

The extension of intellectual property through secrecy of drugs registration: obstacles to the generic drug policy

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Abstract

The pharmaceutical sector is characterized by a great oligopoly, with small and big transnational companies which operate in several countries and perform high levels of investment in research and development, which imply great barriers to the entry of new companies. It's a sector in which appropriation of knowledge occurs principally through the patent of new drugs. Such patents allow monopoly of the developer company of the product over the same product during a determined period. The possibility of abusive practices from this monopoly leads the authorities to take measures for the control of prices and to guarantee the finitude of the patent. Therefore, the United States and the European Union are pressuring the other countries for the establishment of new measures, which go beyond the TRIPS Agreement, such as secrecy of drugs registration, in order to enlarge the monopoly of big pharmaceutical companies and retard the entry of generics

Keywords

intellectual property; patent; generics; drug registration

Introduction

The pharmaceutical sector is characterized by a great oligopoly, with small and big transnational companies which operate in several countries and perform high levels of investment in research and development (R&D), which imply great barriers to the entry of new companies. It's a sector of strong competition through the differentiation of products and with large concentra-

tion in terms of countries. The main producer countries according to IMS Health (2006) are: North America (54%), Europe – the largest five¹ (25%), Japan (15%). The ten world largest pharmaceutical companies are responsible for almost 50% of this market². However, none of them has market share greater than 10%. This is because the concentration in this sector occurs per therapeutical classes (Hasenclever et al. 2000), because

there is no substitutability between products of distinct classes.³ In other words, it's a different oligopoly in which the competition is given in the level of therapeutical classes and not of the sector in a general form (Bastos 2005). In a Brazilian study (Fiúza & Lisboa 2001 *apud* Valentin 2003), the Herfindahl-Hirschman (IHH) Index⁴ per therapeutical class between 1995 and 1998 for tem presented classes is superior to 0.2, with some cases reaching 0.9, confirming the high concentration of the sector when the focus are therapeutical classes.

All private investment in R&D for the production of new drugs requires a high level of protection of knowledge created due to high costs of this activity, duration period and associated risks. In the economics field, the patent institute is a trade-off between public and private: that which invested in research and development and had a practical result – innovative product – will have the right to attain a monopoly of commercialization of this result, however, has the obligation of revealing the knowledge through which attained the result through document of patents which will be available to the general public. The primordial objective of this exchange between public and private is to motivate private investment in innovation, seeing that the nature of knowledge is pervasive and could be used by all without gaining of reimbursement for the investor (Arrow 1962, Nelson 1959).

The efficiency of the patent institute on the appropriability of knowledge protection created is not the same in several industrial sectors. On one hand, the content of information contained in the patent document is not sufficient for the reproduction of the protected object due to the strong nature of tacit document involved chemical technology. On the other hand, information is sufficient to restrain counter factions which eventually proprietary companies are victims. Thus, the pharmaceutical sector characterizes as one of the main, if not the main, sector of patent application as a knowledge appropriation instrument. Other reason for patent efficiency in this sector is the duration period⁵, because the production of a drug from the discovery of the active substance function until the commercialization may take approximately thirteen years (Levin et al. 1987, Radaelli 2006). Therefore, the patent prevalence and consequent monopoly of the production and commercialization generate great problems to the society as the dependency of only one producer and the difficulty of price control. Matter even more important when regarding drugs which are products of high social value.

The patent in the pharmaceutical sector in addition to the fact that it may be applied to a new product or to a new process, it may also protect a new pharmaceutical formulation, an intermediary asset or a second indication for the same drug. Product's patent prohibits any possibility of product's production, even to other commercial utilization, and it may be attained for a substance or active substance or a series of chemically related substances. Process' patent protects processes of attainment of certain product and it may be used to introduce competitive advantages in the company even

after the expiration of the product's patent, leaving the production cost of other firms relatively higher. Patent of pharmaceutical formulations protects formulations of final use or even an existing product which the therapeutical agent is unknown. Patent of intermediary asset protects the use of new compounds useful as intermediaries for the attainment of a substance of pharmaceutical use. Patent of second indication protects a product of determined therapeutical action already known, however, which a new therapeutical use was found for.

On the other hand, the pharmaceutical sector demand is relatively inelastic in relation to price and characterized by the asymmetry of information between consumers and producers. Inelasticity of the demand is related with the loss of health or with the risk of death by the non use of the drug. The asymmetry of information results in the dependency of the patients, in the case of ethical drugs, drugs of medical prescription for the treatment applied and frequency of use, in addition to not having much information on alternative procedures (Rosenberg 2007). Given this asymmetry of information, credibility of drug brand ends up having strong influence on the demand of doctors as well as patients, because consumers tend to remain faithful to the most known and reliable brands.

The high cost of R&D stages, from the discovery until the regulation and commercialization of the drug, low competition per therapeutical class, the brand importance to the sector and high level of defense of intellectual property allow practice of high levels of drug prices. However, because they are products of high importance to the health and life of the population, the matter of access to drugs cannot be ignored by governments and regulatory agencies. From this need the policy of generic drugs, which have the same active substance, dose, administration, form, therapeutical indication and safety of the reference drug or brand and may be commercialized after the expiration of the patent period or by authorization of the company holder of the patent, was created. The production of generics allows the establishment of prices up to 35% lower than brand drugs, thank the reduction of product and marketing development expenses which conjointly represent 40 to 50% of the company's turnover (Bastos 2005, Pró-Genéricos 2007).

In the attempt of enlarging the defense of intellectual property of the knowledge generated in the production of drugs, some European countries and the United States implemented secrecy in the registration of drugs. This action implies the enlargement of monopoly on the use of knowledge because it prevents information of clinical tests and their results, performed for authorization of registration, to be accessed by companies producer of generics. For this reason, producers of generics will also have, in addition to bioequivalence and bioavailability tests, to perform clinical tests to be able to commercialize the drug. The performance of these tests implies great increase of costs and, consequently, greater obstacles for the production of generic drugs⁶.

The objective of this article is to show the relation between the generics' policy and intellectual property. Particularly, showing how some forms of regulation regarding drug registration may represent an obstacle for the implementation of the generics policy, as when it's provided in the legislation a period of secrecy of information provided to make it feasible leading to an extension of the patent's duration. Such issues are debated in two sections, in addition to this introduction and final provisions. In the first section, the objectives of generic drugs are presented and, in the second section issues regarding intellectual property and drug registration are discussed. Although the article does not mention any specific country, the legislation of some countries was used in order to speculate this debate.

Policies of motivation to the production of generic drugs

In the mid 80s, when patents of many drugs commercialized in the United States had already expired, in that country a new specific regulatory milestone was established – the *Hatch-Waxman Act*⁷ – which shortened the term of drug registration copy of those drugs whose patents had expired, allowing its rapid commercialization under generic denomination⁸. At the same time in which the law allowed the restoration of the patent's period to compensate the time and costs spent with new tests instituted for drug regulation, it also reduced tests necessary for the production of copies of drugs which had their patent expired. From this moment on, only bioequivalent test to the original drug would be necessary. The main attraction of this policy is the possibility of enlarging the access by the population to drugs due to lower prices (Grabowski & Vernon 1992, OTA 1993).

The American pharmaceutical market has suffered significant change from the moment in which its products started to be commercialized with no brand and prices lowered significantly. According to the *Congressional Budget Office* (1988) *apud* Valentin (2003), after the *Hatch-Waxman Act*, the time between the patent's expiration and the generics entry reduced from 3 to 1.2 year the probability of the generics entry in the market increased from 40% to 91.5%; and the growth of the market share of generics after 1, 2 and 3 years in the market reached levels 40, 50 and 60% respectively.

The objective of the creation of generic drugs was to counterbalance the possible negative consequences of defense of the intellectual property in the pharmaceutical sector. The patent, main instrument of knowledge appropriation used in the pharmaceutical sector, aims at motivating the investment in R&D and consequent creation of knowledge in the private sector. This motivation is necessary due to the public characteristic of knowledge, seeing that, once created, it may easily be transferred to other players and companies. In this sense, the patent generates positive consequences to the company and society. On the other hand, monopoly over the utilization of this knowledge is established, what may lead to abusive actions by companies. Patent's legislation itself

has some clauses to counterbalance the possible negative effects such as, for example, the possibility of compulsory license in case of abuse of economic power. The creation of generic drugs came to reinforce this effort in a sector in which the need of ample access to products created generated benefits to the society in general. The possibility of production of generic drugs implies the increase of competition and consequent end of monopoly over that product.

The policy of generics has been one of the main governmental attempts to increase the population access to drugs. Its concept is based on the idea that, once the patent expires, the introduction of products based on the original drug, however, commercialized without a brand, contributes with the increase of competition and reduction of information asymmetries⁹ of the drug market. In addition, as the associated laboratories would be in charge of performing bioequivalence and bioavailability tests and of promoting campaign of clarification regarding its meaning, the appearance of generics would serve to better clarify doctors and patients, increasing the search for alternative products to the reference drug.

In this regard, it's important to highlight three distinct effects expected and its respective hypotheses about the results of the implantation of generic drugs: the first effect is regarding the market structure, that is, the result that the introduction of the generics has on sales concentration. This may be important as the generic drugs may substitute reference or similar products (with or without brand) reducing the concentration of the "relevant market"¹⁰. The expected result, in case of similar products, is that the impacts on the structure should be small, while in case of reference products would probably be big. Hasenclever (2002) shows a positive and significant effect of the reduction of market concentration, between 2000 and 2001 in Brazil, in the classes of drugs in which the entry of generic drugs occurred. Rosenberg (2007) and Valentin (2003) describe the increase of participation of generics' companies in the pharmaceutical markets of various countries.

The second effect would be the impact of generics on drugs' prices, that is, as the generic products have a lower price would generate an impact over the average market price. It's expected that, with an increase in competition, there is a fall of the average price of the products in the market. Thus, in Brazil the effect of implantation of generics had positive result in the reduction of prices in markets where the competition increased (Hasenclever 2002, Valentin 2003).

The third effect expected from generic drugs is regarding the sold quantity, that is, the central focus of the governmental policy is to enlarge the access to drugs, increasing the amount of commercialized drugs. In case the effect suffered is only regarding the price, we would be working only on an exchange of excess between the producer and the consumer. If the effect is suffered also regarding the quantity, the final objective of the policy will be achieved. In the study about Brazil, Hasenclever (2002) observed that the variation in sold quantities

was positive, although a more robust statistical result was not achieved. Rosenberg (2007) presents data of the United States, Germany, United Kingdom and Canada of increases of approximately 30% in units sold in these countries in 2003.

In syntheses, the objectives of the generics' policy are: a) reduction of market concentration, which is given through the reduction of the brand power and information asymmetries allowing rational choice of drugs with substitutability; b) price reduction, which occurs with the increase of competition and less needs of investment for the production; and c) extension of the access of society to drugs due to the increase of the produced quantity and lower prices. In addition, in developing countries, the generics' policy has also positive effect for the national industry, due to the possibility of it producing without having to strongly invest in the development of innovation, known as a capacity still very precarious in national companies of these countries.

Given that the adhesion of the public sector to the use of generic drugs may be immediate through change in the procedure of hospital prescription, it's expected that the adhesion to generic products to be quicker in the public market, considering that the private market depends on the adhesion of independent medical professionals (Hasenclever 2004). Grabowski and Vernon (1992) also show that established companies that sell drugs "directly" to patients may prefer to maintain their

price and lose market share to reduce the prices due to the competition of the generics. The same, however, does not occur with the sales of drugs to hospitals, where loyalty to the brand is a lot less and the purchase is made in large lots, therefore, market loss is more significant.

Globally, the segment of generic drugs grows approximately 11% per year (Valentim 2003). In some countries, this growth is greater than the segment of brand drugs. According to Rosenberg (2007), the growth of generics, in 2002, in the United Kingdom was 44%, in the United States 25%, in Canada 16% and in Germany 23% while in these same countries brand drugs grow 6, 9, 11 and 5%, respectively. This growth represented increase of the participation of generics in the pharmaceutical market and sold units of each country. Summing up the four countries the total market of generics reaches US\$ 13.6 billions. In short, the market has assumed each time more relevant dimensions.

The result is that innovator companies, previously operating only in the market of reference drug, have been more and more interested in entering the market of generics after the patent's expiration. In fact, a very common strategy in large world pharmaceutical companies has been the creation of divisions or new companies responsible for the production of generics, in an attempt of maintaining the market share lost with the patent expiration. Table 1 shows some companies which already use this strategy.

Table 1 – Subsidiary companies or divisions of pharmaceutical multinationals operating in the production of generics in 2006

Division of generics	Controller company
<i>Greenstone Ltda.</i>	<i>Pfizer Inc.</i>
Apothecon Inc.	Bristol-Myers Squibb Co.
Dista Products Co.	Eli Lilly and Co.
Elkins-Sinn Inc.	American Home Products Corp.
<i>SANDOZ Inc.</i>	<i>Novartis Corp.</i>
IPR Pharmaceuticals Inc.	AntraZeneca PLC
<i>Sterling Winthrop Inc.</i>	<i>Sanofi-Aventis PLC</i>
DEY L.P.	Merck KGaA

Source: Rosenberg 2007: 79.

Companies in italic are among the five world largest pharmaceutical companies.

In Brazil, the production of generic drugs has been being the responsible for the growth of national companies. Among the four main Brazilian companies – Aché, EMS Sigma-Pharma, Medley and Eurofarma – three are mainly producers of generics¹¹. The segment is shown to be growing in the national market. In 2004, it represented approximately 5.29%, in 2005, 8.95%

and in 2006, 11.44% of the Brazilian market of drugs. In 2005, 151.4 million boxes of generic drugs were commercialized in Brazil, 23.2% higher than 2004. Approximately 80% of these drugs are produced in the country and 74.6% of the sales performed by companies of national capital (Capanema & Palmeira Filho 2007, Pró-Genéricos 2007).

The panorama presented is elucidative of the relevance of the generic drugs' policy for the reduction of the level of concentration in therapeutical classes, increasing the possibility of rational choice by the consumer.

Intellectual property and drug registration

Before the laws of 1984 in the United States, and of 1987 in the European Union¹², which motivated the expansion of generic market to counterbalance the possible negative effects of the patent, the results of clinical tests for drug registration were considered commercial secrets and the legislation would defend the company against unfair competition. Sanjuan et al. (2006) highlights that there was no prohibition against the use of data published to establish safety and efficiency of drugs, and there was still situations limit in which the companies had authorization to use "secret" data not published which had been submitted to regulators.

Currently, in these countries regulatory norms prevail which guarantee to the developer companies a period of exclusive rights over the data of tests for the drug registration. In the United States, this period may last up to 3 years for new indications and 5 years for new chemical entities. In the European Union, 1 year for new indications, 2 years or 8 years for new medical products. Such measure eliminates benefits of generics' producer companies of only needing the realization of bioequivalence and bioavailability tests for the production, because these tests are performed in reference to clinical tests performed in established companies. In other words, what is called "market exclusivity" or "data exclusivity" is clearly a mechanism to retard the approval of generics (Sanjuan et al. 2006).

Thus, if there's no authorization by the company for the use of the results of their clinical tests to the generics' company, the latter will have to perform these tests again or wait for the expiration of the exclusivity period to be able to register and commercialize the generic drug. However, as Sanjuan et al. (2006) highlight, there are practical and ethical reasons so that clinical tests do not need to be repeated when new companies produce the same drugs. In addition to significantly expensive, the tests take long, which retards the time for entry in the market of drugs at more accessible prices, and it's at least anti-ethical to replicate tests in human beings when there's already knowledge regarding the product's efficacy.

The problem most identified by the authors (Sanjuan et al. 2006) is that in addition to applying these norms in their countries, the United States and European Union, influenced by large pharmaceutical companies, has been strongly pressuring other countries so that they take the same measures through the implantation of the TRIPS-plus¹³. It's worth remembering that such secrecy measures of drugs registration tests are beyond the minimum protection obligations determined by the TRIPS in Article 39.3, which provides the protection against abusive use, however, does not establishes a minimum protection period. The article provides:

Members, when required, as a condition for approval of agriculture or pharmaceutical chemical products which use new chemical entities, the submission of non disclosed creation tests or data which involves considerable effort, will protect such data against unfair commercial use. Additionally, members will protect such data against disclosure, except when necessary to protect the public, or unless that measures are taken to ensure that data are protected against unfair commercial use. (WTO 1994, our translation).

Claims of companies developers of innovation and implemented through TRIPS-plus mechanisms are strongly negative for the application of a policy of generics, having as main result the extension of period of validity of intellectual property and a delay in the entry of new producers of generics in the market. This type of pressure may have even more perverse effects in countries in development, where the industry of generics have great importance in the enlargement of access of the population to drugs and in the technological development of national industries. The implantation of measures as these may revert all advance achieved in the last years of development of generics in countries such as Brazil and India. It's necessary a lot of attention of the authorities of these countries so they don't be subject to North-American and European pressure.

The suggestion of Sanjuan et al. (2006) is that countries apply a "division model of pharmaceutical tests' data costs." In this model the use of tests' data by follower companies, generics' producers would be allowed, for registration of the drug, however, they would have to 'ay royalties on the use of such information, in an attempt to compensate the company established by the expenses with the performance of tests. Thus, the countries would be applying measures which go beyond the measures established by TRIPS, however, they wouldn't need to accept TRIPS-plus measures imposed by the United States and European Union.

Final provisions

In many countries, for example Brail and the United States, the generics' policy was implemented in a new institutional context of the implantation of law of patents or extension of benefits to the private player ensured by it. In this sense, the generics policy role is to restrict possible negative effects resulting from patents. However, there are also other two positive consequences of motivation to the production of generics drugs: the increase of access of the population to drugs with more accessible prices and the opening of market opportunity to new companies with less initial needs of investments in R&D.

As presented in the text, North-American and European pressures of implementation of the TRIPS-plus with the use of secrecy of tests' data of drugs registration breaks the positive complementarity between intellectual property's policy, through patents, and generic drugs' policy. The first promotes investment in private knowledge and the second helps to limit the benefit to the optimum of the repayment of these investments. This happens because the secrecy of drugs registration extends

the established company's monopoly period, ending up with the characteristic of patents' concession being established based on the optimum return time to repay investment in R&D made by developer companies.

The contribution of this article is to show the importance to countries, among them Brazil, in not ceding to pressures of application of the TRIPS-plus and to alert regulator agents of the countries in development, responsible for products' registration, for this problem.

Notes

1. Germany, France, United Kingdom, Italy and Spain.
2. world pharmaceutical market moved, in 2004, US\$ 500 billion with an operational margin of 25% (Bastos 2005).
3. Valentim (2003) shows that the crossed elasticity of drugs of different therapeutical classes is normally very low.
4. The closest to 1 the greater the market concentration. Indexes above 0.2 already indicate, according to the antitrust organs analysis practice, such as North-American, certain level of monopoly power of the companies and, therefore, the need for permanent surveillance of defense authorities of the competition regarding the industry.
5. Since 1994, the duration period of the patent is 20 years, as established by Agreement regarding the Aspects of Intellectual Property Rights Related to the Commerce of OMC - known as TRIPS or ADPIC Agreement - which regulated all themes related to intellectual property. Various authors seek to calculate the optimum duration time of the patent, among them Nordhaus (1969), however, with no definitive conclusion. This author concludes, however, that such period is related to invention costs and elasticity of demand.
6. The costs of production of a generic drug vary between US\$ 35 thousand and US\$ 400 thousand (Valentim 2003) while clinical tests are approximately US\$ 100 million (Bastos 2005).
7. *The Drug Price Competition and Patent Term Restoration Act de 1984*.
8. Specifically in the United States a special article – *Roche-Bolar* – in this law allows the producers to have access to active substances, conduct preliminary work for registration of the product and begin the process of registration through the completion and delivery of forms, even before the expiration of patents, what implies that the generic may enter the market in the following day after the patent's expiration (Valentin 2003).
9. The asymmetries of information are related to the fact that the drugs are disclosed through a brand, preventing consumers or prescribers to immediately identify substitute products among themselves, that is, those with the same active substance in their composition, hindering the choice through the price.
10. The relevant product market comprises "all products/ services considered replaceable between themselves, due

to their characteristics, price and utilization" (Resolution 15/98 of CADE *apud* Mello 2002). The relevant drug market, according to Hasenclever (2002), is defined verifying, case by case, which is the capacity of replacement of an active substance for other within the same therapeutical subclass.

11. The purchase of Biosintética by Aché, in October 2005, strengthened its presence in the segment of generics (Aché 2007).

12. In the United States, *Hatch-Waxman Act* and, in the European Union, *87/21/EEC Directive*.

13. The TRIPS-plus concept covers those activities which have the purpose of increment of protection level of holder rights, in addition to those established in the TRIPS Agreement and those measures which intend to reduce the scope or effectivity of limitations of rights and exceptions. Such practices and rules of intellectual property have the effect of reducing the ability of countries in development of protecting public interest and may be adopted in multilateral, plurilateral, regional and/or national levels (*Musungu & Dutfield 2003, our translation*).

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