otherwise the protection of intellectual property will be unnecessary, because the commercial interests of foreign companies will not be under threat. Second, the country needs to have a market large enough to allow foreign companies to capture economies of scale or scope. Even if these two conditions are met, the government has yet to question what form of protection needs to be strengthened in order to promote the country's economic development.

Sattar and Mahmood (2011) conducted a study to investigate the impact of intellectual property rights on economic growth in a sample of 38 countries, including 11 high-income countries; 8 high middle-income countries; 8 countries with lower average incomes; and 11 are low-income countries. The sampling period comprises the intersection between 1975 and 2005. The Sattar and Mahmood (2011) survey results showed that intellectual property rights contribute to economic growth in a positive and significant way in the case of the entire sample of countries. In addition, it has been found that the impact is greater in high-income countries compared to that in middle-and low-income countries.

Based on these analyzes, it is observed that the legal system of intellectual property directly affects the economic and social development of a country and becomes the center of economic and legal debates, a scenario in which the discussion about the additional protection provided in the sole paragraph of article 40 of the LPI.

3. The bill repealing the sole paragraph of art. 40 of Law 9.279/96

The bill 5,402 submitted on April 17, 2013 by the deputies Newton Lima Neto and FlorisvaldoFier (better known as Dr. Rosinha), which proposes, among other changes in the LPI, the revocation of the sole paragraph of its art. 40. The bill presents as justification the following grounds: 1) The patent system should serve as an incentive for technological innovation, protecting it. However, it must also promote access to these innovations, given the balance between exclusivity and competition. Thus,

overlapping patents disrupt this balance, hampering sequential or incremental innovation and frustrating competition; 2) In the absence of balance, the patent system will not be exercising its constitutional function and, as a consequence, it must be reformed by the Legislature, reinterpreted through the Judiciary, or have its public policies reconsidered through the Executive Branch (BRASIL, 2013).

In fact, the patent system was not conceived as an end in itself, being oriented not to mere protection per se, or to meet the interests of the inventor, but to promote inventive activity, transfer of knowledge, scientific, economic, social and technological development.

In this sense, the art. 5, XXIV, of CF / 88, *in verbis*:

> Article 5 - (...) XXIV - the law shall grant to industrial inventors a temporary privilege for their use, as well as protection of industrial creations, trademark ownership, company names and other distinctive signs, with a view to the social interest and the technological and economic development of the Country (BRASIL, 1988).

The literature discusses the meaning of the expression "taking into account the social interest and the technological and economic development of the Country", sometimes using a connotation of condition, that is, the protection guaranteed to the inventor would be conditioned to social interest and technological development and economic sense of the country, sometimes giving it the finalist-value sense, alluding that protection is granted because it generates positive effects in meeting the social interest and providing the technological and economic development of the Country(CERQUEIRA, 2006).

Complementing the above dictum, arts. 218 and 219 of the Basic Law determine that the State shall promote and encourage scientific development, research and technological training, requiring that the latter be focused predominantly on the solution of Brazilian problems and on the development of the national and regional productive system.

Based on the Brazilian Constitution, Barcellos (2010) concludes that the patent system "must meet clear premises of functionality, existing as necessary, sufficient and within the limits to meet the social interest, economic and technological development of the country." In the event of non-observance of these premises, the system must be subjected to a readjustment or reinterpretation, observing the limits of the hermeneutics against the possible needs of changes in the legal order. In this same line of reasoning, Barbosa (2010) states: "What characterizes the patent as a form of social use of property is the fact that it is a right limited by its function: it exists as socially useful."

According to Barbosa (2010), the purposes of the patent have, in our right, a constitutional design. Its immediate end is the reward of the creator, to the point where its immediate purpose is the social interest and the technological and economic development of the Country. Thus, the patent regime is an exception to the principle of market freedom, determined by art. 173, § 4 of the Constitution of the Republic of Brazil, and filed in arts. 1, item IV and 170, IV, and, being exceptional, it imports in a weighted and restricted application, being subject to parameters of use that do not exceed what is strictly necessary for its immediate purpose, that is, the effective but moderate stimulus reasonable to the inventor. Anything that

restricts competition beyond that which is strictly necessary to stimulate the invention exceeds the immediate end of the patent and is therefore an abusive act.

Thus, in order for the patent system to be properly balanced, while allowing fair compensation to the inventor and public access to the patented goods, the period of validity of a patent should be that which is strictly necessary to enable the return of the investment made by its owner - not one more day, not one day less. Any additional term changes the system of exchange between the public interest and the private interest established between the collectivity and the holder of the patent (BRASIL, 2013).

The authors of the bill understand that the extension of the term of validity of the patent due to the delay of the INPI in its granting is a TRIPs-*plus* measure and, as such, should be excluded from the Brazilian legislation, in view of the social interest in patented technology as soon as the 20-year term expires (BRASIL, 2013).

4 The unconstitutionality of the indeterminate term of validity of the patent

The attempt to suppress the sole paragraph of art. 40 of the legal system also reached the judicial route. On 05/18/2016, the Attorney General's Office (PGR) filed a Direct Action of Unconstitutionality-ADI # 5,529 with a report from the Minister Luiz Fux before the Federal Supreme Court. The action was distributed by dependence to ADI No. 5061, which deals with the same theme, filed by the Brazilian Association of Industries of Fine Chemistry, Biotechnology and its Specialties (Abifina), whose judgment was for its lack of knowledge, due to the illegitimacy of that association to proposition of Action of abstract control of constitutionality (STF, 2016).

According to the PGR, the legal system questioned faces the fundamental postulates of the constitutional order, such as the temporariness of the patent protection (Constitution of the Republic, article 5, XXIX, already mentioned), the principle of isonomy (CR, article 5, *caput*)[9], consumer protection (CR, art. 5, chap. II, and 170, V)[10], freedom of competition (Art. 170, IV)[11], legal certainty (CR, article 5, *caput*), the State's strict liability(CR, article 37, paragraph 6)[12], the principle of efficiency of administrative action (CR, article 37, *caput*)[13] and the principle of reasonable length of process (CR, article 5, LXXVIII)[14] (STF, 2016).

Barbosa (2013) is extremely critical to the device in question and understands that the issue under study is "certainly of public policy, or legislative, and not of law". For the renowned author, the legal safeguard for delay is not necessary, since art. 44 of the LPI already assures the holder of the patent the

[9] Art. 5 Everyone is equal before the law, without distinction of any kind, guaranteeing to Brazilians and foreigners residing in the country the inviolability of the right to life, liberty, equality, security and property, as follows: [...] (BRASIL, 1988).
[10] Art. 5 [...] XXXII - the State shall promote, in the form of the law, consumer protection; [...] Art. 170. The economic order, based on the valorization of human labor and free initiative, aims at guaranteeing everyone a dignified existence, according to the dictates of social justice, observing the following principles: IV - free competition; V - consumer protection [...] (BRASIL, 1988).
[11] See transcript in previous note.
[12] Paragraph 6 - Legal entities governed by public law and those of private law that provide public services shall be liable for damages caused by their agents, as such, to third parties, with the right of recourse against those responsible in cases of fraud or guilt (Brasil, 1988).
[13] Article 37. The direct and indirect public administration of any of the Powers of the Union, of the States, of the Federal District and of the Municipalities shall obey the principles of legality, impersonality, morality, publicity and efficiency, and also to the following: Constitutional Amendment No 19 of 1998) [...] (Brasil, 1988).
[14] Article 5 [...] LXXVIII - to all, in the judicial and administrative spheres, the reasonable duration of the process and the means to guarantee the speed of its proceedings are ensured. (Included by Constitutional Amendment No. 45, 2004) [...] (Brasil, 1988).

right to obtain the indemnification protection for the improper exploitation of its object, including in relation to the operation that took place between the date of publication of the application and that of the granting of the patent, concluding that the LPI establishes double protection to the patent applicant in the event of excessive delay of the technical examination: the sole paragraph of art. 40, which authorizes a prolongation of the regular period of the patent if the examination takes too long; and art. 44, which guarantees a retroactive protection of the privilege, once granted - with or without delay.

The illustrious author teaches that the claim that the patent would be born stillborn if it were granted after its normal term of validity (20 years from the date of filing) is unjustifiable, since the retroaction guaranteed to the patent applicant by art. 44 of the LPI would include an efficient way to prevent its violation of the economic risk of full indemnity (BARBOSA, 2013).

In fact, a British study recognizes the dissuasive power of the patent file, which, pending analysis, guarantees the patent applicant a near monopoly:

> As well as deterring legitimate applications, increased pendency also imposed costs by providing patent pending protection and hence (quasi) monopoly power to applicants with non-patentable inventions. The competitors are deterred from entering the market.
>
> [...]
>
> we are able to estimate the increase in the value of a pending patent due to increase in patent pending. This increase reflects the fact that, with pending patent protection, applicants will be able to charge higher prices, as the competitor will not be able to enter the market. (LONDON ECONOMICS, 2010).

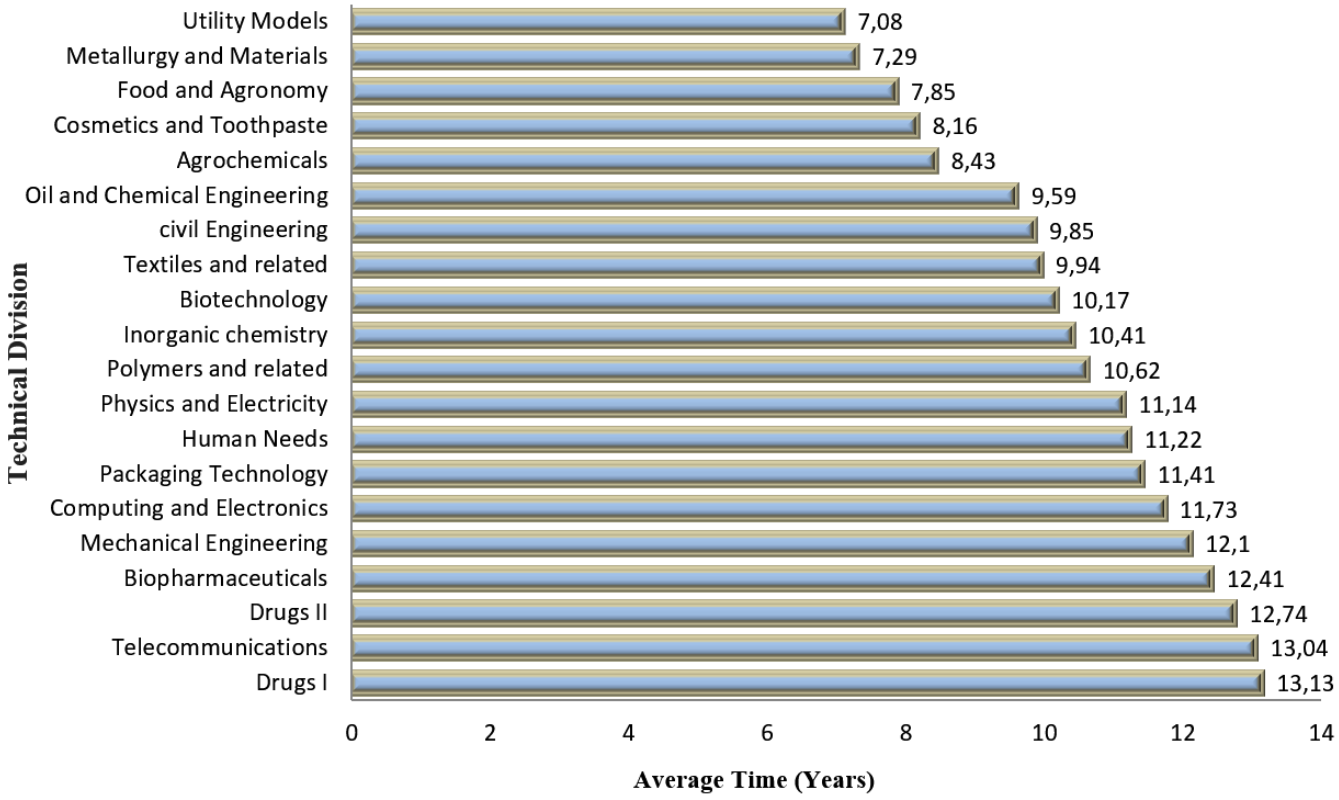
London Economics (2010) points out that many offices offer applicant the ability to expedite the processing of their order. However, only a small minority choose to do so (less than 1% in the USPTO and around 5% in the EPO). Rather, the evidence points to the widespread use of mechanisms and strategies for the purpose of extending or delaying the examination phase of the application for as long as possible. The study makes a surprising conclusion: "This suggests that most applicants are unconcerned with current levels of pendency."

Barroso (2010), in the same vein as the conclusion of the British study, argues that "simple filing of a patent application, even presenting non-patentable matter, already prevents the production and marketing of a given product because it has the expectation of a right of protection". Cerqueira (2010), in turn, argues that "the extension of the term of the privilege is a measure that finds no justification and can only lead to abuse and injustice."

Jensen et al. (2008) in a study based on a set of 9,618 patent applications from the same family submitted to the Australian (APO), European (EPO), Japanese (JPO) and American (USPTO) offices during the period from 1990 to 1995, concluded that applicants of low quality applications, and knowledgeable of this circumstance, are more likely to benefit from the waiting period. In other words, they contribute to increasing the pendency, possibly for strategic reasons, such as prolonging the quasi-monopoly status conferred on the invention.

Considering the patent granting time in Brazil in 2018, the situation causes concern, especially in the light of the conclusions of the study by Jensen et al. (2008), since the average time of granting the privilege by technical division was of 10.6 years for patents of invention, demonstrating the extensive use of the extension period provided for in the sole paragraph of art. 40, of the LPI, as shown in figure 1.

Figure 1 - Average time for granting patents by technical division (2018)



Source: INPI (2018).

In our opinion, there is no legal obstacle for the Brazilian State, by political-legislative option, to decide to establish the term of validity of the patent superior to that indicated by the TRIPs Agreement, after all, what was adjusted there was a minimum level of duration and not maximum. Such an option, because it is impregnated with democratic expression, can only be reviewed by the Judiciary in exceptional cases.

However, such a maximum term must necessarily exist and be known by the market, after all, the constitutional mandate establishes that the privilege is "temporary." And, according to Rocha's (1999: 241) lessons: "(...) it is temporary what has a duration envisaged in time, which does not tend to duration or permanence in time ...". Thus, the lack of definition in the demarcation of the term of patent protection established by the sole paragraph of art. 40 of the LPI is not in keeping with the temporary nature attributed by the Brazilian Constitution to the patents and with the social function of the institute itself.Table 1 shows the patents concede by the INPI with the longest backlog:

Table 1: Patents concede by INPI with a longer backlog (backlog)

Number of Patent	Date of file	Date of granting	Backlog (in years)
PI7606005	10/09/1976	03/06/2018	32,19
PI7900361	19/01/1979	11/04/2006	27,62
PI9106592	21/06/1991	06/03/2018	27,1
PI7908936	09/11/1979	11/04/2006	26,81
PI7907807	30/11/1979	01/03/2006	26,63
PI8103049	15/05/1981	17/07/2007	26,55
PI9207205	11/09/1992	08/08/2017	25,27
PI8103727	11/06/1981	01/03/2006	25,08
PI8708013	27/01/1987	12/07/2011	24,81
PI8107585	20/11/1981	01/03/2006	23,97
PI8103484	02/06/1981	23/11/2004	23,82
PI9702918	25/09/1997	18/09/2018	21,29
PI9715268	19/11/1997	23/10/2018	21,23
PI9611114	17/10/1996	01/08/2017	21,09
PI9710828	18/12/1997	04/09/2018	21,01

Source: Prepared by the author, based in Abrantes (2018).

The granting of privileges of uncertain and indeterminate duration, including a term of more than 32 years from the date of filing[15], means that the application of the extension period would make the patent remain in force for more than twice the time fixed as a rule, perpetuation that subverts the temporary character of the patent and nonexistent anywhere in the world[16]. What is seen, in fact, is the displacement of the State's accountability, for its inefficiency and slowness in the processing of patent applications, for the collectivity. Now, the State must be charged with the social and economic burdens arising from its inertia or arrears, in the exact terms of what is established in art. 37, paragraph 6 of the Constitution of the Republic.

Thus, due to Barbosa's lessons (2013), the issue under focus is public policy and also of law, since the legal system analyzed here causes imbalance in the exchange system underpinning the patent regime,

[15] The INPI has in some occasions adopted the administrative understanding that the patent application filed prior to the LPI do not apply the legal safeguard, declaring the patents extinct after 20 years from the filing date of the patent application, even though the granting has been after that final term. By way of example, reference is made to PI 9106592, whose first license letter, issued on 03/03/2018, provided for the use of the extension term and, later, on 04/09/2018, the municipality canceled the prior publication issuing a new letter with the correction within the term (20 years after the filing date of the patent application), making it extinct from 06/21/2011. With this understanding, the Brazilian office makes clear that it is common knowledge of the same thesis that the patent has economic and legal effects even before the date of grant, and it is not possible to state that in this case you would be born stillborn, notify potential counterfactors as to the possibility of future indemnity action, and may promote the acts necessary to defend their right, ensured by art. 44 of the LPI.

[16] According to Correa (2007: 469), some countries allow an extension of the patent term to compensate for unreasonable delays in the processing of the request attributable to the office. The author cites as an example the American code, which in its title 35 (U.S.C. 35), part II, chapter 14, paragraph 154, (b) establishes a guarantee of a pending request not exceeding three years. The adjustment basically extends a patent day to each day of USPTO delays and imposes a reduction of the term equal to the period of time when the applicant failed to make reasonable efforts to complete the examination of his application. In addition, even SPC (Special Producer Compensation) laws in Europe, the United States, Japan and Australia to compensate for the time spent by the patent holder in obtaining the marketing authorization for their products also set a limit maximum extension, usually five years (ABRANTES, 2014).

with flagrant prejudice to the public interest. To the extent that the public authority rewards the patentee with an uncertain end date privilege, which extends indeterminately, the promised social benefit is exhausted at the same time, making a clean slate of the finalistic clause provided for in subsection XXIX, art. 5, of the Federal Constitution, in what resides its unconstitutionality.

With the undue delay of the INPI and without a definite, definite and reasonable final date for the expiration of the patent, economic agents interested in the economic exploitation of their object can not be programmed to start their activities. In this sea of insecurity, society loses the most. It loses because it does not know if the person who explores the object of the patent has or will have a right to it and, from the date of its applicant, will bear the additional price that the monopoly regime imposes, without perspective when it will have access to generic or similar alternatives, much cheaper.

In the following topic, the social cost of this delay will be demonstrated and the deleterious effects of the sole paragraph of art. (Post-patent business, subject to non-monopoly prices) of the pharmaceutical and phytosanitary sector (agricultural pesticides) to illustrate the negative impact of the validity of the aforementioned device in the Brazilian economy.

5. Measuring the deleterious effects of the sole paragraph of art. 40 of Law 9,279 / 96 in the post-patent segment

The impact of INPI's slowness in the processing of patent applications is not limited to discouraging investment. In the Brazilian case, there is a social cost of at least two orders: 1) costs for the competing segment, since the additional waiting period (due to the pending), if more than 10 years, extends the final term of the patent to an indefinite date, delaying or even rendering unpredictable the free marketing of protected knowledge after the end of the privilege; (2) costs for consumers, since the length of the examination and the length of the patent lifetime lead to an additional charge arising from the postponement of the monopoly, which is caused by the loss of competition, low product variety and higher prices.

The challenge is to measure this cost in a hypothetical scenario where the patent would no longer hold, thus losing its price plus. In an interesting study, Chaudhuri, Goldberg and Jia (2006) empirically investigated the social benefits in post-TRIP India in the face of mandatory patenting of pharmaceuticals, focusing on the sub-segment of fluoroquinolones (antibiotics). In order to do so, counterfactual simulations of prices, profits and consumer welfare were carried out in the hypothesis of patenting fluoroquinolone molecules in India, similarly to what happened in the USA at the time (until then, India had not adhered to TRIPs). Data from a period of two years, from January 1999 to December 2000, were used.

The research findings have suggested that concerns about potential adverse effects on the well-being of TRIPS may have some basis. In the case of monopoly prices, the total annual welfare losses for the Indian economy with the withdrawal from the market of the four groups of domestic products in the fluoroquinolone sub-segment would be in the order of $ 305 million, or about 50% of sales of the entire systemic antibacterial segment in 2000. Of this amount, the lost profits of domestic producers - exempt from marketing because of the patent - constituted about $ 50 million. The overwhelming share, therefore, was derived from the loss of consumer welfare (CHAUDHURI; GOLDBERG; JIA, 2006).

Gaudry and Cumming (2014) estimated that in 2013 the USPTO's patent backlog and the application of the adjustment in the final term of the privilege (with the provision in 35 USC § 154 (b)), resulted in an expense an additional $ 19 billion for a set of 13 blockbuster drugs.

A survey conducted by researchers at the UFRJ (Federal University of Rio de Janeiro), at the request of the Brazilian Interdisciplinary AIDS Association (ABIA), conducted in January 2016, estimated the impact caused by the use of the legal safeguard to the Ministry of Health in centralized purchases of nine patented drugs. In order to carry out the estimation, the researchers assumed that the medicines analyzed, if there was no expansion within the patent period, could have generic versions.

In order to carry out the estimation, the researchers started from the assumption that the drugs analyzed, if there was no expansion within the term of the patent, could have generic versions[17], whose prices were estimated at 60% of the corresponding reference drug price[18]. Thus, based on the values of government purchases and the volume of acquisitions in the period from 2013 to 2015, including those made in response to judicial demand, the additional cost of extending the patent totaled more than R $ 2 billion, equivalent to 10% of the total spent on medicines by the Unified Health System (SUS) in 2015 (PARANHOS, 2016).

Table 2 provides an estimate of the injury to the Brazilian government with the use of the legal safeguard in the drug industry for pending patent applications for more than 10 years:

Table 2: Amount of injury (R$) accumulated by the SUS in regular centralized purchases up to January 2016 with the hypothesis of generic drugs on the market[19]

Medicament	Additional annual cost (millions of R$)	Extension of the patent (in years)	Additional cost with patent extension (R$)	Additional annual cost (millions of R$)
ADALIMUMABE	Crohn's disease, some types of arthritis, psoriasis and ankylosing spondylitis	253,7millions	3,00	761,2millions
ERLOTINIBE	Lungandpancreaticcancer	11,3millions	4,75	54,0millions
MARAVIROQUE	Antiretroviral for HIV	3,9millions	4,75	18,6millions
RALTEGRAVIR	Antiretroviral for HIV	64,8millions	3,25	210,7millions
CINACALCETE	hyperparathyroidism	0,5millions	10,25	5,9millions

[17] Only Sofosbuvir, Raltegravir and Erlotinibe had generic counterparts in other countries, with prices quoted in Brazilian Reais, with the dollar quoted at R$ 3.33 and with values up to 86% lower than in Brazil (PARANHOS, 2016).

[18] ANVISA establishes that the price of an incoming generic "may not exceed 65% of the price of the corresponding reference drug" (ANVISA, 2004). The researchers used this parameter by subtracting still 5% of the average value of royalty in relation to the revenues obtained with patented drugs, attributed value using an average of the parameters observed in other experiments for similar calculations (PARANHOS, 2016). In fact, the 40% reducer is quite reasonable. Nishijima, Biasoto and Lagroteria (2014) found that, generally, the price difference is greater than the 35% stipulated by ANVISA at the time of entering the generic on the market, thus suggesting a more competitive pattern for generics. As an example, see what happened with Lípitor® (Pfazier), the best selling medicine in the world, used to control cholesterol levels; whose patent expired in 2011 and is now sold at discounts of up to 59% given by the brand's laboratory (FURLAN, et al., 2019).

[19] The drugs Sofosbuvir, Raltegravir, TrastuzumabeEntansina, Gefitinibe and Cinacalcete at the time of the research were still in process of patent analysis. Sofosbuvir's patent, for example, after great excitement, was granted by INPI on 01/15/2019, generating an extension period of approximately 4.7 years and increasing the damage to almost R $ 3 billion in that drug alone.

SOFOSBUVIR	Hepatitis C	587,7millions	1,75	1,0Billion
TRASTUZUMABE ENTANSINA	Breastcancer	3,1millions	5,58	17,4millions
GEFITINIBE	Lungcancer	1,5millions	9,75	14,7millions
ETRAVIRINA	Antiretroviral for HIV	6,6 millions	4,17	27,8 millions

Source: Paranhos (2016).

It should be noted that the survey conducted by the researchers of the UFRJ only included drugs that were included in the list forwarded by ABIA. In this way, the damage to the public coffers is even greater than the estimated 2 billion[20]. By way of example, reference is made to Fosamprenavir, whose patent application (PI9912156) was filed on 07/17/1999, granted on 07/26/2016 and effective until 07/26/2026 (27 years after the date of the file). Jannuzzi and Vasconcellos (2017) estimated that for the aforementioned drug alone, at 100 mg dosage, the accumulated loss by the Brazilian government until December 31, 2016 would already be more than 14 million.

PróGenéricos listed five other medicines whose patents benefited from the legal extension: 1) Sitagliptin phosphate (PI0210866), for the treatment of diabetes, with a 21-month extension; 2) Liraglutide (PI9711437), also for diabetes, with 117 months of extension; 3) Sorafenib Tosylate (PI9814375), indicated for the treatment of liver cancer, with application filed on 12/22/1998 and still pending analysis; 4) Lapatinib Ditosylate (PI0111947), used in the treatment of breast cancer, with 39 months of extension; and 5) Varenicline tartrate (PI0209605), prescribed for the treatment of smoking, whose patent was filed on 01/03/2017 for lack of payment of the annuity, when it had already 58 months of extension. The five drugs combined moved around R$ 250 million in 2013, based on IMS Health consultancy, which meant an additional cost to society of about R$ 87.5 million[21] only in that year (ProGenericos, 2014).

Thus, it is verified that the legal safeguard imposes a great burden on public health policy and imposes an insurmountable obstacle to the population's access to essential medicines for the treatment of diseases such as cancer, AIDS, diabetes and hepatitis C. The social and economic impact also presents itself relevant to other markets, such as plant health products[22]. By 2015, about 75% of the products used in the crops were post-patent, indicating the strong presence of generics in the segment (ALBAUGH, 2016). Agricultural pesticides are important inputs that contribute to the increase of agricultural productivity and the formation of food prices[23]. And precisely in this sector comes an emblematic case involving the

[20] It should also be pointed out that the Federal Audit Court (TCU) has found irregularities in the maximum prices of medicines established by the regulatory body in Brazil, the CMED. In the comparison with the international market, it was verified that in a sample with fifty active principles selected based on the volume of commercialization in 2010, the prices of the CMED table were significantly superior to those practiced in public purchases. In 43 of them, the price tag was above the international average. In 23, the country had the highest price among the countries surveyed; and in only three, had the lowest price, estimated savings of about R $ 1.1 billion in 2010 if the international average calculated for each drug (TCU, 2012) was set as the maximum price.

[21] Considering the minimum price difference in the percentage of 35% (thirty-five percent) between the generic and the reference drug.

[22] The selected segment covers the most relevant pesticides from the market point of view (insecticides, fungicides and herbicides) and is characterized by the high financial volume of imports (56% of this market in 2012 was imported), the (Brazil has the largest market for pesticides in the world) and favorable tendencies to increase demand mainly due to population growth and higher per capita consumption of agricultural products (BAIN & COMPANY, 2014).

[23] It is not the scope of this paper to discuss the benefits and harms of the use of pesticides. It is true that these inputs pressure the costs of agriculture and increase crop productivity (SHUMACHER, 2017). As an example, in Brazilian soybean production between the 2007/08 and 2015/16 crop years, expenditures on pesticides accounted for 18.24% of total operating costs, behind fertilizer alone, accounting for 27.82% (CONAB, 2016). The Food and Agriculture Organization of the United Nations (FAO) estimates that world agricultural production loses from

unreasonable application of the legal safeguard, perhaps having been the patent that has been in force for a longer time in Brazil.

The herbicide Clomazone (PI8103484) had its patent application filed on 02/06/1981 and granted on 11/23/2004. On January 18, 2005, a rectification of an official document within the period of validity of the patent was published in the INPI's Industrial Property Magazine (RPI) nr. 1776, dated 01/18/2005, adapting it to the understanding of the INPI already handcuffed above (patent for a period of 20 years from the date of filing)[24]. The company that held the patent filed a writ of mandamus filed under number 2005.5101.507058-6 and filed with the 35th Federal Court of Rio de Janeiro, obtaining a favorable decision for the application of the extension term, establishing the final term of the patent on 23/11/2004. It occurs that in the RPI of number 2030, dated 12/01/2009, a decision notice (order 19.1) of a Judgment given by the Regional Federal Court (TRF) of the 2nd Region was reformed and the application of the proviso contained in the part end of the sole paragraph of art. 40, of the LPI[25]. In short, with that decision the patent should be in force until 02/06/2001 (20 years after the date of file). It occurs that the INPI failed to comply with the decision and only in RPI nº 2298, of 01/21/2015, it declared that the patent had expired on 11/23/2014, that is, ten years after its grating and with incredible 33 years and 5 months of validity[26].

Based on the finalistic clause in Article 5, XXIX of CF / 88, what is the social interest in conferring patent protection on a technology for more than 30 years? In this case, what is the legal and constitutional justification for continuing to protect from free competition an already obsolete technology? The legal safeguard stands as a barrier to the competitive and balanced market, damaging the society, since the generic pesticides, according to Albaugh's estimate (2016), are priced up to 25% less, on average, than the specialty ones.

The Brazilian market for phytosanitary products is mainly supplied by imported products (BAIN & COMPANY, 2014). Shumacher (2017) drew up a list of the fifty-five (55) major agricultural pesticides imported by Brazil in 2016. Out of this total, 50 (fifty) were without patent protection, either due to the expiration date or due to lack of file in Brazil[27] and 8 (eight) had used the extension mechanism, three (3) of which had already expired. When we take as reference the import values of these pesticides[28], as well as a price reducer in the percentage of 25% (twenty five percent), as estimated by the company Albaugh (2016), considering also the hypothesis that the eight (8) patents that were used in the legal safeguard were in force in 2016, we have reached the hypothetical annual cost of applying the legal safeguard, as indicated in Table 3.

20 to 40 percent per year as a result of pests (FAO, 2015).

[24] It is valid to record that during the present research it was verified that this understanding is not applied uniformly in all cases. From the list of Shumacher (2017), containing the 55 main agricultural pesticides imported in 2016, the legal safeguard was verified in the following patents, all with files previous to LPI: Protioconazol (PI9509805); Clomazone (PI8103484); Carfentrazone-ethyl (PI8907626) and Picoxystrobin (PI8800503), according to Table 3.

[25] The final part of the sole paragraph of art. 40 of the LPI establishes that the extension period will not be applied in the event that the INPI is prevented from proceeding to the examination of the merits of the request, due to judicial suspension or due to force majeure.

[26] All of this information is available to the public in the Web search system (INPI patent database). Consult in: http://www.inpi.gov.br/menu-servicos/informacao/search-of-patentes.

[27] It is uncomfortable that of the 55 major agricultural pesticides imported by Brazil in 2016, only 34 have applied for a patent registered in Brazil. It is not excessive to remember that the patent protection is territorial, that is, with limited force within the territory of the conceding country, so that if Brazil is not chosen as a file country the object of the patent will be free of economic exploitation in its territory.

[28] The import values were extracted from the Siscori system of the Brazilian Internal Revenue Service. Available in: <https://siscori.receita.fazenda.gov.br/apoiosiscori/consulta.jsf>.

Table 3: Annual cost of the sole paragraph of art. 40 of the LPI to the agricultural pesticides imported by Brazil in the year 2016.

Product/OrderNumber	Date of File	Date of granting	End of validity	Extension period	Total value Import (U$$)	Annual extension cost(U$$)[29]
Clorantraniliprole/ PI0212023/ BR122012024636	13/08/2002	19/02/2013	19/02/2023	6 meses	829,52	207,38
		16/12/2014	16/12/2024	28 meses		
Flubendiamida/ PI9905766	30/11/1999	30/11/2010	30/11/2020	12 meses	110,70	27,67
Tembotriona/ PI9914390	09/09/1999	19/10/2010	19/10/2020	13 meses	28.352.841,93	7.088.210,48
Aminopiralide/ PI0107649	12/01/2001	12/11/2013	12/11/2023	34 meses	7.031.712,20	1.757.928,05
Protioconazol[30]/ PI9509805	08/11/1995	14/12/2010	14/12/2020	61 meses	218.093.624,15	54.523.406,04
Picoxistrobina/ PI8800503	08/02/1988	25/08/1998	25/08/2008	6 meses	53.396.349,20	13.349.087,30
Carfentrazona-etílica/ PI8907626	16/08/1989	02/05/2001	02/05/2011	20 meses	16.555.412,00	4.138.853,00
Clomazona/PI8103484	02/06/1981	23/11/2004	23/11/2014	161 meses	67.099.941,09	16.774.985,27
					TOTAL	**97.632.705,19**

Source: Prepared by the author, based in Shumacher (2017) and Albaugh (2016).

From the joint analysis of Tables 2 and 3, it is inferred that the social cost of applying the legal safeguard is greater in the drug market than in the pesticide market. In addition to having its own regulation guaranteeing a minimum price difference in the percentage of 35% (thirty-five percent) between the generic and the reference drug, the minimum level is higher than that estimated by Albaugh (2016) for the mean difference of prices between equivalent and specialty pesticides, it was possible to verify that alone the annual cost of the extension of the drug Sofosbuvir is almost double the cumulative hypothetical cost of the eight patents of pesticides that had the extended term.

[29] On 12/30/2016 the dollar was quoted at R$ 3.26, according to the quotation available on the website of the Brazilian Central Bank (https://www.bcb.gov.br), totaling an approximate annual cost of R $ 318 million for the group of eight extended patents.

30 On the patent for Prothioconazole (PI9509805), a note from the authors should be noted: said privilege should have been extinguished since 08/11/2015, since, as pointed out above, the INPI's understanding is that in the case of a patent application filed prior to LPI applies the general rule (20 years from the filing date of the patent application). In the specific case of this patent, there is a flagrant material error of the INPI regarding the preparation of its letter of emission, which indicates validity period until 12/14/2020, according to dispatch with code 16.3 (Correction) published in RPI nº 2483, 08/08/2018. The error is whopping because the aforementioned patent was valid until November 8, 2015, by a final court decision (action filed under No. 2009.5101.812383-2, which was processed in the 37th Federal Court of Rio de Janeiro), as is verified by means of a simple analysis in INPI's own patent bank. As shown in Table 3, the cost of undue protection for more than five years is approximately US $ 84 million (approximately R$ 273 million).

It was also verified that, of the list elaborated by Schumacher (2017), containing the 55 (fifty-five) major agricultural pesticides imported in Brazil by 2016, 21 (twenty one) of them did not request the filing of the patent made in the country, (Glyphosate herbicide and fungicide Trifloxystrobin), which together totaled approximately US $ 770 million, about 35% of the total. It was also found that 90 percent (ninety percent) of the products on that list lacked patent protection in force, which means that these pesticides could be produced and marketed by any supplier with an interest and capital.

In practice, this is not happening due to the structural characteristics of this market - high barriers to entry, high concentration, competition in the most profitable sectors of the market not effected via prices - (TERRA; PELAEZ, 2008). Indeed, from the analysis of plant protection products whose patents were extinguished, many of them still remain without competition in the market and moved around USD 584 million in 2016, as shown in Table 4:

Table 4: "Non-Patent" Agricultural Defenders and Bidders

Active ingredient	Number of patents	Companies	Date of expiry of the patent	Import value in 2016 (U$$)
Piraclostrobina	1	BASF	21/06/2015	78.707.091,68
Picoxistrobina	2	Adama e Dupont	25/08/2008	53.396.349,20
Flumioxazina	2	Sumitomo e Nufarm	23/07/2000	38.458.798,80
Carfentrazona-etílica	1	FMC	02/05/2011	16.555.412,00
Metoxifenozida	2	Dow AgroSciences e Bayer	22/11/2013-	11.770.706,77
Fludioxonil	1	Syngenta	20/06/2001	10.055.313,24
Novalurom	2	Adama e FMC	18/12/2007	7.619.916,67
Piritiobaque	1	Iharabas	04/11/2003	265.200,00
Trifloxistrobina	1	Bayer	Sem patente	300.944.046,60
Diclosulam	1	Dow AgroSciences	Sem patente	33.578.240,89
S-metolacloro	1	Syngenta	Sem patente	21.494.600,33
Espinosade	2	Dow AgroSciences e Isca Tecnologias	Sem patente	4.892.566,18
Zeta-cipermetrina	1	FMC	Sem patente	3.936.007,20
Deltametrina	2	Bayer e Adama	Sem patente	2.126.561,61
Profenofós	1	Syngenta	Sem patente	32,60
			TOTAL	**583.800.843,77**

Source: Prepared by the author, based in Schumacher (2017) and Agrolink[31]

Tsunechiro and Ferreira (2000) analyzed the behavior of pesticide prices in the State of Paraná and concluded that generic products[32] offered by more than one company showed significant decreases in

[31] Available in: <https://www.agrolink.com.br/agrolinkfito/busca-direta-produto>.

[32] In Brazil, Decree No. 4.074 / 2002 officially established the simplified registration by equivalence (BRASIL, 2002). Terra and Pelaez (2008) refuted the lobbyists' argument that such flexibilization in the regulatory framework would provide greater access for firms producing equivalent agrochemicals and, consequently, a reduction in the prices of such products, concluding that equivalence the structural characteristics of the market for pesticides, will hardly bring a lower degree of concentration to the market.

prices, while products under patent or even products whose patent had already expired but continued to be produced by a single company, did not show significant price declines.

According to Santos (2014), in 2011 five manufacturers[33]had 62.5% of the market share (market share) of agricultural pesticides in Brazil, all of them foreign capital, and that Syngenta (Switzerland) alone, held a 21.2% stake. In turn, of the country's top 10 pharmaceutical companies in 2011, five were Brazilian and the leading domestic EMS Pharma held only 7.77% market share[34] (MARTICH, 2013).

The effect of generics on the structure of the pharmaceutical market was measured by Hasenclever et al. (2010), which reduced the Herfindhal-Hirschman index (HHI)[35] from 0.6731 to 0.5651 between April 2000 and April 2001, indicating a clear deconcentration of the sector. The author points to this deconcentration as the cause for the reduction of prices:

> This result suggests that it is not directly the generic policy that is influencing prices, but rather its effects on the market structure, that is, the more the market is deconcentrated, the lower the price of the reference drug. It is the deconcentration of the market, independent if due to the great presence of similar or as a consequence of the introduction of generics, which seems to lead to the reduction of prices of reference medicines (HASENCLEVER *et. al.*., 2010).

In a comparative perspective with the pharmaceutical industry, Gomes (2008) analyzed the potential effects on competition with the adoption of generics in the Brazilian pesticides industry, suggesting that the influence of generics in this segment would be higher than that. The misconception in the assumption was largely based on the premise that both segments would have an equivalent degree of concentration, which is not supported by the lines noted above.

It is true that the social cost of applying the legal safeguard in both segments is relevant, however, due to structural factors such as the strong business concentration, the impact on the market for pesticides is lower than that of medicines. As seen, the sole paragraph of art. 40 of the LPI has made possible the granting of patents with more than thirty years of validity, thus causing a harmful effect not only for the sustainability of the health system of the country but also for the formation of the prices of agricultural products.

In Garcez Júnior and Moreira (2017), it was verified that the determining factor for INPI's backlog is the shortage of personnel, which results in the inability of the office to decide in the same proportion as the increase in the number of applications filed. In 2013, the USPTO had 41 times more employees than the INPI and only 75 requests were pending for each examiner, while in the Brazilian office that ratio was almost 1000: 1. In other words, in order to keep pace with the American office, the INPI would need to hire a further 2,264 servers.

[33] According to Santos (2014), the five leaders of the market for agricultural pesticides in 2011 were: 1) Syngenta (Switzerland); 2) Bayer (Germany); 3) Basf (Germany); FMC (United States); Du Pont (United States).

[34] According to Santos (2014), the five leading pharmaceutical companies (EMS Pharma Medley, Aché, Sanofi Aventis and Europharma) held 28.89% market share in 2011.

[35] The Herfindahl index (also known as the Herfindahl-Hirschman index, or IHH) is an indicator of the degree of concentration in an industrial segment.

The public tender notice made by INPI in 2014[36] to fill the position of Researcher in Industrial Property (patent analyst) provided for a total compensation of R$ 7,421.60. After conducting a search by the name of the named in the Transparency Portal[37], it was verified the perception of a rough gross remuneration of R$ 10,000.00[38] for those servers. Thus, the annual budget impact with the hiring of 2,264 new examiners would be approximately R$ 300 million[39], almost half of the cost of annual extension of the patent for a single drug (Sofosbuvir).

6. Conclusion

The patent system, under the constitutional spectrum, represents a choice between two conflicting public options (trade-offs): providing sufficient incentives to promote innovation and the development of innovations that are novel and socially useful; and ensure that such inventions are readily available to society at an affordable price. In this sense, the patent needs to fulfill an economic, social and utilitarian function: it must serve the public interest and exist while providing the maximization of social welfare. Thus, the exclusivity enjoyed by the inventor is only a means to achieve the social interest and technological and economic development of the Country.

In the present research, sufficient evidence was found that the Brazilian patent system, in its current stage, with a temporal interregnum of more than 10 years for the examination of the patent - and consequent application of the legal safeguard - has allowed the holder of the privilege to receive in addition necessary to encourage the development of the invention, stifling competition and depriving the public of access to competitive prices.

The extension of the term of validity of the patent due to the delay of the INPI, provided for in the sole paragraph of art. 40 of the LPI, in addition to imputing to society the economic and social burdens arising from the inefficiency of the State, shifting to that the blatant responsibility of this, defies constitutional dictates such as the temporariness of patent protection. While the public power grants the patent privilege with the uncertainty about its expiration, lengthening it indeterminately, the promised social welfare disappears at the same time, making clear the unconstitutionality of the legal safeguard.

The indetermination of the term of validity of the patent is an exclusivity of the Brazilian patent system and one of its harmful effects is the restriction for the entry into the market of products equivalent to patents and with more affordable prices. Based on this premise, the social cost of the application of the extension period in the post-patent segment (pharmaceuticals and agricultural pesticides) was analyzed. It was found that the accumulated loss of the public coffers only taking into account nine medicines purchased by SUS in regular centralized purchases up to January 2016 was over R$ 2 billion. As for agricultural pesticides, there was an annual cost of approximately R$ 318 million for the group of eight patents that were extended with the application of the legal safeguard. It was also observed that, due to structural factors, such as high industrial concentration, the impact of the patent extension on the market for pesticides

[36] Available at: <http://www.cespe.unb.br/concursos/INPI_14/arquivos/ED_1_2014_INPI_14_ABERTURA.PDF>.
[37] Available at: <http://www.portaltransparencia.gov.br/servidores>.
[38] On April 23, 2019, the dollar was quoted at R$ 3.94, according to the quotation available on the website of the Brazilian Central Bank (https://www.bcb.gov.br).
[39] Taking into account factor 13.33 (including holidays and 13th salary).

is lower than that of medicines. However, in both sectors, the deleterious effect is relevant, jeopardizing not only the sustainability of the public health system but also negatively impacting the formation of agricultural product prices.

To achieve a backlog compatible with major patent centers, like the USPTO, the Brazilian office would need to hire a further 2,264 servers, which would cost approximately R$ 300 million, almost half of the cost of annual extension of the patent for a single drug (Sofosbuvir).

It is therefore perceived that the solution for the patent backlog in Brazil necessarily passes on to INPI adequate conditions for the efficient fulfillment of its mandate and not for the unreasonable and indeterminate extension of the term of validity of the patent (legal solution). Of all sorts, with or without the investment suggested here, the legal safeguard, besides being unconstitutional, is unnecessary, since, as seen, art. 44 of the LPI already guarantees to the patent applicant sufficient protection in the hypothesis of pending its request.

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