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COMPULSORY LICENSING

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*Abstract:

Despite in decline in the discovery of new chemical entities, there is a significant proliferation of patents on pharmaceutical products that cover minor, incremental innovations. The application of low standards of patentability does not promote innovation in pharmaceuticals in the studied countries (Argentina, Brazil, Colombia, India and South Africa) but rather the use of the patent system to delay or block generic competition. The study of patents granted in the five countries shows the acceptance of overly broad claims, an overwhelming dominance of foreign patenting and a little research and development activities regarding diseases that predominate in developing countries. Insufficient information made available on the covered products makes it difficult to monitor the process of grant and to determine the patent status of particular medicines.

* Key words: PATENTS, EVERGREENING, LOCAL INNOVATION, MEDICINES, COMPULSORY LICENCES, RESEARCH AND DEVELOPMENT.

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Introduction

The patent system was devised in order to reward inventiveness, encourage technical progress and foster the dissemination of innovations. The restriction to the free movement of ideas that the granting of a patent entails has been justified under different theories, namely natural rights, moral reward, incentive to invention, encouragement to innovation. The idea that patents are necessary to allow the investor to recoup its investment in R&D dominates in current debates and jurisprudence of many countries (Gutterman, 1997).

Though the development and exploitation of numerous contributions to technology have been closely linked to, although not necessarily determined by, the possibility of obtaining exclusive rights to exploit inventions (Archibugi and Malaman, 1991), the patenting system is far today from fulfilling its intended objectives. The expansion of the subject matter of patentability from inanimate to living forms, the admission of broad claims encompassing vast fields of technology, the dilution of the patentability requirements, and shortcomings in the examination process, have led to a profound distortion of the system (Jaffe and Lerner, 2004). There is a proliferation of patent applications and grants, in great part motivated by a variety of defensive and offensive patenting strategies (Granstrand, 1999).

One increasingly widespread view is that the patents system is in crisis (Foray, 1995), and that its role in promoting innovation is less substantial than usually claimed (Landes and Posner, 2003; Levin et al., 1997). Patents may even stifle the very innovation they are supposed to foster. The National Academies of the United States have taken up the criticism leveled by many academics and sectors of industry and have expressed their concern about the lax application of the patentability standards (National Academies of Science, 2003), especially as regards non-obviousness and usefulness, in the examination and granting of patents. The application of such standards result in many over-broad (Mazzoleni and Nelson, 1998) or “low quality” patents (Cooper, 2004).

However, even the users and main beneficiaries of the patent system (with annual revenues exceeding U\$10 billion) have become growingly critical about the functioning of the patent system¹.

The efficacy of the patent system for ensuring a satisfactory rate of innovation at the lowest social cost is under serious doubt. A basic question in developed countries is how to ensure that patents actually encourage, rather than unduly limit competition and hold back innovation (Federal Trade Commission, 2003; European Commission, 2008; Samuelson, 2004). As incremental innovations prevail in most sectors (including biomedicine), the patent system has increasingly moved away from its objective of stimulating genuine ‘invention’ towards a system for the protection of investment in incremental innovation, whether truly inventive or not. For some analysts, “the time has come not for marginal changes but for wide-open thinking about designing a new system from the ground up” (Thurow, 1997).

¹ A survey conducted among large companies by the Intellectual Property Owners Association (IPO) in August 2005 showed that its corporate members perceive the quality of patents granted by the U.S. Patent and Trademark Office to be less than satisfactory. Over half of respondents, 51.3 percent, rated the quality of patents issued in the U.S. today as less than satisfactory or poor (47.5 percent less than satisfactory and 3.8 percent poor). Those rating quality more than satisfactory or outstanding were 8.8 percent of all respondents (8.8 percent more than satisfactory and 0 percent outstanding). Respondents' prognosis for the future was not encouraging. Over two-thirds of respondents said they would be spending more, not less, on patent litigation over the coming years. See Patent Litigation Costing More, PR Newswire (press release), New York - Sep 13, 2005.

The observed trend has special implications in the case of pharmaceuticals. While the number of new-developed chemical entities has dramatically fallen during the last fifteen years, the number of patents over simple changes in chemistry/formulation of existing pharmaceutical products (e.g. polymorphs, combinations, dosage forms, isomers) has continuously increased. Thousands of patents are granted per year on these incremental innovations, often trivial for a person skilled in pharmaceutical production.

The development of new chemical entities for pharmaceutical use presents, in effect, a worrisome picture. The number of such entities delivered per year has fallen substantially since the 1990s, thereby increasing the *average* cost of developing new drugs. Furthermore, most new chemical entities do not represent a genuine therapeutic innovation, but present therapeutic effects similar to those of one or more already marketed drugs (Center for Drug Evaluation and Research, 2005; Spector, 2005). That decline seems paradoxical for three main reasons. First, since the 1980s and, particularly as the implementation of the TRIPS Agreement was completed in developed and developing countries², patent protection allowed companies to increase income generation worldwide through the exercise of stronger and, in some cases, longer patent rights³ and data exclusivity⁴. Second, there is a new set of scientific and technological tools – such as genomics, proteomics, combinatorial chemistry — that offer the potential of speeding up drug discovery. Mass screening of potential drug candidates has been substituted by more efficient methods enabling the rational design of drugs. Third, the pharmaceutical industry has been one of the most profitable sectors of the economy, fourth only after mining, crude oil production and commercial banking (Commission on Intellectual Property Rights, Innovation and Public Health, 2006). Moreover, funds allocated to R&D have increased since the last decade. The fall in innovative productivity may indicate a crisis in the model of drug development carried out by large pharmaceutical companies, as ‘the number of new products has not increased whilst the overall level of resources being invested has risen dramatically’ (Charles River Associates, 2004). Increasingly, large firms find it more difficult to maintain a continuous pipeline of new and commercially viable products. They heavily depend for new drugs on advances made by small biotechnology companies, while many of the clinical studies are done by specialized contractors and certain segments of biomedical research are undertaken in cooperative ways following an “open access” model, insofar as computational models utilizing genetic information become more important as part of the product development process (Maurer S, Rai A, Sali A., 2004).

Patents over minor incremental development (often termed as ‘evergreening’ patents⁵) may be used to exclude generic competition and thereby block access to affordable drugs. They may constitute an important obstacle for the realization of the *right to health* recognized in the International Covenant on Economic, Social and Cultural Rights. The reason for this is that patents

2 Transitional periods were provided for developing countries, economies in transition and Least Developed Countries. Developing countries that did not recognize previously pharmaceutical product patent protection could delay its introduction until January 1, 2005 but only a few countries made full use of this possibility.

3 The TRIPS Agreement set out a minimum term of 20 years, obliging many countries (including the US and Canada) to change their legislation.

4 In the context of free trade agreements (FTAs), as a result of demands made in the process of accession to the WTO, or by the US government or the European Union, several countries have implemented sui generis regimes granting exclusivity over the test data necessary to obtain the marketing approval of pharmaceutical products containing new chemical entities. Such an exclusivity is not required by the TRIPS Agreement.

5 ‘Evergreening’ consists in the patenting of minor changes to or versions of existing products (e.g. formulations, dosage forms, polymorphs, salts, etc.) in order to indirectly extend the life of the original patent over an active ingredient.

obtained (including in relation to drugs already in the public domain) are often strategically used to block generic competition, thereby delaying the entry into the market of medicines at a lower cost. This problem affects developed and developing countries alike. In a recent report by the European Commission, for instance, it is noted that ‘originator companies have designed and implemented strategies (a "tool-box" of instruments) aimed at ensuring continued revenue streams for their medicines. Although there may be other reasons for delays to generic entry, the successful implementation of these strategies may have the effect of delaying or blocking such entry. The strategies observed include filing for up to 1,300 patents EU-wide in relation to a single medicine (so-called "patent clusters"), engaging in disputes with generic companies leading to nearly 700 cases of reported patent litigation, concluding settlement agreements with generic companies which may delay generic entry and intervening in national procedures for the approval of generic medicines. The additional costs caused by delays to generic entry can be very significant for the public health budgets and ultimately the consumer (European Commission, 2008, p. 3).

A critical conclusion from this analysis is that **current patent strategies in the pharmaceutical industry may have a direct negative impact on access to drugs**, as patents on minor variants of existing products can be used to block legitimate generic competition.

As analyzed below, the research done confirms the proliferation of patents in pharmaceuticals in the covered countries and a significant level of litigation.

Patents and innovation

As noted, patents are granted to promote innovation. The formulation of a patent regime, hence, should not be dissociated from the characteristics of the national innovation system of the country where it applies. In most developing countries the innovation systems are fragmented and weak, and they overwhelmingly depend on foreign innovations. In many developing countries the public sector modestly invest in scientific activities - generally focused on subjects of research of interest to developed countries- while domestic firms generate “minor” or “incremental” innovations largely derived from the routine exploitation of existing technologies. Domestic firms generally follow “imitative” or “dependent” technological strategies, usually relying on external sources of innovation, such as suppliers, customers and competitors.

However, there are growing differences among developing countries. Some developing countries (such as China, Brazil and India) that are more scientifically advanced than others, are starting to reap benefits from decades of investments in education, research infrastructure, and manufacturing capacity. These countries -which have been called in recent literature as ‘innovative developing countries’ (IDCs) (Morel et al., 2005:401), invest in R&D relatively more than other developing countries, there is a greater involvement of the private sector, and the interactions between public institutions or private companies with innovation agents in developed countries are more frequent.

Adapting the patent regime to different innovation systems is not a simple task. The considerations relevant to an IDC may well be different from those relevant to less technologically advanced countries. These differences, however, should not be overstated since, on the one hand, developing countries, including IDCs are equally vulnerable to patent strategies of large companies from developed countries and, on the other, a large portion of the population in those countries live in poverty, and will equally bear the costs of tight patent regimes in terms of reduced access to essential goods, such as medicines and chemical products for agriculture.

An example of adaptation of the patent law to local conditions is provided by the recent

reform (2005) of the Indian Patent Law. In order to prevent the 'evergreening' of pharmaceutical patents, which delay or impede competition of generic products, the law introduced a specific provision tightening the inventive step requirement as applied to new forms or modifications of existing products (Section 3(d)).

A key question addressed in this project is how to frame a patent regime where the innovations prevailing in the country relate to minor/incremental technical changes. At first sight, such innovations may be regarded as outside the patent system, and a different set of measures to promote them would seem to be called for. However, patents are not granted only when a significant technical development has been achieved. Inventions marked with considerable originality (Merges and Nelson, 1996:128) do not occur frequently, even in highly intensive R&D industries. In fact, the largest part of R&D undertaken (by large and small firms) is devoted to the improvement on and further refinement and patenting of existing technologies. Though not all types of incremental innovations may be eligible for patent protection, many actually do. According to a Guide of the Canadian Intellectual Property Office, for instance, 90% of all patented inventions were minor improvements on existing patented devices (Canadian Intellectual Property Office, 1994).

It has been argued that a patent regime based on a low inventive threshold could be functional to the predominantly incremental innovation path prevailing in developing countries, as patents might encourage minor innovations developed by domestic companies⁶. In accordance with this view, the possibility of patenting minor innovations may encourage such companies to improve on existing technologies and thereby enhance their competitiveness in local or foreign markets.

This expansive approach on inventive step, however, may have negative consequences both generally and, in particular, in the case of pharmaceuticals. On the one hand, large firms with experienced patent lawyers are much better prepared, financially and technically, to exploit a patent regime with a low patentability threshold than domestic firms, and there is a risk of blocking innovation and competition, rather than promoting it. In addition, the public will be bound to pay monopoly prices for access to knowledge and products that should be in the public domain.

On the other, the cost of acquisition and, particularly, exercise of patent rights is too high for most local innovators, generally small and medium enterprises (SMEs). While SMEs could opt in many cases to seek patent protection, they must bear the costs of filing, registration and maintenance. If there is litigation, (either to enforce the patent against infringers or to defend it from validity challenges), victory in courts is not assured, damage claims by counterparts may be high and litigation costs may be prohibitive.

Hence, a main hypothesis of the research has been that the potential benefits for the local industry of applying a low standard of patentability would be offset by the costs associated with the proliferation of patents over minor technical changes (World Bank, 2001). Given the asymmetries in innovation capacities between local and foreign industries, low standards of patentability will ultimately benefit the latter and, in the pharmaceutical field, are likely to negatively affect public health through reduced access to medicines, particularly by the poor.

It is likely to exist an optimal level of patent protection beyond which negative effects would start to dominate positive effects (Guellec, 2007, p. 73). Patents produce a dead weight burden insofar as the benefits of innovations to society would have been greater in their absence, while they

⁶ See the paper by Padmashree Sampath produced by this project.

reduce the ability of other firms to exploit innovations on a competitive basis (Maskus, 1997, p. 3). The latter is a critical problem in the case of cumulative systems of technology, where patents may deter rather than promote follow-on innovations (Foray, 2000, p. 142). In the case of pharmaceuticals, patenting strategies may erect important barriers against the entry of generic competition and, hence, significantly increase the cost of medicines and reduce access to them (European Commission, 2008).

Recent experiences (e.g. in Thailand) show that the application of low standards of patentability has led in some cases to the grant of patents that later may need to be subjected to a compulsory license/government use. Although compulsory license/government use are legitimate under international law⁷, their application has faced considerable resistance from developed countries' governments and retaliations from the pharmaceutical industry. Another hypothesis of this project is that with the application of well defined patentability standards governments could avoid spending the political capital necessary to grant and sustain compulsory licenses/government use. If patent applications were correctly scrutinized, there would be no patent grant and, hence, no need to have recourse to such measures.

Project's objectives

The general objective of the project has been to contribute to the design of patent policies in developing countries that promote local innovation and, at the same time, ensure the broadest possible access to medicines, particularly by the poor.

The specific objectives were the following:

- To document trends in pharmaceutical patenting, particularly in relation to variants of existing products/processes, in selected developing countries
- To document the impact of patents on variants of existing products/processes on generic competition and access to medicines in selected developing countries
- To study the impact of different standards of patentability (particularly in relation to inventive step) on the promotion of pharmaceutical and other innovations in developing countries at different levels of development
- To develop a set of appropriate guidelines for the assessment of pharmaceutical patent applications with the aim of rewarding genuine inventions, ensuring generic competition and improving access to medicines⁸
- To determine whether the application of strict patentability standards by the relevant patent offices may avoid the need to resort to compulsory licenses/ government use

⁷ See article 31 of the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health (2001).

⁸ These guidelines were not developed given the broad diffusion and application in some countries of the guidelines developed by C. Correa contained in WHO, ICTSD, UNCTAD, UNDP, *Guidelines for the examination of pharmaceutical patents: developing a public health perspective, Working Paper*, available at www.ictsd.org, Geneva, 2006.

-To provide recommendations for the design of patent policies in developing countries that promote local innovation and, at the same time, ensure the broadest possible access to medicines, particularly by the poor.

Methodology and outputs

The research has been guided by a large body of literature on national innovation systems⁹ and by literature on the relationship between the level and scope of patent protection, on the one hand, and innovation and access to medicines, on the other.

The research involved Argentina, Brazil, Colombia, India and South Africa. There are important differences in the size of their economies, their innovation systems and policies and, in particular, in the public health systems and their coverage.

A common need in all these countries is to ensure access to medicines to a large part of the population that lives under the poverty line. As patents allow title-holders to exclude competitors, the proliferation of patents can only mean that prices higher than those that would prevail under competitive conditions will be charged. The larger the number and scope of patents on particular medicines, the greater the likelihood of limitations to access by the poor.

The five countries are WTO members and grant patents on pharmaceutical products and processes. South Africa grants patents without prior examination.

The project methodology was based on the proposal approved. Nevertheless it was necessary to adjust some aspects for each one of the proposed objectives. For this reason, a workshop was organized to debate and agree details for the execution of the project.

The meeting was carried out in Rio de Janeiro in September 7 and 8 of 2009, with the support of the World Health Organization (Secretariat for the Commission on Intellectual Property Rights, Innovation and Public Health), the United Nations Development Program. It was hosted by the Brazilian Interdisciplinary AIDS Association/ABIA. The objectives and tasks of researchers in the various countries were discussed and defined, taking into account the local situation and the options to perform them. Furthermore, the time deadlines, the coordination mechanisms, and the administrative procedures for the project were adopted.

The first phase of the investigation was the data collection in each country. To this purpose, IFARMA included a banner in its webpage, with information about the project, and a centralized database where all the participants filled in the patent data.

We decided to use an open source data base, built at the web page of IFARMA, in order to avoid compatibility problems and the consequences of the use of multiple bases, updated by different persons at different times, without a reliable and reproducible protocol. Each researcher had his password and updated the database whenever necessary. All of the researches had permanently access to the data.

The second phase included the classification of identified patents, and the analysis of the implications for the generic competition, and on litigation, focusing on the behaviour of the patentees in each country.

⁹ See, e.g. Lundvall, 1992; OECD, 1997; Patel and Pavitt, 1994.

The third phase included a brief study on the behaviour of local pharmaceutical companies.

The exploration on the relations between patentability and compulsory licenses was limited by the availability of information, and was performed at a global level, including countries that were not part of the case studies.

A final meeting was carried out in Cartagena (Colombia), on February 21st to 23th, 2011 to summarize the results, and formulate recommendations.

The participants in the project were Spanish, English, and Portuguese speakers. The report includes sections in English and in Spanish. The texts are submitted as elaborated by the different country teams. They require considerable editing in order to harmonize styles and formats and, in some cases, translation, with the aim of producing a book in English with the outcomes of the project.

The period covered by the study was 2004-2008. There were some constraints, however, relating to availability of information on granted patents. These constraints prevented the research teams to work on the same period for the gathering and analysis of patent data. This fact limits the comparability of data but not its usefulness to understand the national situations and draw interesting comparisons.

The group adopted and adapted a data base developed by Carlos Correa and an assistant, based on ACCESS. This data base was shared with the Ministry of Health in Argentina.

Every national team incorporated information on national patents into the database, and the project leader developed a template to perform the analysis. The patent system of each country was described, including on the extent of disclosure of patent data.

There is a national chapter for each country covered in the study, which includes information such as:

- A description of the context
- A description of the medicinal market including size, and level of generic penetration
- Industrial capacity, national and foreign industries
- Science and technological infrastructure
- Public health systems
- Pharmaceutical policies
- Legal framework
- Description of patent law
- Patent system
- Guidelines
- Transparency of the system

Patents related to Cancer and Human Immune Deficiency were identified, and an in depth analysis was performed on a selected group of patents.

A key component of the research was the analysis of pharmaceutical patents granted in the covered countries, with the aim of identifying patents on variants of existing products/processes, particularly in the field of ARV's and anticancer drugs. This study considered information such as date of

application and grant, nationality of patent owner, protected subject matter, and type of claims.

A study on the impact of different standards of patentability (particularly in relation to inventive step) on innovation in the pharmaceutical sector in developing countries at different levels of development was also conducted.

This study explored the relationship between the level of inventive step and the type of innovation promoted by the patent system.

This study was supplemented by an analysis of patenting by local companies. In some cases, interviews were conducted on the basis of a semi-structured questionnaire..

The issues considered included

- Cost of developing innovation
- Cost of the patent procedures
- Examination procedures
- Utility of the patent
- Enforcement
- Exploitation of the patent

Another component of the research included an analysis of the hypothesis that the application of strict patentability standards by the relevant patent offices may avoid the need to resort to compulsory licenses/government use. There have been CL requests in South Africa, Brazil, Colombia, and India. Other developing countries have had requests, and have granted CL's.

The grant of compulsory licenses for ARV's and cancer products was analyzed with the aim to establish the extent to which such licenses covered patents of low or inexistent inventive step.

The book will, finally, contain detailed recommendations for the design of patent policies in developing countries that promote local innovation and, at the same time, ensure the broadest possible access to medicines, particularly by the poor. Such recommendations were discussed at a seminar in Cartagena (Colombia), held in February 21 to 23 of 2011 where IFARMA invited different stakeholders in Colombia, including COLCIENCIAS, the Patent Office, the Ministry of Social Protection, and researchers from several Colombian universities. These recommendations will be further elaborated for the book to be produced.

Integrated analysis of pharmaceutical patenting in the covered countries

In the context of the analysis of incentive systems for innovation and research in health, there has been a strong debate about the effectiveness of the patent system as an instrument to achieve the goal of innovation for all countries¹⁰. Moreover, although some people argued that patents do not restrict access to essential drugs in middle- and low income countries¹¹, since in practice there is a very low number of essential drugs covered by patents, there is growing evidence in the sense that

¹⁰ Public health, innovation and intellectual property rights. Report of the commission on intellectual property rights, innovation and public health. CIPIH. Available at <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>

¹¹ Attaran A. "How Do Patents And Economic Policies Affect Access To Essential Medicines in Developing Countries?" Health Affairs, Vol. 23, no.3 (2004):pp. 155-166.

the industrial property protection, primarily with regard to patents, is affecting access to medicines, without the promotion of innovation in those countries¹². The protection of pharmaceutical products and processes through patents is largely responsible for the high costs of new drugs¹³ and the high cost of medicines, which create a constraint for access to drugs in low-and middle-income countries¹⁴.

To mitigate the potential negative impact of patents on access to medicines, various reports and a robust literature recommends the use of different “flexibilities” permitted by the Agreement on Trade-Related Intellectual Property Rights -TRIPS - such as the use of compulsory licensing and parallel importation¹⁵.

In the same way, there is criticism about the fact that innovation in medicines has been oriented towards products that satisfy demands from high-income countries¹⁶. The diseases that disproportionately affect low-and middle-income countries are low in the priorities of companies doing drug research and development. For diseases that are concentrated in these countries, often called “neglected diseases” (such as TB and malaria), a number of institutions and private-public partnerships have developed research strategies based on funding donated by charitable organizations or public institutions¹⁷.

Although purchasing power is much lower in developing countries than in countries like the United States, members of the European Union and Japan, it is estimated that in developing countries over 90% of people bear the cost of drugs out of the pocket and that medicines represent the second highest expense after food. Overall, developed countries account for 80% of the global pharmaceutical market, valued at 520 billion dollars for 2010 according to IMS data¹⁸.

It is worth noting that a wide variety of protected products are indicated for the treatment of high cost diseases such as HIV / AIDS and various cancers. At the international level there has been an intense debate on the limitations to access that occur, especially in relation to HIV / AIDS, when the needed products are covered by patents, but still viable strategies that allow broad and effective access to second-and third-line therapies (which are basically those that are patented)¹⁹ have not been implemented.

This study discusses certain aspects of the patent systems as applied to pharmaceuticals in five countries in three continents: Argentina, Brazil, Colombia, India and South Africa. All they are

¹² Integrating intellectual property rights and development policy. Commission on intellectual property rights. DFID. Available at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf

¹³ Agazzi I. “Intellectual Property Rights Remain A Barrier to Drugs” Interpress Service, Available at <http://ipsnews.net/news.asp?idnews=52215>

¹⁴ Organización Panamericana de la Salud, Área de Tecnología, Atención de la Salud e Investigación Proyecto de Medicamentos Esenciales y Productos Biológicos (THR/EM) “El acceso a los medicamentos de alto costo en las Américas: contexto, desafíos y perspectivas” Washington, DC, 20037 Octubre, 2009

¹⁵ Velasquez G. Correa C. “El acceso a medicamentos en el contexto de los acuerdos internacionales de comercio y las nuevas reglas de propiedad intelectual” CINEP, Bogotá, Colombia. 2008.

¹⁶ CIPIH. Op. Cit.

¹⁷ Moran M, Guzman J, Ropars A-L, McDonald A, Jameson N, et al. (2009) Neglected Disease Research and Development: How Much Are We Really Spending? PLoS Med 6(2): e1000030. doi:10.1371/journal.pmed.1000030

¹⁸ IMS health. World Pharma market summary. March 2011. Available at www.imshealth.com

¹⁹ UNITAID Second line Project. Available at <http://www.unitaid.eu/en/secondline.html>

considered developing countries and emerging economies, according to the World Bank, and account altogether for almost a quarter of the global population (see Table 1).

Table 1. Aggregated population

COUNTRY	POPULATION
INDIA	1.140.000.000
SOUTH AFRICA	49.110.000
ARGENTINA	40.000.000
BRAZIL	192.000.000
COLOMBIA	45.000.000
TOTAL	1.466.110.000

In this section we intend to provide an analysis of aggregate data for the five countries studied. While there are important differences between them, both in their patent system and poverty levels, a comparative analysis of the results obtained permits to draw interesting conclusions.

Table 2 shows the per capita income of the covered countries; five are classified as middle income countries either medium low or medium high²⁰. All have high rates of poverty and face problems of access to medicines that have been addressed in different ways by their governments. All of them adopted patent systems consistent with the TRIPS Agreement and are facing biopiracy practices from Big Pharma²¹.

Table 2. GDP per capita.

Country	GDP Per cápita (2009)	WB classification by GDP Per Capita. 2009
Argentina	7550	Middle High
Brazil	8040	Middle High
Colombia	4990	Middle High
India	1180	Middle Low
South Africa	5760	Middle High

Source: World Bank.

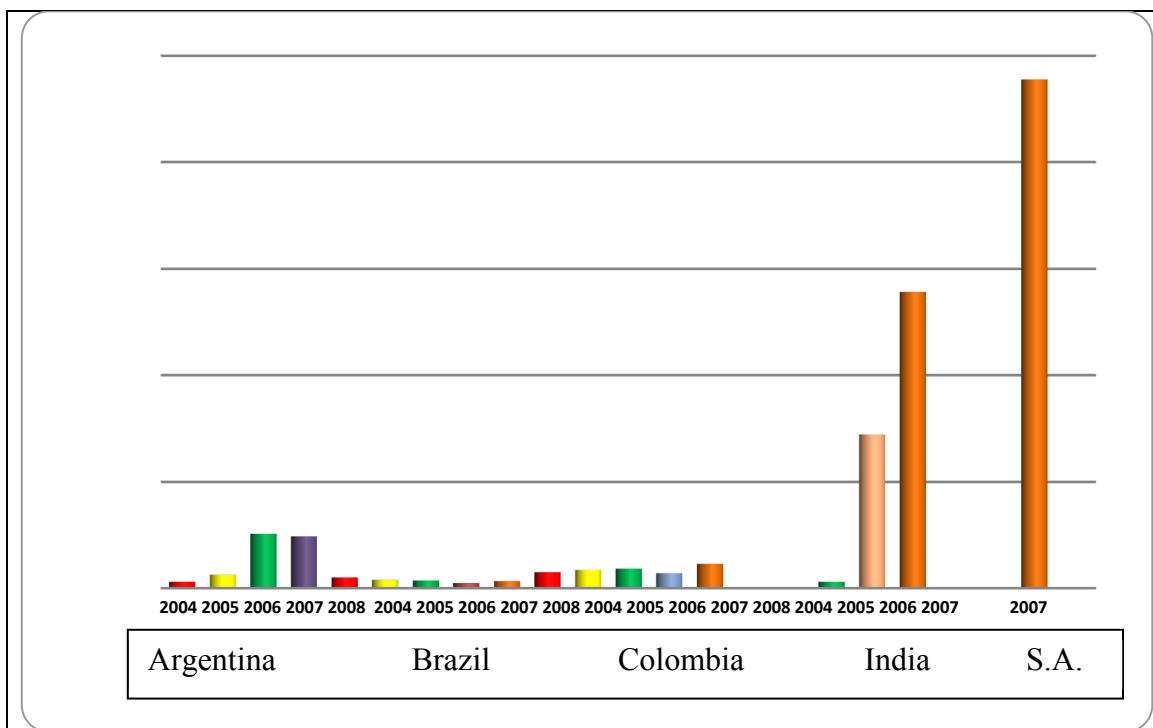
²⁰ The World Bank classifies as low-income countries those with a per capita income (GNI) of U.S. \$ 995 per year or less, those with incomes between 996 to 3,495 dollars per year are classified as middle income countries-low, and countries whose GNI is between 3,496 and U.S. \$ 12,195 per year are classified as upper middle income. Finally, high-income countries are those with a GNI of U.S. \$ 12,916 or more.

²¹ Stenton G. "Biopiracy within the Pharmaceutical Industry: A Stark Illustration of just how Abusive, Manipulative and Perverse the Patenting Process can be towards Countries of the South" Hertfordshire Law Journal, 1(2), 30-47 ISSN 1479-4195 online

Pharmaceutical patents granted

The number of granted pharmaceutical patents in the five surveyed countries (Figure 1), shows a large dispersion, which reflects differences in national systems.

Figure 1. Granted patents per country



The cases of India and South Africa call particular attention. India because it started the granting of patents in 2005, but the number of grants significantly grew in 2007 and 2008. This reflects the mechanism called 'mail box', which allowed patent applications to be deposited before 2005, but to be assessed only after January 1st, 2005, that is, at the end of the transitional period.

The second is due to the fact that in South Africa no substantive examination is performed, so that the grant process is light and fast and the number of granted patents in a single year is much higher than in any of the other countries considered.

Granted patent data confirm that patented drugs in the studied countries bear little relation to the profiles of disease prevalent in developing countries. The patented products are those overwhelmingly developed to satisfy the market demand in developed countries.

Table 3 Therapeutic use of patented products

Therapeutic use	No. of patents
	1699
A - Alimentary tract and metabolism	589
B - Blood and blood forming organs	146

Therapeutic use	No. of patents
C - Cardiovascular system	381
D - Dermatology	138
G – Genito-urinary system and sex hormones	168
H - Systemic hormonal preparations, excluding sex ...	58
J – Anti-infectives for systemic use	707
L - Antineoplastic and immunomodulating agents	785
M - Muscle-skeletal system	233
N - Nervous system	823
P - Antiparasitic products, insecticides and repel...	56
R - Respiratory system	222
S - Sensory organs	58
V - Various	43
L01 – Anti-neoplastic	1

Transparency

It is often argued that patents encourage research and innovation in all fields of science. This is achieved through different mechanisms. One of them is through the public disclosure of information relating to inventions. However, the results show that although theoretically information is made public, there are significant shortcomings.

It was amazing the number of obstacles and difficulties faced by the research teams to have access to primary and complete information about granted patents. Key words are not reliable enough to determine the status of an individual product or process and the patent coverage. In some cases, there is easy-to-obtain public information on the title of the patent but not on the claims granted or rejected.

This is due to a number of factors, including: ongoing difficulties in obtaining patent information from developing country and LDC patent offices on pharmaceutical patents; the lack of human and capital resources to ensure continuity in keeping patent landscapes up to date; and concerns amongst some organizations as to unforeseeable consequences of having transparent patent information. Resolution 61.21 of the 2008 World Health Assembly, urged the WHO to: "compile, maintain and update a user-friendly global database which contains public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products in order to strengthen national capacities for analysis of the information contained in those databases and improve the quality of patents." In the past two years patent information in an electronically search-able format has become increasingly available. More and more national patent offices are providing searchable databases, albeit with some providing more information than others.

In the case of the Indian Patent Office²², it was only after much public pressure that the database

²² Tahir Amin. ICTSD. Bridges. <http://ictsd.org/i/news/bridges/98758/>

provided the full text of published and granted patents, as well as the status of applications. While the last decade has seen improvements in access to patent information and more detailed patent landscapes on medicines, there still remains a considerable lack of transparency. This is particularly so for civil society users not familiar with how to navigate the various sources of patent information.

The obvious solution to the transparency problem is to have patent owners disclose the relevant patents they have on medicines. However, in most cases, pharmaceutical companies are unwilling to share this information. This strategy creates uncertainty in the marketplace for competitors. Peter Drahos in his recent book *The Global Governance of Knowledge - Patent Offices and their Clients* rightly points out that patent offices have a greater obligation to disseminate information on inventions as a public good. Simply publishing patent information and offering databases for searching is not the same as actively promoting transparency. Ideally, patent offices would make the information more easily accessible, including details of patents that have expired or lapsed - information not so readily transparent in current databases.

Access to such information would help give more clarity to freedom-to-operate decisions and save considerable time now spent on time and resource consuming searches by organizations with limited resources.

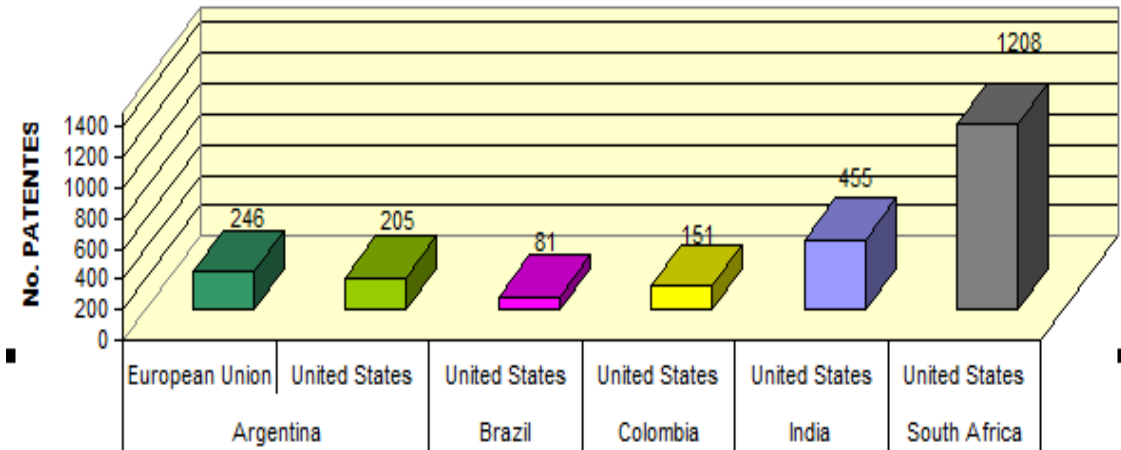
Information asymmetry in the patent system makes procurement decisions for medicines inefficient. The modern patent social contract, which was partly based on the disclosure of the inventions claimed in patents, currently disproportionately favors patent holders. Much more needs to be done if we do not want another decade to go by in the dark.

In particular, we find that the information disclosed by the patent offices is difficult to associate in many cases to an active or specific drug, thereby limiting the potential use of that information and knowledge on the legal situation of a multiplicity of drugs. For example, in Argentina, in the case of the 78% of the 951 pharmaceutical patents granted, the information published by the national patent office did not indicate the generic name of the covered product.

Patents owned by foreign companies

Given the asymmetry in the research and development capabilities between developed and developing countries, it is known that the vast majority of patents are foreign-owned. The study largely confirms this scenario for the pharmaceutical sector, where a high proportion of patents granted are for holders of foreign origin; most of them from the United States (see Figures 2 and 3).

FOREIGN PATENTS
2004 - 2008

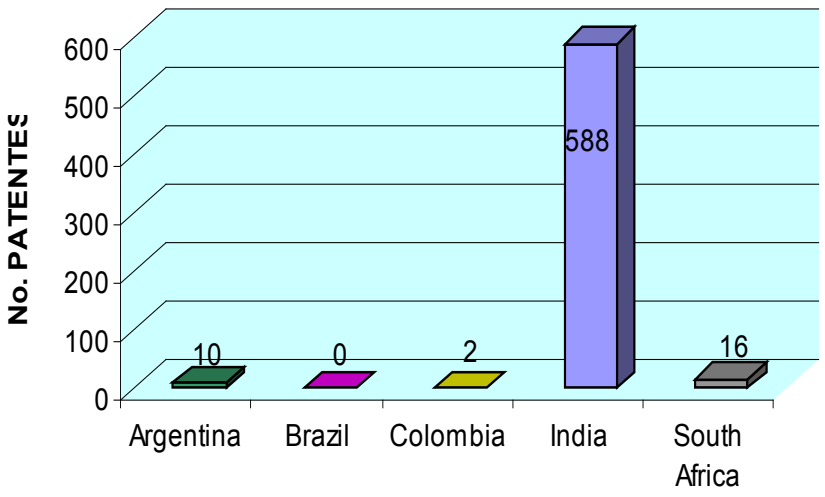


United States is the country with the largest number of patents, followed by the European Union. This suggests that, despite the arguments in favor of the patent system as a means to promote local innovation and local industries, the system seems to be suited to essentially protect innovations made by large multinational enterprises.

Domestic Patents

The graphic above shows the great differences between domestically owned and foreign patents. The case of India is very special in terms of a large number of domestic patents, since in the other four countries there is a negligible number of domestic patents.

LOCAL PATENTS
2004 - 2008



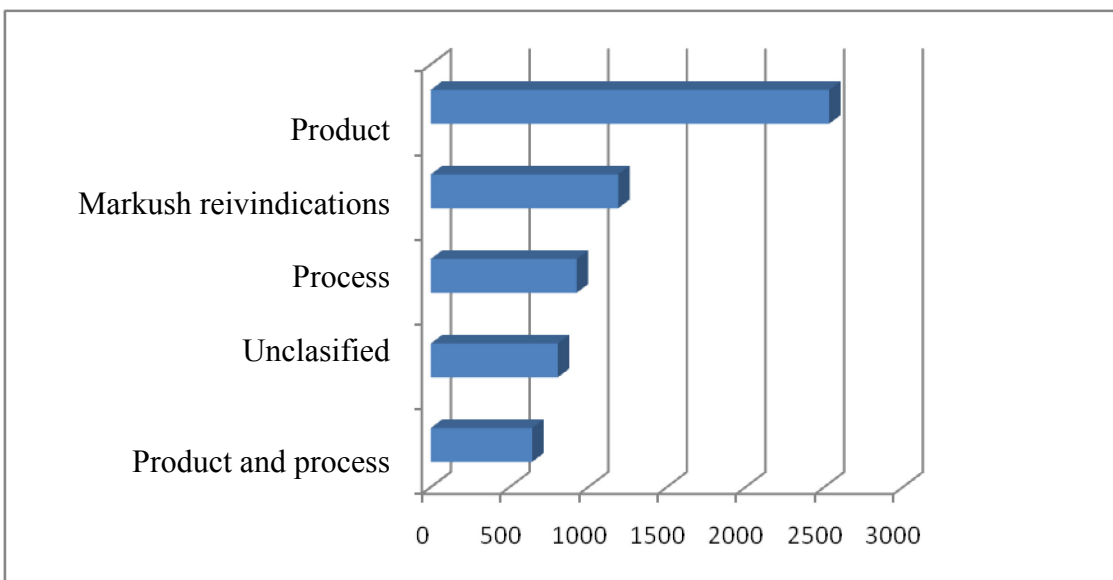
Patent coverage

Another interesting finding is the high number of patents granted with what are known as ‘Markush claims’.

Dr. Eugene A. Markush was the founder and president of Pharma Chemical Corporation of Bayonne, New Jersey. He was a leading manufacturer of dyes in the U.S. Dr. Markush had over 20 patents on synthetic dyes and related fields. In 1924, Dr. Markush obtained a patent on pyrazolone-based dyes (U.S. No. 1,506,316) which protected a generic chemical structure, in addition to the products already synthesized. Since then patenting of such structures were allowed in the U.S.A.

The admission of patents with such claims leads to a rather complex situation when it comes to pharmaceuticals, because a single Markush structures can potentially limit or block the development and commercialization of tens, hundreds, thousands or millions of products depending on how broad the patent specification and claims are. The issue of Markush claims is, therefore, an important aspect that must be analyzed in detail by developing countries, so that the granting of patents with such claims does not become a constraint for research on new molecules needed to meet the health needs of the population or a restriction to competition. Figure 3 describes the aggregated number of patents that have Markush claims in the five countries surveyed.

Fig 3. Type of claims



Regarding the analysis of specific products for the treatment of diseases such as HIV / AIDS and various cancers, it is worth noting that a wide variety of proprietary products are indicated for the treatment of this pathology, particularly the second and third lines of treatment (which are basically those that are patented). It is important to highlight the experience of Brazil, which achieved a considerable reduction in the cost of new drugs to treat HIV / AIDS in the context of a national policy to protect public health. Brazil was able to negotiate lower prices for some drugs with the threat of granting a compulsory license, which was issued in one case (efavirenz).

Some conclusions

The project addressed issues of innovation and public health that are relevant to the development priorities of the countries covered by the study. All of them have plans and programs, and different kinds of incentives, for fostering local innovation (in the case of India, pharmaceuticals is one of the priority sectors). They have also implemented policies to increase access to medicines, particularly by the poor. The problem addressed in this project has only been marginally considered in the literature in a few analyses published a decade ago²³, despite its importance from an academic perspective and for the formulation of national policies.

The problem addressed in this research has raised important political and inter-institutional debates in some countries, as illustrated by the process of approval of the Indian Patent Amendment Act in 2005 and the controversy between the patent office and the drug regulatory agency (ANVISA) in Brazil. The research results will expectedly provide policy makers concrete recommendations to deal with the subject. If implemented, such recommendations would directly benefit, via an increased competition and lower prices, poor patients, particularly those suffering from chronic diseases such as HIV/AIDS.

In view of the implications of evergreening patents, governments may opt for adopting strict criteria to assess patentability, so as to prevent the granting of patents that do not make a substantive technical contribution to the state of the art. Importantly, article 27.1 of the TRIPS Agreement prescribes, that patents "shall be available for any inventions ... provided that they are new, involve an inventive step and are capable of industrial application", but does not contain any specification about the concept of 'invention' nor about the precise way in which the patentability criteria are to be applied. It has, hence, left WTO members room to interpret in good faith the concept of 'invention' within their legal systems, and to adopt more or less strict criteria to apply the patentability standards.

The research results will be relevant for various segments of the pharmaceutical market, including the sensitive area of HIV/AIDS medicines. The conclusions reached in the project are also likely to be of general application outside the pharmaceutical field, as patenting of incremental developments may generate the same kind of distortions found in the pharmaceutical market²⁴.

In implementing the research results there may be considerable room for South-South collaboration, for instance, through activities for establishing regulations or guidelines for the examination of pharmaceutical and other types of patent applications, improving the capacity for such an examination in patent offices and ministries of health and drug regulatory agencies, and through further research on the subject.

Although further analysis of the data obtained would be necessary, the research has confirmed the hypothesis that most of patenting in the pharmaceutical sector is motivated by strategic reasons, namely to restrict generic competition, rather than the need to protect genuine innovations (the traditional motivation for patenting).

²³ See, e.g. World Bank, 2001, p. 147; Hunt, 1999.

²⁴ In other areas, particularly in the mechanical field, innovation that does not meet a high standard of inventive step may be promoted by means of utility models, also known as "petty patents". The requirements for acquiring a utility model are less stringent than for patents. While the requirement of (relative or absolute) "novelty" is always to be met, that of "inventive step" may be much lower or absent altogether. See WIPO at www.wipo.org/sme/en/ip_business/utility_models/.

Governments should apply strict criteria of inventive step and thereby reduce the scope of speculative or strategic patenting. This would not exclude considering other options to promote local innovation and access to drugs since, obviously, factors other than patenting standards may be relevant to innovation and access to medicines. Innovation may be promoted through subsidies, prizes, advanced research contracts and other mechanisms that do not entail later restrictions on the diffusion of the obtained innovations.

It is expected that the outputs of this research will be useful for the design of patent policies regarding pharmaceuticals and compulsory licenses/government use provisions, and for public and private entities (including NGOs) that may be involved in the application of such policies and mechanisms. It will be particularly useful to set standards for the assessment of the patentability of pharmaceutical inventions in the area of HIV/AIDS and anti-cancer drugs.

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