

The international economic discussion on intellectual property: relevant aspects for the Brazilian health sector

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Abstract

Discussion about the impact of the international harmonization of higher-level patent protection in the public health sector of less developed countries just started to take place after the so-called Doha Declaration. This paper advocates a more intense discussion on patents, highlighting not only that estimates of benefits and losses resulting from greater patent protection have been negligent toward the loss of monopoly that result from patents, but especially the fact that they do not take into account the raise in public health costs in less wealthy countries that results from this tendency to harmonize.

Key words

patents; public health; TRIPS JEL Classification: O34; H51; F13

Introduction

The TRIPS agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights), signed at the end of the Uruguay round in 1994, consolidated the movement towards the international standardization of property rights

protection in general, specifically of patents, with a high level of rigor. This movement towards the standardization of intellectual property rights protection at a higher level, consistent with the protection offered by developed countries, became known as the international harmonization of

property rights.

Discussion about the impact of the international harmonization of higher-level patent protection in the public health sector of less developed countries just started to take place, after the so-called Doha Declaration. This paper advocates a more intense discussion about patents, highlighting not only that estimates of benefits and losses resulting from greater patent protection have been negligent toward the loss of monopoly that result from patents, but especially the fact that they do not take into account the raise in public health costs in less wealthy countries that results from this tendency to harmonize.

To this end, this article is organized in three sections. The following section challenges the way we see the cost-benefit ratio of an increased patent protection. It will present arguments proving that not only are the benefits more emphasized than the costs, but also that an important element to be taken into account in the calculation for least developed countries, which is the impact of patents on the cost of public health programs, is simply ignored.

Section two discusses the possible effects of the TRIPS agreement on public health in developing countries and Brazil. The agreement incorporated the international trend towards harmonization of intellectual property rights in general and patents in particular. The third and last section closes the paper.

A partial perception of the economic effects of drug patents on developing countries

It is often said that if the profits resulting from an innovation, whether it is a product or a process cannot be appropriated by the inventor, that is, if the innovation can be reproduced by an imitator at a lower cost than that of the innovator, the latter will have no incentive to bear the full costs needed for the development of the innovation. Thus, a lesser evil (the monopoly created by the patent and a decrease in production, and the price increase resulting therefrom) would be replaced with the incentive that the benefits of the patent monopoly would provide to new products and processes. Therefore, any discussion on patents and property rights in general is based on the comparison between costs, in terms of loss of welfare resulting from the monopoly created by the patents, and benefits in terms of incentives to products and processes innovations, which result from the opportunity to gain property over the same profits resulting from monopoly. The key argument

is that this comparison, based on the conventional theory of patents, incorporates only partially the costs of drug patents for developing countries. However, in order to understand this fact it is necessary to learn a little about the conventional economic assessment of patents.

The conventional economic assessment of patents: monopoly profits versus incentives

Patents (as well as copyrights and trademarks) restrict production by limiting the use of new knowledge about products or processes to the license of the patent holder who, by means of such license or by restricting the application of new knowledge to the product they develop (or to its production process) takes hold of monopoly profits. According to conventional theory, the prospect of exclusive appropriation of these monopoly profits would be the key incentive to encourage innovation.

This approach of conventional economic theory has given rise to numerous analyses about the ideal length and scope of patents. The pioneering work of Nordaus (1969 and 1972) and Scherer (1972) discussed exclusively the optimal length of patents. The basic idea was that an excessive length would provide monopoly profits to the owner of the patent beyond what is necessary to encourage expenditures on research and development of new products and processes. Therefore it would be necessary to determine the ideal length of patents.

More recently, possible trade-offs between the breadth and length of patents have been examined. For instance, Gilbert and Shapiro (1990) attempted to prove that if the benefit to society decreases at an increasing rate with the increase in the profits of the patent holder, and the relevant market is characterized by homogeneous product and price competition, the optimal duration of the patent should be infinite, whereas its breadth should be minimal.

In another model, Klemperer (1990) examined the conditions under which it would be socially optimal to have patents with infinite duration and reduced breadth, or with short duration and encompassing breadth, considering the gains resulting from the incentive to innovation minus losses resulting from the decrease in production resulting from monopoly.⁴ Gallini (1992), on the other hand, built a model in which from a social standpoint it was more efficient to have short-duration and wide-breadth patents, since they discourage imitation of patented products, which are a waste of society's resources.

Denicolò (1996) expressed dismay with the lack of general results of these models, which he expressed through the more general model that he himself designed⁵. He clearly acknowledged that much of what is obtained through such models depends on assumptions made regarding the type and efficiency of the competition that a narrower breadth of patent protection offers: *Loosely speaking, the less efficient is the type of competition prevailing in the product market, the more likely it is that broad and short patents are socially optimal* (DENICOLÒ, 1996: 264).

However, contrary to what this discussion may make it appear, the issue of intellectual property rights in general, and patents in particular, is not as simple as the opposition between the length and breadth of the protection of the right. The case of patents (studied in much greater depth than trademarks, or copyrights by economists) clearly illustrates the difficulties involved in the economic analysis of patents.

Mansfield (1986) examined a random sample of 100 companies from 12 different industries between 1981-1983, and found that few inventions were marketed due to the protection that was offered by patents in the following areas: primary metals, electrical equipment, instruments, office equipment, engines for vehicles, rubber and textiles. In the pharmaceutical and chemical sector, however, patents showed evidence of having a significant positive effect on the introduction of innovations. Mansfield et al. (1981) also noted the importance of the protection offered by patents to the pharmaceutical industry.

There is, therefore, evidence that the importance of patents is not the same for all industries. It is, rather, greater for some sectors, such as the pharmaceutical industry. For other sectors, trade secrets or the fact that they have been pioneers in introducing new technology may be much more important than the protection provided by a patent (Levin et al., 1987: 795).

This fact, along with the essentially monopolistic nature of patents and intellectual property rights in general, meant that for most of the twentieth century intellectual property was considered with some restraints, not to say rejection. Even during the eighties, concern with the fact that patents were a tool of monopolization in academic work was still common: see Gilbert and Newbery (1982), Kamien and Schwartz (1982), Fudenberg et al. (1983) and Harris and Vickers (1985)⁶.

The role of patents as a tool of market monopolization has been widely demonstrated by concerns of competition protection agencies in

developed countries⁷. It is thus possible that the same problems will be faced by developing countries, in cases where the patent owner is a company whose headquarters are located in another country. The situation becomes even more serious when one considers the feeble institutional framework for competition protection in such countries.

These problems faced by developing countries should not be overlooked as a result of arguments on behalf of the positive effects of incentive to patents on investment in innovations, as suggested by the argument posed by Braga et al (2000), for instance. (2000). The reason for this is that this argument does not apply to developing countries, as a greater protection for business patents in developed countries only means a decrease in the production of developing countries (the typical Paretian inefficiency of the patent monopoly), without the benefit of dynamic incentives to innovation that are found in developed countries (fact that had already been pointed out by Penrose (1973: 770).

There is yet another aspect of intellectual property, other than the dilemma of monopoly profits versus incentives, which is even more serious in the case of drug patents and is not always addressed in debates in developed countries, but which holds a vital importance for less wealthy countries: the costs of protection of intellectual property generates for public programs with a strong impact on social welfare. These costs can take on significant dimensions in public health governmental programs. This subject will be discussed below.

Costs of patent protection for public health programs

Access by the world's poorest populations to the so-called essential drugs is one of the crucial issues of public health. According to the explanation of Pécoul et al. (1999: 361): *Important health programs that rely on essential drugs include child survival programs, antenatal care, treatment of enteric and respiratory pathogens, and control of tuberculosis and malaria*⁸.

Although it is difficult to obtain an accurate estimate of drug access needs in poor countries, it is possible to have a sense of the magnitude of the impact of such access: according to one of the surveys carried out about the situation (BLACK et al., 2003), approximately 10 million children die each year simply due to being denied access to essential drugs to combat diseases such as diarrhea, malaria, measles, etc.

The importance of having access to drugs can be measured when we consider, again

according to Black et al., (2003), that the diseases most commonly associated with these deaths are diarrhea and pneumonia, and the occurrence of such deaths is significantly concentrated in a group of countries (six countries would account for half of the preventable deaths of children, and 42 countries would account for 90% of deaths).

It turns out that access to drugs is also quite concentrated in the poorest populations. According to a survey carried out by the World Health Organization (WHO, 2004a: 63) out of the entire world population with no access to essential drugs in 1999, 79.4% was located low-income countries, 20.3% in middle-income countries, and 0.3% in high-income countries.

Even recent studies do not provide encouraging data: in 2004, the WHO estimated that one third of the global population did not have regular access to essential drugs, a ratio that can reach 50% in the poorest countries of Africa and Asia. Even in the developing countries, where there are an estimated 40 million people infected with HIV, antiretroviral drugs (ARVs) are only available for 300,000 out of five to six million who are in need of treatment (WHO, 2004b, p. 3).

The problem posed by the availability of essential drugs obviously has several aspects to it. The first aspect concerns the need for careful definition of *essential drugs*⁹, as well as their proper utilization. One must also consider the funding mechanisms for public health and the reliability of the supplies system.

However, an important aspect concerns drug prices. Excessively expensive drugs may prevent programs aimed at making essential drugs available, either when these programs use public resources, which are scarce in less developed countries, or

when the patients themselves who have to bear the costs, a frequent situation in poorer countries. This is also a serious situation, as the per capita income is lower in those countries.

According to WHO (2004b, p. 4), high drug costs account for between 25% and 70% of total health expenditures in developing countries. Paradoxically, more than 70% of the drugs were financed by public funds in higher income countries, whereas in poorer countries between 50% and 90% of drugs are paid for by the patients themselves (WHO, 2004c, p. 1).

Table 1 below illustrates the impact that essential drugs can have on public health programs. We see that for some of the most important diseases, essential drugs have high prices. This situation becomes even more serious when one considers the relative concentration of diseases that represent public health problems in countries with lower income levels, as shown in Table 1.

In order to have an idea of the magnitude of the impact that the obligation to acquire has on a public policy for patented medicines, one can make a comparison, using the information provided by Table 1, comparing the price of generics and the price of brand-name drugs. Note that the existence of generics indicates that the patent has expired, and that the competition created by the generics tends to reduce the price of brand-name drugs. Thus, a price difference seen in the comparison between the brand-name product and the generic product actually underestimates the costs of brand-name drugs in the absence of a generic one.

The brand-name drug that corresponds to the generic sodium ceftriaxone is Rocephin, manufactured by Roche. If one considers the consumer price, while Rocephin can be purchased

Table 1 – High-cost essential drugs

Disease	Global Deaths	Deaths in Low-Income Countries	Total % of Deaths in Low-Income Countries	High-cost therapeutic drug	Generic
Acute Infections in Lower Respiratory Tract	3.883.872	2.857.980	73,6	Ceftriaxone disodium	Ceftriaxone
Diarrhea	1.797.972	1.536.528	85,5	Ciprofloxacin Chlorhydrate	Ciprofloxacin
HIV	2.777.175	2.139.236	77,0	Antiretroviral Drugs	
Meningitis	173.031	122.829	71,0	Disodium Ceftriaxone	Ceftriaxone

Source: Pécoul et al. (1999: 362) and WHO (2004d).

The definition of low-income countries follows the World Bank criteria.

for R\$ 42.81 in the 1g intravenous version (1 vial), the same version of sodium ceftriaxone can be found for R\$ 17.75 (EMS), R\$ 25.67 (Sandoz), and R\$ 24.40 (AB Farmo)¹⁰. Thus, the price of generic drugs can represent only 41.5% of the final price of the corresponding brand-name drug.

In the case of ciprofloxacin chlorhydrate, whose brand-name drug is Cipro (Bayer), the situation is not very different. While the six-tablet 500mg Cipro pack retail price is R\$ 13.828 per tablet, generic drugs in identical versions can be found for R\$ 3.687 (Ciprobiot - Sandoz), R\$ 3.548 (Ciprofar – Elofar), R\$ 4.085 (Ciproflonax – Pharlab), just to name a few cases. The savings may reach 73% against the final brand-name drug prices.

So far we have looked at data that demonstrate the effect of generic drugs on the price of essential drugs for the final consumer. However, as we already pointed out, essential drugs are objects of public health policies. This brings a new element into the competition and pricing process of essential drugs: the State and its bargaining power

through the acquisition of large amounts of drugs, which makes it possible to achieve significant price reductions in terms of final consumer prices. Table 2 below shows the prices paid by the Brazilian government for some essential drugs.

In Table 2 it is important to note, in the first place, that for the drugs displayed the Ministry of Health does not acquire brand-name drugs, only the generic brand. Secondly, the fact that the Ministry of Health purchases large amounts of drugs can imply substantial savings, even in the case of generic drugs.

Thus, for each tablet of Ciprofloxacin purchased on March 19, 2008 the Ministry of Health obtained a price reduction of about 12% (when compared to Ciprofar). When compared to the brand-name drug (Cipro), the price reduction was of was 77.4%. In the case of Ceftriaxone 1g Injection, the price reduction was so large that the price paid by the Ministry of Health in Table 2 was but a small fraction (R\$ 1.800) of the price of the generic equivalent (Rocefin – R\$ 42.81 – Roche).

Henry and Lexchin (2002) mention

Table 2 – Prices of essential drugs selected by the Ministry of Health (maximum prices)

Drug	Unit	Date	Qty.	Per unit Price
Ceftriaxone 1g Injection	Vial	01/02/2008	150	1,800
Ciprofloxacin (chlorhydrate) 500 mg	Tablets	19/03/2008	63	3,124

Source: Ministry of Health (www.saude.gov.br)

another significant effect, in the specific case of the cost of the combination of antiretroviral drugs in Australia (Stavudine, Lamivudine and Nevirapine), which resulted from the introduction of generic drugs from India (Table 3).

Table 3 clearly shows the impact that the introduction of generic drugs has on the prices of an essential drug of very high price, which was reduced from US\$ 869.92 per month to US\$ 59.33 per month, whereas the generic drug reached a price of US\$ 24.58 per month.

Beyond the issues of price, it is important to note that the expenses of the Ministry of

Health's budget actions aimed at financing the purchase of drugs increased by 123.9% between 2000 and 2006. In the same period, total health expenditures increased by only 9.7% (VIEIRA & MENDES, 2007). These variations result in a growing utilization of the health budget towards the purchase of drugs. Such numbers alone are enough to show that, in order to guarantee the financing of drug purchase, the Ministry of Health had to reduce its expenditures in other areas.

With respect to antiretroviral drugs, the Ministry of Health allocated R\$ 611.8 million in 2003 and R\$ 924.8 million in 2006 at constant

prices. The actual increase was 51.1%. The number of patients receiving treatment, according to the National STD/AIDS¹¹ Program 2%, increased by 28.7% during this period. These data suggest that the utilization of new drugs and the broader usage of higher price drugs contributed to the increase in expenditures in the program. In this context, the initiative by the Brazilian government to resort to the compulsory licensing in 2007 of the antiretroviral Efavirenz, manufactured by Merck Sharp & Dohme, is understandable.

Tables 1 and 2 and 3, as well as data mentioned above, illustrate the positive effect of generic drugs on competition and, consequently, on price reduction. In most cases, these generic drugs can only be produced where the patent is not granted. In the case of granted patents, they need to be expired before generic drugs can be produced. Despite these and other proofs, it is not uncommon to find arguments such as Eric Noehrenberg's (2003) that minimize the impact of patents on drug prices. According to Noehrenberg:

Table 3 - Monthly prices of antiretroviral drug combinations - Australia

Brand-name product		Generic product	
Date	Price (US\$)	Date	Price (US\$)
September 2000	869,92	July 2000	230,59
October 2000	77,58	September 2000	66,67
March 2001	59,33	February 2001	29,17
August 2001	59,33	August 2001	24,58

Source: Henry and Lexchin (2002: 1593)

Let us also not forget that the vast majority of essential drugs as defined by WHO [World Health Organization] are unpatented. Ninety-five percent of them are unpatented. In Africa, 99 percent are unpatented and, as respected Harvard scholar Amir Attaran has shown (...), most African countries do not have patents on most AIDS drugs (...) Patents are not the barrier to access to medicines (NOEHNBERG, 2003: 381).

His argument overlooks an important fact, though. An increase in patent protection has an impact on new and upcoming drugs, not on those whose patents have expired. These new drugs, presumably with higher therapeutic efficiency, will be released under the aegis of a much more stringent patent protection system, which will reduce, in a short term, the potential for an increased international supply, through the supply of generic drugs. Table 1 and 2 show problems that may arise in this scenario, where the manufacture of generic drugs will be impaired by patent protection.

The problem is that in terms of the costs of intellectual property protection, as of the end of the twentieth century not only did the monopolizing aspect of patents and intellectual property rights started to receive less attention in general, but the

impact of patents on public health programs of poorer countries also started to be blatantly ignored. But since the effects of the increased protection of intellectual property rights on economy must be assessed against public welfare, its impact on public health policies must be taken into account (see CORIAT et al., 2006).

However, since the 1980's in the United States, and at a worldwide scale at a later period, the rhetorical emphasis focused on the incentive that patents could offer to invention and creativity. This turnaround was driven, among other things, the realization that (...) while U.S. firms pioneered technologies such as the transistor, the video cassette recorder, and the integrated circuit, other countries, most notably Japan, U.S. successfully commercialized these US inventions (SELL, 2003: 67), ie, that it was necessary to recover the hegemony of American companies in the world economy.

This turnaround resulted, thus, from the action of a well-articulated lobby, with emphasis on the role of pharmaceutical companies, which occurred not only in the United States, after the 1980's, encouraging the U.S. government to take business reprisals against countries that did not comply with the intellectual property rights; it was

also successful in its international connection with Japanese and European companies, in such a way that it was part of the panel on intellectual property rights in the Uruguay Round, thus giving birth to the TRIPS agreement, as will be explained below.

TRIPS and public health in developing countries and in Brazil

The origin of the fusion between commercial problems and protection of intellectual property rights dates back to the Uruguay Round of negotiations on international trade. The Uruguay Round (1986-1994) was the longest and most complex negotiation on international trade. It was an agenda of negotiations which covered virtually all pending trade policy issues, including the breadth of the exchange system of several new areas, particularly services and intellectual property rights.

The novelty caused by the inclusion of intellectual property rights under trade negotiations and the role of different actors were analyzed by Susan K. Sell (2003). Among the players that stood out in the international initiative that convinced trade negotiators from developed countries to agree to discuss intellectual property rights, one can highlight the American Intellectual Property Committee (IPC) (consisting of twenty chief executives of pharmaceutical, entertainment and software companies of the United States), and Edmund T. Pratt, who was a chief executive of Pfizer for twenty years.¹²

Sell (2003) analyzed the relationship among these players:

The IPC succeeded in forging an industry consensus with its Japanese and European industry counterparts, who agreed to work on it and pledged to present these views to their respective governments in time for the launching of the Uruguay Round. Pratt noted that this joint action by the US, European, and Japanese business communities represented a noteworthy breakthrough in the international business community's involvement in trade negotiations. (SELL, 2003:106)

The Final Minute was published in 1991. It contained the texts of the legal instruments created to address all the issues that had been discussed, except for market access measures. Over the course of the next two years, negotiations varied continuously between the tremors of an inevitable failure and prognostics of impending victory.

The Uruguay Round ended in 1994, after almost ten years of discussions and studies at the GATT level. The TRIPS Agreement was

signed in Marrakesh, Morocco, by the twelve participating countries, including Brazil. The approved resolutions would come into force on January 1995, and could be deployed by 2005 in developing countries (e.g. Brazil), and 2011 in less developed countries.

However, as Coriat, Orsi and d'Almeida (2006) explained:

In practice, few countries were able to resist the pressure exercised by developed countries to anticipate the date of compliance. Thus, Brazil modified its IP law to comply with the TRIPS as early as 1996, and Thailand did so by 1994-1995. India constitutes a noteworthy exception, because this country extensively used its right to copy existing molecules until the end of the 2005 deadline, thus playing a crucial role in the supply of generic drugs at low costs. (CORIAT et al., 2006: 1039-1040)

Thus, the adjustment period was practically non-existent for most countries, with few exceptions. In Brazil, the adaptation to the TRIPS required a profound change in the way intellectual property rights and patents of pharmaceuticals in particular were dealt with. In 1942, due to World War II, the drugs were considered non-patentable. As a result, in 1945 the country started to not recognize patents of chemical and pharmaceutical products. Process patents, however, were maintained.

In 1967, and later on, in 1969, two Acts (DL 254, 1967, and 1005, 1969) considered as non-patentable inventions related to drugs and their manufacture procedures (LORDELLO *apud* SUTTON, 2004). There was a change in the former Brazilian Code of Industrial Property (Law No. 5. 772 of 1971) that fully banned patents in the pharmaceutical area. This new procedure was in force until the creation of Law No. 9. 279, which has been in force since 1996, when patent protection was reinstated as a result of Brazil's entry in the WTO, and of the TRIPS Agreement.

The purposes of the TRIPS Agreement are primarily to strengthen and harmonize, on a worldwide basis, a variety of aspects related to intellectual property protection.

He states the obligation to grant patents to inventions in any technological area that meets the requirements of patentability, and of not making any distinctions concerning the rights granted the patent as a result of the location where the invention occurs, field of technology, and due to the imported products being easily manufactured locally. It should be highlighted that exceptions are allowed to protect human, animal or vegetable life, or to prevent serious damage to the environment (BERMUDEZ, 2006).

The TRIPS Agreement sets forth that patent protection be available for any invention, in all fields of technology, in all Member States of the WTO. This provision is directed primarily to pharmaceuticals, to developing countries, as well as other developed countries that had refused to grant patents. In addition to broadening the breadth of patents, though, it is important to discuss the possible impact of TRIPS on the costs of drug patents in the public health area, which are more frequent in developing countries. This will be the next subject.

The first aspect to be highlighted in the discussion of the possible impact of TRIPS on public health in developing countries is that TRIPS defined that the new international standards for the minimum duration of patents was to become 20 years, surpassing the 17-year period, and this maximum period of 17 years was already a norm in the United States themselves when the TRIPS was entered into. Thus, even the trade-off of conventional theory between length and breadth of the patent was abandoned simply on behalf of increasing the length of patents.

The second aspect concerns the monopoly granted by patents, which can substantially increase the price of essential drugs, increasing public health program costs in the least developed countries, which are already faced with a shortage of resources. Developing countries can reduce the high prices of essential drugs, caused by the patent system, by using compulsory licensing.

Circumstances that could trigger such a procedure, however, are quite limited under the TRIPS agreement: "National emergency" or "extreme urgency", with the requirement that the drug whose license is compulsorily granted must be used only for public and non-commercial purposes. Article 31 of the TRIPS set forth that a compulsory license for import measure must mainly be deployed to supply the domestic market of the member countries of the WTO that grant the license. Therefore, this mechanism should not be used by a Member country to export a drug to another country that needs to obtain it at lower prices.

Coriat et al. (2006) highlight that countries without a significant pharmaceutical industry have a very limited use of this right provided for by the TRIPS¹³. Thus, utilization of the compulsory import license system is restricted to the importation of drugs from countries where they have no patent, or from countries where their patent has expired. These authors suggest the existence of a contradiction in Article 31, in that it

implies that the most fragile and poor countries (the ones lacking technical capabilities) are also the ones to which the access to generic copies of patented medicines (through imports) is the most unlikely.

Under pressure of the poorest countries, especially African countries, the city of Doha, Qatar hosted the Fourth WTO Ministerial Conference in 2001, which resulted in the Doha Declaration, which relates the TRIPS Agreement and Public Health. It states that the TRIPS Agreement must be interpreted and implemented to protect public health, namely the TRIPS cannot override Public Health matters. Thus, the social aspect of drug production must remain above commercial interests.

For this reason, paragraph 6 of the Doha Declaration provides guidelines to the TRIPS Council in solving the problem in countries with inadequate or insufficient pharmaceutical manufacturing capacity, in order to make effective use of the compulsory import license set forth by the TRIPS itself. The most conflicting aspect, however, is that for the countries owning large laboratories, only the poorest countries could benefit from the flexibility of paragraph 6 of the Doha Declaration, in contrast to the argument of the representatives of developing countries, such as Brazil.

Conclusions

Drugs have come to represent a growing share of public health expenditures in Brazil. On the other hand, the international discussion on patents has been biased by the interests of manufacturers of developed countries. Thus, not only has the estimate of profits and losses resulting from an increased patent protection been reckless when it comes to assessing the loss of patent monopoly, but mainly it has not taken into account the increasing costs of public health policies in less wealthy countries, which results from this international tendency to harmonize intellectual property rights.

The Doha Declaration, however, shows that, difficult as it may be, it is possible to review the terms of the debate, addressing the public health needs of least developed countries in a way more significant way than what has been done so far. It is essential for the least developed countries not only to emphasize monopoly costs resulting from patents (something that academic literature itself has already acknowledged) but also to develop initiatives so that the costs of international harmonization of intellectual property encompass the burden it poses to public health in those countries.

Notes

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4. Denicolò (1996) considered four possible configurations of the breadth of protection granted by a patent: in the case of process innovation, the breadth would be the share of cost savings resulting from the innovation, which is only granted to the patent owner; in the case of a product innovation, the increased demand would exclusively granted to the patent owner; the existence of an imitation cost (the wider the protection resulting from the patent, the higher the imitation cost will be). And lastly, the number of independent markets where the protection offered by the patent is effective.

5. Here is how Denicolò (1996: 263) described the problems of models that look for an efficient choice between patent breadth and length:

We have shown that the patent breadth-length optimal mix depends in a subtle way (involving second derivatives) on the relationship between social welfare and post-innovation profits, on the one hand, and the breadth of the patent, on the other hand. And economic theory places no restriction on the concavity of those functions. Thus it should not be surprising that different models and examples yield seemingly contradictory conclusions.

6. This concern was not limited to the academia: the former Federal Republic of Germany (until 1967), Italy (until 1979) and Spain (1992), did not recognize patents of pharmaceutical products (see Chang, 2001: 7) In Brazil, Chapter II of Law 5772 of December 21, 1973 (the former “ Code of Intellectual Property”, repealed by the Industrial Property Law nº 9. 279/96), Article 9 provided a list of innovations that would not be granted the privilege of a patent, among which the “substances,

materials, mixtures or food, pharmaceutical and chemical products and drugs of any kind, or their manufacture or modification processes.” Changes in Brazilian legislation will be discussed later.

7. As an example, consider Marquis (2007) (European Union) and Takigawa (2003) (Japan). The United States have a wide range of published literature that is impossible to synthesize. As an example, Werner (1999) addresses the most frequent North American concerns.

8. Drug costs, important as they may be, are not the only aspect.. According to the explanation of Pécoul et al. (1999: 361): “Continuous training for health care professionals, dissemination of reliable pharmacological data, and improvement of the management of drugs are fundamental steps in improving the quality of care in the developing world.

9. According to WHO, “Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness” (OMS, 2004c, p. 1). The definition of essential drug is under the responsibility of each country.

10. All final consumer drug price surveys were done online at <http://www.medicamentos.med.br/>

11. <http://sistemas.aids.gov.br/monitoraids2/>

12. Pratt, along with John Opel (chief executive of IBM) were the creators of the IPC.

13. “[...] This means that the use of compulsory licensing for export to countries without sufficient manufacturing capacity is very limited” (CORIAT et al. 2006: 1042)

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