1-1-2005

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Introduction

According to the data compiled by the UN Millennium Development Goals Project, 40 million people are infected by the AIDS virus in developing countries, with 26.6 million on the African continent. About 93% of those infected with the AIDS virus cannot afford to buy the anti-retroviral medication which they need (1). The Joint Program of the United Nations on AIDS believed that unequal access to treatment at acceptable prices is one of the main reasons for the low levels of survival in poor nations.

Although it may seem a paradigm, the problem of access to patented medicine is not limited to anti-retrovirals for the treatment of AIDS, as notes Brook K. Baker. In developing countries the poor are victims of a large number of infectious diseases such as tuberculosis, malaria, respiratory infections, diarrhea, and Chagas disease, for which there is little or no access to medication (2). The treatment of other illnesses such as diabetes, asthma, heart disease and mental illness is insufficient as the medication available is beyond the purchasing power of a large part of the population.

The 1994 Agreement on Trade-Related Aspects of Property Rights (TRIPs Agreement) states that all signatories are obliged to grant patents to pharmaceutical products. As a result, the price of medicines has tended to increase, affecting people in developing countries. The adoption of a patent system in these countries has harmed poorer people who cannot afford to buy medicine. Nevertheless, the TRIPs agreement contains some provisions which allow countries to eliminate the negative consequences

of granting patents.

In this paper I argue that compulsory licensing is a fundamental tool that developing countries may use in certain conditions to ensure that poor people have access to necessary medicines. This measure may produce positive social effects. Unlike developed nations, developing countries have rarely used the compulsory license as an instrument of public policy.

Moreover, abuse of patent rights has often led to abuse of economic power. Compulsory licensing engenders competition, thereby reducing prices of medicines. Each WTO member also has the right to determine what constitutes a national emergency or other circumstances of extreme urgency to issue compulsory licensing.

My thesis does not ignore the important role that patents play in fostering technological progress. My purpose is only to point out that compulsory licensing promotes social well-being to the extent that it obviates the drawbacks of a patent system. Finally, there is no risk of decreasing investment in research because the market in developing countries is not significant for multinational companies.

This paper is divided into three parts. The first part analyzes the influence of the TRIPs agreement on the increase of prices of the pharmaceutical products in developing countries. The second part deals with compulsory licensing and the impact it has on innovation. The third part discusses the use of compulsory licensing as an instrument of public policy in developing countries.

The TRIPs Agreement and the "patentablility" of medicines

The TRIPs agreement, made in 1994 during the Uruguay Round, determined that all the signatories agree to establish a minimum standard of protection of intellectual property. Various themes were regulated by TRIPs, such as authors' rights, brands, patents, confidential information and industrial designs. The application of these rules was ensured by the system of solution of controversies of the WTO, which improved

the mechanism of resolving disputes which existed in GATT.

TRIPs allowed for the patenting of products and processes which represent innovation and are suitable for industrial use. In this sense, protection of innovation was the main objective. Thus, the link between intellectual property was strengthened in such a way that repression of piracy should foster economic flows among the members of the WTO (3).

Developed countries consider TRIPs a way to reinforce international discipline regarding intellectual property and protect investments made in R&D. The obligation to grant patens for inventions in all the fields of technology had a great impact in developing countries. Patents create incentives for innovation and publication of inventions, remunerating the inventor for the investments he makes. It must be pointed out, however, that the patent system contains a cost represented by the possible abuse of power of the monopoly of the title-holder. The patent may also be used to block the inventive activity of third parties, which would obviously harm society. It is important to note that in most cases government expenses on the management of the patent system are high.

Various reasons are usually put forward to justify the need to concede patents of pharmaceutical products. Firstly, the discovery of new medication requires a long period of time and considerable investments. Secondly, pharmaceutical products can be copied and introduced on the market irregularly. For many years patents were not granted to pharmaceutical products. In developed countries, it was only in 1976 that Japan passed legislation for the sector, while Switzerland adopted a similar measure in 1977. Spain, Portugal, Greece and Norway created patent systems for pharmaceutical products in 1992. Until the end of the 80s about 40 developing countries, including the most densely populated, did not have patent systems for medicines in general. This was based on the social importance of medication and on the belief that patents would lead to the abuse of the power of monopoly (4).

The “patentability” of pharmaceutical products, agreed upon during the Uruguay Round, raised the price of medicine, affecting a large part of the population. As a result, the right to health was seriously affected since various social groups could not have

access to the medicine they need.

The TRIPs agreement does not only contain rules for the protection of intellectual property of interest to the developed nations. The members of the WTO considered it advisable to foresee exceptions to the general rule in order to enable the adoption of public policies in expressly determined situations. Article 7 states that the regime of intellectual property rights should contribute to the promotion of innovation, and the transference and spread of technologies able to lead to financial and social welfare. There was an attempt to obtain a balance between the guarantee of intellectual property rights, decisive for the growth of trade, and the protection of values considered fundamental. Article 8 states that States can adopt the necessary measures to protect public health and nutrition as well as to promote public interest in sectors which are vital for social, economic and technological development. The measures adopted should, however, be compatible with the TRIPs agreement (5).

Some exceptions were made by TRIPs to the general obligation to concede patents. Article 27 (2) authorizes members to restrict the concession of patents if the inventions may endanger human life or health. Article 30, in its turn, allows States to restrict the exclusive privileges granted by the patents. For this to happen, some prerequisites must be present. The exceptions are to be limited to the rights of monopoly, and cannot prevent the exploitation of the patent or cause unreasonable harm to the legitimate interests of the patent holder (6).

Despite the efforts made during the Uruguay Round, it was not possible to reach a definition of the expression limited exceptions in Article 30 of the TRIPs agreement. However, there is a close link between article 7 and article 30, which, when read together leads to the conclusion that States should make compatible the protection of the rights of the patent holder and the need to consider the legitimate interests of third parties (7). It can be argued that in the case of illnesses like AIDS, developing countries can establish restrictions on the rights of patent holders in order to reduce the cost of pharmaceutical products and enable the poorer part of the population to have greater access to them. Countries have the right to regulate the exercise of the rights granted by the patent in order to fulfil the public good. In this context, compulsory licensing appears as an important instrument to increase the supply of medicines at lower prices.

Compulsory Licensing and the TRIPs Agreement

The first agreements on intellectual property, made in the XIX century, assigned compulsory licensing the task of solving problems created by the patent system. It authorizes a third party to manufacture, use or sell a patented invention without the authorization of the title-holder, under clearly stated circumstances (8). Compulsory licensing will be granted in case of national emergency, or when a state wants the invention to have public use on noncommercial grounds. The license will not be exclusive and will be used only for the aim for which it was granted. Its main goal is to supply the domestic market in unusual situations. The title-holder is entitled to be remunerated when it is exploited by a third party. It is possible to appeal to the Judiciary Branch to review the governmental ruling that granted the compulsory license of certain inventions (9).

As can be noted, States enjoy undeniable flexibility to adopt public policies in the field of health. Members of the WTO are free to determine the circumstances that characterize a national emergency, which are extremely important in the public health crises caused by epidemics or pandemics (10). During TRIPs negotiations, attempts to introduce criteria that would define the content of the expression public interest failed because developing nations were uninterested in restraining flexibility to adopt governmental policies of health protection. Also, it was not possible to determine the meaning of situations of urgency, national emergency, noncommercial public use, and noncompetitive conducts. During the Uruguay Round, a proposal presented by India was accepted. It ensured ample freedom for countries to define such expressions (11).

Article 31 allows for the concession of compulsory license in cases of abuse of power of the monopoly granted by the patent, or when public interest demands it. Such flexibility is essential for the adoption of public policies geared to protecting health. The increase in medication costs caused by the “patentability” of pharmaceutical products can be offset by regulatory measures that will enable social groups with a lower income to have access to medications. The objective to be achieved is to strike a balance between protecting intellectual property and promoting the well- being of the

population.

Countries are not entirely free to interpret the provisions of The TRIPs agreement of the World Trade Organization. In the case India-patents, the WTO Appellate Body believed that the terms of TRIPs must be interpreted on the grounds of "common sense resulting from its context and in the light of the object and aim of the agreement", according to the rules of the Vienna Conventions for the interpretation of treaties. Contradicting the wish of the pharmaceutical industry, the appellate body decided that the interpretation would take into account the text of the agreement accepted by members, and not the expectations of one of the parts.

It is interesting to observe that developing nations have seldom made use of the flexibility of the TRIPs agreement. The Doha declaration about TRIPs and public health in 2001 maintained the flexibility of the Agreement negotiated during the Uruguay Round, which allowed the implementation of public policies that facilitate access to medications (12). On that occasion, it was pointed out that: "We stress the importance we attach to the implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs agreement) in a way which supports public health by promoting both access to existing medicines and research into, and development of, new medicines. Due to this connection, we are adopting a separate declaration". In the same way, it was observed that members of the WTO are entitled to determine "what constitutes a national emergency or any other circumstance of extreme urgency". The obligation to negotiate on the grounds of article 31(b) of TRIPs, before granting the compulsory license, disappears when, in good faith, a country states there is a situation of emergency.

On that occasion, it was also necessary to avoid interpretations that would broaden the protection of intellectual property by TRIPs. The decision that nothing in the agreement would be interpreted in such a way as to prevent countries from adopting their own public health policies was of the utmost importance (13). The Doha declaration, however, did not address the possibility of the import of manufactured products through the concession of a compulsory license by other countries. It has been established, in this case, that the title-holder has the right to prevent the medication from being launched on other markets because his rights have not expired. From this

perspective, compulsory licensing aims mainly at supplying the domestic market.

The fact that some countries are unable to benefit from the flexibility offered by TRIPs is particularly serious. Once it is granted, compulsory licensing does not produce the expected results due to the lack of technical ability of local industry. This problem was solved by the General Council of the WTO on August 30, 2003, by a decision that protected the flexibility of TRIPs, as it was agreed that countries that met some requirements would not be subject to the restrictions in article 31(F). The member countries of the WTO will be able to import medicines through compulsory licensing if domestic industry proves unable to supply the needs of the domestic market. This privilege is ensured to less developed members of the WTO and to any member who at any time notifies the Council of TRIPs Agreement of their intention to use the system, which is provided for in the decision of the General Council in cases of national emergency or other circumstances of extreme urgency, or in hypotheses of noncommercial public use. The decision of the General Council established a number of safeguards to prevent medications produced through compulsory licensing for developing countries from supplying the market of developed countries. Such safeguards include, among other requirements, the form, color, and type of packaging of the products sold. The decision, which will be interpreted and implemented in good faith, will deal with public health issues and will not aim at achieving goals of commercial or industrial policies.

Countries can indicate, according to domestic interests, the hypotheses for granting compulsory licensing. Carlos Correia points out that developing countries should use compulsory licensing to promote access to medications in the following situations:

a) refusal to accept, which occurs whenever the patent-holder refuses to grant the required voluntary license in reasonable terms, when the non-granting of the license affects the availability of a product or the development of a new activity;

b) a declared state of national emergency, as in cases of natural catastrophes, wars or epidemics;

c) when there is a public health crisis, to ensure the population's access to essential medications, or situations of public interest, including those of national security;

d) identification of anti-competitive behavior;

e) governmental use, to foster access to medicines on noncommercial grounds;

f) when lack or insufficiency in exploiting the patent hinders access to health or prevents the development of a vital sector of the country's economy;

g) when a certain patent can be made use of through exploiting a preexisting patent, provided that the original patent covers an invention that represents an important technological advance;

h) public interest (14).

The function of compulsory licensing and impact on innovation

Debates about compulsory licensing are old. The theme was analyzed by the US senate in 1790, by the British House of Lords in 1851, and in Germany discussions started in 1853. After this, it was necessary to make the benefits of the patent system compatible with the elimination of possible undesired effects. The patent-holder does not have absolute rights, and is subject to the laws that rule competition. In certain circumstances, the government can force the patent-holder to license his invention to a third party that will exploit it through the payment of royalties. By means of compulsory licensing, the government can exploit the object of invention directly, or allow a third party to do it, without the authorization of the title-holder, in order to perform public policies that facilitate access to medication of the low- income population.

The effects of compulsory licensing are to increase competition, to supply the market, and possibly to reduce prices. It is considered, in certain cases, that access to the invention should have priority over the private interest of the patent-holder and his

exclusive right to exploit it. In developing countries, the patent has a marginal effect in terms of encouraging innovation, with extremely negative consequences for social well-being.

The analysis of the costs and benefits of compulsory licensing is essential to use it as an instrument to create public policies by developing countries. Discouraging innovation is regarded as the main risk caused by compulsory licensing. The prospect that profits obtained from exploiting the patent could suddenly disappear would reduce the incentive to invest in innovations. It would be more beneficial to profit from investments made by third parties than perform one's own research to develop a new product or productive process. It is also stated that inventors have little incentive to patent their inventions, and would rather keep them as industrial secrets (15).

Up to now, there have been no empirical data to prove the thesis that compulsory licensing has reduced investments in R&D in developed and developing countries. Scherer concluded that compulsory licensing granted in the 40s and 50s did not limit the great progress of the North American economy in that period. The need to continue to be competitive in the future encouraged the industry to put a long-term investment plan into practice, even when compulsory licensing was granted.

Shien believes that compulsory licensing affects innovation when the industry can anticipate its concession or when the market in which it will be applied shows great economic importance. The foreseeability of compulsory licensing can affect investments in markets of great importance. However, there will be reduced impact on innovation if royalties are paid according to the existing criteria for the licensing of products on the market. Non-predictable compulsory licensing may affect a company's decision to invest, but the licensing may occur too late for the company to change its behavior.

Research conducted by the British Pharmaceutical Executives suggested that, in extreme cases, compulsory licensing is harmful to innovation. This study addressed only innovation carried out by the licensor, but ignored the impact of compulsory licensing on the licensee, who often benefits from the "spillover effects" of original

innovation (16). In 1977, F.M. Scherer conducted an important investigation that focused on almost seven hundred companies, 44% of which were subjected to compulsory licensing. This research states that companies subjected to compulsory licensing invested more in R&D (17) than companies that were not the object of a similar measure. This conclusion, which applies to pharmaceutical companies, shows that compulsory licensing did not cause a reduction in investments in R&D.

In a recent study, Scherer analyzed the situation of companies that were subject to compulsory licensing or that were about to be subjected to this procedure. The companies investigated did not reduce investments in R&D because they intended to be competitive in the long run.

From 1923 to 1993, Canadian legislation authorized compulsory licensing of medicines based on sections 4 (1) and 39 (4) of the Canadian Patent Act. The main effect of this policy was the development of a domestic industry geared to produce generic medicines. The Eastman Commission observed that between 1969 and 1983 almost 80% of the licensing requests were granted, amounting to an average of about twenty compulsory licenses a year. Compulsory licensing did not affect innovation in Canada significantly, which may be due to the relative insignificance of the Canadian market when compared to the world market of pharmaceutical products (18).

Moreover, it must be remembered that the market in developing countries represents little profit for the pharmaceutical industry. Data available show that the market in developing countries contributes less than 20% of the profits obtained by pharmaceutical companies. This percentage is reduced even more if the importance of each individual market is analyzed (19). Only a small share of the population, usually no more than 10%, has ample access to pharmaceutical products in developing countries. Adequate use of compulsory licensing in these countries would have extremely little impact on investments in R&D. Canada had ample use of compulsory licensing for more than fifty years and even so, the North American pharmaceutical laboratories never failed to invest in innovation. This occurred because during that time, the Canadian market was not significant for profits in the pharmaceutical industry (20).

Compulsory licensing as a public policy tool in developing countries

The use of compulsory licensing by developing countries will contribute to raising the degree of competition, which will certainly cause a reduction in the price of medicine.. If this is the case, there will probably be different prices according to the characteristics of each market. Strict rules of protection of intellectual property in developed nations helped consolidate this situation. It should also be remembered that the prices of pharmaceutical products are established taking into account the reality of the market in developed countries. For this reason, compulsory licensing leads to undeniable social benefits that can be translated into easier access to medication by a significant part of the population.

Some authors state that it is necessary to analyze the kind of medicine to be licensed in order to determine the effect of compulsory licensing on investments in innovation. Certain products aim at the global market, for even if they are primarily destined for the market of developed countries, they are also useful in developing countries, which is the case of medicines to treat cancer and AIDS. Furthermore, there are specific drugs that meet the needs of developing countries and that fight diseases such as malaria or tuberculosis and some viruses found in Africa.

These drugs are not a priority for the pharmaceutical industry, and this is the reason why public and philanthropic resources fund research in the area. The Center for Disease Control, and partnerships between the public and private sectors, like The International AIDS Vaccines Initiative and the Alliance for Tuberculosis Drug Development are examples of successful experiences in the research into medicines of interest to developing countries. Compulsory licensing for global drugs, when limited to developing countries, does not have a negative effect on investments in research in developed countries.

In this case, companies respond to consumer demands, and if this remains unchanged, selective compulsory licensing, which is restricted to developing countries, will have little effect on innovation. If pharmaceutical industries invest funds on a large

scale in the production of medicines used by developing nations, the general concession of compulsory licensing will probably affect investments in R&D. The first conclusion to be drawn, in the opinion of these authors, refers to the need to analyze compulsory licensing in a different way when dealing with global drugs or specific medications for developing countries. Possible compulsory licenses granted to produce drugs that fight AIDS would not have a negative effect on research in the area. The situation is different when medicines are produced for the specific treatment of some diseases typical of developing countries. The threat that there might be systematic use of compulsory licensing of such medicines might force pharmaceutical companies to avoid these markets.

Another frequent argument refers to the potential negative effects of compulsory licensing on the attraction of foreign investment. So far there have been no conclusive studies showing a link between the level of protection of intellectual property and the amount of foreign resources entering a country. Choices of investment are in fact influenced by the analysis of the potential for economic growth of a country and by the soundness of its institutions. High levels of protection of intellectual property do not in themselves guarantee the transfer of technology to developing countries. To reduce the risks of abuse, developing countries should use compulsory licensing in the specific circumstances defined by already existing laws.

The use of compulsory licensing as a strategy to create public policies should be linked to a framework which ensures reasonable remuneration for the patent-holder. This would attenuate the effects of compulsory licensing on technological progress. Article 31(h) of the TRIPs Agreement requires that the patent-holder receive adequate remuneration, established case by case according to the value of the concession. When compulsory licensing is conceded to repress anti-competition conduct, the remuneration may receive special treatment, in the terms of article 31(k). It has already been suggested that this norm would allow the payment of reduced royalties, or even the free concession of the license.

The main problem involving the concession of compulsory licensing lies in the value of the remuneration to be paid to the patent-holder. The payment of royalties similar to those paid to the patent holder in the case of voluntary licensing would

prevent, in practice, the fulfillment of the objectives of compulsory licensing (21). The situation changes when the issue is compulsory licensing conceded to repress anti-competition conduct. In this case, North American anti-trust authorities have established royalties at values ranging from 0.2% to 3 %, figures considered low by the market. In other cases, compulsory licensing was conceded free as happened in the case Dell Corporation Vs Bus patents. The establishment of high royalties for the compulsory licensing of medicines would have extremely negative effects on the poorer sectors of the population. On the other hand, the establishment of royalties at low levels would enable the market to be supplied, thus contributing to raising the level of social welfare (22).

Compulsory licensing is not widely used by developing countries to encourage access to medicines. Greater use of compulsory licensing in developing countries requires the existence of high levels of the protection of patents in developed countries. This factor would make it possible to adopt different prices according to the specific needs of each market. The granting of compulsory licenses would increase competition and decrease the prices of pharmaceutical products in developing countries. On the other hand, the price of medicines would tend to rise in the market of developed countries (23).

For compulsory licensing to be an efficient tool to reduce the costs of the system of patents and provide greater social welfare, the ways in which it can be used must be clearly defined. It would be wrong to believe that compulsory licensing is a panacea for all the problems of public health faced by developing nations. Some questions are of a structural nature and need comprehensive policies which include the adoption of measures of different kinds. It must also be acknowledged that compulsory licensing is an exceptional resource which should be used by governments in exceptional circumstances, established by law. The rational use of compulsory licensing may favor the transfer of technology to produce medicines for countries in areas of vital interest for the health of the population.

Developing countries should use the alternatives offered by the TRIPs Agreement and create legal tools and public policies to exploit the potentials offered by compulsory licensing to allow greater social equality in access to medicines. In this

context it is absolutely necessary to maintain the flexibility established by the TRIPs Agreement for this to happen. The pressure for compulsory licensing not to be conceded and frequent attempts to interpret the TRIPs Agreement in a restrictive manner are extremely damaging to the interests of developing countries, and remove from them the chance to carry out public policies to prevent death and improve the health of a considerable part of the population (24).

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