The Evolution of Brazil's Regime of Intellectual Property Rights and the Accumulation of Technological Capabilities in the Pharmaceutical Industry

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Abstract

The aim of this paper is to analyze the economic policy influence in the low accumulation of technological capabilities in the Brazilian pharmaceutical industry. The weakness of the local pharmaceutical industry and the need to develop domestic capabilities necessary in order to address local public health needs were key reasons for the decision to suspend the patentability of pharmaceutical products in the 1945 law. The events taking place in the industry during the following decades, specially the industrialization policy adopted in the 1950s which offered strong incentives to foreign direct investments, were however at odds with the goal to promote the growth of the Brazilian pharmaceutical industry. The foregoing transformations suggest that while the prohibition of pharmaceutical product patents since 1945 failed to promote a significant process of technological upgrading of the domestic firms, neither did it discourage the entry of multinational corporations.

1. Introduction

The development of the Brazilian economy provides a very interesting perspective on the role of Intellectual Property Rights (IPR) in the process of accumulation of technological capabilities. This is because Brazil was one of the earliest adopters of a regime of protection of the rights of inventors. Indeed, it developed a regime of patent laws before Portugal, of which the country was a colony until 1822. While Brazil was then among the pioneers worldwide in recognizing the social value of inventive activities and the importance of protecting and rewarding the work of inventors, both the industrialization of the country and the development of technological capabilities have lagged significantly behind the creation of patent laws.

Accounts of Brazilian economic development identify in the last quarter of the nineteenth century a first phase of progress in the transformation of its productive activities. However, a sustained process of industrialization began only after the Great Depression, when the collapse of an economic model based largely on the export of primary goods, most notably coffee, promoted the adoption of national economic policies whose intended purpose was to enable the growth and diversification of the industrial sector of the country. These policies, pursued more or less throughout the following half a century, coincide with a substantial increase in the rate of growth of GDP per capita beginning in 1930 and lasting until the early 1980s.

Whereas the country's economic performance lagged behind that of the advanced economies, Brazil was among the world pioneers in the adoption of IPR legislation. Inventors' privileges were first recognized in 1809, and Brazil's first patent law dates back to 1830. This law held that foreign inventions could not be patented in Brazil, a provision that was abolished formally in the revised patent law of 1882, which adopted the Paris Convention principle of national treatment. Even then, technologies patented in Brazil had to be worked in the country subject to forfeiture of patent rights until 1923 and to compulsory licensing since then. Brazil exploited also the freedoms provided by the Paris Convention in the direction of identifying non-patentable subject matter. Thus, since 1945, inventors of chemical products, food preparations, and medical procedures were excluded from the patent privileges. Chemical processes were added to this list in the 1969 patent law. These exclusions were modified again in 1996 in order to comply with the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement. The most important modification concerned the patentability of chemical processes and products.

While Brazil adopted relatively early a comprehensive regime of protection of IPR, the working requirement placed foreign firms at a relative disadvantage, insofar as importation of patented goods into Brazil was not considered an acceptable form of meeting the requirement at least until the patent reform of 1996. The law therefore attempted to strike a balance between providing incentives for invention and promoting the diffusion of technological advances in domestic production activities.

As we will argue in the rest of the paper, the history of Brazil's pharmaceutical industry suggests that the regime of IPR played a weak role either facilitating or hindering the learning processes by which domestic firms have mastered key technologies from abroad. One of the main reasons for this includes the industry "denationalization process" in the 1950-1980 period.

2. The evolution of Brazilian patent law

The historical origins of Brazil's system for protection of intellectual property can be found in the early nineteenth century when the country's economy consisted mostly of agricultural activities dominated by coffee and sugar cane. Reversing a long standing policy stance designed to stifle the development of any branch of industry in Brazil, the Portuguese rulers (inspired by similar legislation in the U.K. and the U.S.) signed a decree in 1809 establishing that exclusive privileges be granted to "inventors and first adopters of any new machine or invention in the arts."[1] The decree provided for the examination of inventors' or adopters' petitions and established a working requirement whereby inventors had to practice the invention locally within two years or lose the patent privilege. The impact of the regime created by the 1809 decree was modest. Only 26 privileges had been granted by 1830 when the first Brazilian patent law came into effect (RODRIGUES, 1973).

While preserving many basic features of the existing system (novelty and usefulness requirements), the 1930 law changed the duration of patents (between five and twenty years depending on the significance of the patented invention) and provided for the patentability of improvements over existing techniques. Another novelty was the substitution of the exclusive commercial privileges for first adopters of foreign inventions (whether patented abroad or not) with a monetary prize. If, as argued by Rodrigues (1973), the Brazilian government never made any budgetary allocation to provide these financial rewards, the provision eliminated any legal incentive to the adoption of technologies invented and patented abroad. To be sure, dissatisfaction with the legal bar against granting patents on foreign inventions built up since the 1860s and patent grants to foreigners, as for example in the case of Thomas Edison in 1879 (RODRIGUES, 1973 p. 662.), were being made even before the provision was repealed in the new patent law of 1882.

The new law (drafted while Brazil participated in the meetings of international delegates that produced the Paris Convention in 1883) incorporated the key principles of the convention, including rules on priority claims and the principle of national treatment of foreign inventors

[1] During the colonial period, the Portuguese rulers discouraged the development of industry in Brazil. The most drastic measure was taken in 1785 by Queen Maria of Portugal, barring all manufacturing activities in the fields of metal products, textiles, and the processing of gold. When the royal family fled from Portugal under British naval protection in 1808, Brazil became the political center of the Portuguese kingdom for a thirteen-year period. Only then, the conditions of Brazil's cultural and economic development began to receive greater attention, and a number of legislative measures were taken in order to promote the modernization of the country.

(GRANSTRAND, 2005). As a result, foreign inventions could be patented in Brazil. In addition to minor changes in patent duration and details of the working requirement, the new law abolished the examination procedure for all patent applications except for those concerning food products, chemicals and pharmaceuticals. These changes contributed to a drastic increase in the number of patents granted. Under the rules of the 1830 law, 677 patents were granted in 52 years. During the first nine years of the new patent regime, 1247 patents were granted. This increase was driven not only by the more favorable conditions of patentability and the extension of patent privileges to foreigners, but also by the increase in the volume and range of industrial production in Brazil since the 1870s (CRUZ and TAVARES, 1986).

During the first half of the twentieth century the regime of IPR was altered twice, in 1923 and 1945. The 1923 patent law restored the examination procedure for all applications, and mandated the publication of invention summaries at the same time that it outlined an external opposition procedure. It also created for the first time the "utility model" patents for minor inventions with a duration of ten years. More importantly, it established that the importation of goods protected by domestic patents constituted a violation of the rights of patent holders. The Code of Industrial Property ratified by the Brazilian government in 1945 modified the working requirement, outlining a procedure for the granting of compulsory licensing after two years of inaction by the patent holder. It also introduced new restrictions on the definition of patentable subject matter. Patent rights were denied on foodstuffs, and materials or substances obtained by means of chemical processes, thus including pharmaceutical drugs. According to Cassier and Correa (2007, p. 85), these changes aimed at promoting the development of specific sectors of the national economy. In particular, the bar on the granting of patents on pharmaceutical preparations reflected President Vargas' twin goal of promoting the progress of public health and of the domestic pharmaceutical industry. These policy goals were also central to the changes in the IPR's regime wrought by the 1969 patent law, when the military government broadened the definition of non-patentable subject matter to include pharmaceutical processes, as well as products, surgical and therapeutic techniques, as well as any use of microorganisms. With this reform, patent protection ceased to be available altogether for the pharmaceutical industry until 1996.

The 1996 patent law reflects fundamental changes in the overall orientation of national economic policies in response to the economic stagnation of the 1980s and to the growing

pressures from the country's trading partners toward market-oriented reforms and a greater level of protection for the rights of foreign inventors. The inclusion of the TRIPS agreement in the WTO treaty left Brazil with no choice but to revise the national patent system. But it is noteworthy that, unlike other developing countries, Brazil complied with the TRIPS standards of patent protection in 1996, almost a decade earlier than required by the agreement. The decision to comply with the TRIPS agreement ahead of schedule has been argued to reflect the economic pressures brought to bear by the U.S. on the Brazilian government since the late 1980s. Indeed, a legislative proposal had already been formulated in 1991 contemplating a reform of the patent law that allowed the granting of patents on pharmaceuticals (GRANGEIRO and TEIXEIRA, 2007).

The most significant changes wrought by the 1996 reform concerned the definition of patentable subject matter. The restrictions on the patentability of pharmaceuticals and food products were lifted, while computer programs per se, surgical and therapeutic methods, living organisms and biological materials and processes found in nature, were identified as non-patentable subject matter. The duration of utility model patents was extended to fifteen years from filing date (with a minimum of seven years from the grant date), at the same time that they were made subject to an inventive step requirement. Exploiting the flexibilities afforded by the TRIPS agreement, the 1996 law identified national medical emergencies and failure by the patent holder to supply adequately the domestic market as legitimate reasons for granting compulsory licenses on patented inventions. These stipulations informed the conflict between the Brazilian government and foreign pharmaceutical companies holding patents on antiretroviral drugs (ARVs) covered by domestic HIV/AIDS public health program.

This brief historical overview of Brazil's patent law is clearly focused on the rights of inventors as they are defined by the letter of the law. This approach was motivated by the limited availability of data, and by the lack of prior historical research in the area of IPR enforcement. While it is inadequate for the purpose of evaluating the strength of the protection of inventors' rights over time, this approach provides at least a coarse map of the concerns and goals behind the legislative reforms. In this sense, one can observe that several aspects of the system of patent protection manifest the Brazilian government's keen interest in promoting the diffusion among domestic firms of technologies developed abroad. Others, particularly those concerned with pharmaceutical inventions, signal the subordination of patent laws to the goals of

industrial policy and public health policy. In light of the government's broad commitment to the industrialization of the Brazilian economy, the weaker protection afforded to pharmaceutical and chemical inventions for much of the last century may appear to be puzzling.

3. Patenting activity and inward technology transfer

The accumulation of technological capabilities by domestic firms that accompanied Brazil's economic development reflected for the most part efforts at acquiring and mastering technological knowledge originating from abroad. Indigenous efforts at developing globally innovative products and processes have so far played a much lesser role, although the balance between these modes of knowledge acquisition has been changing over time and presents substantial variation across industrial sector based on the extent to which foreign technologies could address adequately the technical challenges faced by local firms. In the following sub-sections we will sketch an overview of the historical evidence regarding patenting activity in Brazil and several characteristics of inward technology transfer processes. The historical review will set up a brief discussion of current patterns of innovative activity.

Although Brazil adopted a patent system since early in the nineteenth century, the evidence on patenting activities is rather incomplete. Consequently, existing studies shed light only on patenting during the nineteenth century and then again only in the 1980-1995 period. With respect to the former period, patenting activity has been found to mirror quite closely the structure of industrial activities (CRUZ AND TAVARES, 1986; RODRIGUES, 1973), with three sectors (foodstuffs, metal products, chemicals) accounting for about 60% of all patents granted between 1830 and 1891. We note here that Brazilian law stipulated until 1882 that prizes would be awarded (but not patents) to individuals or firms who introduced technologies already available abroad. Moreover, the 1830 patent statute required that inventors exploited their patents domestically. These provisions weakened substantially the incentives for foreign firms to seek patent protection in Brazil.[2]

Figure 1 illustrates the available data on the number of patent applications since 1883. A break in the secular growth of patent applications occurred around the mid-1960s and lasted until

[2] There is no record of any prize ever been awarded to first adopters of foreign technologies (RODRIGUES, 1973). It appears however that patenting of foreign technologies became accepted practice sometime before the legal restriction was abolished by the 1882 patent law. However, this law (and all the subsequent revisions to this day) upheld the working requirement, and thus continued to limit the attractiveness of Brazilian patents for foreign enterprises. A more detailed discussion of these developments can be found in section 3.

the mid-1990s, when the 1996 TRIPS-compliant patent law was enacted. The increase in the number of applications after 1996 is almost entirely attributable to non-resident applicants, who account for more than 80% of the applications filed in 2006.

While patenting data are an important source of information concerning the innovative activities of domestic firms, the process of inward technology transfer that supported Brazil's industrial development relied upon alternative mechanisms. Among the market-mediated channels, the importation of capital goods was in all likelihood dominant. Foreign direct investment (henceforth, FDI) was an important source of access to foreign technologies, one that has been often argued to be sensitive to the strength of IPR protection in the host country. The link between IPR and FDI inflows is complicated further in Brazil by the working requirement for the validity of patents, and by the effects of other policies that strengthened the incentives for FDI independently of the strength of IPR. Note, for example, that the limits to the patentability of pharmaceutical processes and products sanctioned in the patent laws of 1945 and 1969 did not deter FDI by pharmaceutical firms. Indeed, in the aftermath of the 1969 reform, FDI in pharmaceuticals grew from US$ 113 million in 1971 to US$646 million in 1979, more rapidly than in other sectors of the economy (GEREFFI, 1983).

Patents appear to have played a minor role in the context of the technology transfer agreement between resident and non-resident firms. As shown in Table 1, payments for technology transfer agreements (including royalties for patent licenses) increased very rapidly since World War II, more so than capital goods imports or FDI.[3] However, a government study found that patent licensing agreements were not a dominant form of inward technology transfer for Brazil's industrial firms (BIATO et al., 1970).[4] Only 10.5% of the contracts for technology transfer were accounted for by manufacturing and patent licensing agreements. Technical

[3] As a percentage of GDP, payments for technology transfer rose from 0.12% in the 1947-1953 period to 0.31% in 1970. Moreover, their growth outpaced the growth of the imports of capital goods from 1950 to 1970, going from 3.5% of the latter's value in 1950-1953 to 15.9% in 1969.

[4] This study analyzes nearly 2,000 technology transfer contracts registered between 1963 and 1970 with the Bank of Brazil in compliance with a 1962 law regulating technology transfer contracts requiring payments to foreign entities. Such contracts were subject to regulatory approval) and to legal constraints on royalty payments and the assignment of IPR on the result of the licensees' future inventions. Although the study excluded contracts relative to the primary and tertiary sectors, and refined oil products, the industrial sectors within its scope accounted for between fifty and sixty percent of the technology transfer agreement payments recorded in the international balance of payments on account of technology transfer agreements during the period 1965-1970. About two-thirds of the contracts were accounted for by five sectors (Metal Products, Chemicals, Mechanical Equipment, Electrical and Communications Equipment, and Transportation Equipment). These same sectors plus textiles also accounted for two-thirds of the 729 enterprises represented in the database. All of these industrial sectors had experienced a substantial expansion as a result of the import substitution policies pursued by the governments since 1950.

assistance agreements represented the most common type of technology transfer contract (47%), followed by engineering services agreements (23.6%), and trademark licensing agreements (13.2%). At a sectoral level, only a few industries appeared to be characterized by greater reliance on manufacturing and patent licensing agreements (tobacco products, furniture, textile machinery and components), but they accounted for only small shares of all such agreements. In contrast, the share of technical assistance agreements, trademark licensing, and manufacturing and patent licensing in the pharmaceutical and medicinal products sector were respectively 61.5%, 26.7%, and 11.8%. The analysis of the technology transfer payments made between 1965 and 1970 produced similar results.[5]

The observation that patent licensing agreements represent a small share of the registered technology transfer contracts in this study has to be tempered by two considerations. First, the small volume of licensing agreements might be due to the multinational firms' reluctance to patent and license technologies in an environment characterized by weak enforcement of patent rights, something about which we can only speculate. Second, subsidiaries of multinational corporations were prohibited by law from making royalty payments to their mother company abroad on account of patent licenses, so that technical assistance agreements might have served as a way to carry out implicitly a royalty payment. While payments for licensing agreements between subsidiaries and parent companies would be understated as a result, our examination of the data suggests that the effect is qualitatively small.[6]

A parallel investigation focused instead on the production of technological knowledge at firms and public research institutions located in Brazil (BIATO et al., 1970). The investigation of technological activities carried out in the period 1967-1969 was based on questionnaire responses by 454 of the largest 500 business firms in Brazil and 46 research institutions.[7] Only

[5] Manufacturing and patent licensing agreements accounted for a significantly larger share of total payments only in: tobacco products (57.8%), intermediate products for plastics, resins, synthetic fibers, and detergents (41.3%), and textiles (40.5%). The last two sectors accounted for little more than 30% of all licensing royalties. In contrast, the pharmaceutical and medicinal products' sector accounted for only 1.4% of these royalties. Most (92.4%) of this sector's payments for technology transfer originated from technical assistance agreements.

[6] Agreements between subsidiaries and parent companies accounted for about 40% of all manufacturing and patent licensing payments, which in turn represented less than one tenth of all payments for technology transfer (18.4% for foreign firms' agreement with independent firms, 7.9% for national firms' agreements, and 5.1% for foreign firms' agreements with parent companies).

[7] According to these data, 62% of the responding firms reported that they relied upon foreign sources of know-how in order to establish their activities. Moreover, this share was higher for younger firms. Know-how from domestic sources was relied upon by 51% of national firms, but only by 15% of foreign firms. Among the firms that relied upon foreign sources of know-how, 38% required adaptations of the relevant technologies which were carried out either domestically (21%) or abroad (12%) or both domestically and abroad (5%).

64% of the responding firms (61% of domestic firms and 75% of foreign ones) indicated that they had conducted some industrial research during the survey period. Moreover, for two-thirds of them the research concerned adaptations of existing technologies, whereas only 16% of them reported working on creating new product or process technologies. At the industry level, around 80% of respondents reported carrying out research activities in the machinery industry, transportation equipment, electrical and communications equipment, and metal products. Exploiting the database of technology transfer agreements described above, Biato and Guimarães (1973) established that firms carrying our at least some R&D were more likely to also seek opportunities for technology transfer agreements with foreign firms.

Interactions between firms and research institutions made only modest contributions to the accumulation of technological capabilities by the former. These interactions were not very diffuse, they focused on routine activities such as testing. By the same token, only one-third of the technological activities carried out by research institutions represented the response to specific demands from industrial firms, and these consisted for the most part of routine testing tasks to be performed on behalf of firms in the metal products, foodstuffs, and transportation equipment industries. These sectors, together with chemicals and paper products, accounted also for 85% of the research activities carried out by the surveyed institutions.

The government's tight regulatory control over technology transfer agreements in place since the early 1960s was vanquished by 1993. This policy shift was consistent with the progressive liberalization of markets pursued by the Brazilian government since the late 1980s. More specifically, the liberalization of international technology flows was held to be necessary in order to promote the future development of national firms' technological capabilities and thus their innovative performance. Whether the loosening of restrictions to international technology flows is promoting or hindering such outcome depends largely on the extent to which firms will treat access to foreign technological knowledge as a substitute for, instead of a complement for, their own technological efforts.[8]

[8] Using patent applications as a measure of firms' innovative capabilities, Johnson (2002) establishes that the relationship between firms' R&D and patenting is mediated by the firms' prior experience of technology licensing and the strength of the knowledge spillovers in the relevant areas of technology.

4. The pharmaceutical industry case

The development of a pharmaceutical industry in Brazil began during the 1860s, and over the following decades the country experienced a significant growth in the number of laboratories dedicated to the production of various medical preparations. Thirty-five laboratories were active at the proclamation of the Republic in 1889, and their number reached 60 in 1907 when a national census was realized. This period of development was facilitated by the presence of several educational institutions aimed at the training of pharmacists since the first half of the nineteenth century, and the establishment at the turn of the century of several public laboratories whose activities began to encompass research aimed at developing new serums and vaccines.

These public laboratories were organized in order to address pressing public health problems, such as the epidemics of smallpox, yellow fever, and malaria, or the need for antiophidic serum. For example, the Butantan Institute was established in 1889 to research venomous animals and to produce antiophidic serum. In 1900, the Manguinhos Institute (nowadays called FIOCRUZ) was founded to produce serum and vaccines against bubonic plague and develop biomedical research. These institutions made significant advances in the understanding and the treatment of tropical diseases and the development of sanitary medicine and biomedical science in Brazil until the 1930s, when they started to face financial constraints (SCHWARTZMAN, 1991).

The creation of these institutes made it possible to produce locally vaccines which until then had to be imported. Doing so required knowledge that was not in the public domain that time, as well as efforts to modify, adapt, and standardize production procedures (SCHWARTZMAN, 1991). The production of vaccines against the yellow fever was made possible by the scientific and technical work carried out by researchers like Oswaldo Cruz, Vital Brazil, and Carlos Chagas, whose efforts marked the beginning of scientific medical research in Brazil (STEPAN, 1981). The public health successes achieved thanks to the research work were recognized with the award of the gold medal at the 14th International Congress on Hygiene and Demography, occurred in 1907 in Berlin. Notably, Manguinhos' scientists developed in 1908 a vaccine against a disease that afflicted Brazilian cattle. The patent was assigned to the institute and the profits from the sales became the source of funds needed in order to purchase and maintain laboratory equipment and hire new researchers (SCHWARTZMAN, 1991). Manguinhos's effectiveness as a scientific research center declined since the 1930s when reforms

introduced by President Vargas brought the Institute under the control of the Ministry of Health and stopped the practice of assigning the profits from the sale of the vaccines to the Institute (STEPAN, 1981).

Until the 1930s there were no significant differences between Brazil and other countries with respect to the characteristics of medicines' production. Pharmaceuticals were produced predominantly through the manipulation of natural substances, which were abundant in Brazil, according to small scale processes. The domestic market was accordingly served by many small national firms, although beginning in the late 1910s foreign firms begin to establish affiliates in Brazil. It was only with the advance of synthetic drugs during the 1930s that national firms began to fall behind the global technological leaders. Even the major indigenous pharmaceutical firms did not perform R&D, while U.S. and European firms were advancing in the development of new substances and drugs. As a result, the country was largely dependent on the importation of either formulations or the underlying active principles by the affiliates of foreign pharmaceutical firms (GIOVANNI, 1980; QUINTANEIRO, 2002). The outbreak of World War II, and the consequent disruptions to the flow of imports, provided domestic firms (national and foreign) with the opportunity to expand their share of the national market and to develop their exports to Europe and other Latin American markets. It also forced them to reduce their dependence on imported chemicals and finished products (IFFLAND and STUTTLER, 1973 *apud* GIOVANNI, 1980).[9]

In spite of these developments, local firms continued to neglect carrying out research aimed at the invention of novel drugs and thus to depend on the production of drugs invented abroad. This weakness of the local pharmaceutical industry, and the need to develop domestic capabilities necessary in order to address local public health needs, were key reasons for the decision to suspend the patentability of pharmaceutical products in the 1945 law. The events taking place in the industry during the following decades were however at odds with the goal to promote the growth of the Brazilian pharmaceutical industry.

The process of "denationalization" took place during the 1950s and 1960s confined most Brazilian firms to the market for traditional medicines. Thus, whereas the bulk of medicines

[9] The war period also encouraged U.S. multinational firms to enter the Brazilian market. For instance, Merk-Sharp-Dohm settled in 1941, Bristol Myers in 1943, and Shering in 1944. Bertero (1972) *apud* Giovanni (1980) describe the attempt of a Brazilian firm to produce penicillin that time, but a joint venture between two other Brazilian firms and U.S. firms made it not viable.

sales were realized by national firms in the 1930s, their market share fell to 26% of 1962 sales and to 12% of 1975 sales (GIOVANNI, 1980). The driving force behind "denationalization" was the acquisition of national firms by foreign multinational groups at a time when changes in pharmaceutical technology appeared to be hurting the creation of new local firms: more than 50 indigenous pharmaceutical firms were acquired by foreign groups between 1957 and 1979 (BRASIL, 1980). The surge in foreign direct investment can be attributed to three factors. First, establishing a presence in promising markets was a key aspect of the multinational firms' strategy. Second, rising inflation during the 1950s led to the devaluation of the national currency, making national firms attractive acquisition targets for foreign firms (BRASIL, 1980; MACHADO, 1963). Third, the industrialization policy adopted in the 1950s offered strong incentives to foreign direct investments (BRASIL, 1980; FRENKEL *et al*., 1978 *apud* BERMUDEZ, 1995; GIOVANNI, 1980; MACHADO, 1963). Two policy instruments in particular, Instruction 70 (between 1953/1961) and Instruction 113 (between 1955/1961), provided strong impetus to the multinational firms' takeover of the Brazilian industry.

Instruction 70 classified imports in five different classes according to how essential they were. By allocating foreign exchange to these five classes and letting exchange rates be determined through class-specific auctions, the government could offer varying degrees of protection to the various classes of goods. This exchange rate policy provided strong incentives for multinational corporations to establish subsidiaries in Brazil because imported good that were deemed essential and that could not be sourced from domestic firms received a lesser degree of protection than those that were non-essential or available from domestic sources. Accordingly, formulations that were available from domestic sources received a greater degree of trade protection than active pharmaceutical ingredients and fine chemicals which could not be sourced from domestic firms. This measure created strong incentives for multinational firms to settle in Brazil. According to Bermudez (1995), the share of imported formulations fell between 1953 and 1960 from 70% to almost zero.

Instruction 113 had even more drastic consequences on the relative competitiveness of domestic and foreign firms because it allowed foreign investors to import equipments without foreign exchange coverage, a privilege not available to indigenous firms (Caputo, 2007). In the pharmaceutical industry, this provision reduced the investment costs of multinationals firms vis-à-vis domestic ones, and favored their dominance of the Brazilian market. As a result, national

firms became progressively concentrated in the segments of the drug market holding little interest for multinationals.

The foregoing transformations suggest that while the prohibition of pharmaceutical product patents since 1945 failed to promote a significant process of technological upgrading of the domestic firms, neither did it discourage the entry of multinational corporations. By the beginning of the 1960s, foreign multinationals accounted already for about 80% of sales and their takeover of the most promising among the surviving local firms continued during the following two decades. Giovanni (1980) highlights that the multinational firms' subsidiaries produced drugs that indigenous firms were not capable of producing, like antibiotics and other synthetic drugs. To be sure, foreign firms' activities in Brazil focused mostly on producing formulations, packaging, and distributing imported goods. Few firms produced active pharmaceutical ingredients and their chemical inputs locally, and fewer still carried out local R&D activities. Several surveys found that domestic firms were more likely to introduce product innovation than foreign-owned ones (EVANS, 1979).

The failure of the multinational firms to promote a significant accumulation of technological capabilities and growing concerns about the cost of importing basic pharmaceutical inputs prompted a number of initiatives by the military government of the late 1960s. Hoping to increase the competitiveness of indigenous firms, a 1969 decree abolished patent protection for pharmaceutical processes, as well as products. The government also created a fund for providing financial and fiscal incentives for firms' R&D spending, and began to provide funds for R&D activities to be managed by the Central de Medicamentos (CEME). CEME was created in 1971 in order to provide poor patients with access to basic drugs (LISBOA et al., 2001). Some of these were produced at a network of twenty public pharmaceutical laboratories, but many others were purchased from national or foreign-owned firms. While multinational firms did not consider CEME's core mission to be a competitive threat, they responded differently when CEME began in 1973 to sponsor research at various universities on the synthesis of pharmaceutical raw materials (EVANS, 1979).

Their reaction was twofold. First, they took steps, however minimal, to respond to the growing political pressures for them to carry out undertake or support local R&D efforts. Second, they exploited persistent conflicts within the military government between those supporting nationalist economic policies and those opposing them, in order to undermine the

research program that CEME had supported. Indeed, CEME gradually lost its financial and political autonomy, and it was closed in 1997.

In addition to promoting growing R&D efforts, government policies and political pressures were aimed at reducing the pharmaceutical industry's dependence on imports of active pharmaceutical ingredients and underlying chemicals. Fiscal incentives on machinery imports were deployed in order to reduce the cost of upstream integration for pharmaceutical firms. Moreover, the government announced that, unless foreign firms started producing raw pharmaceutical inputs locally, the government would have purchased them on the international markets and made them available to any interested firm in Brazil. Since active principles and fine chemicals could be purchased in the world markets at prices substantially lower than the transfer prices paid by subsidiaries to the parent company, the government announcement of the policy together with the carrot of the fiscal incentives prompted foreign-owned firms to begin local production.

Even after the IPR's regime had been weakened further in 1969, the development of the Brazilian pharmaceutical industry continued to be dominated by multinational corporations. Foreign direct investment continued to rise throughout the 1970s, leading to numerous acquisitions of leading Brazilian firms by foreign multinationals. The surviving local firms continued to depend on the trade protection offered by the law of similars. Indeed, only three among the 30 major pharmaceutical firms in Brazil in 1989 were indigenous: Aché, Prodôme and Biolab (QUEIROZ, 1993). These and other indigenous firms grew in the 1970s "*supported by the approval of the register of pharmaceutical products by similarity to products existing in the Brazilian market*" (BERMUDEZ et al., 2000). The continuing weakness of the technological capabilities of private indigenous firms appears to have been a crucial constraint on their strategic options. It also explains why the lack of any form of patent protection since 1971 did not suffice to reverse the "denationalization" that began two decades earlier.

The market-liberalizing reforms that took place since the late 1980s wrought drastic changes in the industry's structure. The elimination of trade barriers and the reduction of import tariffs from around 60% to 20% resulted in the end of more than 1,700 lines of production of active pharmaceutical ingredients and syntheses in Brazil (ORSI *et al*., 2003, *apud* GRANGEIRO and TEIXEIRA, 2007). These changes led to a considerable deterioration of the sectoral trade balance. Between 1990 and 2000, imports of active pharmaceutical ingredients

doubled, and those of finished drugs increased by a factor of six (MAGALHÃES et al, 2003). An analysis of the active pharmaceutical ingredients imported in 1998 revealed that half of the imports were accounted for by substances that were patented before 1962, and less than 20% represented substances patented after 1977.

The effects of the 1996 patent law reform were particularly significant for the public health program for the free distribution of drugs for HIV/AIDS carriers that the Brazilian government launched only a few months later. Because of its concern with the cost of procuring the needed drugs from multinational corporations, the Brazilian government supported a research program for reverse engineering and establishing the production of needed antiretrovirals (ARVs) at local laboratories. Initially, the public health program provided for the distribution of ARVs developed prior to the 1996 patent reform, and thus, not protected by domestic patents. But later generations of ARVs became available for which patent applications had been filed in Brazil, the procurement of locally produced generic versions clashed with the patent rights of the multinationals and could only proceed under a compulsory licensing arrangement. The Brazilian government had established in a series of decrees that compulsory licenses could be granted for reasons of public interest, as in the case of the continuing viability of the public health program on HIV/AIDS. These legislative actions and the successful imitation of the relevant ARVs at indigenous laboratories lent credibility to the threat of compulsory licensing that the Brazilian government used in order to extract significant price reductions from the multinational corporations whose ARVs accounted for most of the HIV/AIDS program budget.[10]

While both public and private laboratories were involved in the imitative work, the public laboratory FIOCRUZ (the descendant of the Manguinhos Institute) played a central role in the development of indigenous research and production capabilities related to the synthesis of generic versions of ARVs. Interacting with universities and private labs, the scientists at FIOCRUZ successfully reverse-engineered several ARVs, and collaborated with indigenous firms and other public laboratories in order to begin production of these molecules under the procurement contracts awarded by the Health Ministry. Although the initial focus of this research was on imitation of existing ARVs, the resulting technological learning has supported more distinctly innovative efforts. In fact, part of the profits earned from the sales of generic ARVs

[10] While the threat of compulsory licenses was effective in obtaining price discounts from patent-holding pharmaceutical companies, the Brazilian government never really issued compulsory licenses until May 4, 2007, when compulsory license was issued for the production of a generic version of Merck's Efavirenz.

made it possible for indigenous laboratories to invest further in their R&D capabilities thanks to the recruitment of scientific personnel and the acquisition of modern research equipment. Within a few years then, both public and private labs were not only better able to reverse –engineer existing molecules, but also to develop innovative chemical substances (CASSIER and CORREA, 2007).[11]

Another important policy change occurred in 1999 when the government enacted a law regulating the production and commercialization of generic drugs. Several governmental actions, including financial incentives and the purchase of generic drugs by the government for its public health programs, supported the growth of local production of generics by Brazilian firms, as well as the entry by foreign firms. In 2005, the four major pharmaceutical firms producing generic drugs were indigenous, and accounted for 76.5% of sales (QUENTAL *et al*., 2008). Those changes contributed to strengthen the Brazilian pharmaceutical industry, whose share of total sales rose from 12% in 1975 to 40% in 2005. It has to be noted however that the generics manufacturers are mostly oriented to the national market (only the two largest manufacturers of generics have pursued exports), operate on a scale that is vastly inferior to global leaders like Israel's Teva or India's Ranbaxy, and unlike these global leaders have so far refrained from producing the necessary active pharmaceutical ingredients, for which they continue to be dependent on imports.

5. Conclusions

Within the complex web of policies affecting sectoral development, IPR policy appears to have had at best second-order effects on the accumulation of technological capabilities, as illustrated by the case of pharmaceuticals. In this industry, the weakening of IPR protection accomplished in 1945 and 1969 was meant to spur imitative efforts by national firms and thus the closing of the capabilities' gap between them and their foreign competitors. While these policies did promote the growth of domestic firms early on, the "denationalization" of the industry followed within a short time, as multinationals acquired the most successful domestic firms. These subsidiaries were then relegated to a marginal role in the global R&D strategy of the parent company, a process that frustrated the development of strong technological

[11] Just when these local innovators were beginning to seek patent protection on their inventions, the House of Representatives approved a bill in June 2005 that would suspend the patentability of all HIV/AIDS-related drugs. While this bill was not ratified into law, it is likely that such a measure would have weakened perhaps the incentives for local labs to engage in innovative projects rather than on imitative ones.

capabilities among national firms. The restoration of patent protection for pharmaceuticals in 1996 has not so far brought about a change in the strategy of multinational firms. Instead, renewed government support of (imitative) R&D activities at the public labs and the creation of a regulatory environment for the sale of generic drugs hold the promise of more significant effects on the technological capabilities of national firms than the 1996 reform of the patent law.

Whereas the Brazilian government protected the market for pharmaceuticals, it did not protect domestic firms from foreign multinationals so that even in the absence of IPR protection on foreign technologies national firms failed to develop the technological capabilities necessary to compete with the multinationals in the innovative segments of the market.

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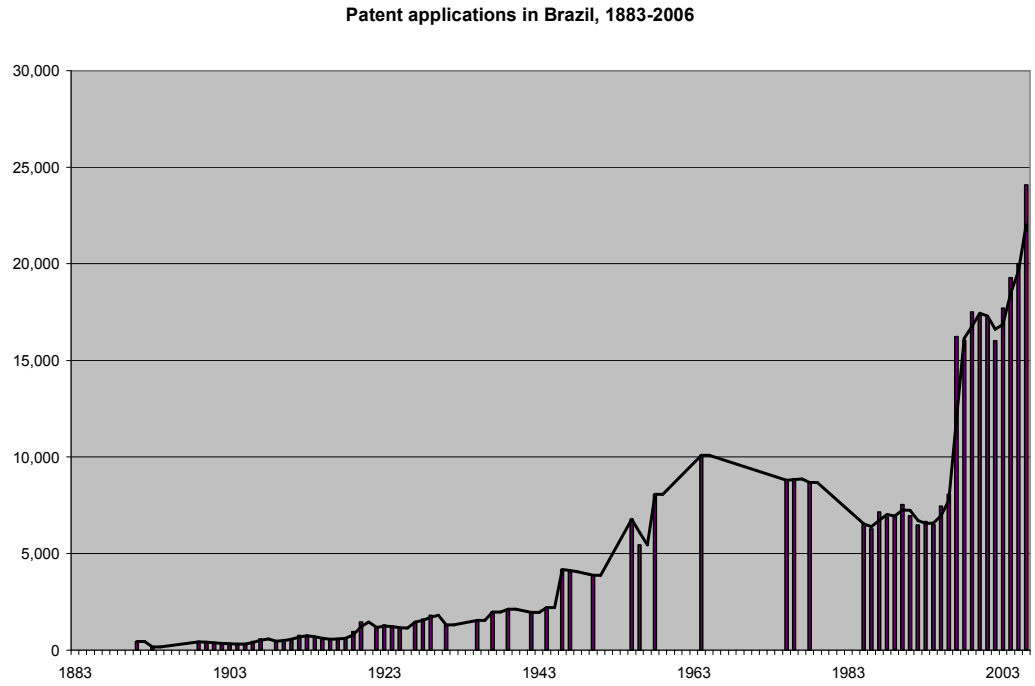
FIGURE 1



Source: World Intellectual Property Organization (2008)

TABLE 1 – Payments for contract-based technology transfer (1947-1971)

		Payments for technology transfer		
	Index		as a percentage of	
	(1965=100)	GDP	Capital goods' imports	FDI
1947-1953	31.8	0.12	3.5	100
1954-1961	75.8	0.18	9.1	35
1962-1964	34.4	0.06	4.6	35
1965	100.0	0.16	24.6	61
1966	107.8	0.16	16.6	62
1967	147.5	0.22	19.6	82
1968	165.2	0.22	16.3	87
1969	214.1	0.26	17.8	67
1970	244.7	0.27	15.9	81
1971	310.6	0.31		90

Source: Biato et al., 1970