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**Research Report**

## Pharmaceutical innovation, incremental patenting and compulsory licensing

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# **PHARMACEUTICAL INNOVATION, INCREMENTAL PATENTING AND COMPULSORY LICENSING**

Carlos M. Correa



# RESEARCH PAPERS

41

## PHARMACEUTICAL INNOVATION, INCREMENTAL PATENTING AND COMPULSORY LICENSING<sup>1</sup>

Carlos M. Correa<sup>\*</sup>

SOUTH CENTRE

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## **EXECUTIVE SUMMARY**

Despite the decline in the discovery of new chemical entities for pharmaceutical use, there is a significant proliferation of patents on products and processes that cover minor, incremental innovations. A study conducted in five developing countries - Argentina, Brazil, Colombia, India and South Africa - evidenced a significant proliferation of 'evergreening' pharmaceutical patents that can block generic competition and thereby limit access to medicines. It also found that both the nature of pharmaceutical learning and innovation and the interest of public health are best served in a framework where rigorous standards of inventive step are used to grant patents. The analysis suggests that local firms in developing countries are better supported in a framework where patent protection for minor incremental innovations is not allowed. The study also suggests 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 need to have recourse to such measures.



## I 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 Research and Development (R&D) dominates in current debates and jurisprudence of many countries (Gutterman, 1997).

Although 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 role of the patent system in promoting innovation is less substantial than usually claimed (Landes and Posner, 2003; Levin et al., 1987). Patents may even stifle the very innovation they are supposed to foster (Jaffe and Lerner, 2004). There is compelling evidence indicating that ‘collective invention’ based on sharing innovations is more efficient than patenting them (Bessen and Meurer, 2008); some studies suggest that innovation not only thrives in a competitive environment, but that more profit can be generated by inventors in a system based on the broad diffusion and common use and improvement on innovations (Torrance and Tomlinson, 2009).

The large number of patents applied for and granted is not a reliable indicator of innovation. While the number of patent applications and grants has increased dramatically, notably in the United States of America but in other countries as well<sup>2</sup>, this growth is not caused mainly by a surge in R&D spending (Bessen and Meurer, 2008, p. 69). One of the probable causes of such a surge in some jurisdictions is the relaxation of patent requirements by patent offices and courts. The National Academies of the United States, for instance, have taken up the criticism levelled 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 (FTC, 2003). In the case of the USA, it has been found that an inadequate search of previous patents and publications leads patent examiners to overlook novelty and inventive step problems; in addition, courts have shown a proclivity to weaken the obviousness test (Bessen and Meurer, 2008). Even the users and main beneficiaries of the patent system have become growingly critical about the functioning of the

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<sup>2</sup> China's State Intellectual Property Office (SIPO) received a record 1.2 million patent applications during calendar year 2010, a 25% jump on the 2009 figure. See Quality is China's biggest patent challenge – available from <http://www.iam-magazine.com/blog/Detail.aspx?g=e81c5421-bccc-4eb5-9895-f347443cf73e>.

patent system<sup>3</sup>.

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

Patents are not granted only when a significant technical development has been achieved. Inventions marked with considerable originality (Merges and Nelson, 1996, p. 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 of existing technologies. Although 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 per cent of all patented inventions were minor improvements on existing patented devices (Canadian Intellectual Property Office, 1994).

As incremental innovations prevail in most sectors, the patent system has increasingly moved away from its objective of stimulating genuine invention towards a system for the protection of investment in developing incremental innovations, whether truly inventive or not. As a result, 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). In fact, an optimal level of patent protection beyond which negative effects would start to dominate positive effects is likely to exist (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 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.

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<sup>4</sup> of the country where such regime 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

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<sup>3</sup> A survey conducted among large companies (with annual revenues exceeding US\$10 billion) by the Intellectual Property Owners association (IPO) in August 2005 showed that its corporate members perceive the quality of patents granted by the US patent and trademark office to be less than satisfactory. Over half of respondents, 51.3 per cent, rated the quality of patents issued in the US today as less than satisfactory or poor (47.5 per cent less than satisfactory and 3.8 per cent poor). Those rating quality more than satisfactory or outstanding were 8.8 per cent of all respondents (8.8 per cent more than satisfactory and 0 per cent 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 (PR ‘, *NewsWire*, 2005.).

<sup>4</sup> See, on this concept, Lundvall, 1992.

literature as ‘innovative developing countries’ (IDCs) (Morel et al., 2005, p. 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.

A key question is how to frame a patent regime in a country where the innovation path is centered on minor/incremental technical changes. At first sight, such innovations may be regarded as outside the patent system, and a different set of measures (such as utility models) to promote them would seem to be called for. It has been argued, however, 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 companies. In accordance with this view, the possibility of patenting minor innovations may encourage such companies to improve on existing technologies.

This expansive approach on inventive step, however, may have negative consequences. On the one hand, large firms with experienced teams of patent lawyers are much better prepared, financially and technically, than domestic firms to exploit a patent regime with a low patentability threshold; 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.

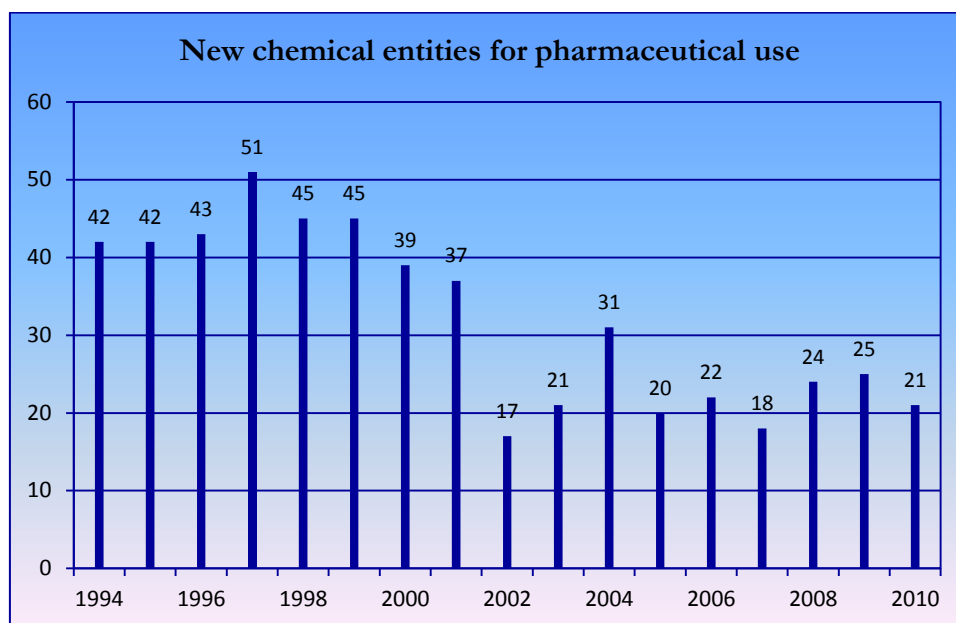
On the other, the cost of acquisition and, particularly, exercise of patent rights is too high for most local innovators, generally small and medium enterprises (SMEs). While SMEs could opt in many cases to seek patent protection, they must bear the costs of filing, registration and maintenance. If there 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. A report on the impact of patents on SMEs in the United Kingdom, for instance, found that “the use of patents as a means to construct and protect proprietary know-how is not the preferred choice of firms”. Despite much emphasis on patents both in the economic literature and in the policy debate, secrecy and lead-time advantages seem to be much more important and this is especially so for smaller firms... Patents could in principle be used as learning inputs by firms seeking to monitor and/or imitate their competitors’ innovative behaviours. However, this function does not appear to be especially important, least of all for SMEs (Hughes and Mina, 2010).

The problems associated to the patenting of minor incremental developments have special implications in the case of pharmaceuticals necessary to protect public health. Patents on pharmaceutical products and processes may be used to block generic competition that lower prices and enhances access to medicines, particularly by the poor. This may be the case

even when the original patent on a medicine has expired and the drug is in the public domain. Patents relating to a known compound (e.g. new formulations, dosages, crystal forms, etc.) are often strategically used to exclude competitors from the market<sup>5</sup>.

While the number of new-developed chemical entities has dramatically fallen during the last fifteen years (see Figure 1), 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 research and production.

**Figure 1**



Source: US FDA

As suggested by Figure 1, the development of new chemical entities for pharmaceutical use presents 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*). This decline seems paradoxical for three main reasons. First, since the 1980s and, particularly as the implementation of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) was completed in developed and developing countries<sup>6</sup>, patent protection allowed companies to increase income generation worldwide through the exercise

<sup>5</sup> In Argentina, Uruguay and other countries, for instance, a patent on a process to produce a tri-hydrate form of docetaxel, an anti-cancer drug, was used to exclude off-patent forms of the drug. A patent on a didanosine tablet for slow release of the active ingredient was used in Argentina to block the commercialization of another, off-patent formulation of the same drug (Levis, 2010).

<sup>6</sup> Transitional periods were provided for developing countries, economies in transition and Least Developed Countries. Developing countries that previously did not recognize pharmaceutical product patent protection could delay its introduction until January 1, 2005 but only a few countries made full use of this term.

of stronger and, in some cases, longer patent rights<sup>7</sup> and data exclusivity<sup>8</sup>. 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, Rai, Sali, 2004).

Patents over minor incremental developments (often termed as ‘evergreening’ patents<sup>9</sup>) 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* and, growingly, in the national constitutions of many countries. The reason for this is that patents 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. An inquiry by the European Commission, for instance, found 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<sup>7</sup>. The European Commission estimated a loss of around three billion Euros due to delays in the entry of generic products caused by misuse of the patent system (European Commission, 2009). The European Commission further found in relation to 219 drugs that:

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<sup>7</sup> The TRIPS Agreement set out a minimum term of 20 years, obliging many countries (including the USA and Canada) to change their legislation.

<sup>8</sup> 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 exclusivity is not required, however, by the TRIPS Agreement which only mandates protection of test data under the discipline of unfair competition.

<sup>9</sup> ‘Evergreening’ is generally based on the patenting of minor changes to or derivatives 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.

“...nearly 40,000 patents had been granted or patent applications (as defined above) were still pending...Of the nearly 40,000 cases, some 87 percent were classified by the companies as involving secondary patents, giving a primary:secondary ratio of approximately 1:7. Of the applications still pending, 93 percent were classified as secondary (a primary:secondary ratio of approximately 1:13), whilst 84 percent of the patents granted were classified as secondary (a primary:secondary ratio of approximately 1:5)” (European Commission, 2009)<sup>10</sup>.

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/improvements of existing products can be used to block legitimate generic competition, which normally lower prices and make medicines more affordable. In particular, the grant of such patents may, in some cases, force governments that need to ensure access to medicines for its population to grant compulsory licenses, whenever patent owners charge high prices and/or refuse to grant voluntary licenses on reasonable commercial terms. Although compulsory licenses/government use are legitimate under international law, their application has faced considerable resistance from developed countries’ governments and retaliations from the pharmaceutical industry. A basic question that arises out in these cases is whether the grant of the patent was justified in the first place and whether governments can avoid the various costs (including of political nature) associated to the grant of compulsory licenses if they applied more rigorous standards in examining the respective patent applications.

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<sup>10</sup> 57% of the ‘secondary’ patent applications related to pharmaceutical formulations.



## II PROLIFERATION OF PHARMACEUTICAL PATENTS

The study made in Argentina, Brazil, Colombia, India and South Africa revealed important differences in the size of their economies, their innovation systems and policies and, in particular, in the public health systems and their coverage. However, there is a common need in all these countries to ensure access to medicines to their population, particularly to the segment 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.

In Argentina, 951 pharmaceutical patents were granted in 2000-2007; in Brazil, 278 patents were granted in 2003-2008; in Colombia 439, in 2004-2008; in India, 2347, in 2005-2008; and in South Africa, 2442 patents were registered in 2008. Although the periods covered in each country are not the same - and the comparability of the data is thereby limited- some interesting conclusions may be drawn from the analysis of these data and the national patent regimes under which patents are issued. It should be noted that while Argentina, Brazil, Colombia and India grant patents based on a prior substantive examination of the applications, in South Africa patents are simply registered without verifying *a priori* if they meet or not the patentability requirements. This explains why South Africa appears with such a comparatively large number of patents issued in one single year.

Based on the average number of patents granted per year, and assuming that pharmaceutical companies are likely to apply for the same patents in all the covered countries, Brazil seems to apply the strictest criteria to assess patentability, followed by Colombia and Argentina. The Brazilian situation may be explained, to some extent, by the mandatory intervention of the health regulatory agency (Health Surveillance Agency-ANVISA) in the assessment of pharmaceutical patent applications<sup>11</sup>, in accordance with article 229(c) of Law 9.279/96. India has the largest average number of patents granted per year, but this is possibly a result of the fact that India only started to grant patents on pharmaceutical products in 2005 since, unlike the other countries considered here, it used the transitional period allowed by article 70.8 of the TRIPS Agreement to the full extent, until January 1st 2005<sup>12</sup>. An additional explanation for the case of India is that, as discussed below, the number of patents applied for and obtained by local pharmaceutical companies is quite significant.

Despite the arguments about the positive impact that the introduction or strengthening of patents would have on local innovation in developing countries, the number of patents granted to local companies/individuals in the pharmaceutical field in the studied countries is minimal, with the exception of India. In all the studied countries, pharmaceutical patents overwhelmingly belong to foreign companies, namely from the USA and a few European

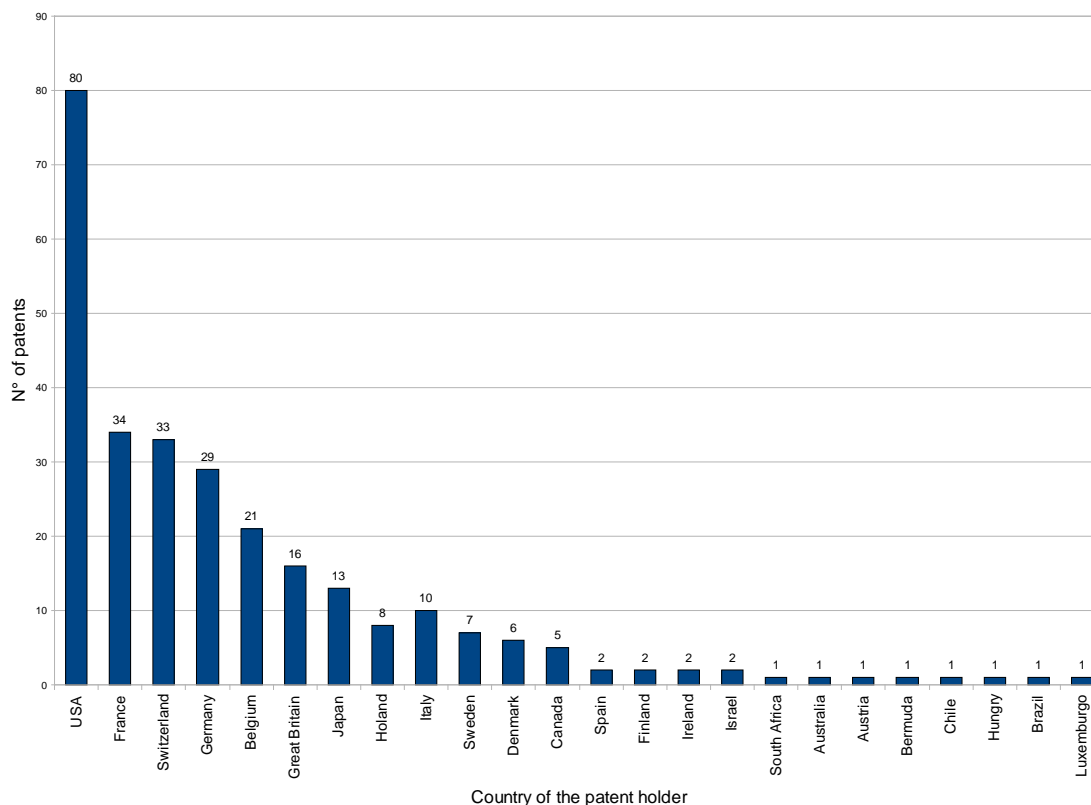
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<sup>11</sup> ANVISA has applied the patentability criteria in a stricter manner than the Brazilian patent office (Instituto Nacional de Propriedade Industrial- INPI), particularly with regard to second indications and polymorphs. The study, however, found that 6% of the pharmaceutical patents were granted by INPI without being analyzed by ANVISA. This raises concerns on whether all pharmaceuticals applications are really going through analysis by both bodies.

<sup>12</sup> The mechanism known as 'mail box' established by article 70.8 of the TRIPS Agreement, allowed patent applications to be deposited after January 1, 1995, to be assessed only after the end of the transitional period.

countries. Figure 2 illustrates the distribution by country of origin of patents granted in Brazil; a similar situation is observable in the other countries (except India).

**Figure 2. Brazil: Distribution of patents granted in the pharmaceutical sector by country of origin of patent holder, 2003-2008**



The results obtained regarding domestic patenting are particularly surprising for Brazil, a country with a large and solid R&D infrastructure. Only one patent out of 287 was identified as owned by a Brazilian manufacturer. In the case of Argentina, only 15 out of 951 patents were obtained by nationals (eight companies, one research institute and 5 individuals) in 2000-2007. In Colombia only two patents in the pharmaceutical field were granted to domestic applicants in the studied period (related to excipients and not to a particular active ingredient). In South Africa, 10 patents were registered by local companies, research institutions or individuals in 2008.

As noted, the situation is radically different in India, which has become a major producer and exporter of active pharmaceutical ingredients and finished medicines. As indicated in table 1 a large portion of the granted patents were filed by local companies<sup>13</sup>. In fact, India itself is apparently the largest source of patents granted in the country. Although R&D for the development of new chemical entities has increased substantially, the large number of grants can only be explained by patents over incremental innovations. The Indian Patent Act was amended in 2005 to introduce, *inter alia*, a special section (section 3(d)) aimed at avoiding 'evergreening' patents. This section has not operated, as further elaborated below, as an absolute ban for the patenting of that type of innovations.

<sup>13</sup> However, some of these companies have recently been taken over by foreign pharmaceutical companies.

A recent study by the United Nations Development Programme (UNDP) noted in this regard that:

“a number of patent applications relating to a specific polymorphic form of a known compound have been granted, despite the lack of any data provided in the application with respect to enhanced efficacy... More troublingly, however, are those instances where the patent application not only appeared to clearly fall under one or more of the exclusions contained in Indian patent law, but were also deemed to lack novelty or inventive step in jurisdictions that have much more liberal patentability criteria than India’ (Chaudhuri et al., 2010, p. 131).”

The UNDP study found cases of patent applications that were unsuccessful under the ‘more lenient patentability criteria’ that prevail in the US, which were granted in India, despite the clear legislative intent of preventing evergreening (Chaudhuri et al., 2010, p. 133).

**Table 1. India: Country of Origin of Patent Owners 2005-2008**

| Country of Patent Holder | Number of Patents |
|--------------------------|-------------------|
| India                    | 588               |
| USA                      | 455               |
| Germany                  | 238               |
| Switzerland              | 184               |
| Japan                    | 132               |
| United Kingdom           | 125               |
| France                   | 100               |
| Sweden                   | 74                |
| Netherlands              | 46                |
| Denmark                  | 42                |
| Belgium                  | 33                |
| Italy                    | 30                |
| Spain                    | 21                |
| Korea, Republic of       | 20                |
| Israel                   | 16                |
| China                    | 14                |
| Argentina                | 2                 |
| Brazil                   | 2                 |
| Cuba                     | 2                 |
| Not Available            | 164               |

Data on granted patents in the five countries covered in the study also show that the therapeutic use of the patented inventions bear little relation to the profiles of disease prevalent in developing countries. The patented products have overwhelmingly been developed to satisfy the market demand in developed countries. Table 2 shows the classification of the subject matter by therapeutic use for patents issued in the five countries.

This table is only illustrative, since in many cases it was not possible to identify the intended use of the claimed invention.

**Table 2. Therapeutic use of patented products/processes in five countries<sup>14</sup>**

| Therapeutic use   | No. of patents |
|---|----------------|
| A - Alimentary tract and metabolism                     | 589            |
| B - Blood and blood forming organs                      | 146            |
| 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 repellents | 56             |
| R - Respiratory system                                  | 222            |
| S - Sensory organs                                      | 58             |
| V - Various   | 43             |
| L01 – Anti-neoplastic                                   | 1              |

Table 2 suggests that there is little patenting of products or processes for use in relation to diseases that disproportionately affect developing countries. Products for the nervous system, antineoplastic and immunomodulating agents, anti-infectives for systemic use<sup>15</sup>, and products for the alimentary tract and metabolism, concentrate the largest portion of granted patents. The insufficient research and development on the ‘diseases of the poor’ is a matter of growing concern and one of the main factors that led to the adoption by the World Health Organization of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA)<sup>16</sup>, in the inception of which several of the countries covered by the study played a significant role (Velasquez, 2011).

The study of patenting trends in the five countries confirms a significant proliferation of patents on developments of incremental nature and, in many cases, of questionable inventive step. This is well illustrated by the case of India where despite the patentability exclusions provided in section 3 of the Patent Act, a significant number of patents have been granted for possibly non-allowable claims. A total of 688 patents of this kind were identified,

<sup>14</sup> The classification in this table is based on the World Health Organization (WHO) Anatomical Therapeutic Chemical Classification System, available at <http://www.who.int/classifications/atcddd/en/>.

<sup>15</sup> This category includes Antibacterials for systemic use (antimycotics for systemic use, antimycobacterials, Antivirals for systemic use, Immune sera and immunoglobulins, and vaccines)

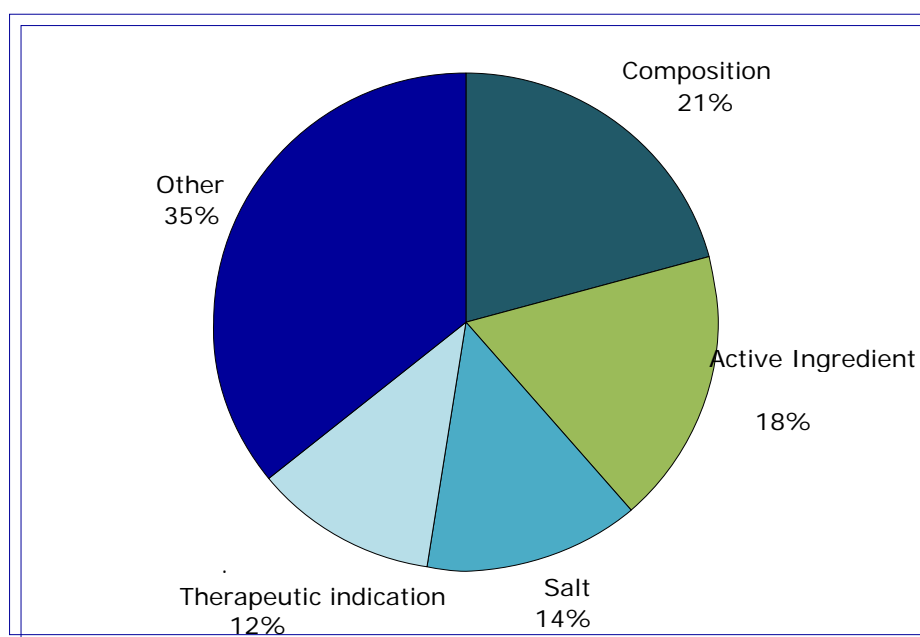
<sup>16</sup> See WHO Resolution WHA62.21.

including claims on compositions (414) and formulations (137) which only in very exceptional cases would satisfy a rigorous examination of inventive step (Correa, 2006).

Claims covering compositions and formulations are often claims for a new use of a known substance that are not patentable under section 3 (d) of the Indian Patent Act. In addition, there is a significant number of patents covering salts, polymorphs and combinations that are also not patentable under section 3 (d) as they are considered to be the same substance unless they differ significantly in properties with regard to efficacy. Moreover, a number of 'method of treatment' claims, that are excluded from patentability under section 3 (i), were also granted. This information suggests shortcomings in the way in which section 3 of the Patent Act is being implemented by the patent offices in India.

A similar situation can be found in the other covered countries (where no provision similar to section 3(d) applies). In Argentina, a large number of patents have been granted on salts, compositions, isomers, polymorphs, esters and ethers (Figure 3), including claims on therapeutic indications and doses that are not patentable under Argentine law.

**Figure 3. Argentina: subject matter of granted patents 2000-2007**



**Source:** Correa et al. (2011), based on information of the Instituto Nacional de Propiedad Industrial.

In Brazil, the study of the patents relating to anti-retrovirals (ARVs) showed that a number of them had been granted on 'compounds' and formulations (Table 3) despite the intervention of ANVISA.

**Table 3. Brazil: Patents Granted on Anti-retrovirals, 2003-2008**

| PATENT NUMBER           | ARV   | TYPE  | PATENT HOLDER           |
|-------------------------|---|---|-------------------------|
| PI9506977-1             | Key-intermediates for synthesis of protease inhibitor | Chemical  | Merck                   |
| PI9808060-1             | Lamivudine  | Formulation   | Glaxo Group Limited     |
| PI9815861-9*(WO9961002) | Didanosine  | Formulation (enteric coated pharmaceutical composition and method of manufacturing) | Bristol Myers Squibb Co |
| PI9701877-5             | Atazanavir  | Compound  | Novartis AG             |
| PI9607625-9             | Darunavir   | Compound  | G.D. Searle & Co.       |

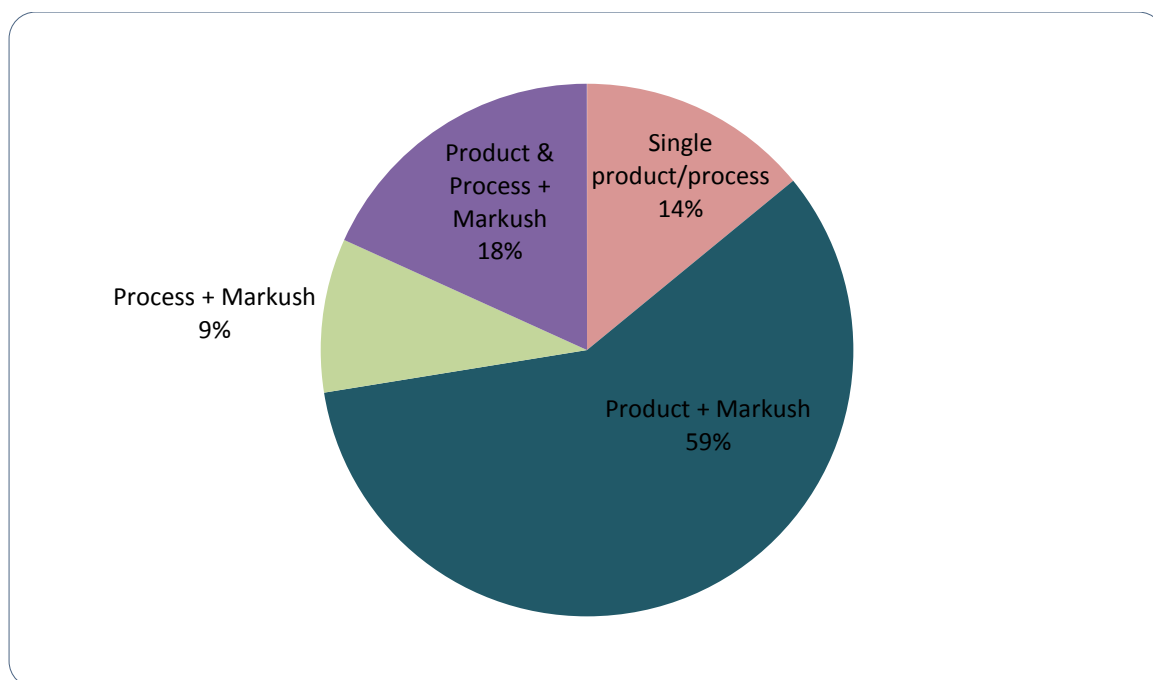
The didanosine case is emblematic, as the active ingredient is in the public domain in Brazil; hence, the government or any other party is free to import or locally produce in Brazil generic versions of, for instance, powder for oral solution. Although the granted patent relates to an enteric coated formulation (Médécins Sans Frontières, 2010), if overbroadly enforced, it may block government's procurement of generic versions of didanosine available in the international market (from companies such as Aurobindo, Cipla and Ranbaxy) or its local production.

In the case of South Africa where, as noted, there is no prior substantive examination of patent applications, it was found that despite the provisions of the Patents Act which set a high standard for patentability, the courts are applying a fairly low standard for patentability. For instance, in a case (Pfizer & Ano v Cipla Medpro & Ors 2005 BIP 1) where revocation proceedings were initiated on the basis that the patent was unclear and obvious the court refused to revoke it, ruling that a besylate salt was unexpected, constituted an advance on the prior art, and represented an inventive step.

Finally, the study found a wide use of the so-called 'Markush claims'<sup>17</sup>, that is, claims that include a general formulae with multiple options that allow for the protection, under a single patent, of up to several millions of molecules. The admission of patents with such claims leads to a rather complex situation when it comes to pharmaceuticals, because a single patent may potentially limit or block research and development on and the commercialization of an extremely large number of products. Figure 4 illustrates the proportion of patents issued in South Africa with Markush claims.

<sup>17</sup> 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 USA.

**Figure 4. South Africa: distribution of patents by type of claim, including Markush claims**



As indicated in Figure 4, Markush claims account for the largest portion of all patents issued in South Africa. In the case of Argentina, around 50 per cent of the patents granted in the 2000-2007 period were also based on Markush-claims. In India, at least 630 out of the 1432 product patents granted in the examined period contained Markush claims.

Markush claims raise issues concerning sufficiency of disclosure, since normally the patent applicant has empirically obtained only a few of the multiple claimed compounds. In addition, it is virtually impossible to make prior art searches for thousands or millions of compounds. They also pose a transparency problem, since it is very difficult for third parties to identify patent applications that would merit a pre or post-grant opposition. Moreover, in some jurisdictions (including India) after a Markush claim has been granted, it is possible to apply for a patent (usually called ‘selection patent’) on a selection of the molecules originally covered in such a way that protection may be extended for an additional patent term (normally 20 years from the filing date).

It is often argued that patents encourage research and innovation in all fields of technology. This would be achieved through different mechanisms. One of them is through the public disclosure in the patent document of information relating to inventions. However, in conducting the study and developing databases for the five covered countries significant shortcomings were found.

It was amazing, in effect, 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. Moreover, the titles of granted patents are often extremely general, such as 'pharmaceutical composition'<sup>18</sup> - and the generic name<sup>19</sup> of the active ingredient to which the patent refers is not mentioned in the title, abstract or published claims. In Argentina, for instance, the generic name of the medicine was not mentioned in the information published by the patent office for 80 per cent of the granted patents. This is a particularly serious problem, particularly for those that would be able and willing to file an opposition to the grant of the patent.

In Brazil, the analysis of the specifications and scope of claims is problematic because the documents available on the INPI's website do not contain the claims approved after the examination by INPI and ANVISA. In order to determine the extent to which a particular medicine is protected, it is necessary to request hard copies of the full document to INPI, at the cost of the requesting party and subject to INPI's delivery delays. The same applies in Argentina, where only the title and first claim of the patents are published. In India, the Patent Office has undergone a positive and significant change in the transparency of the information regarding pending and granted patents. The Indian Patent Office has now started publishing granted patents with complete specifications. It is also possible to search patent applications and granted patents through different search variables. However, there remain many shortcomings in the information available as there are several instances in which the ability to obtain full and accurate information is hindered by gaps in information in the Patent Office database.

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 (Amin, 2010)<sup>20</sup>. More and more national patent offices are providing searchable databases, albeit with some providing more information than others. Despite this, it is very difficult to identify patents related to specific medicines in order to establish what 'freedom to operate' exists in a certain field or to make procurement decisions. This is a complex and in many cases unfeasible task, especially for non-specialists, such as procurement agencies in developing countries.

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<sup>18</sup> See, e.g., South African patent 2007/01932 (expiry date 05.03.27) held by Bayer Healthcare AG.

<sup>19</sup> 'Generic' name is the International Non-Proprietary Name (INN) attributed by WHO to a particular drug.

<sup>20</sup> The Medicines Patent Pool has recently made available a *Patent Status Database for Selected HIV Medicines*. See <http://www.medicinespatentpool.org/patent/search>.



### III PATENTABILITY STANDARDS AND PHARMACEUTICAL INNOVATION<sup>21</sup>

A basic argument for the adoption or strengthening of patent protection in developing countries has been that patents may provide the necessary incentives to foster local innovation. As indicated above, this is not clearly the case in four of the five studied countries, where domestic patenting in pharmaceuticals is minimal. In India, as noted, domestic patenting is more significant, but focused on new processes or derivatives/improvements on existing products. An earlier study observed that:

[T]his steady increase in the patenting activity by the non-residents is indicative of the fact that the Patents Act, as it exists today, accommodates incremental innovations, since the patents granted are not only for new molecules but also for new processes as well as new uses, combinations and dosage forms. During the last three years alone, the Indian Patent Office has granted 3506 patents relating to pharmaceutical innovations. Therefore, on the basis of experience of the last four years it cannot be argued that section 3(d) was against incremental innovations.

It is also worth noting that a limited study by the Indian Pharmaceutical Alliance has come out with a list of 86 patents granted for pharmaceutical products by India after 2005 which inventions are not breakthrough drugs but only minor variations of existing pharmaceutical products (James, 2009).

A review of the economic literature shows that arguments for and against a low level of inventive step are both used to justify policy prescriptions. It has been argued that a high inventive step precludes disclosure of essential information on the state of R&D in industries because in the absence of a patent, small inventions are not disclosed and each inventor has to necessarily personally arrive at all the required complementary expertise to be able to get a patent. Hence low level of disclosures lead to duplicate R&D costs and can be avoided through the grant of patents based on a low inventive step (Meniere, 2005). The counter to this argument is that a lower standard of inventive step is dis-functional for both cumulative (sequential) innovations (such as biotechnology, where disclosure of previous 'state-of-the-art' is important) and complementary inventions (where each invention is a step towards a new technological frontier). In both cumulative and complementary innovations, standards of inventive step not only determine how many innovative pieces of the puzzle need to fall in place for a new technology, but also how small these individual rights can be, and how it can be shared between the different inventors.

In the case of the pharmaceutical sector, in particular, low patentability standards can have detrimental impacts. A low inventive step is prone to abuses, leading to extension of patent monopolies through products embodying very minor change. There is no basis to assume that such a lower technical requirement would be in favour of developing local production and innovation capacity in developing countries. A lax inventive step allows the

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<sup>21</sup> This section is substantially based on the contribution by Padmashree Sampath, 'Promoting Local Pharmaceutical Capacity in Developing Countries: A Discussion on Inventive Step and Compulsory Licensing' (unpublished).

grant of patents that extend existing monopolies and guarantee markets for international firms in developing countries, thus making it harder for local firms to overcome constraints. In other words, this would mean that all those variations of the patented product developed by local firms that are very close to the original product will be considered as equivalent to the original and thus an infringement of the patent. More importantly, given the sectoral dynamics of learning, it is unclear how granting patents that fragment and limit the access to underlying processes and products that in the pharmaceutical sector will add value.

Moreover, from a public health perspective, the objective of an innovation-oriented patent regime in a developing country context should be to promote competition amongst local firms (and also between local and foreign firms) in order to ensure the availability and affordability of drugs within a balanced and supportive framework. Given the particular features of the pharmaceutical sector and the evidence on the impact of a lax inventive step analysed here, the interest of building local capacity is better achieved in a regime based on strict patentability criteria. Setting a high inventive step will help prevent the strategic use of patents by multinational companies to block the generic industry. Such grant of patents leads to costly litigation, since patent owners often aggressively use them against local companies alleging inexistent infringements<sup>22</sup>, and generic firms seeking to revoke them generally need to resort to courts to obtain a final decision.

As illustrated by the evidence on the studied countries, the application of a low inventive step standard does not promote local innovation, while it favours the deployment of aggressive patenting policies by foreign companies. Even if such low standard would allow local companies to obtain some patents, the costs in terms of limitations to generic competition and, consequently, higher prices for medicines, clearly exceed any benefits that might be generated. From the point of view of an innovation policy in a developing country, it is also questionable whether the patent system should create monopolies for technical developments that do not represent a significant contribution to the state of the art, whether claimed by local or foreign companies, as such monopolies will retard dissemination of innovations that could enhance competition and access to medicines.

In India, the only developing country where domestic patenting in pharmaceuticals is significant, the innovative capacity to reverse-engineer and improve on existing processes and products pre-existed the introduction of product patent protection. It can hardly be argued that the availability of product patents on the basis of a relatively low standard of inventive step as of January 1, 2005 was a decisive factor in promoting the development of incremental innovations. It has been noted in this regard that:

...the primary incentive to do R&D has not been the product patent regime in India after TRIPS but the product patent regime in developed countries to which TRIPS has made no difference. While R&D activities have diversified, they are yet to prove their competence in innovating new products. What Indian companies have really demonstrated is the ability to develop generics for the regulated (and other) markets – an ability which they acquired and improved during the pre-TRIPS period (Chaudhuri, 2007).

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<sup>22</sup> In the case of Argentina, for instance, in several cases relating to docetaxel, didanosine and gemcitabine, patent owners were able to get provisional measures that immediately excluded competitors from the market, while the competent courts did not find later infringement of the respective patents.

#### IV INVENTIVE STEP AND COMPULSORY LICENSES<sup>23</sup>

A number of developing countries have granted in the last ten years compulsory licenses in the area of pharmaceuticals; there are also a number of cases in which such licenses have been requested but not granted, due to the government's refusal<sup>24</sup> or the adoption of alternative actions or measures<sup>25</sup>. Table 4 contains information on compulsory licenses or decisions of government use of a granted patent in ten developing countries in the last decade.

**Table 4. Compulsory Licenses/ Government Use Options Exercised by Developing Countries**

| Date/<br>Country              | Reasons  | Type of License  | Impact on Drug Prices   |
|-------------------------------|----------|--|---|
| May 2002-<br>Zimbabwe         | HIV/AIDS | CL to a local generic company Varichem Pharmaceutical Co. to produce seven generic versions of first line ARVs | Prices of the locally produced drugs are determined by the Minister and based on price control mechanisms.  |
| November<br>2003-<br>Malaysia | HIV/AIDS | CL to import generic version of ARVs from Cipla(India) for 2 years beginning on 1 November 2003                | The ceiling price for the said drugs to be supplied to the Ministry of Health, Malaysia shall not exceed the following:<br>(a) Didanosine 100 mg tablet - RM74.58 (per box of 60 tablets)<br>(b) Didanosine 25 mg tablet - RM22.80 (per box of 60 tablets)<br>(c) Zidovudine 100 mg capsules - RM5.89 (one set of 10 capsules)<br>(d) Lamivudine 150mg + Zidovudine 300mg tablet - RM153.50 (per box of 60 tablets) |

<sup>23</sup> This section is substantially based on the contribution by Tahir Amin (2011), 'Strengthening Patent Standards: An Alternative Route to Compulsory Licensing for Low and Middle Income Countries' (unpublished).

<sup>24</sup> For instance, Cipla requested the South African government in 2001 to issue compulsory licenses on several drugs, including nevirapine, lamivudine, zidovudine, stavudine, didanosine, efavirenz, indinavir, abacavir, and combinations of these drugs. The request was denied. In 2002, a compulsory license on imatinib mesylate, also known as 'Gleevec' was requested in South Korea but denied by the Korean Intellectual Property Office.

<sup>25</sup> For instance, the Colombian government rejected a request for compulsory licensing the HIV drug Lopinavir/Ritonavir in 2009. However, as a result of the request, the government set out maximum prices for the drug, driving the price down by 54-68%. According to government statements, the cost savings from these price reductions would be over \$10 million per year, but it is unclear how much the savings would be if a compulsory license would have been granted.

|                            |   |   |   |
|----------------------------|---|---|---|
| April 2004-<br>Mozambique  | National emergency and extreme urgency (HIV/AIDS)   | CL to Pharco Mozambique Ltd. for local manufacture of the mentioned triple compound under the names of PHARCOVIR 30 and PHARCOVIR 40  |   |
| Sept 2004-<br>Zambia       | National emergency and extreme urgency (HIV/AIDS)   | CL to Pharco Ltd., a local producer, production of triple fixed-dose combination.   |   |
| October 2004-<br>Indonesia | Presidential Decree No 83 of 2004 Regarding Exploitation of Patent by the Government on Antiretroviral Drugs for Government use | CL of Minister of Health to appoint a “pharmaceutical factory” as the patent exploiter on behalf of the Government  | Price differential between patented and generic drugs are substantial   |
| June 2005-<br>Eritrea      | National emergency (HIV/AIDS)   | CL for import of generic ARVs   |   |
| Oct 2005-<br>Ghana         | HIV/AIDS  | CL to import Indian generic HIV-AIDS medicine   | ARV costs dropped almost 50% from \$495/year to \$235/year per patient  |
| Nov 2006-<br>Thailand      | Government Use effective up until 31 December 2011  | CL to import Indian generic and locally produce Efavirenz. The amount to not be more than 200,000 patients per year, for those covered under the National Health Security System Act B.E.2545, Social Security Act B.E. 2533, and the Civil Servants and government employees’ medical benefits scheme. | Merck retained the marketing licence rights in Thailand and charges 1,500 baht/month (US \$41).<br><br>Thailand imported a generic version of the drug from India, at an estimated cost of 800 baht/month per person. |
| January 2007-<br>Thailand  | Government use effective up until the patent  | CL for the heart disease drug Plavix (Clopidogrel bisulphate). Allowing the provision of generic drugs  | The cost of Plavix was expected to drop from 120 baht per pill to 6-12 baht per pill.   |

|                        |   |   |  |
|------------------------|---|---|--|
|                        | expired or no essential need.   | of Clopidogrel is unlimited for patients covered under the National Health Security Act B.E.2545, Social Security Act B.E.2533 and Civil Servants and Government Employees Medical Benefit Scheme but is under doctors' judgment.   |  |
| January 2007- Thailand | Government use of the patent rights are effective until 31st January 2012 | CL for the AIDS drug Kaletra (LPV+RTV). The use of the patent rights will be limited to the provision of Efavirenz to not more than 50,000 patients per year, for those covered under the National Health Security System Act B.E. 2545, Social Security Act B.E. 2533, and the Civil Servants and government employee's medical benefits scheme. | In 2007, 6000 Baht/month or 72,000 Baht/ yr per patient charged by Abbott Lab. Expect generic version to be 20% less.  |
| May 2007- Brazil       | Government use after negotiations with patent holder broke down.          | CL to import generic efavirenz from India rather than buy Stocrin – the brand name for patented efavirenz – from its US-based manufacturer Merck & Co.  | Brazil issued compulsory license for efavirenz to be imported at US\$ 0.46 per pill.   |
| Nov 2009- Ecuador      | Public interest   | CL was issued by the national Ecuadorian Institute of Intellectual Property (IEPI), and the term of application of the license is until 14 November 2014 for ritonavir.<br><br>It was granted to Eskegroup SA on 14 April, a Latin American distributor headquartered in Guayaquil for CIPLA, a leading Indian generic drug producer.             | The CL reduced the cost of a major HIV drug by 27%, and prices were expected to drop much further.<br><br>Kaletra (costing \$1,000 annually per person) was available at \$800 under the CL. Prices were expected to continue to fall as the government licensed more competitors. |

Source: Sampath, P. (2011, unpublished) 'Promoting Local Pharmaceutical Capacity in Developing Countries: A Discussion on Inventive Step and Compulsory Licensing'.

Table 4 suggests, first, that although the majority of compulsory licenses /government use refer to anti-retrovirals, products for other diseases have also been covered. Second, that such mechanisms were used either to import or to locally produce the protected drugs, depending on the particular strategies adopted by the governments; and third, that in the cases for which information is available, substantial reduction in prices were obtained.

The experiences of many countries show that the possible grant of a compulsory license triggers a strong reaction and lobbying from the pharmaceutical industry, as well as pressures from the USA and European governments. Thus, the French embassy is reported to have written to the Secretary of State of the Dominican Republic to voice opposition to compulsory license requested in respect of clopidogrel, popularly known as 'Plavix' as branded by Bristol Myers Squibb and Sanofi Aventis, a French company. In Brazil -which threatened to grant compulsory licenses for several products, but only granted one in 2007- the head of the AIDS programme is on record stating that Brazilian government officials were subjected to lobbying from the US, including Congress and the White House, with threats of retaliation (Deere, 2009, p. 230). In Thailand, civil society requested a license on the tablet form of the HIV drug didanosine in 1999 (t'Hoen, 2009). The response from the U.S government was swift, and cautioned against the use of compulsory licenses. In 2006, the Thai Minister of Public Health determined that a compulsory license was required for efavirenz, an HIV drug offered by Merck at high prices, with frequent stockouts (Ford, Wilson, Costa Chaves,, Lotrowskab and Kijtiwatchakul, 2007; Tantivess, Kessomboon, and Laongbua, 2008). Merck responded with a two-pronged strategy, dropping its own prices, and lobbying the US government to pressure the Thai government. Despite the intense pressure, the Thai government issued the license and began importing generic efavirenz. Later, the Thai government issued compulsory licenses on clopidogrel ('Plavix') for the treatment of heart disease, and for the HIV drug combination lopinavir/ritonavir (Ministry of Public Health and National Health Security Office, February 2007). The political costs for this license were significant: Abbott Laboratories engaged in a lobbying campaign to block the license, including withdrawing all of their drug products from the Thai market. Abbott also influenced the US Trade Representative (USTR) to pressure the Thai government (Love, 2006).

In many of these cases, the need to grant a compulsory license would have not existed, if the patent offices had applied a more rigorous standard of patentability. Thus, lopinavir in combination with ritonavir ('Kaletra') for which a compulsory license was requested in Colombia, is a combination which does not show a new and non-obvious synergistic effect and would not be considered patentable if rigorous standards were used to assess the inventive step. The same would apply to the combination of lamivudine and zidovudine ('Combivir'); a patent on this combination was subject to compulsory license in Malaysia. The patent relating to clopidogrel, subject to a compulsory license in Thailand, relates to a polymorph which, under rigorous patentability standards, would probably not be deemed patentable since polymorphs are not invented but constitute an inherent property of chemical compounds; further, it is obvious for a pharmaceutical manufacturer to find the most suitable polymorph for any particular drug (Correa, 2006).

The extent to which patents subject to compulsory licenses could have been refused through a proper examination of their applications would require further and detailed research. The general conclusion that can be made here is, however, that the grant of such licenses is in some cases necessary because the country has not made full use of what is perhaps the most important flexibility under the TRIPS Agreement in the area of patent law: the possibility of rigorously defining the criteria under which the standards of patentability are

applied. 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 World Trade Organization (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.

In view of the implications of the proliferation of patents with low or inexistent inventive step, governments should adopt rigorous 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 (World Bank, 2001) and the use of which may have a negative impact on their development, particularly in the area of public health. In the pharmaceutical sector, in particular, most of patenting is motivated by strategic reasons, namely to restrict generic competition, rather than to protect genuine innovations (the traditional motivation for acquiring patents) (Le Bas, 2007, p. 41).

## V SOME CONCLUSIONS AND RECOMMENDATIONS

The studies made in Argentina, Brazil, Colombia, India and South Africa have confirmed a diverse but significant proliferation of patents in the pharmaceutical sector that can only be explained by the grant of patents on derivatives/improvements on existing drugs. Many –if not most of them- would not be deemed patentable if more rigorous standards of patentability were applied, in particular in relation to compositions, formulations and polymorphs.

Such studies also revealed little patenting activities in relation to diseases that prevail in developing countries, and an overwhelming concentration of patents in the hands of foreign pharmaceutical companies (with the exception of India). The introduction of product patent protection has made very little in terms of promoting local innovation in pharmaceuticals in those countries.

Although the application of low standards of patentability may allow local companies to obtain patents, the potential benefits for the local industry of such a policy seem to be offset by the costs associated with the proliferation of patents over minor technical changes that may be used to create undue constraints on legitimate competition. Given the asymmetries in innovation capacities between local and foreign industries, low standards of patentability will ultimately benefit the latter. Such standards are unlikely to promote local innovation in pharmaceuticals. Most importantly, the exclusion of legitimate generic competition is likely to negatively affect public health through reduced access to medicines.

Given the flexibilities allowed by the TRIPS Agreement, there is considerable room to define the applicable standards of patentability. In particular, stipulating rigorous criteria to assess inventive step, is an important ex-ante measure that will help prevent abuses by patent holders. The issue of ‘Markush’ claims is also an important aspect that must be analysed in detail, so that the granting of patents with such claims does not become a constraint for research on new compounds or an undue restriction to competition, particularly if ‘selection patents’ are conferred on a narrower group of the compounds covered by the original patent.

Compulsory licenses/government use are important tools that governments can and should use when required to ensure access to affordable medicines. There is a growing number of compulsory licenses granted by developing countries, but generally in the context of political pressures that discourage the further use of that tool. A well-defined policy regarding patentability criteria may avoid, in some –but clearly not in all- cases, the need to resort to such licenses.

Governments should, hence, apply rigorous 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.

In summary, the following policy recommendations can be made for the design of patent policies in developing countries in the area of pharmaceuticals:











- Rigorous criteria to assess the novelty and inventive step of patent applications















relating to pharmaceuticals should be applied. Patent offices should develop, in consultation with health authorities, guidelines to examine such applications so as to ensure the patents are only granted where genuine contributions to the state of the art are made.















- Patent claims relating to formulations or compositions, salts, ethers, esters and combinations should be allowed in narrowly defined, exceptional cases. Polymorphs and isomers (when the racemic mixture was already disclosed) should not be patentable.
- Governments should also carefully consider problems relating to sufficiency of disclosure, particularly in the case of the so-called ‘Markush’ claims, so as to ensure that the granting of patents with such claims does not become a constraint for research on new compounds or an undue restriction to competition. ‘Selection patents’ on a narrower group of the compounds covered by the original patent should not be allowed.
- Similarly, claims on second indications of pharmaceutical products, which are equivalent to methods of treatment, should be deemed non-patentable due to lack of novelty and industrial applicability.
- Patent laws should include effective pre-grant and post-grant opposition mechanisms. Governments should encourage civil society’s utilization of such mechanisms through the implementation of simple procedures, timely dissemination of comprehensive information and, where necessary, capacity building.
- In order to improve the transparency of the patent system, the international non-proprietary name (INN) of drugs, when known at the time of filing of a patent application, should be mandatorily disclosed in its title and abstract.
- Compulsory licenses/government use are important tools that governments can and should use when required to ensure access to affordable medicines. The possible invalidation of patents granted should be considered (and legal action taken, where appropriate) before initiating or in parallel to the procedures for obtaining compulsory licenses/government use.
- As patents are unlikely to promote local innovation in pharmaceuticals, governments should consider options other than the patent system to encourage it, particularly with regard to diseases that disproportionately affect the population of developing countries.











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