

INTRODUCING PATENT PROTECTION IN THE PHARMACEUTICAL SECTOR: A FIRST EVALUATION OF THE MEXICAN CASE

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***Abstract** - Reformed under NAFTA negotiations and in compliance with the TRIPs Agreement (Trade Related Intellectual Property Rights) when Mexico joined the World Trade Organization, patent protection for pharmaceuticals in this country has been reinforced since 1991 with the new Industrial Property Law. The aim of this paper is to make a first brief evaluation of the static and dynamic effects of the introduction of patent protection for pharmaceuticals in Mexico and to compare them to those predicted by economic literature. Regarding localization and market power, the absence of patent protection has not prevented multinationals firms from breaking into the Mexican market and ensuring an important market share. Brand promotion and product differentiation seem to have been the main tools to practice market exclusivity. Although the static effects might have been limited since multinationals already controlled the private market before the reforms, dynamic gains are still far from being felt. They suggest that other factors besides patent protection must be taken into account before expecting an increased R&D activity in the Mexican pharmaceutical sector.*

Keywords - INTELLECTUAL PROPERTY RIGHTS, PHARMACEUTICAL INDUSTRY, PATENT REFORMS, MEXICO.

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INTRODUCTION

Reformed under the NAFTA negotiations and in compliance with the TRIPs Agreement (*Trade Related Intellectual Property Rights*) when Mexico joined the World Trade Organization, patent protection for pharmaceuticals in this country has been reinforced since 1991 with the introduction of the new Industrial Property Law. The trend towards the worldwide harmonization of intellectual property rights marks a significant change in the traditional ways of acquiring and creating technology for firms in developing countries. Yet, the empirical work on the economic effects of intellectual property rights (IPRs) has just recently acquired the interest of economists, and only few empirical studies have focused on the case of developing countries that introduce patent protection (see Siebeck, Evenson, Lesser and Primo Braga, 1990).

Our study will therefore focus on the economic impact of patent protection of pharmaceuticals in the Mexican industry. That means, by defining a research agenda inspired by the theoretical and empirical work done on this area, we aim to discuss and present a first approximation of the economic implications of patent reforms. We will thus analyze how the market structure has changed, how prices have evolved and what the trends on investment and technological activity suggest. The importance of other factors that have interacted with patent reforms redefining the current industrial configuration will also be discussed in order to have an idea of what is happening (*and what is not and why*) in the Mexican case.

In the first section, this paper surveys the contributions of theoretical and empirical studies evaluating the impact of strengthening Intellectual Property Rights (IPRs) in southern countries on consumers' welfare and economic activity. It lays particular emphasis on the "ambiguous" effects of introducing patent protection in the pharmaceutical industry. The second section provides a first simple analysis of the pharmaceutical industry in Mexico before and after the patent reform. It is difficult to carry out a thorough analysis owing to the difficulty to access detailed data for multinational and domestic firms. However, some trends may be identified, which suggest important implications on the way current competition between domestic firms and MNs is being implemented. Some preliminary conclusions and an agenda for further empirical research are presented at the end.

1. THE INTERNATIONAL HARMONIZATION OF IPRS

Over the past two decades, the protection of IPRs at the international level has altered dramatically. One of the most striking changes was the adoption of northern IPRs protection standards by some developing countries.

Two reasons may explain the pressure for reforming the global IPR system. The first one is the increasing demand for intellectual property protection, represented for instance by the upward trend of IP applications worldwide, and the growing number of international transactions relying on intellectual assets, particularly the explosion of technology-content trade since the 1980s (patented, trademarked and copyrighted goods, see Maskus, 1993, 2000). The second one is the lobbying of northern countries to harmonize IPR protection. This is a response to the increasing imitation threat of a number of developing countries, who rely on a lax IPR system and weak enforcement mechanisms. As such, they have developed significant reverse engineering skills, enabling them to export copies and counterfeited products to global markets.

Despite the strong opposition of most developing countries, policy shifts since the mid-1980s have therefore emerged through different strategies implemented by northern countries. They notably resorted to aggressive commercial retaliation, the creation of bilateral and regional agreements, and to negotiations at the multilateral level, mainly the inclusion of IPRs protection in the Uruguay Round negotiations of the GATT (1986-1994). The most striking example of unilateral pressure has been the use of *section 301* of the Omnibus Trade and Competitiveness Act of 1984 of the United States. This enables the American government to implement commercial retaliation against those countries not granting effective IP protection. This *credible threat* has driven an important number of developing countries to reinforce their IPRs laws in the beginning of the 1990s¹.

At the regional level, the European Union (EU) and the North American Free Trade Agreement (NAFTA) pursue amongst their different convergence policies the regional harmonisation of IPRs protection. This causes countries like Mexico or some eastern European countries to join common market areas and to reform their IPRs systems –sometimes in a considerable way. The TRIPs (*Trade related Intellectual Property Rights*) agreement and the agreements on *Trade on Counterfeit Goods* still remain the most important and extensive agreements fostering the international harmonization of IPRs. Under the World Trade Organization, and thus under an international trade-conditional protection, TRIPs came to answer the inoperability, of the previous international agreement on IPRs (WIPO), in terms of enforcement. They introduced a dispute settlement mechanism and dispositions on potential commercial retaliation to make countries enforce new legislations. Hence, TRIPs set the minimum standards in IPRs protection (patents, copyrights, trademarks, trade secrets, protection to industrial designs, software, pharmaceuticals, biotechnology, etc.) that all

¹ South Korea passed new legislation in 1987, Indonesia, Bulgaria and Chili in 1991, Thailand, Taiwan, Rumanian, Russia and Ukraine in 1992, Turkey in 1991, Brazil in 1996 after the United States levied 100 % tariffs on \$39 million of imports in retaliation for copying patented drugs (Siebeck et al. 1990).

members and would-be members must progressively enforce (beginning 2000 for most emergent countries and 2006 for the least developed countries, UNCTAD, 1996).

As several authors suggest (notably Lanjouw and Cockburn, 1998; Correa, 1995, 2000), the consequences of this worldwide reinforcement of IPRs remain to be seen. They are difficult to determine as yet firstly because they are long-termed and eventually depend on effective law enforcements in these countries. The second reason is that we know neither the importance nor the direction of the potential economic effects. While recent theoretical studies in the economics of patents open up new prospects for a more profound reflection on the analysis of patents (patent life, patent height, breadth, etc.), the discussion on what must be considered as the "optimal level of patent protection" is still going on. Neither the upholders of strong protection nor those of weak protection have forceful arguments to justify their positions.

Most authors agree though, that patents are, by nature, a second best public policy to the extent that they remain a very unsatisfactory way of increasing incentives to innovate. Indeed, uncertain dynamic gains come at the cost of certain static losses, which are potentially larger for poor countries who are net-importers of technologies (Verspagen, 1999; Combe and Pfister, 1999a). As history has shown, governments have reinforced their IPRs systems as their economies become wealthier and achieve a stronger basis of technological sophistication. Indeed, some empirical studies have found that national regimes of intellectual-property protection strongly depend on the level of economic development (Park and Ginarte, 1997; Gould and Gruben, 1996). It remains to be seen to what extent the developing countries will effectively enforce these standards and how they will interact these policies with their economic development goals and public health needs, as in the case of pharmaceutical products.

1.1. Patent Protection and the Pharmaceutical Industry

The on-going debate whether to extend or not patent protection to southern countries becomes more acute when it refers to drugs and pharmaceutical products. First, following an innovation-diffusion (and lowest-cost innovations access goal) oriented public policy, developing countries have traditionally excluded patent protection for medicines. Through this and other means, they have sought to build a local self-sufficient pharmaceutical industry to ensure the adequate supply of medicines at accessible prices, and to cover the broadest spectrum of diseases (Frischtak, 1989). As noted by Lanjouw (1998), almost fifty developing countries did not grant patent protection for drugs at the time of the Uruguay Round, which began in 1986. In contrast, when lobbying before GATT to include IPRs the largest pharmaceutical firms denounced the absence of patent protection in many developing countries. They argued that this led to a

market deviation of innovations (patented drugs) towards these regions and that competition by imitators implied significant market losses for innovating firms.

Consequently, as is still claimed by the industry, these rent losses limit investment in Research and Development (R&D). They thus hamper the rhythm of innovation (new and better drugs), particularly for diseases typical of developing regions and traditionally neglected in R&D programs. Moreover, it has also been argued that direct investment and technology transfer to the developing world has been discouraged by the weak or non-existent protection of intellectual assets.

Although patents remain an imperfect tool to exclude competitors from a given technological market (and thus, to protect the strategic knowledge of the firm), their unique arguable importance to appropriate the returns to R&D in the pharmaceutical industry relative to other industrial sectors is out of the question as has been confirmed by different industrial survey studies (Taylor and Silberston, 1973; Levin and al., 1987; Cohen and al., 1997; Combe and Pfister, 1999b).

The relative significance of patents for pharmaceutical innovations over other appropriability strategies relies on the "effectiveness" to displace imitators, by altering the costs of producing imitations and thus, by facilitating the prosecution of infringements with important litigation costs (see Lanjouw, 1993, for empirical estimates of the private value of patent protection for different technologies). They also increase the costs of imitative R&D since imitators must invent around patents and differentiate products in order to compete "legally"; briefly, patents reduce *the hazard of imitation*. In this way, according to the classical study by Mansfield (1986) surveying 100 USA firms of different sectors, pharmaceutical firms declared that 65 % of their innovations would have not been developed without resorting to patents, and 68 % would not have been commercialized.

However, pressure to extend patent protection to world markets has not only been a consequence of the so-called global market erosion effect. In addition to the increasing difficulties to innovate for the largest pharmaceutical firms, important institutional and competitive changes in the marketplace have contributed to the reduction of the effective patent life of drugs, thus leading to decreasing returns to R&D investments, on the one hand. On the other hand, they have contributed to the increase in generic competition (Nogués, 1990). Therefore, besides the increasing competition threat from imitators in the developing world, pharmaceutical firms face a double growing competition: first, there is *an exacerbated competition* before patent expiration due to the faster introduction of substitute drugs or *me-too drugs* (within a therapeutic group). They thus increasingly reduce the market exclusivity period that an innovation may enjoy. They also face *an increasing competition after patent*

expiration, due notably to the generics boom. Finally, the pharmaceutical industry remains one of the most intensively regulated sectors. In most countries, especially in developing countries, drugs are subject to price controls; distribution is heavily regulated through hospitals and other health institutions, as is implemented in the TRIPs agreement; and drugs may be subject to compulsory licensing in case of public health emergencies, like in the recent case of HIV/AIDS epidemic in South Africa.

2. THEORETICAL FRAMEWORK

The implications of a tighter IPRs protection of global economic welfare, or of introducing it, are highly complex. Over the last decades, many theoretical and empirical studies have attempted to evaluate the potential benefits and costs of increased intellectual property protection. At the empirical level, they have illustrated in particular the effects of introducing patent protection for pharmaceutical products in a group of developing countries. In short, the economic literature that developed mainly in the 90s is organized in three principal axes:

- The static effects of reinforcing intellectual property rights in the North and South, the question being: How large will the loss of welfare consumers be, following the increased monopoly power of innovative firms in terms of price?
- The dynamic effects of increased patent protection: particularly, to what extent would these additional gains related to monopoly pricing stimulate an increase in R&D activities and patenting in the developing country? How large will the diffusion gains be (disclosure, introduction of new drugs and technologies)?
- The effects on technology transfer and international economic activity: the impact on trade, foreign direct investment (FDI) and licensing. Particularly for developing countries, can patent protection spur multinational firms to set up and to carry on efficiency gains by the development of technology markets (licensing of drugs)?

We will next present a brief discussion based on this literature, laying particular emphasis on the economic implications of patent protection in the pharmaceutical industry.

2.1. Static vs. Dynamic Effects of Strengthening IPRs

Developing countries' fears of and reluctance to stronger patent protection are justified at least for the short-term impact. From theoretical models to empirical simulations regarding the introduction of patent protection into southern countries, most studies conclude that the developing world will arguably suffer a loss in welfare terms in the short run. This result is particularly

relevant to "small" countries highly relying on technology-imports and lagging considerably behind the product cycle. In fact, they may find increasing difficulties to access new patented inventions if other access or commercialization incentives are not implemented (Correa, 2000).

Indeed, the first works (Chin and Grossman, 1988) suggest that even if IPRs may enhance global efficiency at least for substantial innovations, the South would incur important losses and world welfare losses may emerge. Consumers in the North may also suffer from an increase in global prices and other productive inefficiencies if patent protection becomes global.

In a more detailed work explaining how IPRs protection may affect northern and southern welfare, Helpman (1993) warns that stronger IPRs may lead to a two-fold inefficiency in the short run: *an allocative inefficiency* derived from monopoly pricing by innovators for a longer period (*a South-North rent transfer effect*), and *a productive inefficiency*. The latter implies an eventual reallocation of production from South to North since an increasing number of products will be produced in the high production costs region rather than in the low-costs southern region as imitators are driven out of the market. That is, in addition to consumer welfare losses and the displacement of local firms, the southern country may expect a *deterioration of its terms of trade and a loss of self-sufficiency* (other losses may emerge such as the loss of variety in the range of products, etc.). However, the models inspired by Helpman's have some shortcomings. Most of them assume an automatic reduction of imitation, without determining the resource implications of such an important hypothesis for the strategies of both northern and southern firms and the respective welfare decomposition (*economics of imitation*). Another point is that innovation by southern firms is not implemented. As has been argued by different studies, patent protection studies have largely focused on how patents may stimulate innovation and competition. Yet the relevance for developing countries would rather be a better understanding of how patents may affect or redefine imitation strategies and thus competition opportunities between innovators and technology-followers (Glass and Saggi, 1999, 2000; Bessen and Maskin, 2000).

This negative impact of patent reforms has been confirmed by several empirical studies. Simulating the introduction of patent protection for pharmaceuticals by assuming different market structures and different demand price elasticities, some studies suggest that non-negligible price increases and welfare losses may emerge in southern countries (Nogués, 1993; Maskus and Konan, 1994; Subramanian, 1995). A recent group of studies has provided more thorough analysis, by using desegregated data at the therapeutic level. They suggest that the impact of patent protection will vary indeed from one drug to another, from one therapy to another. The more price-elastic the overall demand of the therapeutic group and the higher the degree of substitution among chemical entities (the therapeutic competition) within this group, the smaller

welfare losses will be (see notably Watal, 1996, 1998). Moreover, Fink (2000) highlights the importance of available, close and off-patented therapeutic substitute drugs that can restrain prices and limit potential welfare losses. As the author suggests, the net impact will finally depend on the pace, quality and introduction of new (and better) drugs².

2.1.1 Dynamic Effects

Supporters of increased IPR protection and the TRIPS agreement argue that higher protection standards in the South may spur innovation activity, and thus have a positive effect on worldwide growth, which may not necessarily be to the detriment of developing countries (Taylor, 1994). However, contrary to the academic consensus regarding the negative static effects, the relation between stronger intellectual property protection and innovation activity and diffusion seems to be less clear-cut, both in a theoretical and empirical perspective.

Optimist economists have identified several contexts where incentives to increase R&D following increased patent protection may emerge. Assuming different consumers' preferences between the North and the South, Diwan and Rodrick (1991) point out that patent protection in southern regions may stimulate the creation of technologies appropriate to southern needs. This might lead to an increased R&D focused on developing countries' diseases, entailing an increase in the welfare of Southern consumers.

In contrast to this optimistic view, another group of studies suggests that there is a significant probability that stronger IPRs protection may slow down technological progress in the long run. They suggest that stronger (or longer) market exclusivity would increase incentives to delay the commercialization of innovations (as in Helpmans' model). Firms would still find it profitable to produce current technologies; they would devote fewer resources to or delay investment in development activities and opt to wait longer before marketing a new product or technology (*retarding or delaying innovation rate effect*, see notably Segerstrom and al. 1990; Helpman, 1993; Takalo and Kannianien, 2000). Therefore, extending patent protection to developing countries should not represent a strong stimulus to increase R&D activities, the technology gap separating rich from poor countries may eventually widen.

² The limitations of the empirical analysis focusing on the short-run effects converge in one aspect. When considering the pricing effect, these studies assume that pharmaceutical firms have total freedom to charge monopoly prices ignoring the intensive practice of price control in most developing countries. These studies do not suggest either how these welfare losses could change, for example when medicines are sold mainly to the government for their distribution and local sale (what is the relevance of the type of distribution system for the monopoly pricing?), or when compulsory licensing is allowed for some therapies, etc.

This ambiguity regarding the direction of the impact has been confirmed by the few empirical studies made to date. The assessment of the effects on R&D by the introduction of recent patent protection in developing countries is limited. On the one hand, this is due to the fact that it is still too early to see significant answers in (pharmaceutical) R&D given the long development time required to introduce new medicines (8-10 years). On the other hand, this also stems from the difficulties to get R&D data at the firm level in order to make an effective evaluation of any change on R&D trends.

For the case of Italy which introduced patent protection in 1978, Scherer and Weisburst (1995) found that an increasing drug product patenting was experienced well before the change in the patent regime by foreign firms, and a statistically significant upward jump in the number of Italian patents received per US\$ of R&D outlays. However, the patent reform apparently had little or no impact on the trend of inflation-adjusted R&D expenditures and they did not find an impact on the introduction of new chemical entities either. This increasing patenting activity could be explained as a strategic answer from multinationals. As the latter were more confident about the protection of their intellectual assets, they were more prompted to transfer production or licensing or simply. And as they were more realistic, patenting aimed to deter local competition (blocking entry).

Contrary to the previous study, Pazderka (1999) identified a statistically significant increase in Canadian corporate pharmaceutical R&D (both by multinationals and domestics) after 1987. Yet the author suggests that this trend should not be attributed exclusively to patent protection since the industry had made an extensively public commitment to increase its R&D spending a long time ago when demanding the reinforcement of patent laws.³

2.1.2. The Effects of Patent Protection on Commercial Transactions

Finally, when strengthening their IPRS regimes, developing countries hope to attract greater inflows of technology. There are three interdependent channels through which technology is transferred across borders. These channels are international trades in goods, foreign direct investment (FDI), contractual licensing of technologies and trademarks to unaffiliated firms, and joint ventures. Economic theory finds that technology transfers through each channel depend in part on local protection of IPRS, albeit in complex and subtle ways.

³ For the case concerning the impact on R&D aiming to find cures for developing countries' diseases, the only work available to our knowledge is that of Lanjouw and Cockburn (2000, 2001). Through the analysis of survey data and a variety of statistical sources (patenting, NIH granting awards activity and bibliometric data) they find some, although limited evidence, of an increase in the mid-to late 1980s in the R&D activity focused on tropical diseases particularly for malaria, which appears to have leveled off in the 1990s. However, this percentage remains still very weak compared to other therapeutic areas. For instance, never is patenting related to tropical diseases more than about 0.5 % of overall pharmaceutical patenting.

Specifically, stronger patent protection can influence the extent of commercial transactions between innovating and developing countries at different levels. First, if imitation allowed southern countries to achieve an important exporting activity by facilitating imitation skills, then a tightening of IPRs would reduce this kind of trade (and a potential loss of variety). Such an effect would reduce world transactions if patent owners were not sufficiently stimulated by stronger intellectual property rights to increase the commercialization of original products (the lack of appropriate IPR protection has been pointed as a non-tariff barrier, as is justified by WTO intervention). Secondly, patents can affect the commercialization strategies of patentees by affecting the trade-off that firms face when deciding to serve a foreign market: exports, FDI, licensing or joint ventures (see Maskus for a discussion, 1998).

According to Maskus (1998, 2000), two potential effects can emerge when considering the impact on trade: a contraction of exports as protected firms exercise *stronger market power* (increasing prices and reducing exports) and an *expansion of trade* because such firms would experience higher demand for their products. When studying the impact of cross-country differences of IPRs on the bilateral trade of countries, the main findings of empirical studies are the importance of the interplay of a country's economic development (variables) on the extent of the impact of IPRs. Ferrantino (1993) and Maskus and Penubarti (1995) have found though, that weak patent rights may cause imports to fall from their expected levels. However, later studies (Maskus and Penubarti, 1996; Fink and Primo Braga, 1999) suggest that the impact varies indeed from one industry to another. The exports of patent-sensitive sectors may in fact not be correlated to the strength of patent protection, or simply it would appear that the *market power effect* may be more important than the *market expansion effect* for high technology industries, reducing trade flows or simply, trade is reduced because firms shift to FDI. Fink and Primo Braga (1999) find a positive relationship between IPR protection and total trade flows, through a negative influence of IPRs on high tech trade flows.

As noted in the previous part, the influence of IPR on the volume of FDI is theoretically ambiguous. On the one hand, one may assume that a firm will prefer exports rather than FDI when the host/destination country has weak IPRs, despite lower production costs: FDI and license contracts are deemed to be too risky. Thus, as IPR protection increases, the cost of FDI/license decreases and allows a better exploitation of production costs differentials. Conversely, one may consider that FDI is aimed at deterring would-be imitators since local affiliates may also serve to detect and prosecute infringers. Indeed, the absence of weak patent protection has not prevented pharmaceutical firms from locating in Brazil, Mexico, Argentina. The aim is to deter potential imitators by assuring a local presence in the country (market pre-emption). Finally, as suggested by Viswasrao (1994) and Yang and Maskus (2000), stronger IPRs can induce

licensing activity since patent protection reduces the monitoring and litigation costs, and other enforcement measures.

Little empirical work has been carried out to assess the impact of patent protection on FDI flows. Nonetheless, they suggest a potential negative relationship between a weak patent regime country and the volume of US or European Direct Investment, which seems to be particularly strong for technology-intensive sectors (Lee and Mansfield, 1996; Smarcinszynka, 1999).

3. THE MEXICAN PATENT SYSTEM AND THE PHARMACEUTICAL INDUSTRY

Evaluating the impact of patent protection in a developing country is a complex issue. Two aspects are especially important. On one hand, the very little information available considerably restrains the extent of the analysis. On the other hand, without corporate level data to identify the individual impact of patents (particularly for R&D strategies), the evaluation becomes more complicated in the case of an emerging country. Like many other countries in the mid 1980s and early 1990s, Mexico carried out profound economic reforms such as liberalization, deregulation, etc. while patent reforms were enacted.

Before identifying the effects of patent protection on the pharmaceutical industry, it is important to note the historical evolution of the sector as well as the different industrial policies that have contributed to delineate the industrial organization. As we may suppose, the extent of the implications entailed by patent protection will depend on the heritage left by the no-patent protection regime, particularly, the imitation skills achieved and the nature of competition established between MNs and domestics before the reforms. Finally, the issue of patent protection in drugs should not be dealt with in isolation. We must pay attention to price regulation, the characteristics of the distribution system, public state-buying practices and other aspects concerning the regulation of medicines, including that for generic competition.

3.1. A lax IPRs System and the Infant Industry Hypothesis: the 1950s-1980s

The evolution of the Mexican IPR system has been delineated in accordance with the general economic policy fostered at each period. However, patent protection was introduced contrary to the predictions dictated by the natural evolution of IPR systems, and because of the international pressure of trading partners, that is to say, mainly by the United States. Thus, the first "modern" legislations on Industrial Property (*the 1943 Industrial Property Law and the 1976 Law on patents and Trademarks*) excluded patent protection for pharmaceuticals and chemical products in general, but granted protection for industrial processes. In addition to a strict compulsory licensing system (which was not very successful) and a promoting-technology transfer patent regulation, a strict price control was imposed by the Ministry of Health. Herein, it followed

the recommendations of the World Bank during the 1950s-1960s to ensure access to medicines by poor consumers in developing countries.

The economic goals of this patent system, under the *-imports substitution-* industrial policy, were to facilitate the building of a self-sufficient local industry, to foster vertical integration and to ensure an adequate supply of medicines. Patent restrictions have traditionally been perceived by most countries as an instrument for spurring entry, creating capacity and developing the technological skills of the domestic drug industry. However, these "protectionist" policies have not always succeeded in ensuring a strong position for domestic firms in the local pharmaceutical market or a strong technological capacity, except for some very few successful countries. We can appreciate for instance the explosion of domestic firms in India and Argentina and their respective successful positioning in the market. On the contrary, the absence of patent protection indeed stimulated the entry of numerous domestic firms in countries like Brazil, Turkey, Kenya, Colombia, Costa Rica, Kenya (Watal and Mathai, UNIDO 1995), and spurred competition promotion in a certain way. Yet market shares held by foreign firms were higher than 50 % and even reached 80 to 90 % in some cases, and the dependence on most of the bulk drugs imports has strongly characterized the industry (in Brazil, MNs controlled 80 % of total sales in 1989).

The case of Mexican firms is likely to come within this second group. The lax patent system effectively fostered the entry of local firms into the market: the number increased from 60 pharmaceutical firms in the 1940s to more than 200 at the end of the 1980s. At the same time, the number of fine-chemical firms, supplying inputs to the pharmaceutical industry, surged from 6 in the 1960s to 90 in the early 1990s (CEPAL, 1998). Despite the significant production capabilities that local firms had acquired during the previous years for almost all-different therapeutic drugs, vertical integration has always been limited and firms have largely relied on bulk drug imports. Thus, until the 1980s, the Mexican industry was self-sufficient in the production of most medicines, and imports of bulk drugs used to be around 50 % of total inputs.

Multinational firms, mainly oriented to the private market, already controlled 72 % of the total pharmaceutical market by 1982. As for local firms, they concentrated their production mostly on the public sector (which represented 19 % of the total market), a trend that will persist in the coming decades. Thus, it can be noted that this *market "duality"* has facilitated the positioning of multinationals even when patent protection was excluded, since the private market has represented the most significant market in Mexico from the beginning. At that time, the exporting activity of both multinationals and domestics was weak or non-existent, until the mid-1980s. Moreover, it is unclear how the lack of patent protection has affected the technological capabilities of national firms. There is no evidence of a significant R&D activity from 1943 to

1991; this can possibly support the argument that patent protection has limited the incentives for innovation in the Mexican industry.

3.2. Patent Protection and Industrial Deregulation: the 1990s

Like most developing countries since the mid-1980s, Mexico changed its industrial development strategy for the promotion of exports. Additionally, a series of deep changes were enacted then (Dussel, 1998; CEPAL). Amongst them the most important are: a Gradual Price Liberalization of Medicines and Liberalization of imports of bulk ingredients; the Decentralization of the Public Sector Buying Practices (including national treatment for multinationals. Before, when competing for public buying, firms were chosen on the basis of national content, capital origin and prices, thus favoring local firms), and the liberalization of Foreign Direct investment. The Foreign Investment Law (1993) eliminated practically all restrictions to invest in Mexico.

In 1987, Mexico amended the Patent Law, pronouncing the adoption of patent protection for pharmaceuticals beginning 1997, thus allowing the industry a period of 10 years to prepare. However, as a condition to integrate the NAFTA, with the United States and Canada, Mexico had to reform its IPRs system seriously. Thus, Mexico introduced *the Law on Promotion and Protection of Industrial Property* on 28 June 1991. It recognized 20 years patent protection for pharmaceuticals, chemicals, biotechnology, amongst other dispositions, thus invalidating the previous legislation⁴.

On the other hand, realizing the discriminative practices of the Ministry of Health, NAFTA also specifies the public state buying practices issue, an issue that will be negotiated with the American and Canadian governments beginning 2002. Finally, another regulation directly relevant to the pharmaceutical industry is the introduction by the Ministry of Health of *the 1997 General Law of Health*. It promotes the production of generics by domestics, through an institutional definition of generic drugs and conditions to be approved. Therefore, without the option to imitate by the introduction of patent protection, the government has been seeking to foster the Mexican generic industry over the last years in order to stimulate competition in the pharmaceutical off-patent market, offering the lowest prices.

⁴ Patent protection was still deeply reinforced with NAFTA final negotiations since Mexico was required to adopt *pipeline protection*. It thus granted retrospective protection to innovations patented and marketed elsewhere which had not been introduced to Mexico before 1991. NAFTA also prohibits parallel imports, which are assumed to emerge from India and Central-America. In this way, Mexico has a stricter patent system than that required by TRIPs. Moreover, contrary to the countries strengthening their IPRs systems when joining TRIPs, which have been granted with transitional periods, Mexico did not have this opportunity with NAFTA.

3.3. A First Evaluation of Patent Protection in the Mexican pharmaceutical Industry

The evolution of the Mexican pharmaceutical market associated to patent protection can be studied at two levels: first, the pharmaceutical market and secondly, at the level of the fine-chemical industry, responsible for supplying bulk-drugs and active-ingredients. Contrary to the pharmaceutical markets characterizing some developed countries, the Mexican market has been traditionally divided into three sub-markets: the private market (covering prescription drugs, over-the counter drugs), the generics market and the public-sector market where most commercialized drugs are off-patent drugs. When evaluating patent protection we also have consider the impact on the production chain, particularly in the fine-chemical industry, responsible for supplying bulk drugs (active ingredients) to the pharmaceutical industry.

3.3.1. Market Structure and Drug Price Evolution: why such a Displacement of Local Firms?

3.3.1.1. The Pharmaceutical Industry

According to *CANIFARMA*, the Pharmaceutical Industry National Chamber, out of the 225 pharmaceuticals firms producing drugs at the end of the 1980s, only 178 were reported at the end of 2000 (*CANIFARMA*, 2000). As was expected, the industry has shown a concentration trend over the last decade: the first 10 firms increased their market share from 28.2 % in 1988 to 34.24 % in 1998, the first 30 firms, from 60.3 % to 72.1 % (see figure n° 1 and n° 2). While some firms disappeared indeed, others have been acquired by Multinationals (in fact the pharmaceutical industry has seen important mergers and acquisitions during the last years).

The private market, mainly represented by multinationals, increased from 72 % in 1982 to almost 80 % in 1998-1999, the remaining 15 % account for the public market and 5-6 % for the generics sector. The market share of multinationals has remained relatively stable and the patent effect may indeed have contributed to that 6 % increase of the market. An aspect that can explain this weak participation of domestic firms in the private market is the relatively low cost incurred to compete in the increasing public market, and the higher and fairly prohibitive cost to develop their own brand-name drugs. Furthermore, since the Public Sector was their only buyer, and was in addition in charge of the packaging and distribution (and pricing) of these medicines through the public institution network, domestic firms did not have incentives to invest in brand, image and commercialization. This inertia has thus contributed to delay the marketing skills of domestic firms; indeed, there has never been any trademark recognition for these medicines (considered traditionally as generic drugs).

Mexican domestic firms have not been very entrepreneurial to invest in R&D efforts for developing new molecules either.

Other factors have also contributed to this configuration, delimiting the extent of patent effects on the market structure. In the absence of patent protection, multinational firms have played the strong trademark promotion strategy and product differentiation, in order to ensure market power facing other multinational firms and imitators. Competition with local firms has been limited to low prices, when firms compete for the government drugs buying-offers. Thus, the importance of *brand name* drugs position on the private market even before patent reform could have limited to some extent any dramatic change in monopoly pricing.

3.3.1.2. *The Fine Chemical Industry*

Contrary to the pharmaceutical industry, the chemical sector, the supplier of pharmaceutical inputs, has suffered a more striking evolution. As noted by Scherer and Weisburst (1995) for the Italian case, patents may affect the degree of a country's self-sufficiency, and thus its trade-balance, by displacing local producers of on-patent active ingredients (imitators) and other chemical inputs. Out of those 94 firms producing in 1987, only 35 still exist. This erosion of the fine-chemical industry in favor of bulk drugs imports is reflected in the national content of production: from 1991 to 2000, national inputs fell from 80 % to 20 % and the number of products decreased from 259 in 1987 to 105 in 1998.

However, the main factor fostering this trend seems to be the elimination of 82 tariffs for bulk-drugs in 1989, when the sector began to liberalize. It is difficult to conclude that patent protection in 1991 could have contributed to this loss of self-sufficiency (in 1992 the industry accounted for 48 firms, in 1998 for 34). Moreover, local executives suggest that this downward trend might continue in the coming years because of the increasing competition by India and China in the world market for bulk drugs. The extreme low-production cost offered by these countries would reduce the opportunities to compete for Mexican firms. As we noted before, intra-firm trade can be used strategically by multinational firms due to the leeway it allows through the over-invoicing practice (to charge higher prices on final products). Finally, in order to ensure their reputation, firms are sometimes reluctant to contract local suppliers because of the high-quality production standards required for medicines, which are not always guaranteed by domestic firms.

3.3.1.3. *Prices*

While it would be more useful for the analysis to get reliable data concerning prices for both on-patent drugs and off-patent drugs, the evolution of the pharmaceutical products price index compared to the general price index of the economy index suggests some points (figure n° 3). Indeed, this rather crude

index shows an inflexion point: while the industrial index shows a decreasing trend compared to the general price index before 1991, an emerging upward trend can be noted since patent reform. Although prices seem to have increased by 20 to 25 % in 1992-1993, these figures are far from those predicted in the literature. Different factors have contributed to this rather relative extent of monopoly pricing.

First, it should be noted that on-patent already enjoyed an important market share before patent reform due to strong brand promotion and product differentiation. Secondly, price controls were eliminated during the 80s and current pricing strategies follow the leader drug pricing strategy (the highest price). Finally, production strategies of importing bulk drugs increase prices through the transfer price loophole, in addition to *what the market can bear* pricing strategy.

As noted by Lanjouw (1998), some confounding factors have to be taken into account when evaluating the patent impact on prices. Although the current demand for prescription drugs (of which mostly are on-patent drugs) is rather weak, Mexico will probably experience a growing demand for prescription drugs in the short run. Increasing private insurance coverage is one of the aspects that enhances this trend (the insurance markets will be deregulated, an issue also negotiated in NAFTA). On the other hand, as has been previously noted, the market share for patented medicines in many developing countries constitutes less than 10-15 % of the total market (Lanjouw, 1998). Therefore, the patent impact on prices in the short run must only affect a segment of the drug market. Governments should carefully monitor prices in order to prevent or correct unjustified price increases through different public policies. Governments ought to identify then whether other elements push prices up, and whether such factors contribute or not to restrain access to drugs by consumers.

Patent protection laws with novelty criteria promoting narrow patents may stimulate competition from substitute products or *me too* drugs, limiting the extent of the exclusivity of innovating drugs over a therapeutic group, and thus stimulate price competition. Finally, patent protection should not restrict generic entry and developing countries are free to implement generic promoting policies –*the Bolar exemptions*–, etc. (Maskus, 2000). Therefore, the impressive explosion of generics current in Mexico can exert some pressure to reduce prices for off-patent drugs, crowding out the potential monopoly pricing of new drugs introduced on the Mexican market.

3.3.2. Trade Trends

Liberalization policies have contributed –as in many other sectors– to increase imports, deteriorating the national value added in the production system. Therefore, it is difficult to conclude that patent protection has indeed

consolidated this trend which already appeared a few years before. The pharmaceutical industry has shown an increase in its trade deficit during the last decade (see table n° 2). From 1990 to 1998, the trade balance achieved \$18,000 million USD (\$2,000 million annually), particularly because of the persistent dependence on imports of bulk drugs that has been exacerbated since the elimination of most important tariffs in 1989. However, it must be noted that despite this industrial weakness, exports of pharmaceutical products have shown an important growth rate (40 % for the period 1990-1998, mainly due to the dynamism of some health auxiliary products other than drugs). The main destination countries for Mexican drug exports have been and still are Panama, Colombia, Venezuela, and some south-American countries.

We must be cautious when interpreting these trends relative to the patent reform, because in addition to the liberalization of bulk drug imports, firms did no longer have to comply with national content requirements. Similarly, long authorization procedures to import pharma-chemicals that were produced locally were also eliminated. It must also be noted that exports by Mexican firms have been rather weak. Indeed, the international trade of drugs faces important non-tariff barriers, mainly the stringent and costly approval standards required by Health institutes abroad. For instance, the Food Drug Administration (FDA) of the United States requires firms that want to commercialize drugs in USA, to comply with *Good manufacturing practices* (and *good clinical practices*), and also imposes an important liability system in case of risk for public health.

These *entry barriers* to the world generic market, is currently being exacerbated because of the multiple strategies followed by multinationals to extend their monopoly beyond patent expiration and to hold-off generic competition. Amongst them is the current lobbying by multinationals to restrain generic producers to exploit test data before patent expiration, delaying thus the entry of generics. Another possibility is the strategic patenting around the drug's chemical reaction, which extends patent life on the main drugs commercialized.

3.4. Innovation Activity and Diffusion

3.4.1. Diffusion by Patenting

As expected, patenting by multinational firms shows a hike following the 1991 patent introduction for pharmaceutical products (see figure n° 4). The number of patent applications was reduced during 1993-1994, mainly because multinational firms waited for the final legislation on IPRs, which actually did not change. However, the internal rules framework for the Mexican Institute for Industrial Property (IMPI) was published.

The importance of this upward trend would be significant in terms of *dynamic gains* if these numbers meant indeed that an increasing number of drugs had been commercialized since 1991. It has been estimated that more than

20,000 drugs are currently commercialized in industrialized countries and fewer than 10,000 drugs in the developing world. (CEPAL, 1999). Therefore, it would be interesting to compare this patenting activity to the number of applications presented before the Ministry of Health for approval of new drugs to be commercialized (and to see what the arrival rate of new drugs was like before patent protection). If these trends diverge, patenting by multinationals would only deter production by local firms. If they are not used later either by multinationals or nationals, these sleeping patents will only block competition, at the expense of local consumers' welfare. An analysis of the quality and scope of patenting could also give useful insight on whether ever-greening patenting might be closing-off inventing around opportunities.

Despite this increase in patenting applications by foreign firms, the patenting of domestic firms never amounts to more than 1 % of total numbers. The reason explaining this trend relies on the weak R&D activity in the Mexican Industry. It is worth mentioning that this increased patenting has not been translated into more "information-diffusion gains" (*disclosure*). This is due to the fact that the main problem to exploit the information content on patents by Mexican firms is not the access (IMPI, supported by the American government, introduced an important computer system containing international patent data), but rather the weak interest in or the weak usage of patent data by Mexican firms and institutes when studying or developing technological innovations.

3.4.2. R&D Activity

Given the hierarchical nature of the pharmaceutical industry and the traditional concentration of the corporate R&D laboratories in the countries of origin (and other industrialized countries), one should not expect an increase in R&D investment by MNCs in the developing countries following the patent reforms. As the current re-organization trends of the innovative process in the pharmaceutical industry may suggest (inter-department links, the scale economies sought within the different R&D projects conducted by the innovating firm), it seems that the trend towards the concentration of innovative activities will continue for a while. It also appears that other factors besides patent protection must emerge strongly before a firm decides to locate an R&D activity in a developing country. Amongst these factors, a more coherent and active science and technology policy must be implemented for instance, conciliating Academic and Public R&D efforts, and the pharmaceutical industry R&D activity.

Owing to the difficult access to R&D data at the corporate level, we are not able to detect any potential change in the R&D investment of Multinational firms in Mexico. However, according to the AMIIF (Mexican Association of Pharmaceutical Researchers), multinational firms have increased their development activities, which are mainly related to clinical trials and other

customization-related activities. The average R&D ratio to sales for the chemical industry surged from 0.8 % in 1989 to 2.9 %, but is still lower compared to the current 18-20 % ratios invested by the largest pharmaceutical firms (CONACYT, CIS, 1998).

However, we must say that it is still too early to detect a significant increase in R&D investment and new drugs introduced by Mexican firms in the short run. Indeed, the average development time for a new chemical entity is between 8-10 years. Nevertheless, thinking about a global market (and economic efficiency) where northern countries develop technological innovation more easily than southern countries, must innovation by domestics necessarily be a reason for concern? Is it still valid to expect increased pharmaceutical R&D in southern countries following patent reforms? It would be more important to determine whether innovations are indeed available and affordable for consumers in southern regions, innovations that will be developed at any rate by the more efficient and -knowledge embedded firms.

Entrusting research and development activities with domestic firms is still far from being promoted by multinationals. Nevertheless, the IMPI points that few local firms are making R&D efforts and embracing the new patent regime, some of them currently preparing their patent applications for new pharmaceutical preparations.⁵

3.5. Foreign Direct Investment and Licensing Trends

According to a multinational executive, patent protection has stimulated the entry of firms that were previously reluctant to set up in Mexico, and the expansion of those firms already settled. Indeed, only 18 multinational firms were established in Mexico in 1987, whereas today they are 28 foreign pharmaceutical firms (CANIFARMA). Looking at the statistical figures which are desegregated only since 1994, FDI in the pharmaceutical industry almost doubled from 157 in 1994 to 312 million USD in 1999, though it is not clear to what extent this answer is related to the expanding-market effect implied by NAFTA (introduced in 1993) or to the reinforcement of IPRs (Ministry of Economy, DGIE). Nevertheless, it seems that investment activity will show a positive trend for the coming years, according to AMIIF (Pharmaceutical Industry Mexican Association). Indeed, multinationals plan to invest 830 million for the following three years.

⁵ Concerning the nature of R&D projects, Mexico is an interesting market to commercialize soon new drugs (adapting drugs to local needs) because the most common diseases of the population can be found both in the developed and the developing world –diabetes, hearth-related diseases and infective, parasitic and nutritional diseases. It would be interesting therefore to identify the R&D strategies currently followed by both national and multinational firms in terms of the type of disease they are covering.

As suggested by other executives, MNs expect to increase FDI in Mexico, among other reasons, because of the increasing importance of the Mexican market, the increased confidence in patent reforms, and the opportunities to supply Central and South America through the Mexican low-cost production plants. As these trends suggest, patent protection is important when firms decide to transfer production overseas. However, as has been suggested by Mansfield survey studies (1994, 1995), multinationals also take into account other factors when making decisions concerning their location, the most important being: market size, resource advantages, the health care system, the need for a technical presence to support local sales, etc.

It is difficult to have data on licensing because since 1987 firms have no longer been required to declare technology transfer contracts before authorities (elimination of the 1976 Technology Transfer Law). Thus, according to the IMPI records, those few firms declaring their activities, state that there are currently fewer than 40 licenses for pharmaceutical preparations, which emerged since 1991. However, most of these licenses concern technology transfers from headquarters firms to subsidiaries in Mexico, for example, Beecham Group PLC to Smithkline Beecham Mexico, Glaxo Group Limited to Glaxo Wellcome Mexico, etc. Therefore, licensing activity promoted by patent protection has been rather weak compared to the strong emerging trends in other countries like India (which has been required to grant exclusive marketing rights, *EMRs* under TRIPs).

Yet current trends in the global pharmaceutical industry fostering the international optimization of production systems suggest an increase in licensing, and manufacturing outsourcing, especially for fine chemical intermediates and active ingredients. As these activities represent less than 5-6 % of the total costs, pharmaceutical firms prefer to concentrate on the final production of formulations, marketing and distribution, and R&D activities. Increasing licensing activity for bulk drugs (off-patent mainly, and to a lesser extent on-patent) and drugs whose patents will soon expire, are supposed to increase in the coming years for another important reason. Through licensing, innovating firms seek to restrain competition from generic producers by making alliances on expiring-patents drugs, attempting to keep their market shares on best-selling drugs.

4. CONCLUDING COMMENTS

Economic theory studying the impact of IPRs protection in developing countries predicts ambiguous effects on economic transactions and welfare. Most of the studies conclude that patent protection will largely entail a negative effect on welfare in the short run. Yet some elements can limit the extent of price increases, particularly when the pre-patent market structure was already dominated by multinational firms and when the market share of patent drugs is considerably lower than that concerning off-patent drugs.

Regarding the pharmaceutical industry, one could expect large answers in terms of investment, technology transfer and R&D activity since patent protection stands as the most important appropriation strategy in this sector. However, the impact of patents on economic strategies is a complex issue to analyze to the extent that other aspects interplay with patent protection. Some such elements are the questions when pharmaceutical firms decide to invest in some R&D specific disease, which particular country they decide to invest in, and whether or not they want to launch a drug on a developing country market. *A priori*, it is not clear how (additional or stronger) patent protection in these countries may affect commercialization and investment decisions, since international market prospects are without doubt one of the most important elements for pharmaceutical firms. While the access to more detailed data could make the analysis richer, some points can be suggested for the Mexican case.

As in the case of Brazil and Turkey, the absence of patent protection did not prevent multinationals firms from breaking into the Mexican market and ensuring an important market share. A strong brand promotion and product differentiation strategies have played a significant role to exert market exclusivity in the absence of patent protection. Moreover, this configuration has been facilitated by the existence of a dual pharmaceutical market (private and public) where local firms have traditionally concentrated their production on the public sector market, thus delaying their commercialization skills to compete on the private market. Therefore, when evaluating patent reforms, it is important to look at the distribution system and the importance and weight of public-sector buying in the pharmaceutical market. It is equally interesting to examine the extent to which these factors can increase or restraint the patent effect on prices and on the commercialization of new drugs.

It is difficult to conclude to what extent patents may have consolidated the already deteriorating trade balance. As in the Italian case, patents may have contributed to replacing local suppliers by imports, a trend that has emerged since 1989 when liberalization began. In addition, patent protection and NAFTA seem to have strengthened FDI since the number of multinationals located in Mexico increased after the patent reform and there is an upward trend in the figures. Nevertheless, the effect on licensing remains to be seen, as there has not been any significant change in licensing activity by now.

Given the shift from imitative R&D towards innovative R&D is prohibitive for most local firms, except for very few cases, an important number of Mexican firms are recently emerging on the private market by competing in the generics sector. In this way, the introduction of patent protection might provoke a market polarization. On the one hand, there is a highly elastic market relying on the lowest prices (off-patent drugs) on which previous imitators are currently focusing. On the other hand, there exists a less-elastic market where innovators and a few emergent groups of local firms compete inventing around

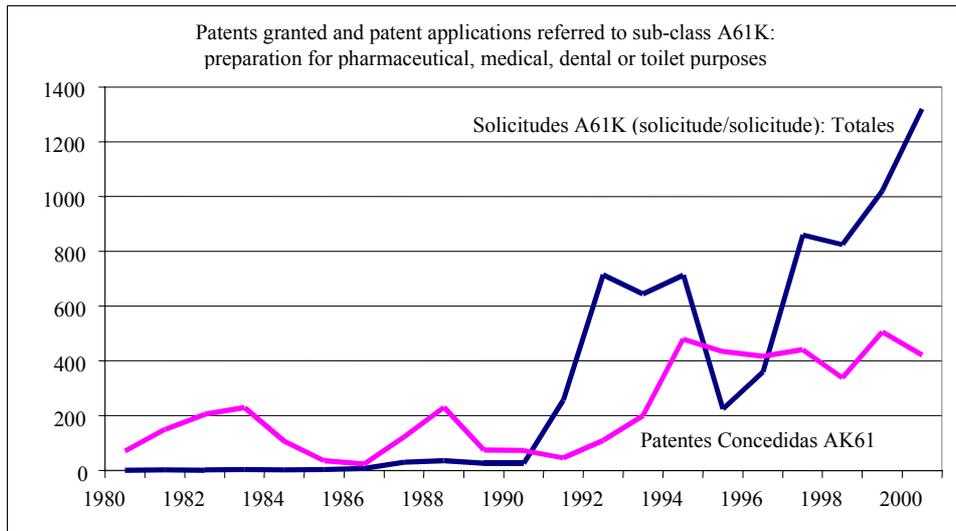
patents (technology-followers). The risks are nevertheless, that the first market segment might find difficulties to access new and better medicines which would be commercialized only for the rich market.

Regarding overall R&D activity, ten years after patent protection was introduced, technological creation in the Mexican pharmaceutical industry is still negligible. However, it is still too early to have a significant change in R&D patterns, since a new chemical entity requires 8-10 years to be developed. This suggests that dynamic gains are still far from being felt and a redefinition of a more active public policy concerning science and technology is needed to stimulate research and development efforts. Reinforcing patent protection will not automatically change the access and the ways to finance R&D projects. Neither can the technological capacity to develop new drugs by domestic firms dramatically change in the short run. However, since markets are global, and according to economic theory and the predictions about economic efficiency, technological innovation will emerge where the conditions to create knowledge are the best. It remains to be seen to what extent patent reforms stimulate or deter a faster commercialization of these pharmaceutical innovations in the developing world.

The policy challenge faced by governments strengthening their IPRs is therefore how to conciliate or to complement patent reforms with industrial goals, such as the building of a generic industry, and how to respond to urgent social needs such as ensuring access to medicines for poor consumers. Through a better understanding of these issues, further research is necessary to facilitate the correct policy making.

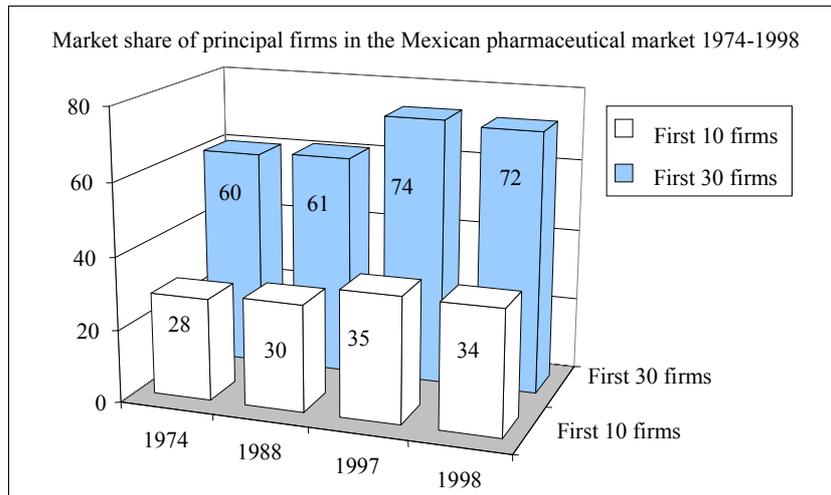
APPENDIX

Figure n° 1: Number of Firms in the Pharmaceutical Industry



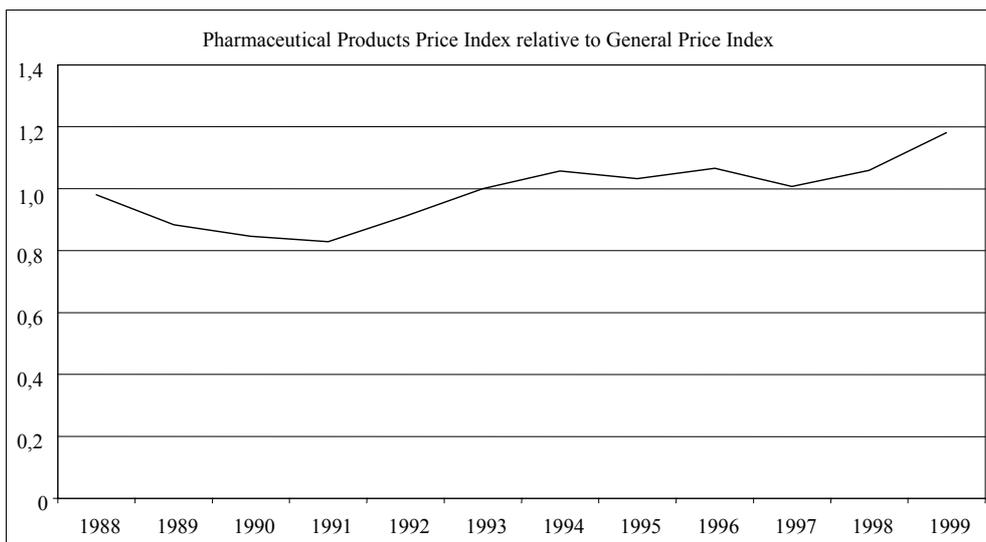
Source : CANIFARMA, CEPAL, 1998.

Figure n° 2: Market Concentration in the Pharmaceutical Industry



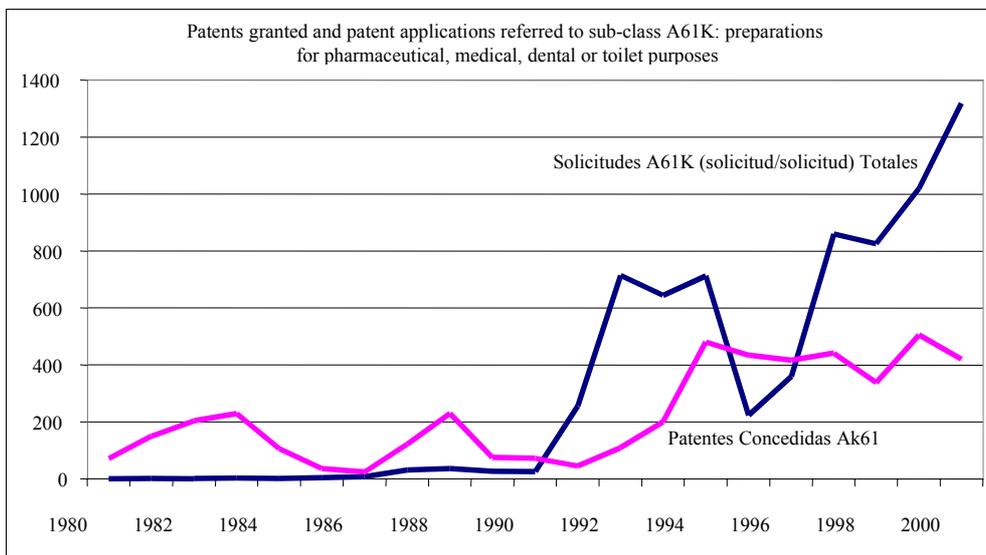
Source: CEPAL, 1998.

Figure n° 3



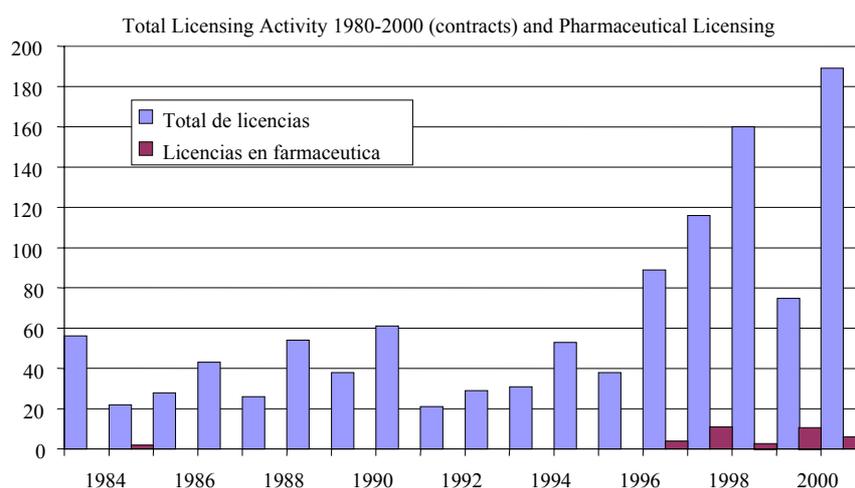
Source: INEGI.

Figure n° 4: Patenting Activity in Pharmaceuticals



Source: IMPI (Mexican Institut of Industrial Property).

Figure n° 5



Source: IMPI.

Table n° 1: Evolution of the Pharma-Chemical Industry

	1987	1989	1992	1994	1995	1998
Number of firms	94	-	48	0	0	34
Number of products	259	-	130	0	0	105
Total sales (million pesos)	-	683	512	590	595	-
% of firms under sales control (importing authorization)	-	30 %	45.4 %	43.78 %	61.8 %	-
Employment	-	3668	3317	2850	2720	-

Source: Dussel, CEPAL, 1998.

Table n° 2: Pharmaceutical Industry Trade Balance (Million USD 1994)

	1990	1991	1992	1993	1994	1995	1996	1997	1998	1990-1998
<i>Exports</i>	264	789	1159	1271	1384	1618	2197	2895	3738	1,5315
Drugs	27	42	64	78	115	172	248	319	40	1,469
PAPS	79	559	878	960	1003	1099	1601	2199	2778	11,156
Chemicals	159	187	216	232	265	347	349	376	558	2,689
<i>Imports</i>	1934	2662	3065	3336	3941	3510	4245	4920	5360	32,973
Drugs	81	137	166	232	321	287	376	485	613	2,697
PAPS	484	924	1108	1281	1641	1304	1488	1698	1925	11,854
Chemicals	1369	1601	1791	1822	1978	1920	2381	2737	2822	18,421

Source: INEGI.

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RÉFORME DES BREVETS DANS LA PHARMACIE : UNE PREMIÈRE ÉVALUATION DU CAS MEXICAIN

Résumé - Depuis 1991, la nouvelle loi de propriété industrielle a profondément renforcé la protection des brevets pharmaceutiques au Mexique. L'objectif de cet article est d'apporter une première évaluation des effets statiques et dynamiques qui peuvent en résulter. Bien que la plupart des travaux prévoient une perte importante en termes de bien être à court terme, il s'avère que la structure de marché constituée avant la réforme des brevets peut atténuer l'impact sur les prix et la configuration du secteur. L'absence de protection en matière de brevets n'a pas entravé dans le passé l'implantation des firmes multinationales ni l'acquisition d'une part significative de marché, leur compétitivité étant basée sur la différenciation des produits et la promotion des marques. L'investissement direct étranger est en croissance mais il semble que les gains dynamiques sont encore faibles, voire nuls, et qu'il est nécessaire de considérer d'autres éléments (de politique industrielle et technologique) avant d'assister à un développement accru de l'activité de Recherche et Développement des firmes.

**REFORMAS DE LAS PATENTES EN LA FARMACIA:
UNA PRIMERA EVALUACIÓN DEL CASO MEXICANO**

Resumen - Desde 1991, la nueva ley de propiedad industrial ha reforzado mucho la protección de las patentes farmacéuticas en México. La meta de este artículo es dar una primera evaluación de los efectos estáticos y dinámicos que pueden resultar de ello. Aunque en la mayoría de los trabajos una pérdida importante en término de bienestar a corto plazo está prevista, vemos que la estructura del mercado constituida antes de la reforma de las patentes puede atenuar el impacto sobre los precios y la configuración del sector. La ausencia de protección de las patentes no impidió en el pasado la implementación de firmas multinacionales ni tampoco la adquisición de una parte significativa del mercado, la competitividad siendo basada en la diferenciación de los productos y la promoción de las marcas. La inversión directa extranjera va creciendo pero parece que las ganancias dinámicas siguen siendo todavía bajas, casi inexistentes, y que hace falta considerar otros elementos (de política industrial y tecnológica) antes de asistir a un desarrollo fuerte de la actividad de investigación y desarrollo de las firmas farmacéuticas.