

**Explaining divergence in catching-up in pharmaceuticals
between India and Brazil using the NSI framework**

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Abstract

Since the mid-twentieth century, the national objective of India and Brazil has been to develop industrial capabilities in essential sectors such as pharmaceuticals. At the outset they shared some common features: a considerable period of lax intellectual property rights regimes, a large internal market and a reasonably strong cadre of scientists and engineers. However, over sixty years, India has had much more success in building indigenous capabilities in pharmaceuticals than Brazil, at least to date. Why? In exploring the answer to this question we show that in both countries the design of State policy played a crucial role and the endogenous responses in the national system of innovation consisted of two parts. On the one hand, most of the time, the predicted and desired outcome was partially realized and on the other hand, there were invariably, other unpredicted responses that emerged. The latter unexpected elements, which were specific to the two countries, pushed them along distinctive trajectories.

Keywords: Pharmaceutical industry, India, Brazil, industrial capabilities, Catch-up, National System of Innovation.

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1. Introduction

Since the mid-twentieth century, developing industrial capabilities in essential sectors such as pharmaceuticals has been the national objective of India and Brazil. While at the end of WWII both countries differed enormously in their demographic structure and their socio-economic history, they also shared some common features: a large internal market, a reasonably strong cadre of scientists and engineers, and, over time, a similar evolution of policy regimes, namely a State policy of import substitution followed by a period of economic liberalization. However, at the beginning of the New Millennium, India had much stronger indigenous capabilities in pharmaceuticals than Brazil. How is it that after starting out with a comparable set of industrial capabilities and being subjected to similar development doctrines, their patterns of catching-up resulted in such different outcomes? What factors contributed to such divergent trajectories? These are the questions we will attempt to answer in this paper using the ‘national system of innovation’ (NSI) framework.

The NSI approach was spearheaded by the seminal work of Lundvall (1992), Nelson (1993) and Freeman (1995). Emerging from an older stream of literature of the evolutionist school of economics on industrial ‘catching-up’ of late-comer countries, it was initially proposed as a possible alternative to the macroeconomic models of growth. These models postulate that if knowledge is codified and freely available, latecomer countries will grow faster than leader countries for the reason that the former will benefit from existing technologies developed by the latter at a lower cost and at a more rapid pace and thereby the gap between the two would be reduced. However, this ‘convergence hypothesis’ has been invalidated by decades of uneven economic growth and persistent gaps in income per capita between backward and advanced countries (Landes, 1998)¹. The ‘catch-up’ literature has explored the reasons for such divergence through case studies of the historical evolution of countries and sectors and showed that rather than being a homogeneous or linear process, catching-up in terms of scientific, technological and industrial capabilities building is likely to be costly, difficult, nation-specific and non-systematic with sectoral and cluster idiosyncrasies. Thus, technological catching-up cannot be taken for granted.

Starting from the premise that the creation of technological and industrial competence in any knowledge intensive sector is a collective and cumulative process, the NSI builds upon the rationale of actors and institutions within the country, involved in the creation, adoption and diffusion of new technologies. The principal actors of the NSI are the State, public laboratories, firms, financial organisations and consumers while the institutions refer to main policies and regulations shaping and being shaped by organizations aimed at the production and diffusion of new technologies². In the last three decades, the NSI approach has emerged as a useful framework to organize historical evidence and study the ‘catching-up’ processes of ‘late-comer’ countries with respect to the accumulation of industrial capabilities. It has also

¹ According to Landes, over 250 years, the difference in income per capita between the richest and poorest country in the world has increased from 5:1 to 400:1.

² “Institutions are set of common habits, routines, established practices, rules or laws that regulate the relations and interactions between individuals, groups and organisations. They are the rules of the games” (Edquist, 2001, p. 5).

inspired the notion of a sectoral system of innovation (SSI) incorporating sectoral specificities in an innovation system (Lee and Lim, 2001; Malerba, 2002).

The NSI approach indicates that the catch-up trajectories of countries will be path dependent and as different nations pursue different strategies for capabilities accumulation, they will attain different results. Therefore, using the NSI framework, we can explore why at certain points of time, countries with similar resource structures and investment patterns, have had different trajectories in accumulation of industrial capabilities. Nevertheless, the NSI approach remains a conceptual framework rather than a theory, open to many forms of interpretations and investigations (Lundvall, 1998; Edquist, 2001). In order to move towards a workable theory of NSI, and arrive at a typology of systems, with an understanding of their concomitant impact on knowledge accumulation, more empirical studies are called for. The present article may be considered as a step in this direction and in this perspective its contribution to the existing literature on catching-up using the NSI framework may be understood as follows.

First, even while the fruitful hybrid of the catch-up and the NSI approach is being increasingly used to examine the evolutionary trajectories of catching-up, most of the analysis is focussed on how a developing country strives to attain the benchmarks set by a leading developed country. Indeed, these works are in the spirit of Fagerberg's (1989) Schumpeterian argument that the catching-up process is dynamic and results from the confrontation of two conflicting forces: innovation in advanced countries that tends to increase the economic and technical gaps between backward and advanced countries; and diffusion and imitation of such innovation, which tends to reduce the gaps. In contrast, we compare the catching-up trajectories of two developing countries and try to explain the differences in their path using the NSI framework. Moreover, a comparative study of the evolution of a particular sector in two countries improves our understanding of the factors influencing the catch-up process at a meso-level, while an analysis of their NSI gives us more insight on why they diverged in their evolutionary trajectories.

Second, the present article highlights the role of the State not only as a financier for the development of capabilities, but also as a catalyser of change through initiation of regulatory shifts. In the catch-up literature, 'windows of opportunity' are mostly created by radical shifts in technology paradigms, whose exploitation by prescient firms leads to sweeping changes in the industrial organization (Soete, 1985). In contrast, the present paper demonstrates that endogenous changes in State policy can achieve the same effect. In other words, our case studies demonstrate that *radical regulatory changes* can open '*windows of opportunity*' and generate positive externalities, in a way very similar to radical technological discontinuities.

Third, the paper clearly demonstrates the limits of State policy and public investment. While these may be formulated and implemented with specific objectives, the final outcome will depend on the perceptions of the stakeholders of the opportunities and threats opened up, their responses to the same, and band-wagon or mimicry effects that are provoked within the system. The catch-up literature is full of examples of windows of opportunity that were effectively seized and this could give rise to an implicit conviction that any window of opportunity will be perceived and acted upon. But this need not be the case. Our case studies show that the beliefs and expectations of firms determine whether or not 'windows of opportunity' are perceived or exploited. In addition, firms may evolve not only in response to regulatory changes within the NSI, but also to those initiated abroad which cannot be controlled. Thus, forces affecting the SSI may complement or contradict the impact of NSI.

In terms of methodology, the focus is on the intersection of the NSI and SSI for pharmaceuticals in India and Brazil, with brief attention being given to the pharma SSI

outside of the countries whenever pertinent. The case study method is used to unravel the process of catching-up in pharmaceuticals, the focus being on the ‘how’ rather than the ‘why’ – assuming it is an objective to which the NSI actors were committed. The research was organized in two stages. In the first stage, the existing economics literature on the evolution of the pharmaceutical sector in India and Brazil was compiled and analysed to unfold the main findings. These yielded a road map of future strategies for catch-up and recommendations for firm strategy and policy design. In the second stage, this construct was validated and refined in a series of interviews conducted with 30 selected representatives of firms and public agencies. The interviews were semi-structured, but in-depth and lasted between 1 to 2 hours during 2008/2009. Relevant points were then integrated into our inferences on future options and recommendations.

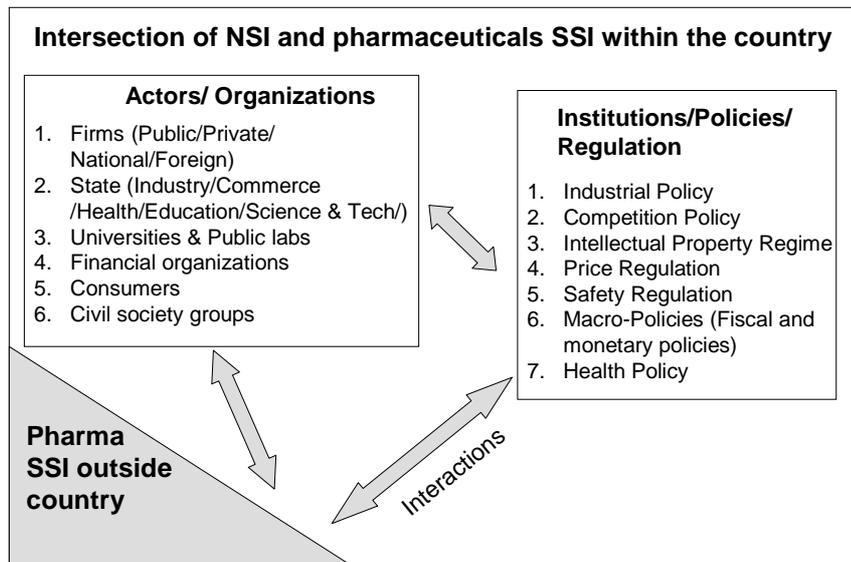
The rest of the paper is organized as follows. Section 2 describes the conceptual framework developed to construct the case studies and highlights the specificities of the pharmaceutical sector. Section 3 contains our case studies. Finally, section 4 discusses our results and concludes.

2. From NSI to catch-up dynamics in pharmaceuticals: A conceptual framework

Medicines and health care services, like food and housing, are essential goods, and it is necessary to promote their access to all to ensure inclusive development. Thus, with respect to pharmaceuticals, the State has two main objectives: (i) to ensure access to essential medicines for its citizens; (ii) to attain self-sufficiency in the production of essential medicines. Notwithstanding that these objectives are closely interlinked, for the purposes of this paper, we will only focus on how India and Brazil strived to achieve the second goal. To organize the case studies, we propose a conceptual framework made of three elements: (i) field of study; (ii) typology of firm capabilities in pharmaceutical sector at a micro level; (iii) dynamics of catch-up at a meso level.

Field of study: Following Edquist (1997, 2001), in figure 1, we define the field of examination for studying the catch-up trajectory as the interaction between actors/organizations with institutions/policies in NSI. The main actors in any innovation system are the State, public laboratories, universities, firms, financial organizations, consumers and civil society groups. With respect to the study of catching-up in pharmaceuticals, our focus will be on the State and manufacturing firms. Moreover, medicines being essential to ensure healthcare, not only will the usual panorama of policies affecting any industry be considered, but also health policy.

Figure 1: The field considered



Firm capabilities at the micro-level: By firm capabilities in pharmaceuticals, we refer to a three component vector comprising *production capabilities*, *innovation capabilities* and *regulation handling capabilities*.

Production capabilities: The manufacturing of drugs involves three main operations and the associated capabilities are different in terms of technological complexity:

- The least complex step is ‘formulation’ of drugs, which refers to the processing and packing of basic ingredients called ‘bulk drugs’ into a consumable form such as a tablet, capsule, syrup, injection, plaster, etc.
- The production of a ‘bulk drug’ containing the therapeutic molecule in powder or liquid is a more complex process requiring a higher level of scientific and technological capabilities.
- Finally, the making of the core component of bulk drugs termed the ‘active pharmaceutical ingredients’ (API) is the most complex step of all.

Thus, the greater the degree of backward integration over the production process (starting from formulation and going up to API) and larger the market share of national firms, the greater are the industrial capabilities in pharmaceuticals of the country concerned.

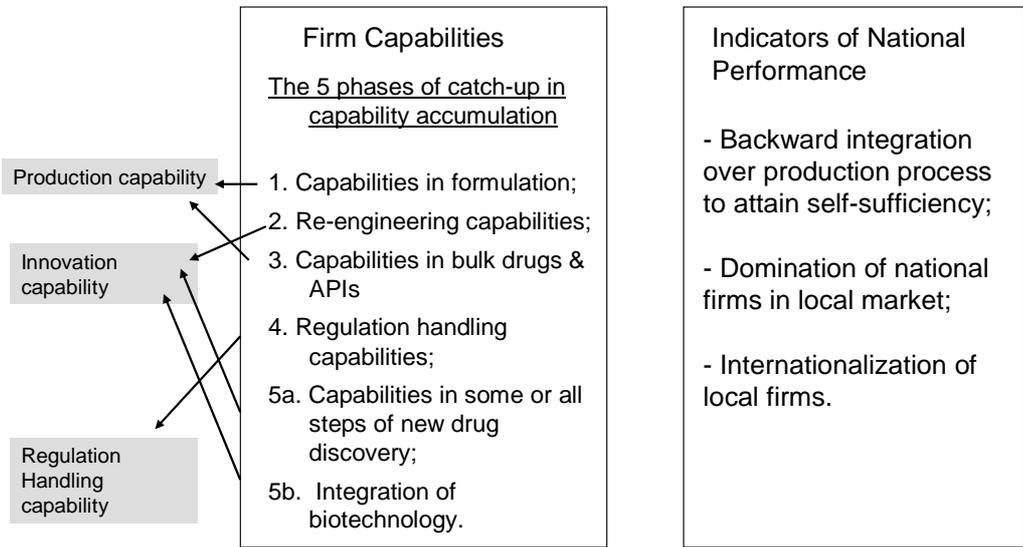
Innovation Capabilities: Re-engineering capabilities and new drug-discovery capabilities are the two main variants of innovation capabilities in pharmaceuticals. A country acquires first self-sufficiency in the production of essential drugs through the development of re-engineering capabilities, i.e. through their firms re-engineering original innovations (medicines) created elsewhere assuming that this is possible under the country’s intellectual property regime (IPR). Then, the country can envisage investing in the development of ‘new drug discovery capabilities’ through integration of biotechnology and/or research capabilities in one or more of the steps in the new drug discovery process.

Regulation handling capabilities: Finally, developing country firms have to build up complementary competencies that go beyond technology to satisfy regulatory requirements, if they want to commercialize new drugs. For instance, to introduce a generic in a regulated

market, i.e. a market with stringent requirements on the efficiency, safety and quality of drugs, firms have to provide bioequivalence data demonstrating that the product has the same effect on the body as the original drug. For the commercialisation of a new drug, they have to furnish extensive data on clinical trials. Besides, firms are also obliged to submit ‘Drug Master Files’ with comprehensive details on the manufacturing and distribution process. Finally, they have to prove that their manufacturing methods conform to current ‘good manufacturing practices’.

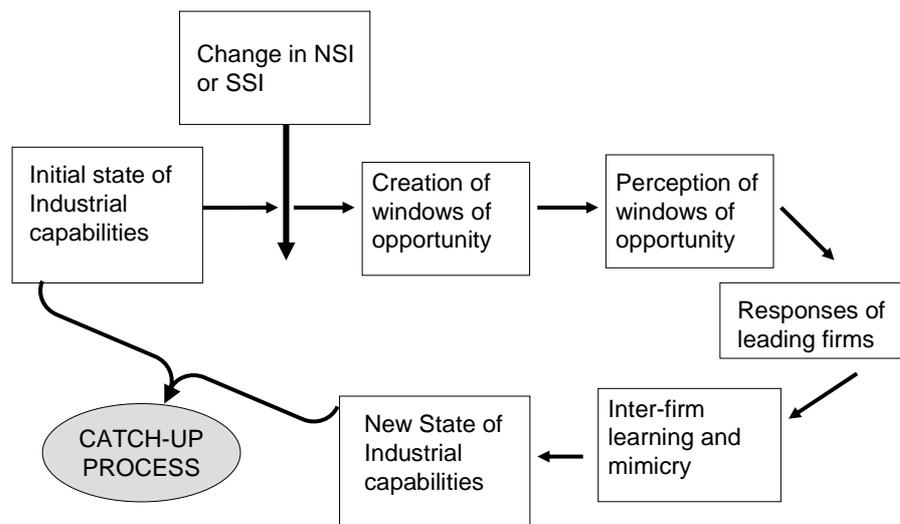
These indicators of firm capabilities at the micro-level and the targets at the meso-level are summarized in figure 2.

Figure 2: Catching-up in pharmaceuticals in terms of firm capabilities and national performance



Dynamics of catch-up at meso-level: Drawing upon the well known concepts of firm capabilities and their evolution over time (Penrose, 1959; Nelson and Winter, 1982; Teece et al. 1997), we suppose that at any point of time in a country and in an industry, firms are endowed with a set of accumulated capabilities, which they mobilize to maximize profit. Then as endogenous changes are generated within the system or as external shocks hit the system, new windows of opportunity are created and firm capabilities evolve to exploit them. In so doing, firms accumulate more capabilities and catch-up further. Through inter-organizational learning, the first winners give rise to imitators or emulators, who may in turn provoke band-wagon effects. As winners increase their market share and losers exit, the industrial organization may also change. Finally, as these endogenous responses (i.e. response to window of opportunity and mimicry effects) need not be the same or even similar in different contexts, their analysis can serve to explain divergence in evolutionary trajectories. This flow is summarized in figure 3.

Figure 3: Dynamics of catch-up at meso level



This completes our presentation of the conceptual framework that will be used to construct the case studies.

3. India and Brazil: Racing to Catch-up in Pharmaceuticals

Following the conceptual framework presented in the preceding section, we start by examining the industrial capabilities in pharmaceuticals in India³ and Brazil in 1950. Then we identify the changes either in the NSI or SSI that created windows of opportunity for the firms in the sector. Next, we trace the endogenous responses of firms, any bandwagon effects created and their impact on the accumulation of firm capabilities, the industrial organization and performance.

3.1. Similar starting conditions in 1950

With the spectacular success of penicillin during WWII, leading Western pharmaceutical firms developed technological capabilities in chemical synthesis and began a serious offensive of internationalization worldwide. Thus, when India attained its independence in 1947, Western multinationals (MNCs) held about 80% of the market and drug prices were among the highest in the world (Ahmad, 1988). Brazil was in a better position with the market shares of the foreign firms being around 47.1% (Queiroz, 1993).

In this context, the principle objective of both the Indian and Brazilian governments was to reduce domination by foreign firms and achieve self-sufficiency in pharmaceuticals. They began by constructing scientific capabilities through investment in higher education. One of the first tasks of the Government of India after independence was to create institutes of higher

³ A comprehensive list of references on the Indian pharmaceutical sector can be built from Ramani and Venkataramani (2001), Ramani (2002), Guennif (2004), Ramani and Maria (2005), Greene (2007) and Gehl-Sampath (2008).

education and research⁴. In Brazil also, the State invested in higher education with the creation of a network of universities and public laboratories⁵.

Secondly, both countries adopted an import substitution policy, which seemed reasonable given the large internal size of their domestic markets. Each embraced it to a different degree to curb imports and promote exports and local industries. In India a complex system of price controls, high import duties and export subsidies was put in place and any firm wanting to expand its manufacturing base, export or import, had to get a license from the government to proceed under the so-called 'License Raj'. In parallel, the State undertook large investments to establish public sector enterprises (Singh, 1985)⁶. The very tight system of IPR inherited from British colonial rule was left untouched so that patent holders had exclusive rights to make, sell and use both new processes and products for 14 years. In contrast, Brazil adopted a similar regime of high import duties but the patent system was overhauled in 1945 to permit only process patents. Besides, there was no License Raj.

3.2. First window of opportunity: a flop in both countries

By adopting an import substitution policy, both governments assumed that a window of opportunity had been opened for domestic firms to accumulate production capabilities. But this did not happen in either of the countries.

In India, local firms developed capabilities only in formulation. Firms did not want to invest in expanding their manufacturing base, because price ceilings depressed their revenues while the License Raj increased their transaction costs. There was also no possibility to develop re-engineering capabilities because of the strict IPR regime (i.e. permitting product as well as process patents).

Unsurprisingly, at the industry level, in 1970, after twenty years of the 'License Raj' and an import substitution policy, 80% of the market share was still held by foreign controlled firms and almost all patents of branded drugs were held by MNCs. Drug prices remained among the highest in the world, partially due to import duties, but mostly because firms were focused on brand competition and promotional activities. Indian consumers suffered from a shortage of essential drugs and a crisis in terms of healthcare provision. MNCs on the other hand fared well (Lall, 1974a, 1974b).

In Brazil also, the only firms which fared well under the import substitution policy regime were the MNCs. The positive incentives generated by the high import duties on final products were nullified in the 1950s by a macroeconomic policy aimed at attracting foreign direct investment (FDI) through differentially low exchange rates. As a result, MNCs found it in their interest to import raw materials (bulk drugs and API) and equipment from their home

⁴ It expanded the network of universities; it set up institutes for technical training such as the Indian Institute of Technology (IIT). It also established research institutions for advanced research outside the university system such as the Indian Council of Medical Research (ICMR), the Indian Council of Agricultural Research (ICAR) and the Council of Scientific, and Industrial Research (CSIR).

⁵ Among others, Fiocruz is a public institution in charge of the promotion of public health and social development, through the creation and the diffusion of scientific and technical knowledge. Besides, the National Council for Scientific and Technological Development (CNPq), is a public agency linked to the Ministry of Science and Technology, that works for the promotion of scientific and technological research and for the formation of human resources for research in the country. It works in close relation with the Federal University of Rio de Janeiro and its 'Chemical Institute' founded in 1963 with the support of the BNDE, the Bank for economic development, and the Ministry of Planning.

⁶ The most important among these were Hindustan Antibiotics Limited and Indian Drugs and Pharmaceuticals Limited created respectively in 1954 and 1961.

countries on a large scale and expand their operating base in Brazil. On the other hand, the measures taken to facilitate the import of equipment could not be exploited by local firms of modest size: the scale of imports of equipment that was needed to be competitive with MNCs was beyond what any Brazilian firm could afford (Queiroz, 1993).

The absence of an industrial policy aimed specifically at protecting national industries coupled with an explicit policy to attract FDI brought about a denationalization of the pharmaceutical sector. Brazilian firms caught in a lurch ceded their place to foreign firms by exiting the market or being bought out by MNCs. Between 1958 and 1972, 43 domestic companies were acquired by foreign firms, mostly from USA (Frenkel et al., 1978; Bermudez, 1992)⁷. By 1970, MNCs accounted for 77.7% of the market share with only 4 national firms being among the top twenty (Queiroz, 1993).

3.3. Policy responses and creation of windows of opportunity during the 1970s and 1980s

By the end of the 1960s, there was a health care crisis in terms of access to essential medicines in India and Brazil, and policies had to respond to find a quick solution. There were two possible options: either essential medicines could be imported in large quantities or incentives could be provided for the development of the local pharmaceutical industry. Both governments opted for the latter solution.

Taking note of the fact that most of the developed countries had put in place a strong IPR system only after having acquired a certain level of technological competence in knowledge-intensive sectors, in 1970 the Indian government finally acted to pass the recommendation of the Ayyangar Report submitted in 1959 that only process patents be recognized for essential commodities like food and drugs. The change in the Indian patent law was essentially designed for the public sector firms to accumulate technological capabilities in order to serve low-income communities in public hospitals (Lall, 1974b). Otherwise throughout the 1970s and 1980s the policies of import substitution mixed with price control and monopoly regulation via the ‘License Raj’ continued.

Unlike in India where the change in the IPR regime remained the main new element for two decades, in Brazil there were waves of policy changes that affected the pharmaceutical industry. Upstream, to promote production by local firms and improve self-sufficiency, process patents were removed in 1969 (Frischtak, 1989). Downstream, to ensure access to medicines, a system of price control was put into place in 1968 guaranteeing a lower rate of price increases in medicines vis-a-vis the inflation rate (Romano and Bernardo, 2001).

Another unique Brazilian feature was a series of private-public partnership initiated right from the 1970s to promote catching-up. A public procurement agency, the CEME (Central de Medicamentos) was created in 1971 to ensure the supply of essential drugs to public hospitals but its mission was enlarged over the years to support the building of a 100% Brazilian pharmaceutical industry, right from the purchases of raw materials to the final products, through diversification of procurement (Queiroz, 1993). During the 1980s the CEME also moved forward to develop technological capabilities needed to produce important API in collaboration with the private sector. In 1984, the CEME launched a collaboration with the CODETEC⁸ and some private pharmaceutical firms to identify research output from

⁷ In this paper we make use of information in Frenkel et al. (1978), Bermudez (1992) and Romano and Bernardo (2001) as cited in Urias and Furtado (2009). These references are in Portuguese.

⁸ The CODETEC (Company for technology development) was created in 1976 through collaboration between the State University of Campinas (UNICAMP), the Ministry of industry and trade, and a group of firms, mostly from the public sector.

universities with commercial potential and social benefit, and explore ways in which they could be brought to the market.

In the midst of these initiatives, the Brazilian economy entered into a grave economic crisis due to serious external debt during the 1980s. Being feebly competitive in many sectors, the government tried to improve the balance of payment through reduction of public investment and institutional changes. As a consequence, the import substitution policy regime intensified in bursts and spurts over the decade. Institutional changes took the form of protectionist measures to reduce imports such as the system of ‘market reservations’ for products that could be locally manufactured, fixing high tariffs or banning imports, and preventing the duplication of industrial projects by limiting market competition in favour of domestic firms (Queiroz, 1994; Urias and Furtado, 2009; Robine, 2008).

To sum it up, both the Indian and Brazilian governments made their IPR regime looser in order to create ‘windows of opportunity’ for local firms, presumably Indian public sector firms and Brazilian private sector firms to accumulate production capabilities through re-engineering and thereby increase their market share. We now examine to what extent these opportunities were perceived and exploited.

3.4. Exploitation of the ‘loose IPR’ windows of opportunity: Unexpected outcomes

In India, it was the private sector firms rather than the public sector firms, which correctly sized-up the window of opportunity opened by the new process patent regime. Leading private pharmaceutical firms began to invest in building re-engineering capabilities and started producing essential drugs – slashing market prices heavily. Indian firms even entered into production contracts with the original MNC inventors, permitting them also to enjoy lower costs and a greater mark-up. As a result, slowly but surely, the industrial organization changed, bearing witness to the downfall of the previous market leaders.

The share of MNCs which was 68% in 1970 dropped to 50% by 1980 (Chaudhuri, 2005). By the mid-1980s leading Indian pharmaceutical firms were producing both bulk drugs and formulations for the domestic market. By the end of the 1980s, India was exporting bulk drugs and final therapeutics, supplying many parts of the developing and developed world at lower prices and edging towards a positive trade balance. In short, the change in the IPR regime coupled with the dynamic response of local firms to acquire capabilities in all stages of drugs production led to a sharp reduction in import dependence and MNC domination. Thereby, the ultimate objective of accumulating industrial capabilities, namely to improve access to medicines to underserved communities, could be tackled.

In contrast, in Brazil, private sector performance still lacked luster. Even private-public partnership launched by the CEME did not lead to significant backward integration over the production process. With an investment of \$5 million till 1990, the CEME-CODETEC partnership generated the know-how to produce about 60 API, but among these only 13 reached the production phase, with the rest being abandoned (Queiroz, 1994). In other words, even when know-how was available from CEME and CODETEC, the local firms did not invest to acquire re-engineering skills in the production of API and instead of giving competition to Western MNCs, they began to imitate them. Following a “commercial logic” (Frenkel, 2001), they imported raw materials to manufacture finished products just like the MNCs and then competed in the final market by focusing on the quality and quantity of their medical sales force.

Three main causes seem to be responsible for the non-response of the Brazilian firms. First, for both private firms and public-private partnerships, the regulation on API price

imposed a low margin over costs. The last few stages of the production process of API are not capital intensive and therefore compatible with low profit margins. In contrast, intermediate steps of the production process require high fixed cost which cannot be borne by a low margin unless the scale of manufacturing is very large. Therefore, more often than not, Brazilian firms renounced the production of API and instead concentrated on the production of finished products, for which MNCs' imports were highly taxed or banned. Moreover, their production was enabled by large imports of raw materials for which tariffs were still low given the absence of local production.

Second, at a macro-level, the failure to catch-up in pharmaceuticals during the 1970s and 1980s seems to be linked to the constant confrontation between the advocates of two types of logic that thwarted the implementation of any industrial policy (Andréa-Loyola, 2009). One pushed for an 'autonomous' route to development and the building of a national pharmaceutical industry committed to the production of raw materials, as well as finished products, to increase self-sufficiency. The other argued that satisfying local demand, whether through the production of local firms or foreign MNCs, was primordial. This more 'neo-liberal' or 'dependant' logic was largely supported by MNCs.

Third, the vicissitudes of macroeconomic policy during the 1980s further lowered the impact of industrial policy (Suzigan and Furtado, 2006). Matters were made worse by a steep slashing of public investment in the development of scientific capabilities in terms of education and infrastructures. For instance, budget cuts were imposed on nodal bodies such as the 'National Scientific and Technical Development Fund' and the discretionary powers of the 'Economic Development Council' in the decision making process was steadily lowered⁹. Brutal stopping of plans for scientific and technological development as well as programs for sectoral development led to a serious skills constraint in terms of qualified scientists, technicians and engineers. These drastic cuts undermined the 'social capabilities' (Abramovitz, 1986) of Brazil and also acted as a brake on industrial development during the so-called first lost decade of 1980-1990.

In summary, the window of opportunity opened up by loose IPR was perceived and exploited in different ways in India and Brazil and in turn provoked different types of responses from the other actors in the innovation system. In India, the window of opportunity targeting public sector firms was amply exploited by the private sector and significantly helped to improve access to medicines. In Brazil, despite the investments of the public sector, the window of opportunity was under-exploited by national firms dashing the expectations of catching-up in the pharmaceutical sector and preserving MNCs domination (80%) in the domestic market right to the end of the 1980's (Frenkel, 2001).

3.5. Embracing liberalization during the 1990s

Both in India and Brazil, during the 1990's, there were a number of extremes changes in the regulatory environment, which influenced the accumulation of technological capabilities in almost all sectors. In both countries, the impact on the pharmaceutical industry is deemed to have been positive.

In 1991, the Indian economy was liberalized. It was no longer necessary to get a license to expand the manufacturing base, export or import goods. The price control regime was narrowed with 50% of the drugs being removed from price control by 1995. Hot on the heels of liberalization, India became a member of the WTO in 1995 and thereby changed its IPR to

⁹ The former was responsible for the financing of scientific and technological projects, while the latter had been charged with the mission of defining the targets for economic development.

comply with TRIPS. Accordingly, from 2005 onwards commercialization of branded medicines through re-engineering was no longer possible.

The 1990's also witnessed radical regulatory changes in Brazil. Burdened with excessive debt, Brazil was obliged to borrow and adopt a set of economic liberalization policies as decreed by the IMF, including the opening and the deregulation of markets. Then, under pressure from the US Trade representatives, Brazil renounced the transitional period permitting a developing country to implement TRIPS by 2005 and proceeded with a reinforcement of its patent regime in 1996. In compliance with TRIPS, both product and process patents were reintroduced with a 20 year validity period.

In Brazil too, starting from 1991, the 1980s price control scheme was dismantled and price ceilings on many of the drugs were removed. As a consequence and also boosted by repeated devaluation of currency and soaring inflation and hyperinflation, drug prices rose dramatically. In response to the new crisis in drugs accessibility, from 1993 onwards, supply for public procurement representing 26% of domestic market sales, was obtained through a formal system of public bidding via the so-called 'Law of Tenders' (Sweet, 2007). Only price was taken into account without much attention being paid to quality, leading to very stiff market competition. Finally, in order to improve the quality and safety of drugs, the 'Generics Act' was promulgated in 1999 stipulating the conditions under which re-engineered drugs could be introduced in the market and a new agency, the ANVISA, was created to monitor the quality of drugs marketed in the country¹⁰. On the demand side, the purpose was to increase the consumption of generics, which were cheaper than branded drugs. To order in build the required social trust in generics, the public authorities massively promoted their quality.

Thus, after a little more 40 years of the import substitution regime, both India and Brazil embraced a completely new set of rules of governance corresponding to liberalization. How did their pharmaceutical firms respond to this new context? We turn to this issue now.

3.6. Exploiting the windows of opportunity from liberalization: The expected outcomes

In India, after liberalization, production, exports and imports of pharmaceuticals shot up and the industry grew rapidly in the 1990s, with an average annual growth rate of 15% for bulk drugs and 20% for formulations (OPPI, 2001, 2004). New firms entered the market and incumbents increased their manufacturing base. This was expected, but liberalization was not the only cause (see next section).

In Brazil, on the other hand, liberalization put severe stress on local pharmaceutical firms trying to protect their turf against foreign MNCs. There was a second wave of denationalization with the closure of about 1700 production units of intermediary goods destined for the pharmaceutical industry in the first half of the 1990s (Orsi et al., 2003). Import restrictions were decreased as part of the liberalization policy, lowering the tariff on pharmaceutical products from 70% to 14% and enabling the MNCs to increase their presence in the Brazilian market (Sweet, 2007).

Indeed, the inferior performance of Brazil during the 'second lost decade' of 1990-2000 was due to an over-enthusiastic embrace of the advice offered by the Washington Consensus, instead of a selective implementation as in India: *"compared to India, the much more profound incorporation of the majority of the recommendations of the original Washington Consensus and some of the augmented ones in Brazil have not only been responsible for*

¹⁰ The mission of ANVISA also covers price control and counselling of the 'National Agency' in charge of granting patents, regarding the assessment of drug novelty.

reducing the efficiency of the coordination of the macroeconomic policies with its National Innovation System, but also explain to a great extent the bad general economic performance expressed, notably, by slower economic growth” (Nassif, 2007, p.13).

Following liberalization, as described in the previous section, the second biggest shock to the market environment came from TRIPS. Starting from 1995 and continuing till 2005, when TRIPS became effective in India also, the IPR framework in India and Brazil moved through a series of transformations to become very tight, permitting only product patents in pharmaceuticals (see Shadlen, 2009, for Brazil and Gehl-Sampath, 2005, for India). This meant that firms could no longer use ‘re-engineering’ as a strategy to catch-up in terms of production of branded drugs patented by other firms. In other words, firms had to focus more on building of internal R&D capabilities and also enlarge the acquisition of knowledge and new technology from outside.

Unsurprisingly, following the signing of TRIPS in 1995, pharmaceutical firms in both countries began increasing their internal R&D expenditure and exploring various avenues for external acquisition of technology. Kale and Wield (2008) term this phenomenon for Indian firms as the development of ‘exploratory capabilities’ as a complement to their ‘exploitative capabilities’. Even during the transition period to full compliance with TRIPS, i.e. 1995 to 2005, leading Indian pharmaceutical firms began to increase their R&D expenditures and their patent applications (utility) in the United States Patent Office (USPTO) as well as in the Indian Patent Office (Chaudhuri, 2007; Simonetti et al. 2007; Chadha, 2009)).

Sourcing of technology from abroad swelled up in terms of both magnitude and variety. Technology imports increased in both countries in the pharmaceutical sector (Chittoor et al. 2008; da Silva and Oliviera, 2007). Strategic technology alliances (especially in US) began growing for a variety of reasons ranging from access to technology assets, market penetration and a better understanding of local regulation to boost their market competitiveness (Greene, 2007; Ryan 2009). Chaturvedi (2006) estimates that for 2003 alone, the total number of strategic alliances between Indian biotech organizations and foreign firms was 129 (35 agriculture; 70 human health; 1 environment; 11 industrial and 12 others).

In terms of knowledge acquisition from abroad, Indian firms are clearly ahead of their Brazilian counterparts. In addition to technology imports and alliances, they are also active as outsourcing partners of Western MNCs for contract research and manufacturing services (CRAMS), bioinformatics services for genomics based drug research, and clinical trials (Ramani and Maria, 2005). Furthermore, they are even acquiring firms in Europe and the USA (Greene, 2007; Chittoor et al., 2008).

Now what about the role of MNCs after the signing of TRIPS? Though TRIPS was supposed to favour cooperation and spillover generation by MNCs to promote capability building in local firms, history indicates otherwise. Chittoor et al. (2008) conclude that for the period of their study 1995-2005 the spillovers generated and integrated by MNCs were mainly with their subsidiaries in India and not other local firms¹¹. For Brazil, Oliveira et al. (2004) observe a nearly 33% decrease in contracts between local firms and foreign ones between 1992 and 2001. The most favoured form of technology transfer during this stage was ‘licensing of brand-name’ rather than ‘joint-venture’ or ‘mergers’. Furthermore, licensing decreased from 94% to 34% by the end of the period as foreign firms simply prefer to export to an open Brazilian market rather than license their brand-name to local firms. Cooperation in R&D between Brazilian and foreign firms also remains marginal. However, ‘technical assistance services’ are low but seem to be rising.

¹¹ Feinberg and Majumdar (2001) reiterate the same result for the previous period 1980-1994.

At the policy level also, in the new millennium, despite the differences in their evolutionary trajectories, at the micro-level, both countries have begun to exhibit a remarkable similarity in the strategies deployed. To provide incentives for university and public lab researchers to patent and induce technology transfers from public labs to private firms, the State passed a US Bayh-Dole like law in Brazil in 2005. In India, an informal Bayh-Dole policy was already operational in the leading network of scientific institutions, the CSIR, and the question was whether such a policy should govern all research institutes. This is being debated in the Indian parliament. In terms of innovation capabilities and catch-up, State policy impacting pharmaceuticals (e.g. corporate taxes, firm subventions, infrastructure support, technology transfer, quality regulation etc.) is more centred on capacity building in biotechnology in India (Chaturvedi, 2007). In Brazil it is more diffused targeting catch-up in all stages of drugs production to boost vertical integration (da Silva and Oliviera, 2007) as well as biotechnology (Marques and Neto, 2007).

3.7. Exploiting the windows of opportunity from liberalization: Some unexpected outcomes

Not all outcomes in the post-TRIPS liberalization period were entirely anticipated. In particular we highlight four trends that surprised academic and industrial watchers alike. They were the nature of the internationalization process of Indian firms, the backlash of the multinationals in India, the impact of quality regulation in Brazil that provoked technological capability accumulation and the new and powerful role of patent litigations in both countries.

Internalisation due to policy change in USA: Interestingly, the rise of exports was partly due to the foray of Indian firms into regulated markets of Western countries, with the principal target being the USA. During the 1980s, American policy makers had become sensitive to the need for improving access to medicines and curbing the growth of health expenditures in the USA. With this objective, the Hatch-Waxman Act was passed in 1984 to stimulate the market for generics, making demonstration of bio-equivalence sufficient to acquire marketing approval for a generic drug without the requirement of extensive clinical trials. Ironically, the concerns that prompted the Hatch-Waxman Act were quite similar to those, which had provoked the Indian Patent Act of 1970.

Indian firms with foresight like Ranbaxy recognized that the Hatch-Waxman Act in the USA in combination with the liberal economic policies in India was opening up new ‘windows of opportunity’. Such leader firms immediately attracted followers, which also attempted to penetrate the regulated markets of the USA and Europe (Athreya et al. 2008). The consequent building of regulatory handling capabilities, i.e. initiation of routines to document the entire production process under specific formats, resulted in India having the largest number of manufacturing units validated by the FDA outside of the USA by 2007: India had 75, Italy 55, Spain 25 and China 27 (Tribune des droits humains, 2007).

Internationalisation through catering to international agencies serving South: In addition, to exporting medicines to unregulated Southern markets, from 2000 onwards Indian firms began to get supply contracts from international agencies¹² supporting public health programs in developing countries, thus responding effectively to yet another ‘windows of opportunity’. Again, Indian firms had to learn to comply with a prequalification process of product-selection and the leading pharmaceutical firms adopted ‘good manufacturing practices’ even when it was not required within India, thereby acquiring new regulation handling capabilities. The success of the Indian firms is illustrated by the fact that out of the

¹² The WHO, the US President’s Emergency Plan AIDS Relief, the Global fund to fight AIDS, tuberculosis and Malaria, the Bill and Melinda Gates Foundation, the Bill Clinton Foundation, etc. .

190 antiretrovirals prequalified by the WHO to treat HIV/AIDS, 108 are produced by firms such as Ranbaxy, Cipla or Matrix Laboratories (WHO, 2010). As a result of being recognized as suppliers of quality drugs at low cost, Indian firms have been supplying more than 80% of donor-funded AIDS medicines to developing countries in the last five years (Waning et al., 2010).

Mergers and Acquisitions – becoming a two way road to industrial organization change: A number of recent articles on Indian pharmaceutical firms (cited in section 3.6) correctly point out that no academic pundits arguing for or against TRIPS during the debate phase (1990-2000) imagined that Indian firms would be pragmatic enough to consider external sourcing of technology or have the financial force to acquire foreign firms. Furthermore, as Chittoor et al. (2008) show most of the acquisitions are by private entrepreneurial firms with no backing from the government.

However, what was even less foreseen was the backlash of MNCs through acquisition of Indian firms. Indian firms have such high production capabilities and can manufacture generics at such low prices that they are becoming attractive to global players. Since liberalization permits 100% equity holding even in pharmaceuticals, the stars of the Indian pharmaceutical industry are being bought out by foreign multinationals. Thus, in 2008, the leading pharmaceutical firm Ranbaxy was bought off by the Japanese firm Daiichi-Sankyo; in 2009, Shantha Biotechnics, which was the first to produce an indigenous recombinant product (Shanvac B, a hepatitis B vaccine) was acquired by Sanofi-Aventis and in 2010, Abbott acquired Piramal Healthcare. There have been also bids on Cipla, Wockhart and Dr. Reddys.

Regulation to improve drug safety provokes technological capability accumulation: The Generics Act promulgated in the interest of public health pushed Brazilian firms to do what loose IPR designed to facilitate accumulation of re-engineering skills had failed to do – namely invest in developing technological capabilities. Brazilian firms recognized the Generics Act as a window of opportunity and finally started moving towards a ‘technology based competition logic’ by switching to the production of generics complying to the new regulation (Frenkel, 2001). Between 2000 and 2003, generic producers in Brazil invested nearly a billion dollars in the construction and modernization of units, and the development of technological capabilities (Bermudez and Oliveira, 2004). The generics market itself increased from 1 to 10.7% of total pharmaceutical market between 2000 and 2006. This increase has clearly benefited the Brazilian firms as the number of local firms among the top 20 generics producers in Brazil increased to 7 holding about 25% of the market share by 2005¹³.

Patent litigation as an instrument of defence and offence: Under the TRIPS environment patent litigations are likely to increase as local firms strive to commercialize generics and MNCs work to protect their branded products through ever-greening their patents. In India, there are an increasing number of patent disputes regarding life saving drugs between patent owners, generic producers and the public. For instance, using a pre-grant opposition mechanism introduced in 2005 in the patent law, Indian firms and a civic association challenged Novartis’ application for a patent on its anticancer drug Glivec. The patent was rejected on the ground that the API was based on a derivative of a molecule known before 1995, which “does not result in the enhancement of the known efficacy of the substance” as stated the Section 3(d) of the Indian Patent Act (Srinivasan, 2007). Furthermore, these problems are exacerbated by a lack of coordination between governmental bodies. For example, Cipla gained marketing approval for a generic version of a lung cancer drug from the Central Drugs Standard Control Organization (CDSCO), which operates under

¹³ See www.progenericos.org.br, last visited February 2010.

the aegis of the Ministry of health and family welfare, while the original innovator Roche was granted a patent by the Indian patent office at the same time for its branded drug Tarseva (Gehl-Sampath, 2008). Again, in the interests of the public, the Indian court sided with the generic producer.

Till the end of the 1990's, only the patent office was involved in the patent application process in Brazil. Adopting a broad interpretation of 'novelty', it was only interested in monitoring the number of patents granted as the indicator of its performance and Brazilian market dynamics. However, with the introduction of a 'prior consent' mechanism in 1999, the drug monitoring agency ANVISA has to first agree on the patentability of a drug before the Brazilian patent office takes a decision (Shadlen, 2009). As ANVISA may not consent to the patentability of a drug on the basis of the narrow criteria for 'novelty', the patent application process is made more uncertain for MNCs trying to evergreen their patents.

Thus, clearly Indian and Brazilian firms need to develop a new capability – namely that of pursuing patent litigations in order to protect their turf in their home countries and perhaps abroad as well.

4. Discussion of results

The purpose of the present paper was to provide insight on an issue that has not received enough attention in the existing literature on catch-up namely – what are the determinants of divergence in industrial trajectories of developing countries? We tried to contribute to filling some of the lacunae in the catch-up literature signalled by eminent scholars through our focus on the evolution of a single sector in two countries as a function of their NSI¹⁴. Thus, a conceptual framework of catch-up dynamics was developed to compare the evolutionary trajectory of the pharmaceutical industry in India and Brazil from the 1950s to the present day.

4.1. The catching up process in Brazil and India and their outcomes

The main results of the case study are summarized in table 1. It clearly reveals that despite the similarity between India and Brazil, in terms of capabilities and public policy during the 1950's, the evolution of their pharmaceutical industry over 60 years has led to very different outcomes in terms of the degree of backward integration of local firms, the domination of MNCs in the domestic market, the internalization of local firms and the role of public sector.

The case studies confirm that catching-up in the pharmaceutical sector is a three-stage process. Both India and Brazil started by creating '*production capabilities*' in some niches, then moved on to develop '*re-engineering capabilities*' and in the post-TRIPS period are reaching out to acquire '*new drug-discovery capabilities*' in upstream research or downstream clinical trials, after establishing innovation capabilities in specific drug niches.

To create 'production capabilities', both countries started by importing API and focussed on acquiring 'packaging skills' or '*skills in formulations*'. Then, they integrated backwards to be able to incorporate '*bulk drug production capabilities*'. After that, depending on the cost efficiency, the safety and quality of the product concerned, and the identification of uncontested niches in the international market, India developed '*international production and marketing capabilities*'. There was no possibility for 'leap-frogging' over any of these

¹⁴ Nelson notes that in the NSI-Catch up literature: "there has been very little detailed study of the process of transformation of firm and industry structure" (2008, p.17). Edquist points out: "Another weakness of the SI approach is that it lacks theoretical component about the role of the State. This is an important neglect since the State and its agencies are obviously important determinants of innovation in any SI" (2001, p. 3).

Table 1: Looking back at the catching-up process in India and Brazil in pharmaceuticals

| Salient features of the catching-up process | India | Brazil |
|---|---|---|
| Catching-up route in production capabilities | Stages of evolution: (i) skills in formulations; (ii) large scale bulk drug production ; (iii) large scale production of API; (iv) integration of biotechnology; (v) focus on niches of drug discovery process. | Stages of evolution: (i) skills in formulations; (ii) integration of biotechnology with focus on niches of bulk drugs and API; (iii) focus on niches of drug discovery process. |
| Catching-up route in marketing capabilities | Stages of evolution: (i) satisfaction of domestic market; (ii) exports of East European and developing countries; (ii) exports to regulated markets in USA and Europe; (iv) Exports to regulated Southern markets | Stages of evolution: (i) satisfaction of domestic market; |
| Catching-up route in innovation capabilities | Stages of evolution: (i) re-engineering skills; (ii) integration of biotechnology; (iii) focus on niches of drug discovery process. Though public-private cooperation remains crucial - innovation generation led by private firms. | Stages of evolution: (i) re-engineering skills; (ii) integration of biotechnology; (iii) focus on niches of drug discovery process. Public-private cooperation is being strengthened - but public sector firms are also leaders in innovation generation. |
| Performance | India | Brazil |
| Production autonomy | developed capabilities in all 5 phases of catch-up (refer to figure 2) | Vertical integration remains a major challenge in many drugs. As of 2005, more than 90% of required API was still imported. |
| Size of pharmaceutical market in terms of local sales in 2005 | 10.8\$ billion | 5.3\$ billion |
| Trade balance in pharmaceuticals in 2005 | 3.8\$ billion | -2.7\$ billion |
| Internationalization | Mergers and acquisitions abroad; Manufacturing units abroad | underdeveloped |
| Exports | Forumulations and bulk drugs to both developed and developing countries | underdeveloped |
| MNC dominance in 2005-2006 | less than 20% in 2005-2006, but over 40% in 2011 with mergers and acquisitions*. | 70% of the market held by foreign firms |

*Economic Times, May 24, 2010; Rest of the figures are from the cited references.

three phases. However, the catch-up process was not linear over time or complete in terms of all possible niches in the different phases. Nor was the trajectory similar in the two countries leading to different outcomes albeit with some common features. Details at the firm level tracing this kind of a catch-up trajectory with case studies can be found in Chaturvedi, et al. (2007), Kale and Little (2007) and Athreya et al. (2009) for India; and in Ryan (2009) for Brazil.

As a result of their divergent capabilities accumulation, today Indian firms produce most generics, making the corresponding API by themselves; while Brazilian firms have to count on imported API to formulate the drugs. Indeed, Brazilian firms are paying a double price for having missed catching-up in terms of technological capabilities – they are missing out on their very large internal market, and furthermore, are still overly dependent on imports. But in the post-TRIPS world, both countries are engaging in similar strategies to acquire knowledge from abroad and generate knowledge from within, especially in biotechnology.

4.2. Insights on windows of opportunity and actors' behaviour

First and foremost, in the catch-up literature windows of opportunity are usually synonymous with radical technological discontinuity whereas the case studies highlight that this need not be so. During the period considered, there was no radical change in the technology paradigm in these countries. The traditional source of 'shock' on the innovation system was totally absent. Biotechnology did emerge as a radical new technology paradigm in the West from the late-1970's, but its integration in India and Brazil had very small ripple effects and zero impact on the industrial organization. In contrast, radical regulatory changes in the two countries created 'windows of opportunity' and generated positive externalities, in a way very similar to radical technological discontinuities.

Second, the case studies illustrate that the mere existence of windows of opportunity while being necessary for catching-up may not be sufficient. Whether or not actors perceive the windows of opportunity, whether and how they act upon them crucially determines the extent of accumulation of the industrial capabilities and the scope of catching-up. Turning to the other side of the coin, poor perceptions and/or feeble actions of actors can also serve to explain low levels of capability accumulation and finally divergence in catching-up between countries.

Classic examples of the above hypotheses are provided by the response of Indian and Brazilian pharmaceutical firms to two major policy regime changes.

When the State adopted the import substitution model of growth after WWII in India and Brazil, it was implicitly assumed that windows of opportunity had been opened and catching-up would automatically follow. But this simply did not happen, because the firms had a different perception and could not identify any windows of opportunity opened by the regulatory change.

However, in addition to an import substitution regime, when India switched to a loose patent regime in 1972, suddenly a window of opportunity to increase profits through the development of re-engineering capabilities was recognized. It did not lead the Indian firms to patent new processes in the Indian patent office en masse, but it forced them to look for new methods of production compatible with local resources and constraints, since the original method could not be copied. Then, when some firms made profits via the creation and commercialization of lower priced generics, a secondary 'bandwagon effect' was triggered within the market.

In contrast in Brazil, even the absence of IPR did not induce firms to invest in acquiring reengineering skills. No window of opportunity was spotted to accumulate technological capabilities. As a business strategy, Brazilian firms perceived it to be more profitable to focus on the last stages of formulations requiring little capital investment and technical skills. Indeed, they found it better to mimic Western MNCs rather than compete with them. But such ‘commercial logic’ of Brazilian firms had a secondary effect on the innovation system: it pushed the public sector to become active and attend to the needs of the citizens (detailed more in section 5.1).

Third, it is usually assumed that catching-up is most influenced by policies that impact knowledge or technological learning directly. But the Brazilian case study proves that this need not always be the case. The Brazilian State had overhauled the patent system to facilitate accumulation of re-engineering skills but this had little impact on catching-up, whereas the Generics Act, promulgated in 1999 mainly in the interest of public health, had a tremendous impact on catching-up. The Generics Act was perceived as a window of opportunity and initiated a late accumulation of production capabilities among national firms. Thus, policies that do not have a direct bearing on new technology generation can provoke the same.

Fourth, actors may identify distant windows of opportunity, far beyond their domestic market and act upon them in a desirable way from a national perspective. Definitely, the US ‘Hatch-Waxman Act of 1984’ and later the Brazilian Generics Act, which were not at all designed with the objective of promoting foreign firms, did exactly that for Indian firms whose astute exploitation of these opportunities contributed to their becoming multinationals.

All in all, the case studies demonstrate that even if two countries like India and Brazil are motivated by the same rationale and implement similar policies, the catch-up outcomes can diverge, as a function of the content, timing and implementation platform of the policies concerned. Indeed, a set of expected and unexpected outcomes can trigger further secondary effects through inter-organizational observation and learning that provoke ‘mimicry’ and ‘bandwagon effects’. As a result of this set of expected and unexpected outcomes and bandwagon effects, which are specific to countries, catch-up trajectories may diverge.

5. Perspectives and Conclusions

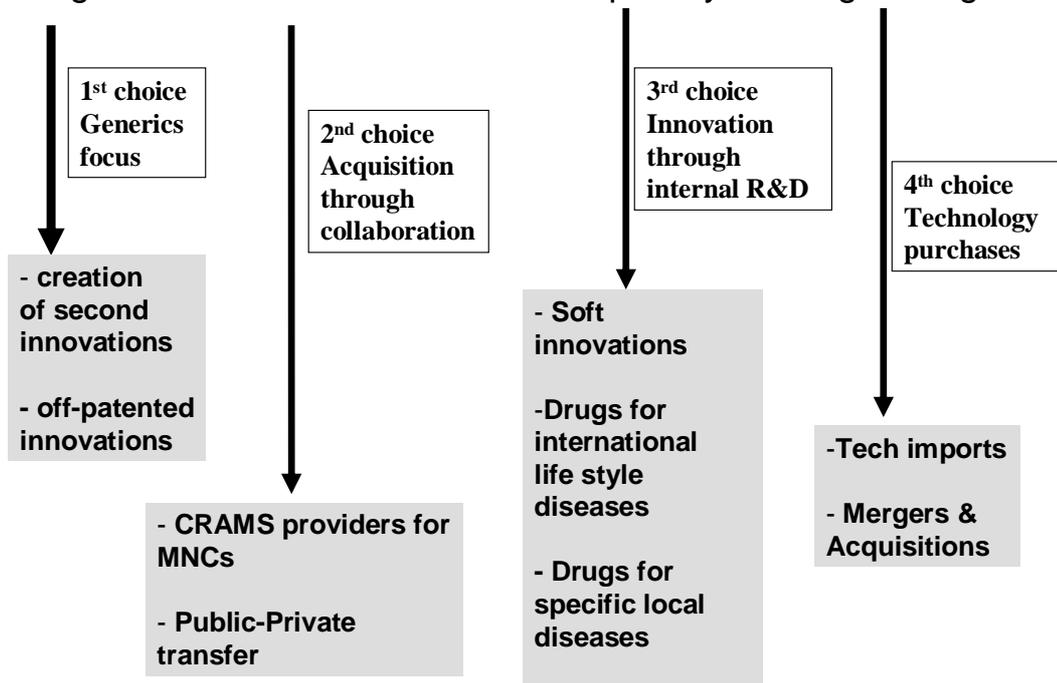
After sixty years of evolution, in both India and Brazil, in some ways, there is a sense of déjà vu. Despite the great progress made, the IPR system has returned to the post WWII regime. Local firms in Brazil still do not command the majority of the market and MNCs are making speedy inroads through inorganic growth in India. Yet, in India and Brazil there has been tremendous capability building. So, what of the future, knowing well that TRIPS imposes the same rules on all countries for technology races and developing countries have much less resources to allocate for the preparation of such races. Does the TRIPS-liberalisation regime mean a return to the neoclassical framework, where policy and institutions have a minimal impact on catching-up and firms have to create their own ‘windows of opportunity’ through own R&D? We turn to this question now, using the results obtained so far as a reference on which to base future projections and recommendations. These are the inferences that have also been validated by the interviews conducted.

5.1. What windows of opportunity in the post-TRIPS liberalised globalising world?

TRIPS essentially constitutes a broadening of the IPR regime by which fewer loopholes are left around which second innovators can commercialise branded products, without having

to enter into some sort of a licensing agreement with the first innovator. But, while TRIPS lowers the appropriation of innovation rent, it does not eliminate it. From the study of current firm strategies outlined in sections 3.6 and 3.7, the roadmap of future options can be projected as in figure 4. The first option would be to continue to exploit accumulated re-engineering skills by focusing on generics. Second, firms can attempt to learn through collaboration via strategic technology alliances, either with more technologically competent firms, typically foreign ones; or public-private research partnerships. Third, they can invest in the creation of original innovations through internal R&D. Fourth, they can acquire new technology through market transactions.

Figure 4: Post-TRIPS innovation capability building strategies



Of the four options, the internal R&D route is going to be the most challenging. Neither Indian nor Brazilian firms can match the deep pockets of MNCs. The sum of the R&D expenditures of the top 11 companies in India in 2005-2006 was only \$379 million, while that of Pfizer was almost 20 times more at \$7440 million (Chaudhuri, 2007). In Brazil, the overall R&D expenditure on pharmaceuticals in the country touched a low \$125 million in 2005, obstructing opportunities for the building of industrial capabilities in general and innovation capabilities in particular (De Lemos Capanema, 2006).

Indeed, given their small pockets, the strategic choice of Indian and Brazilian firms will depend on their risk preference. In developing a competitive advantage through focus on generics, there is least risk of financial loss but also least learning. The collaboration route may or may not enable the firms to move up the learning curve. The impact of market acquisitions of new technology will depend on the firm's own absorptive capacity. Finally, own R&D while holding the potential for maximum learning, is also the most risky financially.

Which of these three roads are most likely to lead to further catching-up for Indian and Brazilian firms? Which combination of these strategic options will yield the maximum short term returns, while ensuring long term sustainability? Though only the future will reveal the answer to the above questions, the stakes for the future appear to be different for India and Brazil.

First, the primary objective of Indian firms is to accumulate innovation capabilities, whereas Brazilian firms need to expand their production capabilities to include API, while accumulating new drug discovery capabilities. Moreover, Brazilian firms have to catch-up vis-à-vis India in terms of regulation handling capabilities, but this is not their primary concern. For Brazilian firms, even to achieve backward integration over the production process, the problem is not lack of scientific capabilities, but rather the lack of funds to buy the equipment that would enable the necessary research to re-engineer API and make their commercialization a worthwhile business proposition. This constraint is made doubly difficult as their main competitors, the MNCs (from both Developed and Emerging countries), already exploit these economies of scale at a global level and export massively to the Brazilian market.

Second, for Indian firms, even a steady focus on accumulating strong generics manufacturing capabilities carries a real risk, as it might make them more attractive and vulnerable for a foreign MNC take-over.

Third, while Indian firms are more likely to collaborate with foreign firms to accumulate innovation capabilities, in Brazil it is more likely to happen through public-private partnership. For instance, Far-Manguinhos, a public research institute in pharmaceuticals, is the nodal organisation around which a strong and dense network of public units and private firms has been constructed to promote the production of API through reverse-engineering and copying of existing molecules (Cassier and Correa, 2008).

Still, there could be windows of opportunity to catch-up further through a mix of three strategies involving refining capabilities in generics, while learning through collaboration and astute investment on 'niche' innovations. Moreover, whether or not the Indian and Brazilian pharmaceutical trajectories ever cross each other is likely to be determined by the performance of the private sector Indian firms vs. that of the public sector Brazilian units and the public-private partnerships in pursuing these mixed strategies. These arguments lead to the following recommendations for firm strategy.

Continue to reinforce comparative advantage in generics and soft innovations: The comparative advantage of India and Brazil is their relatively cheap qualified labour. Such labour pools can enable investment in labour-intensive incremental innovation generation. Therefore, possible secondary windows of opportunity may lie in the creation of cheaper generics, or incremental innovations in terms of drug delivery, dosage, and software to complement an original innovation. Much will also depend on how flexibilities in TRIPS are exploited, for instance whether emerging country firms can innovate 'around' a known molecule exploiting provisions that allow for patenting if the efficiency of the drug is significantly improved.

Explore public-private partnerships and make them more effective: Public-private cooperation played an important role in the development of re-engineering skills in pharmaceuticals in both the countries studied, though it is on the wane in India as compared to Brazil. Clearly, if the innovation capacity of public laboratories can be mobilized effectively

to work on targeted goals with local firms, then firm learning and eventually social welfare is more likely to improve than through contracting with foreign MNCs.

Watch out for new opportunities: New or previously unexploited ‘windows of opportunity’ may contribute to further accumulation of technological capabilities. Some possibilities are new uses of old technology, traditional knowledge and traditional medicines¹⁵.

5.2. Policy Recommendations

The experience of India and Brazil prove that even accumulation of organizations, institutions and scientific and technological capabilities need not be sufficient for catching-up. In addition, the NSI must induce appropriate endogenous responses from the concerned stakeholders. In other words, if policy is to succeed, the incentives generated must be perceived and exploited appropriately. Thus, in the present context, with respect to further catching-up in pharmaceuticals, the case studies yield the following recommendations for State policy and firm strategy.

Make policy design more rational: Given financial constraints, more than ever policy makers and other stakeholders in developing countries, have to interact to design policy that matches the expectations of the different stakeholders to the maximum extent possible. Only with more dialogue and explicit bargaining can there be fewer surprises and more coordinated development. This implies that the different stakeholders, in particular policy makers, have to get out of their ivory towers to interact more with one another and contribute to a policy formulation that induces the desired responses as far as possible.

Invest in public research and improve its contribution to catching-up: Investment in universities and public research is not only necessary to ensure pools of qualified labour and technology transfer to private firms, but also to create a vibrant public sector that can fill in crucial niches underserved by private firms whenever necessary. Given the challenges of biotechnology (and now nanotechnology), the contribution of public institutions is more important than ever.

Build regulation handling capabilities: Catching-up in terms of regulatory bureaucracy could also impinge on the accumulation of technological capabilities in the future. At present, in most developing countries, there is a manpower crisis in patent offices as there are not enough qualified personnel who are familiar with both the technology (especially biotechnology) and the law. This forces leading emerging country pharmaceutical firms, such as those from India to seek EPO and USPTO patents, which are far most costly and uncertain.

Support options for international cooperation: A myriad of possibilities can open up with a strategic exploration of South-South and North-South cooperation to develop common R&D programs, sharing of information about respective patenting and marketing approval procedures for drugs, cross-licensing agreements or sharing of patent pools (see Thorsteinsdóttir et al., 2010 for example in biopharma).

To conclude, the challenge under the present TRIPS cum liberalization regime for developing country pharmaceutical firms is to identify and seize possible existing windows of opportunities, while preparing for new opportunities in the future by accumulating innovation capabilities. Given that developing country firms cannot compete with the deep pockets of

¹⁵ For instance, in the future, the exploration and exploitation of the rich Brazilian biodiversity may offer new opportunities for national players to be part of the next generation of new drugs development in one way or another (Fialho et al, 2004).

developed country MNCs, the competitive positions of developing country firms in pharmaceuticals is crucially going to depend on the support of their governments for public research – especially in biotechnology. It is quite possible that only publicly funded basic research can provide ways to squeeze in innovations through patent thickets.

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