

Comparative Analysis of the Extension Mechanisms of Medicine Patent: a criticism of the Brazilian system

Fabrcio de Souza Oliveira¹

Introduction

The paper investigates the extension right foreseen on the unique paragraph, art. 40, of the Act n. 9.279/96 – The Brazilian Intellectual Property Law -, highlighting that in Brazil this rule can allow the strategic use of the time expended with patent process. This problem is delimited on the patents of medicines, where there must be considered the time for the approval by the health authority.

It states, through the comparison of patent systems, that the solution of the European system (and the Portuguese one, consequently), which is related to the limits of the problem posed in the previous paragraph, is more efficient because it preserves the incentives for innovation – by predicting supplementary protection – but it limits the strategic use of the term of the patent application procedure and it avoids unreasonable extension of the exclusive shopping term, by predicting a maximum limit for this additional protection, as well as it predicts a material limit (content), when working with a new industrial law not derived from basic patent. What is argued in the previous paragraph, as well as all the research proposed, starts from a value assertion, with the support of the theoretical framework used here - the jurist João Paulo Remdio Marques and the political economist Walter Eucken ¹

¹ Universidade Federal de Juiz de Fora.

It is noted that the context of the Patent Law presents a fundamental specificity, highlighted by James Boyle (Boyle, 2003): the patent protection object – the information – is not rival, in other words, a use of the information by an individual does not interfere in the use of other individuals may do and it is not exclusionary, i.e., is impossible, or at least hard, to stop one unit used from the good from satisfying an infinite number of users at zero marginal cost is it (Boyle, 2003, p. 41-42). These two characteristics indicate a market failure - with regard to the incentives for innovative movement.

The Law interferes with this space, building, normatively, the temporary exclusivity. The question versed in this paper is: the measure and the limit of time necessary and sufficient to stimulate innovative movements in the pharmaceutical industry², without harming the individual interests, ¹Assuming that the system of law can not be indifferent to empirical truth (Posner, 2007, p.73), due to be specialized in prescribing human behavior. If the aim is that, on one hand, by means of practical philosophy, it should be worry about desired behaviors by a given society at a given time, and on the other hand, it must occupy in knowing the "world" - achieve the objective-relative (in Popper's language. On this point see his "A Lógica da Pesquisa Científica" (Popper, 2007).) - or better, it must prepare using appropriate methodological tools to describe human behavior in order to build better preventive and sanction mechanisms - incentives to desired behaviors and disincentives to behaviors repelled. Thus, Law relating to human health, and the community interests with respect to health, while public policy, and the public budget³. Thus, there is a tension between the necessity to give the temporary one who invests resources in research processes and the necessity to supply the public domain with exclusive new features.

Contextualizing a little more the problem treated, it is known that, in general, there are two main types of pharmaceutical companies (1) companies that manufacture and / or import generic drugs (...) and (2) the pharmaceutical companies who spend most of their budget on research projects and development of new drugs. (...) The first develop their economic activity at the expense of research carried out by the latter (...)(Remédio Marques, 2003, p.66) (free translation) 4

These aspects indicate this paper for the purpose of comparing the extension term of the patent system foreseen by the single paragraph of art. 40, in the Brazilian IPL with the supplementary protection certificate under Regulation 469 of the European Parliament and of the Council of 6 May 2009, analyzing and criticizing, furthermore, the draft amendment to the Brazilian Industrial Property Law, with regard to deletion of the sole paragraph of art. 40, the Brazilian IPL. These objectives are delimited on patent of medicines.

The Logic of Brazilian Pharmaceutical Patent System

The Filing of an Application for a Patent and the e_ects Arising from it

The economic e_iciency of a patent is not limited to its lifetime. From the first application of deposit made, arises to the applicant the right to demand exclusivity in any country that recognizes the right of priority or the right to request foreign. (Barbosa, 2013, p.23)

The Brazilian IPL, in art. 445, regulates the right to compensation to the patent holder, even if the violation occurs between the date of publication of the application and the date of grant of the patent. The paragraphs also prescribe that this right exists if the o_ender has knowledge of the content of the application filed by any means. Thus, a notification (cease and desist), containing a description of the contents of the patent or to request early publication of the application for transfer is su_cient to extend over the period of the economic e_ectiveness of patent.

Thus, it is observed that the standard extension foreseen in the sole paragraph of the article 40, the Brazilian LPI can extend, in practice, the period of economic e_ectiveness of the patent for over 20 years. This problem will become more evident throughout the work⁶ generic copy and secure FDA approval. Such a short period would be inadequate to attract anything approaching the current level of investment in pharmaceutical research(Kuhlik, 2003, p.95-96) and development.

³About community interests, it is important read statistical data presented by Remédio Marques (Remédio Marques, 2003, 299- 388) In this text, the author cites an interesting estimate.

If there were no generic medicines in the European Community, around 17 billion euros would be spent over by public budget. ⁴It is highlighted, however, the speech of Remédio Marques:

(...) This does not mean that pharmaceutical generic companies do not contribute to scientific and technological innovation. Rather, they contribute indirectly to this goal, taking into consideration that, by withdrawing marketing margins and market areas from the drugs companies holders of patents on references, encourage them to undertake further improvements in the properties of such drugs or undertake new research. Moreover, the fact that generic companies testing, often, the active substances of reference drugs and mix them with many excipients different from the ones used by these, may result in the acquisition of knowledge about the best way to, for example, stabilize the active substance or to modify their organoleptic properties(Remédio Marques, 2003, p.67) (free translation) ⁵LPI - Art. 44: A patent is guaranteed the right to obtain compensation for the unauthorised exploitation of the subject matter of the patent, including exploitation that occurred between the date of publication of the application and that of grant of the patent. Paragraph1: If the infringer obtains, by any means, knowledge of the contents of a filed application, prior to publication, the period of undue exploitation, for the effect of compensation, will be counted from the date of commencement of the exploitation.

Paragraph2: When the subject matter of a patent application relates to biological material, deposited under the terms of the sole paragraph of article 24, the right to compensation will only be conferred when the biological material has been made available to the public. Paragraph3: The right to obtain compensation for unauthorised exploitation, including with respect to the period prior to grant of the patent, is limited to the contents of the subject matter of the patent, under the terms of article 41. Available on the

website:(<http://www.inpi.gov.br/images/stories/Lei9279-ingles.pdf>)

⁶It is said, however, that this is a limited protection. Accordingly, the judgment of the Court of Minas Gerais(Brazil): Abstract: Civil Appeal - punitive action in conjunction with claim damages for patent misuse - letter patent - not achieved - expectation of rights- the right to use exclusively the invention - not recognition.

The passive illegitimacy is technically confused with question of merit (checking or not the counterfeiting), which removes the possibility of judicial review of legal in status assertion is (Assertion Theory), because it is benefited by the production and use of utility model whose rights are discussed. Deposit held at INPI, without the application for patent letter has been granted, the inventor has the right to practice the invention, earning income from their exploitation, as well as the right to dispose of the invention, transferring it to third parties at any title, however the exclusive use of the invention is not assured to him, i.e., cannot prevent third parties from exploiting it. Appeal provided. (Apelação Cível 1.0672.11.012452-2/001,

30.11.2012)(free translation) does not exempt an option for principle when work together with economic sciences. Rather, its purpose is to develop regulatory systems with the highest possible degree of freedom for each individual

- this is a statement of principle. On this point, it is important the reflection of Walter Oswalt-Eucken on the Eucken's Theory of Social Orders: (...) One can not reach a maximum of scientific and legalconstitutional objectivity with an indi_erent behavior: science, as well as the Rule of Law, shall vigorously confront all formations of economic power. Whatever their nature.(free translation) (Eucken 1998, XXXVII)

Given this methodological proposal, the economic theory, specialized in studying the formations of power, will be used as a descriptive tool of reality, while the Law, impregnated with a set of principles also common to the economic theory in focus, is critically studied in its normative aspect (also as hard law) to determine if and when promotes the greatest possible degree of freedom. The

Patent Law and, in a more delimited way, the problem posed in this study, will be investigated in a scenario that considers a certain degree (temporality) exclusive (or monopoly) is required to stimulate innovative movements, but the excess on this exclusivity position by an economic agent reveals a power formation that threatens individual liberties and the Rule of Law.

This, ultimately, is the criterion to study and compare the legal systems concerned. 2(...) the end product of the investment in most cases consists overwhelmingly in the information that is generated about the drug's safety and e_ectiveness, rather than in the physical properties of the compound.

In the absence of intellectual property protections, generic market entry could occur within a few years of brand entry, depending primarily on the time needed to develop the

The ANVISA's (the National Agency for Sanitary

Surveillance) approval – the Brazilian health authority The National Authority for Sanitary Surveillance – ANVISA – was created in 1999 by Law no. 9.782/99, having as one of its tasks the regulation, control and inspection of products or services that involve risk to human health⁷.

In 2001, the Law no. 10.196 of 14 February 2001, amended the Brazilian LPI to prescribe, among other changes, that the granting of patents for pharmaceutical products and processes require prior approval of the National Health Surveillance Agency – ANVISA⁸.

Thus, the figure of the previous approval of the health authority, in casu ANVISA, was established in the procedure for the granting of patents for Brazilian pharmaceutical products and processes. The previous consent may be characterized as a previous authorization or binding opinion that, while opinionated act, conditions the production of another administrative act, which is the act of granting the patent by INPI (Remédio Marques, 2010-2011, p.381). It is an additional requirement for patentability (...) (Remédio Marques, 2010-2011, p. 374)(translated freely)

It was established in the regulatory system of the Brazilian Intellectual Property the linkage between the Brazilian patent office and the health authority. What is in question, in the Brazilian case, is not exactly the existence of this linkage⁹, but the amplitude of the powers conferred or exercised by ANVISA.

Once being an additional requirement for patentability, it is expected that this one be predicted in law, however, as observed by part of the doctrine, there would be here an affront to the principle of legality, when ANVISA (...)demands the exercise of administrative implied powers to not only carry out health checks on production and marketing of medicines, but also to analyze and judge the verification of the criteria for patentability of inventions for which protection part.(Remédio Marques, 2010-2011, p.375)

There is, in this case, an overlapping of assignment¹⁰, namely the INPI and ANVISA, and, in relation to ANVISA, there would be an extrapolation of their legal authority. This agency would not only performing the sanitary control, but typical assignments exerting a patent o_c.11

This problem emerged from the overlapping functions of the Brazilian INPI with ANVISA and it will be even more aggravated in the case of the Project of Law no.5402 of 2013 be approved, in progress in the Chamber of Deputies in Brazil.

That's because project predicts a legal instrument that modifies the wording of article. 229 - C12 of the Brazilian LPI, prescribing the assignment to ANVISA verify, the requirements for patentability, among others. We can observe that in

7Law n. 9.782/99 - Art. 8: The Agency is responsible, respecting the legislation in force, to regulate, control and supervise the products and services that involve risk to public health.

Paragraph 1: The goods and products considered subject to sanitary control and supervision by the Agency are:

I - medicines for human use, their active substances and other inputs, processes and technologies; (...) (free translation)

⁸Law n. 9.279/1996, Art. 229 – C.

⁹Tasks, functions, departments, and organizations integrated to achieve shared objective are related to each other, having interactions that promote the flow of information and idea:<http://thelawdictionary.org/linkages>(Black's Law Dictionary on line) Access im 11.12.2013.

¹⁰Marcela Trigo and Viviane Trojan report two trend movements that question this ANVISA's linkage. The first jurisprudence movement is about Article 229-C and its application highlighted the prohibition of the patentability requirements examination by ANVISA.

On several occasions, was defined by the Judiciary that ANVISA is not responsible for "review" the requirements of patentability once examined. (cf. decisions by JF/RJ, in the actions n. 2004.5101506840-0 e 2005.51.01.500427-9). The second movement, cited by the authors, is related to ANVISA's claim to revisit the patentability requirements, now on the grounds of Art. 18, paragraph I, of the Brazilian IPL

¹¹On this subject, specifically read (Remédio Marques, 2010- 2011) In this paper the author develops arguments against Brazilian linkage. There is, for him, an affront to the principle of legality when ANVISA exerts typical assignments of the INPI; Regarding pipeline patents, ANVISA assumes for itself the merits examination, of this specific category of inventions. In cases involving the application of drugs patent, the granting of patents have two authors (INPI and ANVISA), featuring a complex administrative act and highlighting the degree of participation of the two bodies is equal. The paper also presents the argument that the Brazilian prior approval would have transient nature and is designed for applications submitted at INPI between January 1, 1995 and May 14, 1997. This argument is based on the understanding that the prior consent would serve to verify if the object of the request pipeline would have been placed on the market or not. However, the author reports that the

Brazilian administrative bodies, including the AGU, have denied the transient nature of prior informed consent, arguing that its application is not restricted to pipeline applications. Furthermore, it is contrary to conditioner or preclusive interference of ANVISA into administrative procedure for granting the patent at the INPI, when the health authority perform a double syndication of patentability requirements(p. 389)

¹²Art. 229-C. The granting of patents for pharmaceutical products and processes require prior approval of the National Health Surveillance Agency - ANVISA, which should examine the object of the patent application in the light of public health. paragraph 1: The patent application will be contrary to public health, according to the regulation, when: (...)

II - the application for product or pharmaceutical process patent be of interest to drug policy or pharmaceutical care within the Unified

Health System - SUS and does not meet the patentability requirements and other criteria established by this law. (emphasis added) (free translation) the case of approval of this project, the argument of a_ront to legality loses strength. However, according to the argument of Remédio Marques, this would be the case of trend prohibition of conditioner or preclusive interference of the health administrative authority in the administrative procedure for granting patent(Remédio Marques, 2010-2011, p.389).

The General Extension Right Foressen in the Single Paragraph of Art. 40 of Law N. 9.279/96: An Approach with the Specific Extension Right for Sectors Regulated by the U.S. Health Agency?

The sole paragraph of art. 40 of the Brazilian LPI was introduced in order to compensate the INPI's backlog¹³ in the analysis of the patent applications. This standard, in principle, is not intended for regulated industries, such as medicines, but for the general patent applications as a legal way of giving back to the interested the time spent by

Brazilian patent o_ce in the examination and processing of patent applications. However, from Law no. 10.196, which introduced a new patentability requirement for drugs, without prescribing mechanism to compensate for the time that the person was unable to introduce on the market his invention, due to the analysis of the health agency, the general extension rule passes, in practice, to also fulfill the function of so-called extension mechanisms of patent protection. On the other hand, see Denis Borges Barbosa in The inexplicable public policy behind the sole paragraph of art. 40 of the Industrial Property Law.

We can observe that there are two reasons for the provision in question: one is the INPI's backlog, and other one is the linkage of the regulatory system of patents with sanitary regulation.

Therefore, the Draft Law. 5.402, 2013 in progress in the Chamber of Deputies in Brazil is defective by reason of predict the removal of the sole paragraph of art. 40, the Brazilian IPL, without, however, differentiate the two situations and treat them by specific rules.

This is also because the experience in Comparative Law is vast with respect to such mechanisms. As we can see, in the United States of America - USA - studies indicate that patents on drugs effectively last 11 to 12 years, while others last about 18 and a half years, it is because of the deposits of patent applications, in this area, occur relatively early – as soon as laboratory studies indicate a beneficial biological activity - due to the time spent in processing these orders until the approval of the Food and Drugs Administration- FDA.¹⁴ As a result, in 1984, was edited the Drug Price Competition and Patent Term Restoration Act, known as the Hatch- Waxman Act, rule that for the first time linked the Patent Law of the approval of the health authority.

As a partial solution to this problem, the Hatch-Waxman Act prescribes a period of extension of the patent, in case of that patent be related to certain products or methods, including medicinal products, which are subject to approval by the FDA (35 USC, paragraph 156, and *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990)). A patent may be extended for a maximum of 5 years or 14 years of actual use, whichever is smaller. Only one extension may be granted.¹⁵ Despite the fact that the standard contained in one paragraph of art. 40, the Brazilian LPI does not relate the patent right to the approval of the health authority - is a standard extension of the period of general patent - its nature is close to that of the right of U.S. extension made in the previous paragraphs. It's important to observe that this right extension does not arise an autonomous right, new and exclusive, as in European Union Law, what will be worked ahead. It is the basic patent right itself that is extended in time. The limits of patents' object are exactly those described when filing the initial application.

Another important aspect to note, moving away from the solution Hatch-Waxman Act of that under Brazilian IPL, is the fact that there is a time limit for the extension of the U.S. patent, while the Brazilian standard does not foreseen a time limit, only a minimum of effective use of 10 years after the grant of the patent.

It is at this point that the Brazilian system externalizes their fragility, which has already be pointed out in this paper: without a prescribed limit for the extension, there is space for strategic use of time needed to process the application. This feature, in practice, can lead to patents with a period over 20 years.¹³The value of orders that are not yet filled or the undone jobs on any day. This shows that there is area for growth in the company. Law Dictionary: <http://thelawdictionary.org/backlog/> (Black's Law Dictionary on line) Access 12.1.2014.

¹⁴(...) Patents typically are applied for relatively early in the research and development process, soon after there are initial indications from laboratory studies that a compound may have beneficial biological activity. Although the term of a patent is twenty years from filing, the e_ective patent life for pharmaceuticals –the time remaining following FDA approval is approximately eleven to twelve years in practice. E_ective patent life for other industries averages approximately 18.5 year(Kuhlik, 2003, p.96-97) 15As a partial remedy, the Hatch-Waxman Act provides a patent term extension for patents covering certain products and methods, including human drug products, that are subject to FDA approval (35 U.S.C. paragraph 156 and *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990)). The patent's term can be extended by a maximum of five years or 14 years of e_ective patent life, whichever is less. Specifically, the patentee is entitled to a credit for the time the FDA was reviewing the first drug application. Only one extension can be granted in connection with a particular product, and it must be for a patent that claims either a: Drug product, which means the active ingredient and any approved drug using that active ingredient; Method of using a drug product; Method of manufacturing a drug product(Pensabene, n.d., p.5).

The Logic of Drug Patent System Portuguese The filing of an application for a patent and the economic e_ects arising from it:

The art. 104, the Portuguese CPI prescribes that therights conferred by the patent are not opposable, in the country and before the filing date, or the date of priority when it is claimed, against who, acting in good faith, has reached by his own means to the knowledge of the invention and used or made e_ective and serious preparations with the aim of such use. (emphasis added).(translated freely) We can infer that, in Portuguese law, patent protection starts from the date of filing of the application, as well as it happens in Brazilian law.

The economic efficiency may be provided from the date of filing. What, however, does not imply the same problem of Brazilian Law: the unreasonable extension of the effective period of exclusive use, for reasons that will be articulated in the topics that follow.

The INFARMED's approval – the Portuguese health authority: In Portugal, INFARMED is the health authority responsible for the marketing authorization of medicinal products for human use. (Remédio Marques, 2008, p.23–25).¹⁶ This authorization aims to verify the effectiveness of molecules or innovative biological materials - if they have therapeutic properties regarding the disease or syndrome in question - the safety, bioavailability and possible side effects. (Remédio Marques, 2010-2011, p.465). In the European Union, similar organ is the European Medicines Agency.

The INFARMED must decide on the authorization patent the medicinal product on the patent for 210 days – according to Decree - Law 176/2006.¹⁷ This decision can only be based on objective scientific criteria of quality, safety and therapeutic efficacy of the product in question - art. 14, n. 2 of the Decree-Law in question. Thus, the tasks of INFARMED don't coincide or overlap those of Portuguese INPI. Regarding INFARMED, there is a concern about the quality of the product, while in Portuguese INPI there is a concern with filling or not the patent requirements. It must be informed that, in Portugal, the INFARMED's administrative process whose object is the application for marketing authorization (MA), is followed by another administrative process whose purpose is to fix the maximum selling price of medicine to the public, in charge of the Directorate-General for Economic Activities, under the Ministry of Economy (Remédio Marques, 2010-2011, p.468).¹⁸ The deadline for setting this price varies from 45 or 60 days depending on whether the drug in question is generic or reference.¹⁹

The supplementary protection certificate predicted by Regulation 469 of the European Parliament and of the Council of 6 May 2009

The supplementary protection certificate had its origin in European Union's Regulation 1768/92, which entered into force on January 2nd 1993, covering all pharmaceutical products protected by patent rights for which the first authorization to place on market had been granted in the European Community after the day 01/01/85 (Remédio Marques, 2010-2011, p.474). However, in Portugal, only the issue of the supplementary protection certificate was permitted from the day 02/01/1998.

²⁰This instrument is currently recoded by means of Regulation 469 of the European Parliament and of the Council of 6 May 2009.

One should take into account that, dealing with the European Union Law, the regulations are defined as acts of general character, binding in its entirety and directly applicable in all Member States, is characterized by its abstract nature and by no need or even illegitimacy of incorporation into national law of the Member States, this does not preclude the adoption of certain measures of implementation (Moura Ramos, 2003, p.75). Within these limits, the supplementary protection certificate is regulated in Articles 155, 115-A and 116 of the Portuguese Industrial Property Code.

The supplementary protection certificate is not a mechanism to extend the protected rights by the original patent. In fact, this is a new right, which is not derived from the right of the basic patent. It aims to rebalance the investment-return equation in the case of the pharmaceutical industry, that having its activity regulated in a high degree, take advantage of the unique business obtained by a patent on a new drug in Europe for a medium term 8-11 years (Remédio Marques, 2010-2011, p.475). Thus, the supplementary protection certificate is a strategic mechanism that restores competitiveness

¹⁶Decree - Law 176/2006 - Article 14, n. 1: Unless otherwise stated, the sale of medicines in the country is subject to authorization by the highest body of INFARMED, I.P.

¹⁷Art 23, 1 - INFARMED decides on the request for authorization of a medicinal product within two hundred ten days from the date of receipt of a valid application in accordance with the provisions of Article 15 and no. n. 1 of article 16

¹⁸On this point, see Directive n. 89/105/EEC

¹⁹Ordinance no. 300-a/2007, art. 4: The prices fixed by the DGE, in accordance with Articles 6 and 9 of Decree-Law No 65/2007 of 14 March, practiced by the MA, or their legal representatives, after the receipt of their communications or, in the absence of any communication by the DGE, within 60 or 45 days, depending on whether general or generic medicines from the date of receipt of the application, considering in this case, tacitly authorized prices proposed by the applicant.

²⁰EEC 1768/92 Regulation - 21: In Member States whose law of January 1, 1990 did not predict the patentability of pharmaceutical products, this Regulation shall apply within five years from the date of its entry into force. of the European pharmaceutical industry, since other systems already had adopted mechanisms for extension of the patent right, such as the U.S., in reference to the previous topic. This legal mechanism is regulated autonomously in relation to the basic patent, su_ering temporal limits and materials (Content):

Time limitation. the supplementary protection certificate has a very specific validity period. It is regulated by art. 13 of Regulation 469 of the European Parliament and of the Council for 6 May 2009, the certificate is valid for a period between the date of application of the basic patent and the date of the first authorization to place on the market in the Community, reduced a period of five years. However, shall not exceed five years from the date on which it takes e_ect²¹. Material limitation. the new industrial property right is only based on the basic patent, whose object of protection is usually smaller: there is just a protection of the active substance covered by a marketing authorization (MA) but not of other substances or technical elements claimed in the basic patent (Remédio Marques, 2010-2011, p.474). The object for the supplementary protection certificate is not the drug that has been in favor of AIM 22. (Remédio Marques, 2012, p.40)(free translation)

(...) Another patent may be related to new formulations (with di_erent structure) of the same active substance, to the new dosages, to new ways of administration or controlled release and new therapeutic applications. (Remédio Marques, 2012, p.40) (free translation) What is protected through Supplementary Protection Certificate is the concrete use that is authorized in the MA. Therefore, it is characterized in the specialized literature as a second generation patent, a hybrid type of industrial property located at the intersection of patent law subsystem and the administrative system of regulation on medicines' marketing (Remédio Marques, 2010-2011, p.474)(translated freely)

These characteristics of the supplementary protection certificate are di_erent from the Brazilian's solution prescribed by the sole paragraph of art. 40 of the Law of Industrial Property and also from the solution predicted by the U.S. Hatch- Waxman Act. In Brazil, as already said in previous lines, there is no connection between the extension of the patent right and the sanitary approval, besides there is no time and material limits. In the U.S. case, the solution di_ers from European Union law, insofar as the latter provides, besides a time limit, a material limit (content).

Based on these recent appointments, one argument for (there are other arguments) inapplicable to Brazilian pipelines patent of the extension protection related to the term of any additional certificates issued in the European system: as already explained, these certificates do not prolong the life of the basic patent, but are autonomous regarding them. In the particular case of Brazilian pipelines, the expression "remaining deadlines" foreseen in paragraph 4., Art. 230 of Law n. 9.279/96²³, refers to the basic patent and not to the autonomous right relating to supplementary protection certificates²⁴.

Conclusion

Walter Eucken, analyzing the relationship between the legal order and economic order says that: the legal order – insofar as it is economically relevant – it appears in most cases to give a setting to certain pre-existing economic facts. (...) The legislator and jurisprudence seek, through the rules and decisions of justice, to form a pre-existing economic order. (Eucken, 1998, p.90)(free translation) In the study of Industrial Property this distinction reverberates differently. As pointed out in the opening lines, the object of patent protection is the information. And this infor-

²¹REGULATION (EC) No 469/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009- Article 13 Duration of the certificate: 1. The certificate shall take effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorisation to place the product on the market in the Community, reduced by a period of five years. 2. Notwithstanding paragraph 1, the duration of the certificate may not exceed five years from the date on which it takes effect. (...)DOI: <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0001:0010:en:PDF>

²²REGULATION (EC) No 469/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 May 2009 -Article 4 Subject matter of protection: Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

(<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:152:0001:0010:en:PDF>)

²³Paragraph 4., Art. 230 of Law 9.279/96 - (...) is assured to patents granted under the present Article the remaining term of protection in the country where the first application was filed from the date of filing in Brazil and limited to the period referred to in art. 40, not applying the provisions of sole paragraph.(free translation) 24On this specific aspect it is interesting the argument used by the Minister Luiz Fux, in monocratic decision on the case 755 981 on 30.10.2013, in the Supreme Court. The argument is: So, the fact that the author had abandoned the patent application does not only allow to be considered the date of filing which was later converted into a patent, even in this case where it is' continuation in part ', systematic admissible only in European and American patent system, all considering from the patent originally filed on 24/04/1990, the date to be considered to fix the period of validity of the patent in our country, according to the legal provisions already mentioned.(free translation) mation tends to be inserted into the company through a non –exclusive and non – rival way. This feature – which has also been pointed out – removes from that information the necessary scarcity so that it presents economic value. Without this economic value, the patent's holder would receive only moral incentives. This is an economical description of the social fact.

The law interferes in that order, reconfiguring this fact. The legal requirements add exclusivity to the descriptive framework - here, the legal regulation establishes the social fact. The legal order precedes the economic order. The economic value of this particular class of good exists only from the legal regulation. So, it is in the legal order and not in the economic order that should be thinking the exact extent of this exclusivity.

In other words: Actually, rules are structured from behavioral regularities and, at the same time, serving as a parameter to induce behaviors. (...) (Feres, n.d., p.7) (free translation)

In this context, Eucken warns: wherever the fundamental character of the market economic order is, where, therefore, economic units are market dependent and that are also directed at it in the preparation of their plans and their actions, economic power will make itself feel otherwise. Here also can form very strong economic powers, which are often supported by government and which in turn exert political power. (Eucken, 1998, p.317)(translated freely)

However, analyzing the Brazilian patent system within the limits defined by the problem presented in the introduction, it is observed that the absence of a limit to the effective enjoyment of economic efficiency of patents turns out to enable strategic moves by the patent holders to extend, in concrete, unreasonably its validity. There is the case of the economic agent, that using the structure of regulation, captures its mechanisms to use to their advantage. It is in this sense that the introductory hypothesis is remedied: the solution of the European system (and the Portuguese, therefore), which is related to the limits of the problem posed in the previous paragraph, is more efficient because it preserves the incentives for innovation - by prescribing additional protection - but limits the strategic use of the term of the patent application procedure and avoids unreasonable extension of the term of exclusive shopping, by predicting a maximum limit for this additional protection, as well as predict a material limit (content) when working with a new Industrial Law not derived from the basic patent.

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