The importance of generic drugs in the South: behind the Brazilian anti-AIDS program, the Indian performance in the pharmaceutical sector.

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(En soumission)

1. Introduction
In a report published in 1993, the World Bank expressed its concern about the spread of the HIV/AIDS epidemic in Brazil. Due to its large population, the important number of poor people and the precarious state of the healthcare system, experts estimated that there would be nearly 1.2 million people infected by HIV/AIDS by the end of the decade against 400 000 in 1991 (World Bank, 1993). However, an appropriate intervention in the country could help to avoid new infections with at last 800 000 people living with HIV/AIDS by 2001. Precisely, the report insisted on the need to induce significant changes in behavior so to provoke major decline in HIV/AIDS trend. Accordingly, a focus on prevention was recommended.

Fourteen years later, WHO praised Brazil for its capacity to stabilizing the epidemic: 600 000 people are living with the infection, far less than the most optimistic estimation formulated by the World Bank in 1993. Thus, the country has succeeded in implementing an effective intervention, which altered the course of the epidemic with 0.6% of adults living with the infection today (WHO, 2004a, UNAIDS, 2008).

More importantly, Brazil has demonstrated that the combination of prevention and care is critical for stabilizing the epidemic. Definitely, the distribution of condoms among the general population and the specific ones at high risk of contracting and transmitting the virus, the provision of needles and syringes among injected drug users, or the communication efforts devoted at reducing the stigmatization and the discrimination associated with the infection have contributed to the dramatic decrease of new infections and mortality rates in Brazil. Significant behavioral changes have occurred with the result of noteworthy drops in the incidence of HIV/AIDS among sex workers and injected drugs users. Nevertheless, these achievements owe a lot to the implementation of a free and universal access program to HIV infection diagnosis, opportunistic infections treatments, laboratory monitoring and antiretroviral therapies. Indeed, this program has reduced stigmatization (Abadia-Barrero and Castro, 2005), induced people to undergo voluntary and confidential testing, and permitting early detection of the infection (Serra, 2004, Berkman et al., 2005). It has also increased the number of people aware of their HIV status, thus reducing the transmission rate.

At the end, while a large consensus was commending the focus on prevention to inflect drastically the spread of the epidemic, the Brazilian experience points out in contrast the intertwined link between prevention and care. Besides, it demonstrated that even within precarious healthcare systems, the provision of treatment to people living with HIV/AIDS does not necessarily increase the risk of weak adherence from patients and high risk of resistance to treatment. At last, it shows that a free and universal access program can be cost-effective, allowing substantial savings in hospitalization and treatments for symptomatic patients: 2 billion dollars saved from 1998 to 2003 (Teixeira et al. 2003).

Today, Brazil is presented worldwide as a model whose replication in developing countries, more severely hit by the epidemic, is greatly discussed as a mean to prevent dramatic socioeconomic impacts in terms of reduction in labor productivity, agricultural production or pressures on the health sector (Danziger, 1994). In particular, it is reminded the role played by the sanitary reform movement and the strong commitment of the civil society in a context marked by a redemocratization of the country, all historical conditions that brought crucial changes in the health landscape: the constitutional right to health, the implementation of the Unified healthcare system in 1988 and the instauration of the free and universal access program to HIV/AIDS in 1996 (Levi and Vitoria, 2002, Serra, 2004, Berkman

As regards the successful implementation of the anti-AIDS program which covers today more than 180,000 people, a large literature emphasizes the capacity of the Brazilian government to reduce the price of treatments. This capacity results from hard bargaining with patent holders, based on the threat to resort to compulsory license and the existence of a domestic pharmaceutical industry involved in the production of antiretrovirals (Rev Panam Salud Publica, 2001, Galvao, 2005, Levi and Vitoria, 2002, Cohen and Lybecker, 2005, Berkman et al., 2005, Pinheiro et al., 2007, Ford et al., 2007, Nunn et al., 2007, Flynn, 2008, Ferro do Lago and Rosario Costa, 2009).

The present paper proposes to enlighten further the industrial dimension of this successful program, refine the conditions lying at the heart of it and re-specify the issues concerning its potential replication in other developing countries, particularly those deprived of industrial capabilities. Our argument is that the success of the free and universal access program in Brazil hides another success, that of India in the pharmaceutical field. Indeed, endowed with a strong political will, on a demand side and a public health ground, Brazil has been able to carry out an offensive public health policy and ensure the scaling-up of the largest free and universal access program to anti-AIDS drugs in the developing world. However, on the supply side and an industrial ground, this policy owes a lot to the existence of competitive Indian firms in the global antiretroviral market.

Building on case studies of industrial policies that took place in the pharmaceutical sector in Brazil and India, we intend to enlighten the divergent industrial trajectories followed by the two countries. We propose to scrutinize how India has supported the development of a pharmaceutical industry capable of producing both active principle ingredients (APIs) and finished products (medicines), significantly improving national self-sufficiency and largely exporting to the rest of the world. As a key result of this performance, from the beginning of the 2000s Indian firms have become major players in the global antiretroviral market, being at the origin of sharp price reductions and notable social benefits for developing countries. In contrast, Brazil failed to ensure the rising of a pharmaceutical industry and deepened over the decades its large dependence vis-à-vis foreign suppliers for pharmaceutical products, especially Indian producers regarding their huge needs for antiretroviral.

So doing, first, the scaling-up of the Brazilian free and universal access program is briefly recounted regarding more specifically the manifold announcements to use compulsory license (section 2)1. Then, the Brazilian and Indian divergent trajectories in terms of industrial capabilities building in pharmaceuticals are presented, from the production of APIs to the formulation of drugs (section 3). Thus, the strong industrial support from Indian firms to the free and universal access program is put forward in comparison to the weak support offered by Brazilian firms lacking significant industrial capabilities (section 4). Finally, incorporating these elements about the genuine industrial basis of the successful Brazilian free and universal access program, the debate about possibilities for developing countries to replicate this model is examined. Especially their capacity to negotiate lower price is discussed through the provision of good and bad news (section 5).

2. The successful scaling-up of the Brazilian free and universal access program

In the developing world, Brazil is a leader in implementing a free and universal access program to antiretroviral. As recounted in the following table, this program began with the provision of drugs to more than 36,000 people living with HIV/AIDS in 1997 (Chequer, 2007). The annual budget allocated to the purchase of antiretrovirals was then 224 million dollars. In 2005, the program was covering 180,000 people infected by HIV/AIDS and the budget reached 395 million dollars. The per capita expenditures decreased from 6222 dollars in 1997 to 2194 dollars in 2005.

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1 The Trade Related Intellectual Property Rights agreement (TRIPS) ratified by all countries members of the World Trade Organization in 1994 provides countries members with flexibilities to circumvent patents and ensure the promotion of public health. In particular, compulsory license allows the domestic production of a patented drug and its supply at more affordable price.
When questioning the ins and outs of the successful scaling-up of the program, two correlated elements are enlightened in the literature. On one side, the commitment of the Brazilian government to resort to flexibilities provided by TRIPS in order to bargain lower prices for antiretrovirals is underlined. On the other side, the strong support provided by the local pharmaceutical industry for the procurement of more affordable antiretrovirals is put forward.

Indeed, in 2001, the Brazilian government considered for the first time the resort to compulsory license. At this date, concerns were raised that more and more patients had to switch to second line regimen treatments made of patented drugs, much more expensive than the off-patent ones composing the first line regimen. In particular, Efavirenz was absorbing 10% of the drug budget. Therefore, Brazil was considering to circumvent the patent for this expensive drug and to allow the production of more affordable copies. As summarized in the table below, this announcement marked just the beginning of a modus operandi followed by the Brazilian government: evoking compulsory license and bargaining lower price to ensure the sustainability of the free and universal access program (Levi and Vitoria, 2002, Grangeiro et al, 2006, Greco and Simao, 2007, Possas de Albuquerque, 2008, PIJIP, 2008).

Furthermore, the literature emphasizes the threat to resort to compulsory license was based on robust local industrial capabilities for the production of antiretrovirals. When Brazil announced its intention to issue a compulsory license for Efavirenz, 63% of antiretroviral were supplied by local firms and among the 17 medicines freely supplied, eight were produced locally in 2005 (Ford et al, 2007). Far-Manguinhos, the public research and development (R&D) and production unit, was carrying out the manufacture of most of these non-patented drugs in the country with the support of private firms. Hence, the scaling-up of the Brazilian free and universal access program was largely described as the result of local firms’ capacity to produce antiretroviral, strengthening the credibility of the Brazilian government to resort to compulsory license, increasing its bargaining power and finally exerting a constant downward pressure on prices (Galvao, 2005, Berkman et al, 2005, Cohen and Lybecker, 2005, Nunn et al, 2007, Ford et al, 2007, Salama and Benoliel, 2010).

Definitely, following the announcement made to issue a compulsory license for Efavirenz and the start of R&D activity on the molecule on the part of Far-Manguinhos, Brazil gained nearly 60% price reductions by Merck, interrupted the procedure for a compulsory license and saved 39 million dollars per year. This strategy was adopted by Brazil on several occasions but in 2007, after the country tried to obtain new price reduction and a voluntary license from Merck for Efavirenz (Cassier and Correa, 2008), the government finally issued its first compulsory license. Then, Far-Manguinhos was expected to produce a copy at a price comparable to the Indian generic by 2009 (Kaiser Daily HIV/AIDS Report, 2008). The local production began in 2009 with some mishaps (see below). At the end, on the basis of constant negotiations with patent holders, Brazil saved 1.2 billion dollars between 2001 and 2005 (Nunn et al., 2007).

### The universal access program to HIV-AIDS treatment in Brazil

<table>
<thead>
<tr>
<th>Year</th>
<th>Expenditures (in millions USD)</th>
<th>Number of patients under treatment (in thousands)</th>
<th>Expenditure per capita (in USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>224</td>
<td>36</td>
<td>6 222,22</td>
</tr>
<tr>
<td>1998</td>
<td>305</td>
<td>57</td>
<td>5 350,88</td>
</tr>
<tr>
<td>1999</td>
<td>336</td>
<td>64</td>
<td>5 250,00</td>
</tr>
<tr>
<td>2000</td>
<td>303</td>
<td>79</td>
<td>3 835,00</td>
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<tr>
<td>2001</td>
<td>232</td>
<td>90</td>
<td>2 577,78</td>
</tr>
<tr>
<td>2002</td>
<td>179</td>
<td>105</td>
<td>1 704,76</td>
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<tr>
<td>2003</td>
<td>181</td>
<td>120</td>
<td>1 508,33</td>
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<tr>
<td>2004</td>
<td>203</td>
<td>155</td>
<td>1 309,68</td>
</tr>
<tr>
<td>2005</td>
<td>395</td>
<td>180</td>
<td>2 194,44</td>
</tr>
<tr>
<td>2008(p)</td>
<td>520</td>
<td>215</td>
<td>2 418,60</td>
</tr>
</tbody>
</table>

p : previsions.

While the success of the Brazilian free and universal access program is celebrated as a model whose replication in other developing countries is discussed, while the role of local manufacturers are defined as a key factor, little is known indeed about the state and extent of these industrial capabilities (i.e. Brazilian capacities to produce finished products, APIs and market drugs observing high quality standards), and their exact contribution to this program. At best, one learns that today most of antiretrovirals are supplied by national units and some imports from India occurred with a view to supplying more affordable drugs. Though, the support provided by Brazilian production units is weak compared to the one provided by Indian firms insofar as a lack of consistent industrial policy did not permit to date the building of strong industrial capabilities in Brazil. In contrast, boosted by a solid industrial policy, notable industrial capabilities have been erected in India as illustrates the impressive entry of Indian competitors in the global antiretroviral market.

### 3. Content and result of industrial policies in Brazil and India

During mainly the second half of the 20th century, Brazil and India underwent a similar policy framework in order to ensure the rising of a national pharmaceutical industry. However, the industrial trajectory of the two countries significantly differed over the decades. Brazil has in the long run confirmed its strong dependence vis-à-vis foreign firms whereas India succeeded in ensuring the rising of a performing pharmaceutical industry today assaulting international markets.

#### 3.1. The divergent effects of an import substitution model

By 1950, foreign firms accounted for 47.1% of the pharmaceutical market in Brazil (Queiroz, 1993). In comparison, when India attained its independence in 1947, foreign firms held about 80% of the market (Singh, 1985, Ahmad, 1988). To reverse the situation, the two countries adopted both a substitution model of industrialization.

As part of this model aimed at promoting industrialization and self-sufficiency, Brazil overhauled the patent system in 1945 to permit only process patents. At the same time, a macroeconomic policy was implemented to attract foreign direct investments (FDI). Therefore, foreign firms were induced to import raw materials and equipments from their home countries on a large scale and expand their operation in Brazil. Thus, for lack of a consistent industrial policy dedicated to the development of a national industry, a denationalization of the sector was observed: Brazilian firms exited the market or were bought by multinationals. And this was the beginning of a long period marked by a growing domination of multinationals, holding 73.3% of the domestic market in 1960 and involved neither in R&D activities nor in the local production of raw materials (Queiroz, 1993).

Even when process patents were removed in 1969 to provide further incentives for the development of industrial capabilities, the permanent conflict between two industrial logics had inhibiting effects from the end of the 1960s to the 1980s (Loyola, 2009). An autonomous route insisted on the building of a national pharmaceutical industry involved in the production of APIs and medicines and the improvement of self-sufficiency. On the contrary, supported by foreign firms, a more dependant logic

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2 This part is largely drawn from Guennif and Ramani (2010).
emphasized the satisfaction of local demand, whether by local production or imports. As a result, by the beginning of the 1980s, an autonomous local industry was nowhere in sight while multinationals continued to increase their domination, holding about 82.7% of the Brazilian market (Queiroz, 1993).

In the 1980s, industrial policy was largely constrained by the macroeconomic environment (Suzigan and Furtado, 2006). Mired in a severe economic crisis and massive external debt, Brazil had to improve its balance of payments. Thus, budget cuts were imposed to institutions in charge of industrial policy. Besides, to reduce imports, protectionist measures were implemented and a public-private partnership was launched to improve industrial capabilities and increase national production in APIs and medicines (Queiroz, 1993, Urias and Furtado, 2009). However, Brazilian firms began to import raw materials like multinationals to manufacture finished products and to compete with them in the final market through their sales force. At the end, the Brazilian pharmaceutical industry was characterized by a weak backward integration and a strong domination of multinationals in the domestic market.

In the meanwhile, the Indian trajectory was far less chaotic. To reduce the dependence on imports and multinationals, throughout the 1960s and 1970s, the country established high import duties and export subsidies, and a system of price controls. Furthermore, under the ‘Licence Raj’, firms had to get a license from the government to expand their manufacturing base, export or import (Singh, 1985, Ahmad, 1988).

After twenty years, 80% of the market share was still held by multinationals. In 1970, Indian firms had capabilities only in formulations and drug prices were among the highest in the world. This situation was partially due to import duties and most of all to firms’ strategy featured by brand competition. Besides, the IPR regime inherited from the British colonial rule was incriminated: patents were provided for processes and products for 14 years, most of them were held by multinationals forbidding the copying of drugs.

In 1972, India implemented a new IPR regime. Henceforth, patents were granted to process and the marketing of copies was allowed. Indian firms began to invest in building industrial capabilities and started producing essential drugs, provoking significant price reductions. Thus, the market shares of multinationals dropped from 68% to 50% between 1970 and 1980 (Chaudhuri, 2005). By the mid-1980s, Indian firms were producing both APIs and medicines for the domestic market. By the end of the 1980s, India was exporting APIs and medicines, supplying many parts of the developed and developing world at lower prices and contributing to a positive trade balance.

Thus, unlike Brazil, as part of an import substitution model, the new IPR regime coupled with the dynamic response of national firms permitted the development of industrial capabilities in all stages of drug production in India. In turn, this led to a sharp reduction in multinationals domination in the local market.

3.2. Liberalization and deeper industrial divergences

The 1990s were characterized by the beginning of a liberalization process both in Brazil and India. The process did not reverse neither inflect the steady divergences between the two countries.

Burdened with excessive debt, Brazil adopted a set of economic liberalization measures recommended by the IMF, including the opening and the deregulation of markets. Therefore, import restrictions were decreased, lowering drastically the tariff on pharmaceutical products (Sweet, 2007). This prompted a new denationalization in the sector with the closure of production units in the first half of the 1990s (Orsi et al., 2003).

In 1996, under international pressure, without even making use of the transitional period provided by the TRIPS3, Brazil initiated a new reinforcement of its patent regime. Both product and process patents were reintroduced with a 20 years validity period. In addition, a pipeline protection was implemented ensuring patent protection for medicines developed prior to 1997 provided those medicines were already patented abroad had not been marketed previously in Brazil (ABIA, 2009).

At last, the drug policy was progressively changed. To induce competition and improve access to essential drugs, a tender law was put in place in 1993. Furthermore, the Generics Act was

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3 According to this transitional period provision, developing countries like Brazil and India had till 2005 to comply with the TRIPS agreement. India took benefits of this provision.
promulgated in 1999 with the objective to improve the quality of drugs sold, to increase market competition and boost the consumption of generics, cheaper than branded drugs. As a result, from 2000 to 2003, generic producers invested nearly a billion dollars in the construction and modernization of units, and the development of industrial capabilities in Brazil (Bermudez et al., 2004). The generics market increased from 1 to 10.7% of total pharmaceutical market between 2000 and 2006, clearly benefiting to the Brazilian firms. Still, 70% of the market was held by foreign firms and more than 90% of raw materials were imported leading to a record deficit of $2.7 billion in 2007, more than double of the value in a decade (Urias and Furtado, 2009).

In India, the liberalization process initiated in 1991 put an end to the Licence Raj and narrowed considerably the price control regime. The result was a noteworthy effect on the growth of the pharmaceutical industry, with more firms entering the market, and the established ones increasing their manufacturing base. Production, exports and imports shot up and the industry grew rapidly in the 1990s, with an average annual growth rate of 15% for APIs and 20% for formulations (OPPI, 2004). In particular, the rise of exports had been partly due to the assault of Indian firms in regulated markets of developed countries, especially the US market (Guennif and Ramani, 2010).

At the end, after several decades of industrial policy marked out successively by import substitution model and liberalization process, Brazil and India have deepened the gap. India has ensured the rising of a pharmaceutical industry capable of producing APIs and drugs enabling domestic firms to become major suppliers in international markets. In contrast, Brazil failed to build a strong pharmaceutical industry, increasing in the long run its dependence towards foreign firms, which dominates in the local market for the supply of both APIs and drugs.

All these statements require a reassessment of the contribution of the Brazilian industry to the free and universal access program praised by a large literature and of the genuine role played by Indian firms.

4. The extent of Indian and Brazilian industrial capabilities in the specific antiretroviral market

Beyond the gap between Brazil and India in industrial capabilities achieved in the pharmaceutical sector, the one observed in the antiretroviral field is all the more vivid. Again India displays crucial accomplishments in APIs production, drug formulation and quality control, which benefit to the developing world, in the first place Brazil whose industrial capabilities remain limited in comparison.

In India, the antiretroviral production began in 1991 (Guennif, 2004). At that time, Cipla began working on the formulation of antiretrovirals with low content in raw materials and relatively low complexity in the formulation process. Ten years later, in the absence of product patents on their territory, Indian firms were the first in the world to produce cocktails. Made of several drugs encapsulated in one pill to be taken several times a day, these cocktail bring down the number of pills to be taken, improve compliance and finally reduce drug resistance among patients.

Nowadays, many Indian firms are producing antiretrovirals, from APIs production to drugs formulation, and are exporting to international markets. The massive foray of those firms has induced huge competition and sharp price reduction. For instance, between 2000 and 2010, the price of a first line regimen, recommended by WHO to naive patient and made of three antiretrovirals, has fallen from 10 439 dollars per year and per patient under patented drugs to 67 dollars under generics supplied by Cipla (Médecins sans frontières, 2010).

From 2000 onwards Indian firms began to supply antiretrovirals within public health programs implemented in developing countries with the financial support of international organizations: the World Bank, the Global Fund, the US President’s Emergency Plan AIDS Relief, the Melinda and Bill Gates Foundation, the Bill Clinton Foundation, UNITAID,... To ensure the supply of high quality standard drugs, these organizations require countries recipients to provide patients with drugs holding WHO-prequalification or USFDA approval. Therefore, generic producers are induced to improve their quality standards to become suppliers of these public health programs.

According to the last WHO List of prequalified medicinal products in the HIV therapeutic area (WHO, 2010), out of 190 products prequalified, 108 are produced today by Indian firms: 57% of the whole sample as indicated in the table below. Moreover, among the prequalified products, 56 hold US FDA approval: 30% of all products prequalified or 52% of Indian products prequalified. As an international acknowledgment of the high quality and low price of their drugs, Indian manufacturers have been supplying more than 80% of donor-funded AIDS medicines to developing countries in the last five
years (Waning et al., 2010). To sum up, Indian firms have become key partners for public health authorities in the developing world.

<table>
<thead>
<tr>
<th>Prequalified products manufactured by Indian firms in the antiretroviral field</th>
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<tr>
<td>Prequalified medicinal products in the therapeutic area of HIV</td>
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<tr>
<td>Prequalification gained by Indian Firms</td>
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<tr>
<td>Prequalification gained by firms from other developing countries</td>
</tr>
<tr>
<td>Firms prequalified</td>
</tr>
</tbody>
</table>
| Main Indian firms prequalified | Cipla - 34 products  
Matrix - 27 products  
Ranbaxy – 20 products  
A total of 81 products or 42% of total prequalified products total, 75% of Indian prequalified products |
| Number of Indian products holding also US FDA approval | 56 : 30% of whole products prequalified  
52% of Indian products prequalified |
| Main Indian firms holding also US FDA approval | Cipla – 15 products  
Matrix – 15 products  
Ranbaxy – 2 products |


In comparison, since 2000, there has been a real effort in Brazil to revive industrial policy and encourage capabilities building in the pharmaceutical sector. Several measures have been implemented to promote spin-offs and technology transfer from universities, boost R&D in private firms and support public-private joint research projects in the sector. Besides, the implementation of the free and universal access program, the expanding of social demand for antiretroviral and the rising of prices lead the Ministry of public health to encourage the local production of these life-saving medicines. As a result, Far-Manguinhos has become the nodal organization around which a network of public institutions and private firms has been constructed with.

From 1997, on the basis of collaboration with national firms, the public lab has been ensuring the production and the supply of antiretrovirals to the public health program (Nunn et al, 2007, Cassier and Correa, 2008, Loyola, 2009). Precisely, private firms are producing APIs supplied to Far-Manguinhos, which is in charge finally of formulating medicines. As a result of this partnership, as stated above, half of the antiretrovirals available within the free and universal access program is supplied by the public lab.

Nevertheless, there is a crucial need to develop further industrial capabilities (Fortunak and Antunes, 2006). First, the formulation capabilities need to be extended to sensible technology. Whether Far-Manguinhos has formulation capabilities for the production of tablets, capsules, suspensions and solutions, it needs to develop technical competences for the production of soft gelatin capsule. Secondly, two national firms (Nortec and Cristalia) have the technical capacity to produce APIs, but they are currently producing very modest quantities. For lack of economies of scale primordial in the pharmaceutical sector, these APIs are 94% costlier than those supplied by Indian or Chinese firms. Therefore, more than 90% of APIs are imported from India or China (Sweet, 2007, Cassier and Correa, 2008). As a matter of fact, the public procurement system, which calls for the selection of the most competitive suppliers on the basis of price to ensure the sustainability of the free and universal access program, does not benefit national firms but foreign ones, mainly from India and China.

Last but not least, industrial capabilities regarding quality control need to be solidly established. When Brazil announced the issuance of the first compulsory license for Efavirenz in 2007 to gain substantial price reduction, the drug was finally imported from India at half price. Since 2003, a scientific team from Far-Manguinhos was sent to India to gather technical expertise to prepare the whole reverse engineering of Efavirenz (Cassier and Correa, 2008). But it appeared that the last steps of the production process were delicate with the particular need to invest in expensive equipments for the freezing of raw materials under minus 45 degrees (Fortunak and Antunes, 2006). So, the public lab
decided to simply formulate the final product on the basis of APIs imported from India. Furthermore, the marketing approval of the drug was thorny insofar as Far-Manguinhos faced difficulties going through bioequivalence studies required to guaranty the quality of the drug produced compared to the original drug. Finally, the first batch of Efavirenz produced locally was delivered at the end of 2009. The public lab was then able to meet 10% of local needs, the rest being imported from India at more affordable price.

Therefore, it should be acknowledge that when Brazil was threatening multinationals to use compulsory license and was trying to gain substantial price reduction, the favorable outcome of these offensives were less related to the development of industrial capabilities by national firms and mostly linked to large industrial capabilities built by Indian firms. Definitely, in 2006, when Gilead announced its intention to reduce the price of Tenofovir by 50% and to grant voluntary licenses, this had less to do with the Brazilian repeated threats to issue a compulsory license and to allow the local production of the drug. Most of all, it had to do with the declaration made at the same time by Cipla to launch its generic version of the drug and to export it at more affordable price in developing countries. Similarly, under the pressure of Indian generic producers, Abbott reduced the price of its Kaletra for forty low and middle income countries, including Brazil (Nunn et al., 2007).

Undoubtedly, the issuance of a compulsory license in Brazil has permitted the mobilization of national industrial capabilities, but it has merely revealed the limited option offered by national actors. While Far-Manguinhos has been overcoming progressively industrial obstacles regarding the production of APIs, the formulation of finished products and the quality control of drugs, large quantities of APIs and drugs are imported from India.

5. Discussion

According to a large literature, the Brazilian public health model implemented to address the HIV/AIDS epidemic is built on three pillars: free and universal access to antiretrovirals, bargaining with multinationals for price reduction and national production of medicines. A strong political commitment from Brazil has permitted the implementation of a free and universal access program to anti-AIDS treatments in 1996. Then, the decrease of the per capita expenditure over the years and the successful scaling-up of the program have been the result of the constant bargaining over price from Brazilian authorities. In turn, this has been built on the repeated threat to activate national industrial capabilities in the pharmaceutical sector for the production and supply of more affordable antiretrovirals.

Though, the elements presented here indicate that the Brazilian model is merely based on two pillars: free and universal access to medicines and bargaining with drugs’ patent holders. Definitely, the Brazilian capacity to bargain advantageously with multinationals relies on the very existence of competitive alternative suppliers. But this has less to do with competitive Brazilian firms operating in the local market than the performance of competitive suppliers acting on a global scale, mainly Indian manufacturers. This is explained by the divergent outcomes of industrial policies conducted in Brazil and India since the 50s.

In contrast to analysis celebrating the industrial achievement of Brazil in the pharmaceutical sector, indeed the country has failed to support the development of industrial capabilities, to achieve a high level of backward integration and lessen the domination of multinationals in the local market. Besides, a strong promotion of public health through specifically the implementation of a free and universal access program has not enabled the rising of noteworthy industrial capabilities in the production of antiretrovirals, mostly in APIs. As a matter of fact, in addition to the domination of western multinationals in the domestic market, Brazil notes the rising of new players, generic manufacturers from India and China.

In the meanwhile, Indian firms have built conclusive industrial capabilities in APIs production and formulation, becoming strong competitors in international markets. As an illuminating illustration of this achievement, the number of antiretrovirals produced by Indian firms holding WHO prequalification or USFDA approval has increased. Therefore, these new players have significantly increased the number of quality generics available in the global market, fueled competition and provoked sharp price declines which benefit public health programs in the developing world and Brazil in the first place.

Furthermore, none of the drugs formulated by Far-Manguinhos has been granted US FDA approval or WHO prequalification, revealing ultimately the limited Brazilian industrial capabilities hold in the antiretroviral field.
Following these statements, there are good and bad news for developing countries, which express huge concerns about the promotion of public health and the accessibility of essential drugs. Good news is that the capacity of a developing country to bargain lower prices is not related to the existence of national industrial capabilities in the pharmaceutical sector. This point is not trivial as very few emerging countries have significant industrial capabilities and most developing countries have nearly none (WHO, 2004b). As suggested by the Brazilian experience, the capacity of a developing country to bargain lower prices and ensure the supply of essential drugs to the population relies on alternative industrial capabilities to the ones built by western multinationals, whether be local or not.

A bad news is that the institutional landscape has greatly evolved over the last years in the country described as the 'pharmacy of the world'. India proceeded to a new strengthening of its patent regime in 2005. Among others, to be compliance with the TRIPS, product patents were reintroduced. Thus, antiretrovirals and other essential drugs patented abroad after 1995 are now patentable in India. So the possibilities for local firms to copy and supply more affordable medicines in local and international markets are severely limited. With the perspective of less competition pressure exerted by Indian firms in this new institutional landscape, patents holders firms are less sensible to bargain and less inclined to grant price reduction. This is already suggested by the rising of some critical antiretrovirals patented and recommended by WHO: they remain prohibitive and induce sharp rising in per capita expenditures within the free and universal access program (see table 1).

The good news is that the 2003 Doha declaration allows WTO countries-members to import under compulsory license. Accordingly, in case an antiretroviral is patented in India while Brazil, lacking industrial capabilities in the production of this medicine, wants to ensure an affordable supplying from India, a legal procedure will have to be observed. On one side, Brazil will have to issue a compulsory license to allow the marketing of a generic for a medicine patented within its territory. On the other, India will have to deliver a compulsory license to authorize the local production of a medicine patented in its territory and export to Brazil. To be clear, in 2007, when Brazil issued its first compulsory license so to import Efavirenz from India, the situation was different. Although being patented abroad after 1994, the drug was patented in Brazil under the pipeline protection; it was not in India. Consequently, Indian authorities did not have to issue a compulsory license to produce and export the medicine toward Brazil.

The bad news is that the use of this provision requires the observance of strict administrative requirements. Among others, the duration of the compulsory license and the quantities of medicines to be exported must be specified. Besides, the labeling of generics produced must be distinguishing so to avoid any confusion with the patented drug and prevent the illegal re-exportation of generics to another country. A Canadian firm, Apotek, had such difficulties to deal with these legal requirements that it decided not to renew the compulsory license issued to allow the production and the export of antiretrovirals toward Rwanda (Bourassa Forcier and Morin, 2009). This indeed explains the recent rising of per capita expenditure in the Brazilian free and universal access program, which is expected to rise to 2500 dollars per year and per patient against 1309 dollars in 2004. The complexity of the procedure makes its practical use difficult and releases competition in the global market with a risk for accessibility to decrease for new antiretrovirals.

Last but not least, the good news is that India does its best to continue, even in this new institutional landscape, to be a major player in international markets. This will is revealed by the number of patent litigations observed in India since 2005 and the recent rejection of a patent application for Kaletra, an anti-AIDS cocktail marketed by Abbott. On the basis of a strict delimitation of patent criteria and the provision of post and ex-post patent opposition, Indian firms and the civil society have been challenging the granting of patents for medicines in consideration of public health and industrial issues. Hence, this position permits Brazil today to envisage the issuance of a compulsory license with a view to supplying more affordable Kaletra; India will not have to go through a complicated procedure to issue a compulsory license and proceed to the producing and export of the cocktail. Additionally, this rejection permits Indian firms to keep on producing generics and expanding their market shares in India and in the global market. Thus, the future will tell whether Brazil will benefit from price reduction for new antiretrovirals thank to the Indian legal initiative and ensure the sustainability of its public health program. This supposes India to solve the seizure of these legal copies within the European Union on their way to developing counties in demand of affordable quality drugs and to avoid TRIPS plus provision during the negotiation of a Free-Trade Agreement with the European Community.

5 The Indian Patent Act provides that patent will not be granted for new forms of a known molecule, unless this enhances significantly efficacy.
At the end, developing countries, especially those deprived of industrial capabilities, must be very careful about the way they amended their patent law to be compliance with the TRIPS, regarding merely the patentability criteria implemented as well as the other flexibilities provided. Here, the Indian position should be followed as far as possible, at least for patentability criteria. Besides, developing countries need also to explore other means such as the price control of essential drugs as the one adopted for a while in Thailand, even of patented drugs. But then again, this supposes developing countries be able to support the pressure exerted by developed country during bilateral negotiations preceding the ratification of Free-Trade Agreement with the United States or the European Community.

Yet, the discussion about the progression of patent protection in the world and the practical implications for public health in developing countries should not elude other critical issues. First, the replication of the Brazilian model in developing countries is highly questionable regarding the role played by specific historical conditions aforementioned: the implementation of a constitutional right to health and a Unified health system in a context of re-democratisation. Second, it should not be omitted that the concern expresses by developing countries about public health issues focuses in the first place on the precarious healthcare infrastructures, linked to the scarcity of funding and the shortage of human resource (Van Damme and al., 2008).

References


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