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**The new Industrial Property Law in Brazil and its influence on drugs innovation in the national pharmaceutical sector**

Abstract:

Brazil's economic and regulatory changes occurring in the nineties ensured growth business strategies for pharmaceutical companies operating in the country. Among the main changes, few should be numbered: the reduction of tariff protection and non-tariff barriers; currency stabilization; flexible exchange rate policy; inflation control; creation of the regulatory agency for the sector (National Health Surveillance Agency - ANVISA); disassemble mechanisms for price control; promulgation of the Law of Patents; introduction of generic drugs and imposition of new rules to the industrial sector in order to ensure the quality of drugs commercialized in the country. The paper examines the impacts occurred in the national drug industry, caused by the current Law of Industrial Property - IPL 1996, that allowed again the patenting of processes and products in the area of pharmaceuticals. In this way, patent applications filed in Brazil in the pharmaceutical industry were raised, for residents and non-residents in the country, identifying the major applicants of patent applications in the period between 1987 and 2005. The results show that the deposits have increased from 2.404 to 21.642 applications after the entry into force of the new Patents Law. The ratio of deposits of residents and non-residents for the period before the law and after it was 2% and 4% respectively. The relationship between the number of patent applications of the biggest applicants and the total apply decreased from 48% to 36% after the promulgation of the IPL, and no Brazilian applicants was included among the biggest depositors. The paper concludes that the change made in the IPL, by itself, did not contribute to make the national pharmaceutical industry competitive.

Subtheme S6.5: Government policies for enterprises and industries

Keywords: pharmaceutical industry, patents, innovation, Brazil

INTRODUCTION

Brazil enacted on May 14, 1996 Law Nº 9279 - Industrial Property Law (IPL), adapting national legislation to the international agreement TRIPS (Trade-Related Aspects of Intellectual Property Rights), signed by several countries in 1994[[1]](#footnote-1), allowing among other changes, the patenting for pharmaceuticals sector. Analysis of the period preceding the current IPL takes into account the fact that the national pharmaceutical industry could have used the patent system by applying the patent applications in Brazil, whether they were not under the patent protection. Such a procedure would aim to ensure the absolute novelty of the invention, through the unionist[[2]](#footnote-2) priority of the Paris Union Convntion (PUC)[[3]](#footnote-3), which could be expected in cases of innovative industries with strong performance in R&D and international markets. The hypothesis of this paper is that only the entry into force of the current IPL did not changed the patenting profile in the pharmaceutical sector by resident[[4]](#footnote-4)companies and there are no resident companies among the largest patent applicants of this sector in Brazil. However, entry into force of the current IPL may have produced a significant increase in patent filings in the area of pharmaceuticals by non-residents.

**PHARMACEUTICAL INDUSTRY AND RIGHT OF INTELLECTUAL PROPERTY**

According to Vieira and Ohayon (2006), technological innovation is a widely recognized differential factor of competitiveness between companies and countries. The Pharmaceutical Industry (PhI) is based on science and stands out as one of the most lucrative. Innovate in this sector means to let available commercially for human consumption of a new drug for the treatment of diseases. They emphasize also that the development of new active ingredients for drugs has occurred most often, “by accident”. This means that investments made for the development of new drugs have some degree of risk because there is no guarantee that it will be obtained a final product, and even if this goal is achieved, it will be required an approval by regulatory organisms for the final lifting for human consumption.

According to Rosenberg (2007), the leading companies in the pharmaceutical industry, allocate an average of 15% of its sales for R&D. However, besides investments in R&D, other factors impact on the industry development, such as marketing expenses which, according to Matraves (1999), reach 1.4% of sales value. Since the last decades, the US, with support from developed countries, has exerted pressure on developing countries, aiming to reshape of the international system of industrial property. This reform intended, among others, the recognition of patents in all technology sectors, mainly in the area of pharmaceuticals, for all countries (STIGLITZ, 2007). In 1994, occurred the most important trade negotiations in recent years, the GATT Uruguay Round, which resulted in the creation of the World Trade Organization (WTO) and the TRIPS. Regarding the implementation of the agreement by countries members, it has been established that the developed countries should implement it as soon as the WTO would begin its functions, and developing countries and less developing countries (LDCs), would have longer deadlines, which would range from five to ten years, starting from 1995. Brazil decided not to use the entire period that was given to it by the TRIPS, and promulgated the IPL on May 14, 1996, through which the mentioned "minimum standards of protection" required by the Agreement were met. The IPL not only met the requirements of the Agreement, as well, created the "pipeline" figure which in brief is the retroactive award of patents for pharmaceuticals. Profiting from this facility, about 1,200 patents of pharmaceuticals were required in the country between 1996/97. The main recipient countries were the USA, with 46% of the requests, the UK, with 13% and Germany with 10%. Regarding residents, they were requested only 17 patents which represented only 1.7% of the total applications (BERMUDEZ *et al.*, 2000), showing that the “pipeline” was better used by non-residents. It has been also altered the duration of patents for inventions, which became 20 years, following a worldwide trend for terms harmonization. Until 1945 there were no restrictions to the patenting of pharmaceuticals in the country. From 1945 (through Law 7903 of August 27, 1945) until 1969, it was prohibited the patenting of pharmaceuticals, but it was kept the patenting for pharmaceutical processes. In 1969, through Law 1005 of October 21, 1969, it was also banned to grant patents for processes of obtaining pharmaceuticals. The Law 5772 of December 21, 1971, continued to ban both for the recognition of patents for pharmaceutical products and for processes of obtaining them.

In the Brazilian process of industrialization, in the '70s and '80s, it has been adopted a protectionist policy which prohibited or at least restricted the import of an extensive list of goods, due to the existence of similar in the country such as computers, among others (SUZIGAN, 1996). In this logic, and within the limits allowed by international treaties, few sectors were no longer covered by intellectual property protection law, among them stands out, as established by Law 5772, the non-recognition of patents on products and chemical processes, food and pharmaceuticals. According to Mankiw (2001), the effects of patent laws are clearly visible. Since the law grants the patent holder a monopoly, this one can charge higher prices due to lack of competition. In the other hand, this is one more reason to pharmaceutical companies invest part of those profits in research and development of new active principles. The theory of brand loyalty is supported by Radaelli (2003), stating that brand loyalty is considered a historical characteristic of the industry that allows continuous profits, even after the expiry of exclusivity granted by patent. This implies that the appropriation process extends beyond the patent, therefore, the patent is not the only form of protection. When the exclusive rights of a drug expire, other companies come to market and cater to so-called generic drugs, causing their price decrease. However, this practice does not determine the total loss of the market by the monopolist, since many consumers, for different reasons, remain loyal to the brand. Aiming to create alternatives to the use of branded products, the government created the Law Nº 9787 of February 10, 1999 establishing the generic drug in Brazil. According to Tannus (2008), even in past times, when Brazilian law of industrial property did not granted any kind of protection for products and processes in the pharmaceutical sector, no sufficient investment were made by Brazilian pharmaceutical industry for generating technologies able to stimulate its development and competitiveness, based on innovation.

###### METHODOLOGY

In this paper, for the assessment of the national pharmaceutical industry capacity of innovation development, following the entry into force of Law 9279/96, Current Industrial Property Law, it has been considered the total number of patent applications[[5]](#footnote-5) from residents and non- residents, published by the National Institute of Industrial Property - INPI during the period 1987-2005 in the area of pharmaceuticals. For the data gathering related to deposits of patent applications in the pharmaceutical industry in Brazil, it has been chosen a database of patent which would enable the statistical treatment of results obtained in surveys.

The period covered patent applications filed from January 1987 until December 2005. There were not included in this study patent application filed on or after January 2006, according to the existing deadlines for publication of applications filed in the country directly or through for Patent Cooperation Treaty (PCT[[6]](#footnote-6)). The applications filed directly in the country are published after a period of 18 months of secrecy, being given an early publication by request of the applicant. Applications filed through the PCT are published in the country within 30 months after the initial file. In this period was surveyed patent applications for invention (IP[[7]](#footnote-7)) and utility models (UM[[8]](#footnote-8)), filed in Brazil.

The index used in the survey was the International Patent Classification (IPC), which limits the data gathering to the pharmaceuticals technological sector. The classification consists of a hierarchical structure formed by sections, subsections, classes, subclasses and groups representing different technologies being essential for the indexing of patent documentation. The Strasbourg Agreement (1971) established the mandatory use of classification for the patent applications among its signatory countries. The IPC codes used in order to limit pharmaceutical patent applications in this survey were: A61K 9/00; A61K 31/00; A61K 35/00; A61K 38/00; A61K 39/00; A61K 41/00; A61K 45/00; A61K 47/00; A61K 48/00; A61K 49/00; A61K 51/00; A61K 101:00; A61K 103:00; A61K 121:00; A61K 123:00 and A61P.

In this survey, it has been considered as larger applicants, year by year, the individuals or companies who fit the following criteria: applicants who owns more than one filed application, limited to the 15th place in the ranking. The restriction in more than one application is due to the fact that in preliminary study it has been shown the existence, in a given period, of a high dispersion of the number of deposits among the different applicants and a large number of applicants with only a unique application, making impossible the classification of these data.

Finally, they were raised the fifteen largest applicants of patent applications in the pharmaceutical sector, from 1987 to 1995, 1996 to 2005, and 1987 to 2005. In this survey, it has not been used the restriction on the number of deposits, ie, they were computed all patent applications filed by the fifteen largest applicants for each period.

**RESULTS OBTAINED AND ANALYSIS**

Several comparative analysis were made based on data collection of the number of patent applications in the pharmaceutical sector, filed in Brazil in the period between the years 1987 and 2005, whether individuals or legal entities, residents or non-residents. Graphic 1 shows the evolution of all patent applications in the pharmaceutical sector, during the period of 1987 until 1995.

Graphic 1 - Evolution of all patent applications in the pharmaceutical sector, during the period of 1987 until 1995

The analysis of Graphic 1 showed the occurrence of patent applications filed in this sector, even without the law prevailing at the time of the considered period (1987-1995) making possible the protection through patents in the pharmaceutical sector.

However, early in the series the values were remarkably low, only showing significant growth since 1990, reaching a growth of about 80% between 1994 and 1995, immediately prior to IPL. Making a linear fit to data for the period 1987-1995, an average growth rate of about 79 patent applications per year is observed.

This growth could be linked to the fact that companies, in anticipation to impending changes in Brazilian legislation related to the protection for pharmaceuticals by the way of patents, began to file patent applications, even with the possibility of the law be enacted and including a retroactivity through *pipeline* device. Graphic 2 shows the evolution of all patent applications in the pharmaceutical sector, during the period of 1996 until 2005.

Graphic 2 - Evolution of all patent applications in the pharmaceutical sector, during the period of 1996 until 2005

The analysis of the chart showed that the deposits of patent present significant growth after the entry into force of the IPL, which now allow a protection by patents in the pharmaceutical sector, about 54% between 1996 and 1997, and from this date to the present an average growth of about 7% per year between 1997 and 2004 is observed, the latest year where the data were consolidated.

Making a linear fit to data for the period 1996-2004, we can find an average growth rate of about 119 patent applications per year, representing a growth rate of 50% over the previous period. The decrease has been observed between the years 2004 and 2005 must not be taken for representative, as the value for 2005 was still not consolidated when the survey was conducted. This was due to the fact that patent applications filed through the Patent Cooperation Treaty (PCT), adopt common rules that allow such applications to open its national phase after a period of thirty months, that is to say, its first publication in the country generally occurs after thirty months where, however, delays can occur.

Graphic 3 - Evolution of all patent applications from residents in the pharmaceutical sector during the period of 1987 until 1995.

The analysis of the graphic 3 showed that in the period surveyed (1987-1995), in which there was in the existing law no possibility of protection through patents in the pharmaceutical sector, the values were so small that they did not allow an analysis regarding the pattern of growth occurred.

Graphic 4 - Evolution of all patent applications from residents in the pharmaceutical sector during the period of 1996 until 2005.

The analysis of the graphic 4 showed that, even continuing remarkably low compared to total deposits in this sector, deposits of patent showed significant growth after the entry into force of the IPL, which now allows for protection through patents in the pharmaceutical sector. However, this growth that was approximately 175% between 1996 and 1997 and 150% between 1997 and 1998, did not maintained a constant trajectory beginning, from there, to present increase and decrease, ending in 2004, last year in which the data was consolidated, with practically the same value of 1999.

Comparing the patent applications by residents and non-resident for the periods surveyed, it was found that in the first period they were observed 51 applications filed by residents, whereas non-residents have placed orders in 2353. In the period after the entry into force of the current IPL, they were 840 applications filed by residents, while non-residents have placed 20.802 orders.

Graphic 5 - Evolution of pharmaceutical patent applications of the largest applicants, year by year, during the period of 1987 until 1995.

For the period 1987-1995, a prior period of the IPL, it was observed that, with the exception of 1993, where there was a decrease in the number of requests in relation to 1992, there was growth in the number of patent applications in this sector, peaked in 1995, as shown in the curve of the graph in Graphic 5.

When the curve of Graphic 5 was compared with the curve shown in Graphic 1, it was found that the patenting curve profile of the largest applicants obeyed the same pattern found in data related to the set of overall applicants.

This growth can be linked, among other possible reasons, to the fact that non-resident companies were adapting themselves to the significant changes that Brazilian law related to industrial property was about to suffer, such as allowing protection for pharmaceuticals and patents so-called "pipeline” which is, as already mentioned, in short, the granting of patents for pharmaceuticals, based on patent applications or patents granted, under certain conditions, not considering the concept of absolute novelty - basic principle for granting patents, universally adopted.

It was also found that in 1995, were filed 342 patent applications, which represents about 30% of all requests made by the largest applicants in this period (1155 requests).

It was already apparent a change from the patenting strategy employed by non-resident companies, with significant increase in the number of applications filed. For the distribution of total applications filed during this period (1987-1995), as compared to applications filed by major depositors every year, it appeared that the latter had about 48% of total deposits.

Graphic 6 - Evolution of patent applications for pharmaceuticals of the largest applicants, each year, during the period of 1996 until 2005.

Regarding this period, it was observed that there was a growth behavior in the number of patent applications in this sector. This growth, about 10% per year in the period, contrasts with findings in the previous period, as shown by the curve in Graphic 2, where growth is variable. Making a linear fit to the data period, it is found an average growth rate of about 67 patent applications per year. The decline that is observed between the years 2004 and 2005 should not be considered, as explained above. For the distribution of total applications filed during this period (1996-2005), and the one for applications filed by major applicants year by year during the same period, it is observed that the latter had 36% of total files. Regardless the significant increase in absolute values occurred in the number of requests for deposits of the largest applicants in the pharmaceutical sector, the ratio between their files and those from other applicants fell from 48% to 36%, which represents a percentage reduction of about 25%. Which could indicate an increased competition among the largest applicants showing a decentralization.

Graphic 7 - Distribution of the number of patent applications of the fifteen largest patent applicants in the sector of pharmaceuticals, during the period of 1987 until 1995.

The ranking of companies that have placed more patent applications from 1987 until 1995, when the law prohibited the patenting in the pharmaceutical sector, is formed entirely by non-residents. The absence of resident companies among the fifteen largest demonstrates that the prohibition for patenting in the sector of pharmaceuticals, by itself, has not been enough to encourage innovation in domestic industry.

For several decades Brazil missed policies for the industrial sector, including the pharmaceutical area. Aiming to stimulate the national industry, in 2004, was launched by the Brazilian Government a policy for industrial development which prioritizes strategic areas as semiconductors, software, capital goods and pharmaceuticals, in order to strengthen the innovative activities in the country in these segments. Additionally, to support this initiative, a specific policy for innovation was also created. For the pharmaceutical area, a Program to Support Development of the Pharmaceutical Productive Chain - PROFARMA was created by the National Bank for Economic Development - BNDES (PALMEIRA FILHO, CAPANEMA, 2008).

Graphic 8 - Distribution of the number of patent applications of the fifteen largest applicants identified for the period between 1996 until 2005.

The ranking of companies that have placed more patent applications from 1996 until 2005, when the legislation allowed once again, the patenting in the pharmaceutical sector, is also formed entirely by non-residents. The absence of resident companies among the fifteen largest depositors of patent applications shows that the change of the IPL, now allowing the patenting in the sector of pharmaceuticals, has not been enough to reverse the apparent standoff in the national industry of pharmaceuticals with respect to innovation.

Graphic 9 - Number of patent applications of the fifteen largest applicants, during the period of 1987 until 2005.

As noted earlier, the IPL not only met the requirements of the Agreement but, also, created the figure of “*pipeline*”. In the period provided by IPL to file pipeline patent applications (1996/1997), among the total of 2989 patent applications filed in the pharmaceutical sector, 1.200 were requested as "pipeline".

Graphic 10 - Relationship between the number of pipeline patent filings achieved by the fifteen largest applicants of patent applications in the pharmaceutical sector (307), in relation to its total patent applications in the pharmaceutical sector, filed in 1996 and 1997 (1038).

It is observed that a significant percentage of the total applications filed, thirty-seven per cent of requests were "pipeline" where, as a rule, if this provision was not created in the IPL, they would not have the necessary conditions (the novelty requirement) for obtaining patent protection in Brazil.

Another aspect to be considered when analyzing the group of the largest applicants of patent applications is the fact that few of these companies during the period surveyed, went through mergers and acquisitions, which are intended to strengthen them. The process of mergers and acquisitions of companies in the pharmaceutical industry began during the '70s. These transformations become decisive in the late 1980s and early 1990s, and continue until these days. Examples of merger and acquisition of these companies are available on the internet INTERFARMA site (<http://www.interfarma.org.br> ) as listed below:

- The company Astrazeneca, the 4th ranking position in patent filings (1996-2005) that did not appear in the first ranking (1987-1995), is the result of a merger between the Swedish company Astra, which occupied the 6th position ranking from 1987 to 1995 and the British company Zeneca, which was not involved in the ranking of the fifteen largest in this period.

**-** The company Aventis, in 8th position in the ranking of patent filings (1996-2005), is the result of the merger between the companies Hoechst, occupying the 7th position (1987-2005) and the Rhône-Poulenc occupying the 9th position (1987-1995) in December 1998, with sales estimated at US$ 20 billion per year. In 2004, Aventis joined Sanofi, however, many of the patents of this new conglomerate are deposited on behalf of both companies separately.

- Novartis, in 3rd position in the ranking of patent filings (1996-2005), arose from the merger of Swiss companies Sandoz and Ciba-Geigy.

- The company GlaxoSmithKline (GSK), in 5th position in the ranking of patent filings (1996-2005), is the result of the merger between Glaxo Wellcome and SmithKline Beecham in 2000, although the patent databases continue maintaining information related to entitlements prior to the merger.

- The company Schering, in 10th position in the ranking of patent filings (1996-2005), who had association with Bayer, announced its merger with Merck, ranking 6th, held in March 2009. These companies are among the ten largest companies in sales in the world[[9]](#footnote-9) and among the fifteen largest depositors of patent applications in Brazil.

The high expense required in R&D and innovation in the pharmaceutical industry may be one of the factors that make firms within the industry take the lead in conducting mergers and acquisitions.

CONCLUSIONS

The ban on patenting in the drugs sector, as occurred in previous legislation, or the possibility of patenting, as it occurs currently, by itself, were not effective mechanisms for promoting technological innovation activities by the domestic industry in this sector.

Data analysis in the period before the current IPL shows the occurrence of patent applications filed in this sector, even not having the possibility of protection through patents in the pharmaceutical due to the law prevailing at the time. However, early in the series studied the number of deposits was low.

From 1990, with a project of law on the way to be sent to Congress, this number grew significantly, both for resident and non-resident requests, and reached the peak between 1993 and 1995. This increase in the number of deposits in an area not yet privileged, through patent protection, may be an indication that companies were preparing themselves for needed changes.

The data analysis for the period immediately following the entry into force of the IPL, which now allows the protection by patents in the pharmaceutical sector, shows a strong growth of deposits of patent applications from both residents and non-residents, between 1996 and 1997. Thereafter, however, only the patent filings of non-residents continued showing growth of about 7% per year.

It has been observed that the IPL has changed significantly the number of patent applications filed in the periods immediately before and after its entry into force, for both residents and non-residents, showing the importance of patenting in the industry, although the national industry did not continue being benefited from these changes in legislation.

Marked difference was found between the numbers of applications filed by non-residents related to applications filed by residents. For the period studied 24,046 patent applications were filed by non-residents and 891 by residents.

The lack of public policies for the sector, in addition to the new IPL, may be one of the reasons that justify the fact that the residents were unable to maintain a steady growth after the significant growth rates of the number of patent applications submitted in the moments immediately preceding and subsequent to the entry into force of the current IPL.

It was identified that 100% of participating companies in the ranking of the fifteen largest applicants of patent applications in the pharmaceutical sector in Brazil during the period studied, were non-residents, and hold 30% of total patent applications in this segment. Among these applicants, eight are included among the ten largest in worldwide revenue and six are stand out among the largest in R&D investment over the world.

The changing current level of resident drug industry should be guided on innovation and differentiation of its products, in order to achieve their integration and recognition in major world markets.

The influence that mergers and acquisitions occurred in this sector has in maintaining market leadership was observed. This influence can be seen among the leading companies in sales, when one considers the creation and disappearance of many companies.

With respect to filings of patent called "pipeline", it was found that almost all were filed by non-residents who took advantage of the additional benefit provided by IPL.

Regarding the government program PROFARMA implemented in order to encourage domestic firms in this sector in 2004, it was found that, despite its creation to boost the performance of R&D and innovation activities in the country and to strengthen the Brazilian industry, mainly in its pharmaceutical sector, they are still low compared to the investments made by major global companies.

Whereas the PROFARMA started in the first half of 2004, it has not been possible to assess whether there were positive outcomes as a result of funding made within the domestic industry for R&D and innovation. The effects of PROFARMA could have been potentiated if it had been created as a government program aiming to support national industries, compared to the expected changes in legislation in order to strengthen them for competition with non-resident companies.

The adoption of public policies for stimulating technological development of resident industries in the sector of pharmaceuticals, so much important, both economically and socially, should be taken as a priority, seeking in respect to the law and international agreements, new possible opportunities.

It would be also important to note the investment model used by developed countries, seeking a formula that would enable the increase of funding for R&D and innovation for sectors considered strategic, through government action. These actions should determine a term so that the amounts involved in this type of financing should gradually be inverted by increasing the involvement of private companies and the consequent reduction of government involvement.

In this sense, the current IPL, associated with other policies for the sector, could create a proper business environment for the attraction of the investments on R&D by the private companies of this sector, allowing the changing of the current scenery of the national industry in this context.

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1. For more information, see [www.wto.int](http://www.wto.int). [↑](#footnote-ref-1)
2. This principle established by the Paris Convention in its Article 4 states that the first patent application or industrial design filed in one of the member countries constitutes a basis for subsequent deposits related to the same subject made by the same applicant or his legal successor. It has the Right of Priority. The deadlines for exercising that right are: 12 (twelve) months for invention and utility model and six (6) months for industrial design. The Convention, establishing the Right of Unionist Priority, regulates the parameters that must be met by countries of the Union. [↑](#footnote-ref-2)
3. The Paris Union Convention for protection of industrial property had its beginnings in the form of draft, drawn up in a Diplomatic Conference held in Paris in 1880. New conference was convened on March 6, 1883 for final approval of the text, which came into force one month after the deposit of ratification instruments, on July 7, 1883. (Available at: <[www.inpi.gov.br](http://www.inpi.gov.br)>. Accessed: June 15, 2009. [↑](#footnote-ref-3)
4. For this study, it has been considered patent applications for those residents in which Brazil is listed as country of origin of at least one of the depositors. [↑](#footnote-ref-4)
5. Patent application means that a request was made for patent application at the INPI. [↑](#footnote-ref-5)
6. The Patent Cooperation Treaty - PCT was established on June 19, 1970 in Washington, aiming to develop of the patents system and the technology transfer. The PCT came into force in 1978 in Brazil. It aims to simplify the procedure to be followed in the case of a request for patent protection in different countries, becoming in this way more efficient and economical for both the user and the government agencies responsible in managing the patent system. [↑](#footnote-ref-6)
7. Invention (PI): innovation with higher technological content must full fill in addition to the requirements of novelty and industrial application, "inventive activity” step, ie, not being an obvious consequence of the technical state of art (IPL, art. 8). [↑](#footnote-ref-7)
8. Utility model (UM): object of practical use, or part thereof susceptible of industrial application, which presents a new form or arrangement, resulting in functional improvement in its use or manufacture (IPL, art. 9). [↑](#footnote-ref-8)
9. Source: IMS Health MIDAS – December 2009. [↑](#footnote-ref-9)