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CESPRI

Centro di Ricerca sui Processi di Innovazione e Internazionalizzazione

Università Commerciale “Luigi Bocconi”

Via R. Sarfatti, 25 – 20136 Milano

Tel. 02 58363395/7 – fax 02 58363399

<http://www.cespri.unibocconi.it>

Francesco Laforgia, Fabio Montobbio, Luigi Orsenigo

IPRs, technological and industrial development and growth:

the case of the pharmaceutical industry

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IPRs, technological and industrial development and growth: the case of the pharmaceutical industry[♦]

Francesco Laforgia, Fabio Montobbio** and Luigi Orsenigo****

**University of Brescia, and CESPRI, Bocconi University, Italy*

*** University of Insubria and CESPRI, Bocconi University, Italy*

**** University of Brescia, CESPRI, Bocconi University, Italy, and Open University, UK*

Abstract.

In this paper we provide an introduction to some of the most salient aspects of the debate regarding the relationships between stronger intellectual property rights (IPRs) regimes and innovation in the pharmaceutical industry. We emphasize that, despite increased knowledge on the subject, little is known on the relationships between IPRs, innovation, and growth, especially as developing countries are concerned. We report on preliminary research on the patenting activities in Brazil using domestic patent data, rather than – as it is customary – international patents. Firstly, we show that the adoption of the TRIPs had substantial positive impact on the number of patent applications in Brazil, but that the great majority of these new patent applications have come from nonresidents, most likely as extensions of foreign patents. However it is too early to assess if this substantial increase in (foreign) patents is a permanent characteristic of patenting activity in Brazil. Secondly, the introduction of TRIPs has not changed the technological composition of patenting activity in Brazil, with one major exception, the growth of the share of the chemical and pharmaceutical patents, few years after the upsurge of patenting in other fields.

Keywords: Intellectual Property Rights; Patents; Pharmaceuticals; Brazil; Developing Countries.

JEL Codes: O31; O34

1. Introduction

The adoption of the TRIPs Agreement – and more generally the global tendency to strengthen intellectual property rights – has raised a heated debate regarding the relationships between stronger intellectual property rights (IPRs) regimes, innovation, and development. After years of stagnation, the economic analysis of the patent system is experiencing a substantial revival. Interestingly, most

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of the new contributions to the literature have an empirical nature. Indeed, the economic theory of patents was often deemed to be inconclusive by many economists, given that radically different results could be obtained by slight changes in even ancillary assumptions and – above all – the empirical evidence was so flimsy that it was hard to discriminate against alternative conclusions.

The debate has been particularly virulent with respect to the pharmaceutical industry. Indeed, this sector brings the trade-offs and issues involved in patent theory to their extreme consequences. Pharmaceuticals are an industry – one of the few – where patents are unambiguously recognized as being key instruments for privately appropriating the economic benefits of innovation and therefore serving as an important incentive for innovation. In this sector, competition is largely based on innovation and basic science is becoming increasingly crucial for the discovery and development of new products. The pharmaceutical industry also has many of the characteristics usually associated with “strategic” industries. It is a high growth and skill-intensive sector, which provides products that are in themselves associated with further growth: health is a major engine of growth and growth is associated with higher health standards. The pharmaceutical industry also occupies an extremely socially sensitive sector: large parts of the population increasingly perceive health care as a fundamental human right. The very definition of what a just society should look like increasingly involves references to health care. For developing countries in particular, health has become a major issue, magnified by the tragedies of pandemics like HIV/AIDS. Thus, it should come as no surprise that TRIPs – of which the pharmaceutical industry was one of the main supporters – has ignited raging controversies regarding the desirability of property rights in drugs, both between developed and developing countries and within rich countries.

An analysis of the relationships between IPRs, innovation, and growth in the context of pharmaceuticals is made even more difficult and irksome because – especially for developing countries – there are intricate relationships between health and growth. Moreover, the pharmaceutical industry itself is undergoing deep and unforeseeable transformations.

In this paper, we try to provide an introduction to some of the most salient aspects of the debate, reviewing the relevant theoretical issues and above all the sparse empirical evidence available. The main thrust of our argument is as follows:

- there are indeed profound trade-offs between the incentives to innovate and access to medicines which do not have any obvious and simple solution,
- the effects of strengthening the patent regime depend on a wide variety of conditions: institutions (antitrust, patent offices, etc); capabilities; modes of competition; specific nature of patent laws themselves and court interpretations (scope, novelty, etc.); in the

specific case of pharmaceuticals other complementary institutions have a key role: price controls, health systems in general, basic research, etc.

- however, both economic theory and the evidence increasingly suggest that the strengthening of IPR regimes in developing countries is likely to impose a series of negative consequences upon those countries, which probably outweigh any comparable benefits that developing countries' more robust IPR regimes bring to developed countries.
- if anything, the IPR system governing pharmaceuticals has become increasingly dysfunctional even in countries like the USA. The efficacy and desirability of extending strong IPR protection in the rest of the world raises very legitimate doubts.

We also emphasize that, despite increased knowledge on the subject, little is known on the relationships between IPRs, innovation, and growth, especially as developing countries are concerned. Thus, theoretical development and especially new empirical evidence are badly needed.

In this vein, we report on very preliminary research on the patenting activities in Brazil using domestic patent data, rather than – as it is customary – international (that is, US or European) patents. A first look at these data suggests indeed that domestic patents reveal somewhat different and relevant insights into the nature and patterns of innovation in developing countries. In particular we show that the adoption of the TRIPs had a great impact on the number of patent applications in Brazil and that after 1996 there was a great inflow of non-resident patents. Importantly the impact of the TRIPs is heterogeneous across different technological fields. In particular the number of pharmaceutical patent applications started increasing in 2000, at least three years after the number of patents in other fields, and kept increasing thereafter.

2. Pharmaceuticals: the background

Ever since its inception, the pharmaceutical industry has traditionally been dominated by a stable core of large, globalized innovative firms based in a few countries: the USA, UK, Switzerland, Germany, Japan, and France. However, this sector is highly competitive. Concentration is very low as compared to other R&D and marketing intensive industries, mainly because the market is composed of several independent sub-markets (for example, tranquilizers are not substitutable as cardiovascular drugs), economies of scale are not very strong and cumulativeness in innovation is quite low: finding and successfully developing a new drug remains still today a highly uncertain activity and firms find it hard to use the knowledge accumulated in developing one product for developing a truly different one. Still today – after substantial industry mergers and acquisitions, the largest pharmaceutical company controls a market share lower than 10

percent of the world market. In the USA, the market share of the top five and the top ten firms are respectively less than 36 percent and around 60 percent.

Moreover, the industry is composed of many other types of firms competing and in some cases collaborating with the major corporations: small domestic firms involved in adaptation, manufacturing, or marketing; biotech firms mainly active in the early stages of the research and development process; and producers of generics.

Pharmaceuticals have been systematically characterised by little entry and turbulence: the biotechnology revolution and the diffusion of generics constitutes a major change in this respect, but still most of the biotech companies do not compete directly on the final product market, while the generics segment is already undergoing a process of consolidation. Schumpeterian competition is however a distinct feature of this industry. Firms compete first by trying to discover and develop new drugs. The process is highly costly and risky, and only a very small number of molecules actually reaches the market. Innovators – thanks to patent protection - enjoy high profits after the introduction of a new, successful drug. But quite early, innovative products become exposed to the competition by imitators who provide patented variants of the original drug. After patent expiration, generics enter the market, in some cases substantially eroding the profits of the original innovator.

Finally, the industry is characterized by strong information asymmetries. Consumers are typically unable to properly evaluate the quality of a drug. It is the prescribing doctor who makes the decision, but even doctors often do not know in detail the properties of a drug, especially when it is a new one and much of the information available to physicians is provided by the companies themselves. Given the value that users may attribute to the product, especially in extreme cases, demand price elasticity tends to be low. Moreover, most consumers are insured (privately or publicly) against at least a part of the cost of prescription drugs, so they are only partially interested in drug prices. The prescribing physicians are likewise not completely sensitive to prices, both because they will not pay for the prescribed drugs, and because the respect of professional norms makes them more attentive to the safety and therapeutic value of medicines than price.

The industry has been undergoing deep transformations in the past twenty-five years. First, the advent of the molecular biology revolution has substantially changed the relevant knowledge base and the research procedures. From the chemical analysis and synthesis of molecules based on the procedures of random screening, the drug discovery process is now guided by the biological understanding of diseases, drugs, and cures. Second, the organization of the industry and of individual firms is profoundly changing, through the entry of the specialized firms called biotechnology companies and more generally processes of partial vertical disintegration, not only as it concerns pre-clinical research, but also clinical trials. Thus, drug discovery and development now

rely on a dense web of interactions between universities, biotech companies, hospitals, firms organizing trials, etc., although large corporations still maintain a key position as integrators of the whole process (Orsenigo *et al.*, 2001).

However, the new opportunities promised by the new technologies do not appear to have materialized yet. Over the period 1978-2003, research “productivity,” measured by the number of patents per dollar of R&D expenditure, has in fact fallen: R&D expenditures increased ten-fold, while patenting output increased by only seven-fold (Nightingale and Martin 2004). This is further corroborated by the number of New Chemical Entities (NCE) (a much more demanding measure of innovativeness than patents) approved by the FDA in the USA over the period 1983-2003, displaying some increase until the mid 1990’s, followed by a sharp decline since. So, in 2002, US R&D expenditures in pharmaceuticals were thirty times greater than in the early 1980’s, while roughly the same number of drugs were approved annually. At the same time, marketing expenditures have increased substantially, reaching in the US more than one third of sales (Orsenigo *et al.*, 2006).

To some extent, the productivity paradox in pharmaceuticals can be attributed to more demanding regulation. Over time, the regulatory system for product approval has become more stringent, before and after product approval, increasing the cost and the time for launching a new drug on the market¹. In addition, cost containment policies have put pressures on the price of drugs in many countries and – with considerable differences across countries – have stimulated the diffusion of generics. The generic industry is today a growing segment of the industry, already undergoing a consolidation phase.

It is important to emphasize, though, that the opening and growth of the generics markets has also changed the geography of the industry. As in other industries, entry of new companies and new countries occurs in lower value added segments of the industries and/or in specific market niches. Indeed, countries like India, Israel, Thailand, Brazil have been able to develop lively domestic industries in this segment and some of these firms have acquired significant positions in the world market. An Israeli company is now in the league of the twenty largest pharmaceutical corporations worldwide in terms of sales and a couple of Indian companies are among the first fifty.

3. Strengthening IPRs regimes and TRIPs

A further important change in the industry is linked to the progressive tightening of the IPR regime. In the USA in particular, various actions and court decisions have introduced reforms essentially aiming at saving costs and time linked to patent procedures; extending patent duration

¹ However, in more recent years regulations have become more relaxed and approval times shortened (due to the Prescription Drug User free Act in 1992 and the FDA Modernization Act in 1997)

for some classes of products; and encouraging “non-profit research institutions” to patent and market technologies developed with public funding. Moreover, a series of court cases in the mid 1990’s overturned previous practices, granting patents on upstream research and significantly extending patents scope, even to cases where the practical application of the patented invention had not been clearly demonstrated. Just to recall a few important steps in this direction, in 1980, the Bayh – Dole act was introduced which greatly facilitated patenting and licensing of the results of publicly funded research. In the same year the US Supreme Court ruled in favor of granting patent protection to living organisms (*Diamond v Chakrabarty*). These two decisions practically made possible the birth of the biotechnology industry. In 1982 the Court of Appeal of the Federal Circuit (CAFC) was created: as a result, the whole “inventing system” became more homogeneous (Adelman, 1987). Moreover, the CAFC strongly supported the “equivalents doctrine,” through which inventors were protected not only from imitative products and processes but also from those substantially similar (or similar in their results), although outside the *literal patent’s scope*. Also, the Court strongly encouraged significant compensation for all the damages stemming from the violation of patent protection. In the subsequent years, a number of patents were granted establishing the right for very broad claims (Merges and Nelson, 1994). Finally, a one year grace period was introduced for filing a patent after the publication of the invention.

Last, the adoption of TRIPs in 1994 extended and sought to homogenize patent protection in all countries participating to the WTO. Subsequent bilateral agreements even strengthened the TRIPs provisions.

4. Patents as an incentive to innovation

The debate sparked by TRIPs – and by the developments in the USA – touches a mind-boggling series of difficult questions. Summarizing them briefly, they have to do with the following issues:

- What are the effects of stronger IPRs on domestic innovative activities in pharmaceuticals in the South of the world?
- What are the effects of stronger IPRs on innovation in the North of the world?
- Would stronger patent protection induce higher levels of Foreign Direct Investment (FDI) and possibly – through this channel – higher rates of R&D and innovation in the South?
- What are the effects on drugs prices and access to drugs?

- How can the negative effects of stronger patent protection be offset? In particular, is price discrimination and parallel trade a viable solution for granting access to drugs at lower prices in poorer countries?
- Are alternative mechanisms for incentivizing and funding research possible and viable?

To start introducing the discussion on these issues, it might be worthwhile to go back to the basics.

The first fundamental motivation for patents is that they provide an incentive for private agents to engage in innovative activities. Thus, theory predicts that stronger IPRs should increase the propensity for R&D and therefore innovation. Yet, neither the theoretical nor the empirical literature clearly show how big this incentive is and should be. Results depend critically on a series of variables, some of which are extremely hard to measure. For example, effects depend on the curvature of the innovation function and/or the probability distribution of innovating for any given dollar spent in R&D (the space of innovative opportunities); on the composition of the population of potential and actual innovators (Baumol 1990, Murphy *et al.*, 1991) and in particular on their technological competences; on the cost structure of R&D; on the costs of imitation with respect to the costs of innovation; on the actual patterns of imitation (how much does imitation erode innovators profits?); and of course, on the specifics of R&D decision making process.

Moreover, stronger patent protection might actually hinder technological progress. This is the case whenever incentives for innovation with a monopoly are lower than in more competitive markets. Earlier theoretical literature suggested that the threat of a new firm entering the market would ‘force’ the incumbent monopolist to have a high rate of innovation (Arrow 1962; Dasgupta and Stiglitz 1980 and 1981; Gilbert and Newbery 1982). But then it was recognized that, given the “sunk cost” nature of research expenditures, an incumbent could deter competitive entry with only a limited amount of research, so that innovation with a monopoly could be substantially lower than with more competition (Dasgupta and Stiglitz 1981 and 1982; Dasgupta *et al.*, 1982; Farrell *et al.*, 2003). Even more important, strong patent protection can significantly slow down technological progress when innovation is sequential or cumulative, that is, it builds on previous innovations (Scotchmer, 1991; Merges and Nelson, 1994; Bessen and Maskin, 2000). Strategic use of patents and litigation costs further deters innovation. Finally, strong patents can distort the directions, in addition to the rates, of innovation. To the extent that patents imply higher prices, research will be focused towards diseases in areas where patients are rich enough to pay for them and more generally on patentable cures and treatments (excluding for example, nutrition, exercise,

environment, etc.). Moreover, to the extent that firms engage in patent races (winner takes all), duplication of efforts may occur.

The empirical evidence on these issues is surprisingly thin. A few studies have tried to measure the impact of patent protection on innovation in pharmaceuticals. Scherer (2001) finds evidence of cyclical co-movement in pharmaceutical industry gross margins and R&D outlays. Schankerman (1988) estimates the value of patent rights using data on patent renewal rates and fees for France and computes equivalent cash subsidy to R&D, obtaining a value of only 4 percent. However, this result might depend on the fact that in France drug prices are very low. Indeed, a similar exercise for Germany yields a value of 15.2 percent (Lanjouw, 1998). These studies focus on the impact of patents on R&D or on innovation as measured by patents themselves. Arora *et al.* (2005) using survey data estimate the so-called patent premium, that is, the proportional increment to the value of an innovation realized by patenting it. A value of the premium less than one would therefore imply a loss. Results indicate an expected patent premium around 1.3 in biotechnology and 1.05 for drugs. However, these values increase considerably- respectively to 2.45 and 2.3 - if the patent premium is computed conditionally on having actually patented the innovation. These results imply that a 10 percent increase in patent premium increases R&D by 10.6 percent in biotech and by 8.9 percent in drugs, corresponding to an equivalent subsidy rate equal to 22 percent.

Moreover, a 10 percent increase in patent premium increases patent applications by 14.3 percent in biotech and by 12.5 percent in drugs. These results are broadly in line with the findings by Acemoglu and Linn (2004), who estimate that in pharmaceuticals a 1 percent increase in the size of the market for pharmaceutical products raises the number of new drugs by 4 percent to 6 percent, implying an elasticity of innovations to R&D ranging from .8 to .85.

These results confirm that patent protection is important in pharmaceuticals, but they refer to highly developed countries and they do not consider the effects of changes in the strength of the patenting regimes. Moreover, critics maintain that the degree of innovativeness of the pharmaceutical industry might be overstated, since only a few of the new drugs are really innovative but many only introduce minor modifications (for example, in terms of dosage) to existing products.

In this respect, it is important to recall that throughout the history of pharmaceuticals the scope and efficacy of patent protection has varied significantly over time and across countries. The US has provided relatively strong patent protection in pharmaceuticals. Yet, many other European countries, including Germany, France, Germany, Italy, Japan, Sweden, and Switzerland, traditionally did not offer protection for pharmaceutical products: only process technologies could

be patented. France introduced product patents in 1960, Germany in 1968, Japan in 1976, Switzerland in 1977, Italy, Netherlands and Sweden in 1978, and Canada and Denmark in 1983. In many cases, as in Japan and Italy (and possibly France), the absence of product patent protection induced firms to avoid product R&D and to concentrate instead on finding novel processes for making existing molecules. In these countries, the development of me-too drugs, inventing around and getting licenses from other companies became the main research activity.

In other cases, primarily Germany and Switzerland, but also Denmark and Sweden, the absence of product patent protection did not seem to produce such negative effects. Similarly, the reforms of patent laws do not appear to have had a visible and significant impact on the innovative capabilities of industries like the Italian or Japanese pharmaceutical industries. If anything, it has been argued that according patent protection to pharmaceutical products might have had a negative effect, further weakening national industries mainly composed of generic producers (Scherer and Weisburst, 1995).

Conversely, in India pharmaceutical product patents were abolished in 1970. After these reform, a tremendous growth of a domestic pharmaceutical industry producing generics was observed. India became an exporter of bulk drugs and final therapeutics, providing them to many parts of the developing and developed world at lower costs. Almost all the empirical studies on the Indian case agree that a weaker intellectual protection system encouraged the development of indigenous technological capabilities and catching-up (see, among others, Lanjouw 1998; Kumar 1998 and 2002; Ramani and Maria, 2005; Chaudhuri, 2006).

The effects of TRIPs-compliant patent protection² on the Indian industry are not clear yet. However, the available evidence suggests that indeed a few Indian companies are trying to enter the club of innovative firms, raising significantly their R&D intensity, with mixed results so far. On the other hand, while evidence does not yet show any dramatic shake-out of local producers of generics, most analysts seem to agree that a substantial restructuring is bound to occur. In the best scenarios most local generic firms would become intermediate product manufacturers or service providers to larger foreign companies or would continue as generics producers but with much higher costs linked to access to licences, litigation, etc.

These insights are confirmed by other more recent studies on the effects of strengthening patent protection on innovation. Theoretical analysis suggests that when patents are already strong, increasing patent protection further may actually depress the level of innovation (Gallini, 1992; Cadot and Lippman, 1995; Horowitz and Lai, 2006). Similarly, in countries lagging behind the

² India signed the Uruguay round of GATT in 1994, but it availed itself of the complete term of the transition period, i. e. 10 years, which was accorded to developing countries to set up a TRIPs-compliant IPR system.

technological frontier and with low per capita income, stronger patent protection has little effect on the rate of innovation (Deardorff 1992; Helpman 1993; Lall 2003).

Empirically, various studies have confirmed these predictions. Examples include studies of the broadening of Japanese patent scope (Sakakibara and Branstetter, 2001), the establishment of the Court of Appeals for the Federal Circuit in the United States (Kortum and Lerner, 1998; Hall and Ziedonis 2001), and statistical analyses of episodes of strengthening IPR over a 150 years period (Lerner, 2005). Moser (2003) examines data constructed from the catalogues of two 19th century world fairs: the Crystal Palace Exhibition in London, 1851, and the Centennial Exhibition in Philadelphia, 1876. She also finds no evidence that patent laws increased levels of innovative activity but strong evidence that patent systems influenced the distribution of innovative activity across industries, that is, the direction of innovative activity³.

In sum, there are strong reasons to doubt that strengthening IPRs in developing countries would have a positive impact on domestic innovative activities. Such effect presumes sufficient scientific and technological capabilities, access to knowledge and active participation in research networks, large domestic markets and/or ability to export. If anything, stronger IPRs might possibly make life more difficult for local brands and generics producers, especially if data exclusivity agreement and patentability for second use provisions are enforced.

It is even harder to evaluate the effect on R&D and innovation of the companies located in rich countries. This will depend on how big the increase in sales and profits might be (which depends also on the resulting price increase), on how much of that will be translated into higher R&D, and on the elasticity of innovation to R&D.

5. Patents as incentives to the commercialization of innovations

One finds less skepticism towards the effects of IPRs on innovation when a second set of arguments concerning the role of patents is advocated, namely that patents disclose information. In the absence of patents, innovation are much more likely to remain secret. Moreover, patents may induce the commercialization of innovation and the development of markets for technology (Arora *et al.*, 2004; Lamoreaux and Sokoloff, 1999; Kahn and Sokoloff, 1998). The establishment of property rights on the outcomes of research facilitates the economic exploitation of such knowledge (in the absence of patents, firms would not invest in R&D based on the new discovery because

³ In this respect, it has been sometimes argued that stronger IPRs in developing countries could introduce incentives for developing drugs for local diseases, for example, malaria. However, there seems to be no evidence that this is or could be the case. Decisions concerning the directions of innovative activities would still be influenced by considerations of profitability, both by local and foreign innovators.

everybody could have access to it) and allows an “ordered” path of exploitation of such knowledge avoiding wasteful duplication of efforts. The Bayh-Dole Act is clearly based on these assumptions and the boom in biotech companies (often founded by university scientists) is typically cited as an example of the positive effects of the “new” IPR regime on the commercial exploitation of basic scientific research.

In sum, one finds less skepticism when patents are conceived not so much as an incentive to innovation but a mechanism for creating market for technologies. Several objections, however, have been raised against this argument. First, this incentive is not needed in the case of publicly funded scientific research: the invention has been already been paid for (by the public) and it has already been realized. Moreover, the argument in favor of the imposition of property rights on otherwise open science rests on a series of specific assumptions on the mechanisms of generation and economic exploitation of knowledge that – as argued by Mazzoleni and Nelson (1998) – makes it very hard to accept them in general. In particular, the argument for patent implies that no further mechanisms of protection are available in the development process.

Indeed, broad patents on basic inventions might hinder further innovation, especially if licenses are given on exclusive terms or at very high prices. First, bringing science into the “market” is likely to distort incentives away from basic research and into specific practical areas that promise commercial rewards. Second, science “*proceeds most effectively and cumulatively when those who do science are part of a community where open publication and access to research results is the norm, and rewards are tied to recognized contributions to the communal scientific effort.*” (Nelson, 2004). But widening the scope of appropriability runs precisely against this principle. Other sources of worry related to the “anticommons problem” (Heller and Eisenberg, 1998) concerning the possibility that the extension of patents into research tools will limit innovation due to the numerous property right claims to separate building blocks for some product or line of research.

In this case the evidence is mixed. First, various studies have shown that the Bayh-Dole Act did not give birth to technology transfer from university to industry and that the surge in university patents and licences pre-dates Bayh – Dole (Mowery *et al.* 2001). Rather, university patenting seems to be triggered by new technological opportunities (biotechnology, software, etc..) and from improvements in the management of the innovative processes (Kortum and Lerner, 1998). Moreover, patents are just one instrument of technology transfer, nor are they the most important one (Cohen *et al.* 2002, Agrawal and Henderson 2002). Second, there is contrasting evidence that university scientists may shift their focus from basic research to applied research. Indeed, much of

the research conducted in universities is located in the so-called Pasteur's quadrant, *i.e.* it is at the same time basic and use - inspired (Stokes, 1997) and if anything the evidence seems to indicate strong correlations between patenting and publishing (Agrawal and Henderson 2002, Azoulay *et al.*, 2004, Geuna and Nesta 2006; Breschi *et al.*, 2005). Walsh *et al.* (2003) in a survey of biomedical researchers in universities and private companies find no major delays or abandonment of projects due to transaction costs, but some evidence of increasing obstacles and delays in securing material transfer agreements for research purposes. Other studies, however, find evidence for a quantitatively modest but statistically significant anti-commons effect (Murray and Stern, 2006) and document solid evidence on publication restrictions for sponsored research in the life sciences (Thursby and Thursby, 2003 and 2006).

In the case of developing countries, stronger IPRs might hinder development of domestic scientific capabilities, if royalties on basic research tools are too expensive. However, for these countries the argument that well-defined IPRs may contribute to the development of markets for technologies and to the commercialization of inventions has a further facet, they could attract foreign direct investment (FDI) and – possibly – related R&D. This argument has some empirical support (Maskus, 2001), particularly as it concerns clinical trials and market development activities. Yet, it is also widely recognized that IPRs are only one of the motivations leading to FDI and other consideration linked to availability of local skills, research infrastructures and capabilities, demand characteristics as well as other institutional and legal pre-conditions are usually more important⁴.

6. Impact on prices

The obvious cost of stronger IPR is higher prices. In turn, the impact on prices depends on a series of variables, like market structure before and after the new patent regime (including the number of domestic and foreign firms, the nature of that competition, the ease of market entry and exit, quality differentiation among products, openness to trade, and wholesale and retail distribution mechanisms); demand elasticity; pricing regulations and competition policies, in particular as it concerns parallel imports and sole distributorship laws (Maskus, 2001; Nogues 1993).

Once again, it is very hard to evaluate in general the effects of TRIPs on drug prices. Scarcity of data and the extreme difficulties in computing comparable price indexes (Danzon, 1997; Danzon and Kim 1998) prevent systematic analysis. Clearly such effect will be different across countries. The evidence surveyed by Maskus (2001), suggests, however, a substantial impact. Price increases after introduction of patents were estimated by Watal (2000) and Fink (2000) to range from 50 percent to 200 percent in India, while Baker and Chatani (2002) suggest that the average increase

⁴ A counter-argument is that increased foreign direct investment might produce a crowding-out effect on skilled labour and local researchers for domestic companies.

in price for pharmaceuticals due to patent protection is probably close to 400 percent. More specific analyses of specific drugs report that in Brazil free market version of AIDS drugs were available at \$200 against \$10,000 a year for patent-protected versions (Coriat *et al.* 2006).

Two issues deserve specific attention. First, price regulations certainly have a large role to play in limiting price increases. However, patent holders may choose not to supply the local market at the regulated prices. Moreover, when price regulations are based on “cost-plus” formula, firms are encouraged to set high transfer prices on imported ingredients, leading to potentially higher prices (Lanjouw, 1998). Conversely, when prices are defined on the basis of reference indexes of prices in other markets, firms have an incentive to bargain for the highest possible prices in the low-price economies in order to gain a higher set of global reference prices (Maskus, 2001).

Second, price discrimination is often considered as a possible counter-balance to unaffordable drug prices in poor countries. However, this implies banning parallel imports, an important source of low price drugs in many countries (and a source of exports for producers in developing countries). Further, price discrimination is often viewed as anticompetitive because it allows firms to set prices according to market power in each country. Indeed, Maskus (2001) shows that that prices are often higher in developing nations than would be expected under a simple price discrimination equilibrium and, indeed, are at times higher than in the rich nations.

7 . TRIPs agreement and patenting activity: the case of Brazil

Given the complexity of the relationships between the strength of IPRs protection and innovative activities (and access to medicines) it is increasingly important to be able to collect reliable and disaggregated patent data from national patent offices in developing countries. In this section we focus in particular on the Brazilian case and we show some preliminary evidence.

Typically international patent databases (European Patent Office – EPO - and US Patent and Trademark Office - USPTO) have been used to assess the technological activity and specialization of developing countries (Montobbio and Rampa, 2005; Huang and Miozzo, 2004), because they allow for international comparability (Pavitt, 1988). Since patenting abroad is expensive, patents at the EPO and USPTO should also have the highest perceived economic value by applicants and inventors. However the use of EPO and USPTO patents is not particularly appropriate for the analysis of the economic impact of the IPRs reinforcement in developing countries and, in this case, Brazil.

In the first place the analysis of international patenting activity can only be based on patents with a Brazilian applicant or inventor. In principle one could argue that if reinforced IPRs in Brazil really constituted an incentive to perform more R&D, this could be observed also in the patenting

activity abroad. Still the analysis of the patenting activity of foreign companies in Brazil would remain out of the picture. Secondly there is a small number of Brazilian (owned or invented) EPO and USPTO patents relatively to the overall economic and technological activity of the country (Montobbio, 2006; Fapesp, 2005; Albuquerque, 2000). Brazilian patents number 1715 at the USPTO in the period 1968-2001 and 1244 at the EPO in the period 1978-2001. Thus, Brazilian firms do not patent systematically abroad (in particular the small and medium ones) and international patents provide a partial view of the national inventive activities. International patents mainly reflect the activities of exporters and in many cases they are the results of technological cooperation between Brazilian and US or EU inventors. In fact, the important Brazilian actors involved in international patenting are mainly US and German companies with a foreign address or their foreign subsidiaries with a Brazilian address. The main Brazilian patenting company is Petrobras with patents in a set of heterogeneous sectors of activity (oil, glass, electric, metals and machinery).

In particular in the pharmaceutical sector in the period 1975-2001 there are 190 USPTO patents invented in Brazil with a quite dispersed ownership. Only one-third of the applicants have a Brazilian address and the top patentees are (excluding 57 patents that are 'Individually Owned'): Johnson & Johnson (10), Fond. Osvaldo Cruz (5) and St.Jude Medical (4)⁵.

Thus, analysis of the data from the national patent offices is more appropriate if the research question concerns the effects of strengthening patent protection within a country. Domestic data provide a much more accurate description of the nature of patenting activity in a developing country and they allow for investigating the impact in changes in legislation. Typically these data are very hard to obtain, coverage is partial and not all the information contained in a patent is available. We provide here an introductory picture of the patenting activity at the domestic patent office in Brazil, using the PATSTAT database⁶. The database contains 442,070 patent applications between 1972 and 2006, 342,453 patents are from firms and other institutions and 62,162 are from individual applicants (but 37,445 patents whose applicants are not identified)⁷. Moreover the database contains 155,871 applicants (47,037 are individuals). Among the 110,008 applicants with an address (most of them are companies), 68,176 are from Brazil, i.e. 62%. However the share of patents of Brazilian applicants on the total number of patents from applicants with an address is only 41 percent%.

⁵ Consistently with what is observed above it can be noted that most of the 10 patents by Johnson & Johnson are related to a specific project and reflect the activity of a specific team of inventors on different types of sanitary napkins and absorbent articles. Finally it can be noted that 19 USPTO patents with a Brazilian inventor are owned by US universities or medical schools.

⁶ PATSTAT is the OECD and EPO Worldwide Patent Statistical Database.

⁷ The dataset contain also utility model applications.

[Figure 1 about here]

Inspection of these data suggests a number of findings.

a) The number of patents increases rapidly after 1996

Figure 1 shows the total number of patent applications at INPI⁸ between 1974 and 2004 from PATSTAT and from the official data provided by INPI through WIPO⁹. The coverage of the PATSTAT database is good and in particular in recent years the number of patents of the two databases are very similar. In the PATSTAT database the total number of patents remains stable between 1974 and 1991, it declines sharply between 1992 and 1996 and finally it increases significantly after 1996.

In fact between 1996 and 2001 we observe a four-fold increase in the number patents. The new Industrial Property Law 9.279/96 was approved in 1996 and, in accordance with the TRIPs, introduced patent protection for pharmaceuticals, biotechnological products, and chemical products and processes that were excluded from patentability in the previous 1971 IP code. At the same time data also show a declining trend between 2001 and 2003. This may suggest that the impact of the legislative change is temporary even if there is another sharp increase in 2004.

[Figure 2 about here]

b) The sectoral composition of patenting activity does not vary substantially except for the increased weight of chemicals and pharmaceuticals after 2002

This aggregate trend covers a heterogeneous sectoral dynamic. Figure 2 shows the breakdown by six broad sectors and Figure 3 shows a more detailed picture of four smaller technological fields¹⁰. In Brazil 40 percent of all patents come from the mechanical sector. This share is substantially constant until 2002. Patents in all sectors increase proportionally after 1996, with the exception of a sharp increase in patenting activity in the chemical and pharmaceutical sectors in the period 2002 – 2004. In particular in the pharmaceutical sector in 2004 the number of patent applications is more than four times as big as the 2001 figure (from 778 to 3271)¹¹. However, this trend reflects in all likelihood, that pharmaceuticals were not patentable (nor products nor

⁸ The law of creation of the INPI (Instituto Nacional de Propriedad Industrial) was approved in 1970 and the law on industrial property is the n° 5,772 on to December 1971.

⁹ In the PATSTAT database we have the publication date of the patent; for WIPO data see <http://www.wipo.int/ipstats/fr/statistics/patents/>

¹⁰ The different IPC classes have been re-aggregated into economic sectors and technological fields following OECD(1994). The sectoral classification is available from authors on request.

¹¹ We define pharmaceutical patents all the patents corresponding to the class named “pharmaceuticals and cosmetics” of the classification OST30. The IPC 4-digits codes corresponding to such class are: A61K, A61P.

processes) from 1971 to 1996. Thus, this increase is likely to be due mainly to the extension of foreign patents.

[Figure 3 about here]

Some other relevant facts emerge from these figures. First there is substantial patenting activity in Brazil between 1974 and 1979 in the pharmaceutical field. A question arises on what type of technological activities they indicate and which are the main economic actors. Second, all throughout the 1990s there are very few patents in pharmaceuticals, with only thirty patents in 1994.

c) The number of non resident patents grows much faster than the resident ones.

Figure 4 shows that the increase in the number of patents between 1996 and 2000 is mainly due to patent applications filed by nonresidents, with a more than a three-fold increase (from 5446 in 1996 to 17741 in 2000, according to WIPO). In the same period, patents by residents increased by 50 percent. After 1999, according to the PATSTAT database (and after 2000 according to WIPO), the ratio of resident patents to total patents starts raising again. Note that in the PATSTAT databases on average the percentage of resident patents is lower. This is probably due to the fact that we do not have the addresses for all the applicants. Overall these data show that there has been a massive inflow of patent applications after the introduction of the law 9.279. Many of these applications are probably patents already filed abroad and extended to Brazil.

Moreover Figure 4 shows a sudden drop in the share of patents applied for by Brazilian residents, particularly in pharmaceuticals. As pharmaceutical patents grow rapidly after 2000, the shares of patent applications from Brazilian residents goes from 66 percent (in the period 1993-1998) to 15 percent (in the period 1999-2004).

Finally Table 1 shows that all the top pharmaceutical companies are multinational foreign owned corporations. After 2001, the top five companies accounted for more than one fifth of the total number of patents in the pharmaceutical sector and the top ten companies accounted for 27 percent of pharmaceutical patents¹². In particular L'Oreal, Astrazeneca and the group Pfizer-Pharmacia have 19% of all pharmaceutical patents in Brazil.

¹² However it is important to note that the number of firms increased substantially with the number of patents. In the period 1993-1996 in the pharmaceutical sector there were 249 patents and 114 patenting firms (2.18 patents per firm) and in the period 2001-2004 there were 4583 patents and 848 firms (5.4 patents per firm). Moreover, between the sub-period 1997-2000 and the sub-period 2001-2004 there was not a decline in the concentration rate even if the number of companies was almost four times higher.

[Table 1 about here]

d) The increase in the number of patent applications in the pharmaceutical sector lags at least three years with respect to the other sectors. The number of patents granted in pharmaceuticals is still very low.

The substantial take off of pharmaceutical and biotech patents takes place in 2000. These numbers refer however to patent applications and not to patents granted. The number of patents granted is still very low¹³. These observations are probably the outcome of some specific features of the process through which TRIPS were implemented in Brazil, in particular as it concerns pharmaceuticals.

First, according to the Brazilian Government, article 65(2) of TRIPs is applicable to Brazil as a developing country and therefore the transitional period of 4 years (ended in 2000) may have created uncertainty on the validity of some pharmaceutical patents. Moreover, the highly disputed 1999 Provisional Measure 2014 - transformed into law n° 10.196 in 2001 - conditions the granting of pharmaceutical patents on ANVISA's approval (Agência Nacional de Vigilância Sanitária¹⁴) and rejects applications for some substances, matters, and products related to pharmaceutical inventions that lack pipeline protection.¹⁵ In general since the ratification of TRIPs, Brazil has imposed relatively more restrictions on pharmaceutical related patents than have other countries. This concerns in particular the issues of compulsory licensing, high fees and obligations for pipeline applications, international exhaustion and parallel imports, and, finally, a permissive attitude towards actions intended exclusively to produce information, data and test results by unauthorized parties (e.g. Provisional Measure 2014 claims that these actions, aimed to obtain marketing approval for a patented pharmaceutical product, are not considered infringement of the patent). Thus, the data suggest that the inflow of foreign patents in pharmaceuticals was delayed until 2000 by actions of the Brazilian authorities aiming at softening the actual strength of patent protection in this sector.

¹³ See for example INPI statistics on www.inpi.gov.br or EFPIA (2004). According to EFPIA (2004) Brazil has only issued 428 non-pipeline and 628 pipeline pharmaceutical patents in the period 2000-2004. Unfortunately we do not have data on the number of patents granted in different sectors.

¹⁴ The National Health Surveillance Agency (Anvisa), established in 1999, is an independent and financially-autonomous regulatory agency that exercises sanitary control over production and marketing of products and services subject to sanitary surveillance (<http://www.anvisa.gov.br>).

¹⁵ A pipeline protection is available as an "extension" of the patent granted in some other country. Any Brazilian patent granted on such a pipeline application must be identical with the foreign patent on which it is based and will expire on the same date as that foreign patent. No patents shall be issued however for such inventions: a) that were already commercialized in any market by the holder or with his consent; or b) that were already worked by third parties in Brazil; or c) that any third party in Brazil has been engaged in serious and effective undertakings with a view to start working the invention.

Conclusion

The available evidence – including Brazilian patent data -, while difficult to assess, would seem to suggest that, the links between patent protection and innovative performance are less direct than it is usually assumed, even in pharmaceuticals and especially in the short – medium run. Strong patent laws do indeed confer an advantage to innovators in the pharmaceutical industry but they may not be enough to promote innovation in contexts where innovative capabilities are low or missing altogether.

In particular, our preliminary analysis of Brazilian data suggests that the adoption of the TRIPs had substantial positive impact on the number of patent applications in Brazil. However, the great majority of these new patent applications have come from nonresidents, most likely as extensions of foreign patents. Thus, it is too early to assess if this substantial increase in (foreign) patents is due to pipeline patents under the TRIPs mailbox provision or it will become a permanent characteristic of patenting activity in Brazil.

Second, the impact of the TRIPs is heterogeneous across different technological fields. In general, the introduction of TRIPs does not seem to have changed the pattern of technological specialization of Brazil, with one major exception, the growth of the share of the chemical and pharmaceutical patents, especially after the year 2000, three years after the upsurge of patenting in other fields. After 2000, pharmaceutical patents continued to grow, and five big foreign industrial groups account for more than one fifth of all the pharmaceutical patents after 2001.

These data show also that domestic patent statistics are very sensitive to changes in the legislation and administrative procedures of the national patent office. Still they provide a crucial source of information for evaluating the impact of the TRIPs, and to appreciate how relative specific national provisions may expand or reduce patent effective protection.

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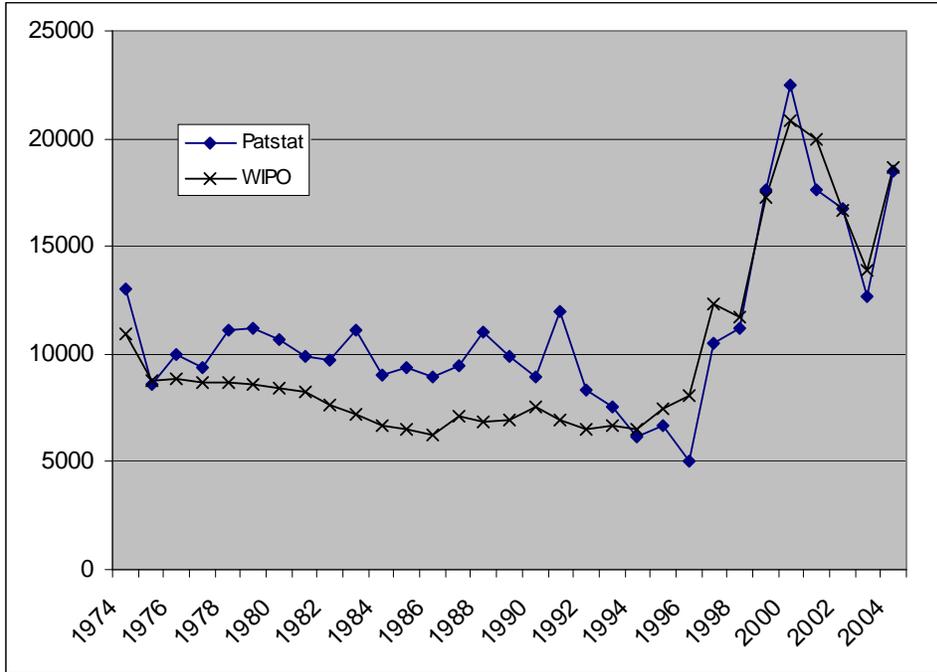
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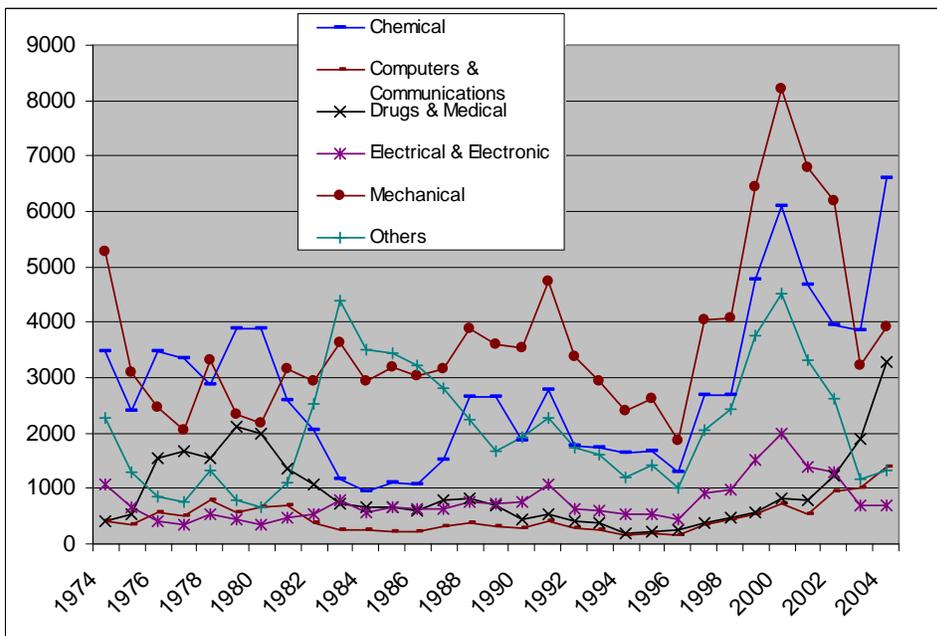
Figures and Tables

Figure 1. Number of patent applications in Brazil



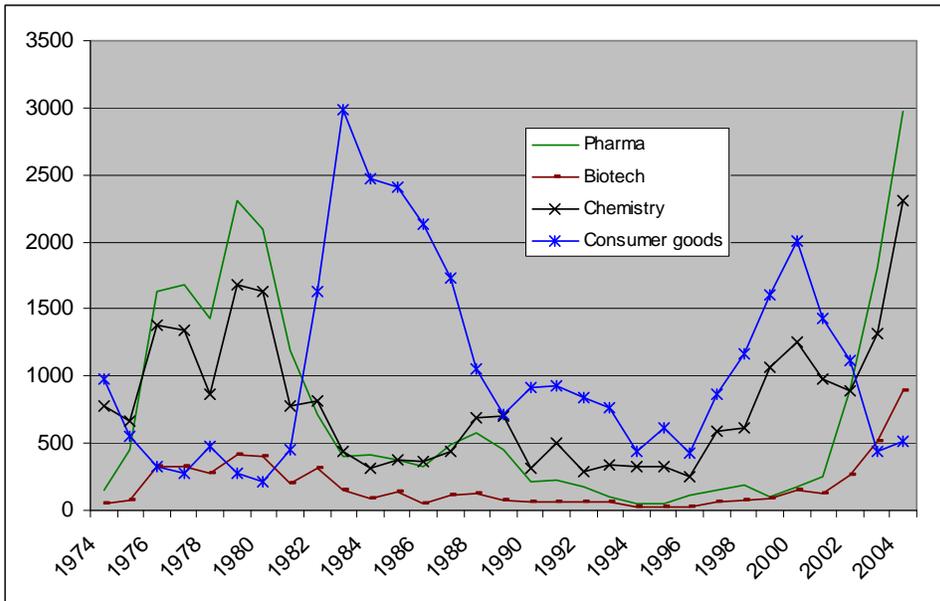
Source: our elaboration on PATSTAT data

Figure 2. Number of patent applications in Brazil in 6 sectors



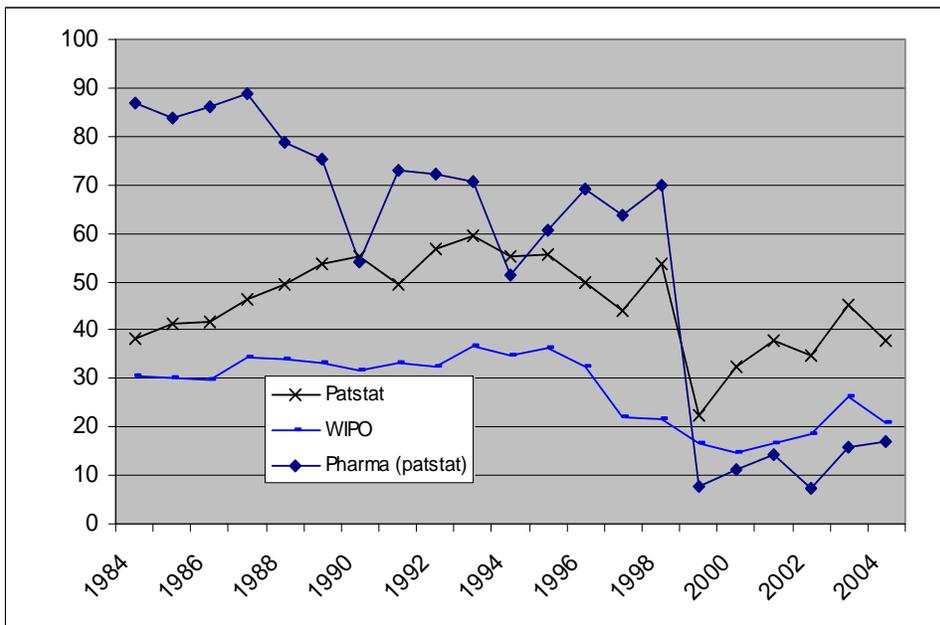
Source: our elaboration on PATSTAT data

Figure 3. Number of patent applications in Brazil in 4 technological classes



Source: our elaboration on PATSTAT data

Figure 4. Resident share of total patents



Source: our elaboration on PATSTAT data

Table 1. Top 10 patenting pharmaceutical companies in Brazil in 3 sub-periods

| 93-96 | | Country | patents | %patents on tot patents |
|--------------------------------------|------------------------|----------------|----------------|--------------------------------|
| 1 | L'OREAL | FR | 34 | 13,65 |
| 2 | PFIZER | US | 13 | 5,22 |
| 3 | GLAXO | GB | 12 | 4,82 |
| 4 | ASTRAZENECA | SE | 7 | 2,81 |
| 5 | GRUNENTHAL | DE | 7 | 2,81 |
| 6 | BAYER | DE | 7 | 2,81 |
| 7 | NOVARTIS | CH | 6 | 2,41 |
| 8 | BRISTOL-MYERS SQUIBB | US | 6 | 2,41 |
| 9 | AVON PRODUCTS | US | 6 | 2,41 |
| 10 | EMISPHERE TECHNOLOGIES | US | 5 | 2,01 |
| TOT PATENTS IN THE SUB PERIOD | | | 249 | 100,00 |
| TOT FIRMS IN THE SUB PERIOD | | | 114 | |
| 97-2000 | | | | |
| 1 | L'OREAL | FR | 26 | 5,46 |
| 2 | COLGATE PALMOLIVE | US | 20 | 4,20 |
| 3 | NOVARTIS | CH | 18 | 3,78 |
| 4 | HOFFMANN LA ROCHE | DE | 18 | 3,78 |
| 5 | ASTRAZENECA | SE | 13 | 2,73 |
| 6 | GRUNENTHAL | DE | 11 | 2,31 |
| 7 | HOECHST | DE | 10 | 2,10 |
| 8 | NIPPON SHINYAKU | JP | 9 | 1,89 |
| 9 | EISAI CO | JP | 7 | 1,47 |
| 10 | HENKEL | DE | 7 | 1,47 |
| TOT PATENTS IN THE SUB PERIOD | | | 476 | 100,00 |
| TOT FIRMS IN THE SUB PERIOD | | | 224 | |
| 2001-2004 | | | | |
| 1 | PFIZER | US | 358 | 7,81 |
| 2 | L'OREAL | FR | 297 | 6,48 |
| 3 | ASTRAZENECA | SE | 178 | 3,88 |
| 4 | BASF | DE | 71 | 1,55 |
| 5 | HOFFMANN-LA ROCHE | DE | 69 | 1,51 |
| 6 | ELI LILLY | US | 60 | 1,31 |
| 7 | AVENTIS | DE | 60 | 1,31 |
| 8 | JOHNSON & JOHNSON | US | 53 | 1,16 |
| 9 | PHARMACIA | US | 50 | 1,09 |
| 10 | NOVARTIS | CH | 48 | 1,05 |
| TOT PATENTS IN THE SUB PERIOD | | | 4583 | 100,00 |
| TOT FIRMS IN THE SUB PERIOD | | | 848 | |

Source: our elaboration on PATSTAT data