

## **TRANSFER OF TECHNOLOGIES, PUBLIC POLICIES AND THE BUILDING OF TECHNOLOGICAL CAPABILITIES UNDER THE TRIPS AGREEMENT**

### **COMPLEMENTARY PUBLIC POLICY COMPONENTS OF A POSITIVE IP AGENDA**

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Ten years after its signing, the evaluation of the practical effects of the TRIPS agreement continues to be a rather controversial issue. Many countries of the South, in particular, are questioning the Treaty. These countries uphold that the granting of a patent to an innovator should not be considered as a natural right, but as a social contract. Consequently, they argue, each country must be free to choose their own compromise between the two dimensions involved in all patent systems: - providing incentives to innovate and favouring wide dissemination of the new knowledge thus produced.

Taking this as our background, our purpose in this paper is twofold: i) to envisage how IP systems can be designed to provide more room for policies aimed at building indigenous technological capabilities, ii) on this basis, and making use of the lessons to be drawn from past experience, to propose a very simplified “model” that can serve as a reference for developing countries (DCs) seeking to adopt voluntarist policies for the local building of technological capabilities. Although the paper aims at a level of general relevance, our actual argumentation draws on the more specific case of IP on drugs. We call attention to the public health problems raised by the signing of the TRIPS agreement, through the imposition of the patent protection of therapeutic molecules as a new minimum standard for member countries of the WTO.

#### **I. How should IP systems be designed?**

##### **The simple economics of “strong” versus “weak” patent systems**

Whether “strong” IP protection<sup>1</sup> is conducive to innovative activities and more generally to economic development is a long-standing and debated issue. While the developed countries, arguing that IP protection is a key to economic development, have insisted on the world-wide enforcement of so-called “minimum standards” of IP protection, most developing countries have tried to oppose – and in many ways continue to resist – this perspective (Reichman and Lange, 2000; Rémiche et Desterbecq, 1996)<sup>2</sup>.

One of the main arguments advanced by the champions of “strong IP systems” is that IP protection is a pre-requisite for FDI and technological transfers, because multinational corporations will not invest in DCs unless their intellectual assets are guaranteed a certain level of protection. DCs, on the contrary, being more concerned with encouraging indigenous processes of capability-building, demand the right to “learn by imitating”, a right, it should be noted, that was extensively used by most current developed countries in the early stages of their development. This difference in point of view between the advocates of “strong” and “weak” IP protection has long given rise to conflicting arguments<sup>3</sup>.

To shed more light on this debate and to gain a better appreciation of the cases in which one or the other system may be more appropriate, it is worth recalling some of the findings of a recent study by Lall (2003), dedicated to this tricky question. In his study, Lall distinguishes between four groups of countries, according to their levels of “innovative capability”. On the basis of this categorisation<sup>4</sup>, and bearing in mind the balance that all patent systems must

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<sup>1</sup> By “strong” IP systems we mean those systems characterised : i) by a high level of protection granted to patent holders ii) for a long duration of patent protection (20 years seems to be a new standard); iii) large recognition to the claims of the applicants (“large scope”); finally iv) in such strong systems a series of judicial institutions are guaranteeing the enforcement of the rights attributed to patent holders. “Weak” patent systems on the contrary are designed to favour quick and easy diffusion of the knowledge embedded in new and innovative products, including the right for local producers to manufacture local copies of the new products.

<sup>2</sup> See the recent book UNCTAD-ICTSD (2005) for a precise and well documented history of the TRIPS negotiations, issues by issues.

<sup>3</sup> On the two dimensions (creation/diffusion) of innovation and the role that IP can play therein, see the seminal article of Ordovery (1991), which shows how the Japanese patent system was designed to favour strong incremental innovation at the same time as the quick diffusion of innovations through society. The key element here is the important role accorded to a particular category of patents in the IP Law: - “utility patents” designed to favour incremental innovation.

<sup>4</sup> The four groups are the following: i) the “technological leaders”, who are the originators of new products and processes; this group is composed of the USA, Western European countries and Japan; ii) countries with existing but “moderate technological capabilities”; moderate meaning that some (but not much) R&D is carried out in these countries, which are characterised by medium levels of industrial development; the typical countries in this group are China, Russia and Brazil; iii) countries with low levels of technological capability and the presence of

strike between incentives to innovate on the one hand and dissemination of new ideas on the other, the question of the “optimum” level of protection can be considered from a less ideological viewpoint. It can be approached as a purely empirical and contingent question. On this point, Lall concludes that strong patent systems only have beneficial effects *in countries with a sufficient level of development*. More precisely, according to the author, the “frontier” between the two groups of countries (those which gain more benefit from “strong” IP protection systems and those which profit more from “weak” ones) is fairly high: “the turning point is \$7,750 per capita in 1985” (id), which places the vast majority of developing countries on the “weak” side of the border.

An additional, complex question that arises in connection with this issue of the “frontier” beyond which strong patents can be justified relates to the “adjustment costs” to be met when a country adopts a stronger patent system. These adjustment costs provide another argument in favour of pragmatism in IP policy. These costs must be evaluated and compared with the expected benefits of the change in IP regime before committing to the change. At least three types of costs need to be considered. i) Firstly, with the enforcement of stronger IP protection, the prices of newly-patented products and technologies may rise. A patent, we should recall, is a monopoly especially designed to enable patent owners to benefit from their previous investments in R&D. To “pay back” their investments, patent holders are authorised to charge prices high above marginal costs. During a long period before they can enjoy the benefits of dissemination (when the patent expires), countries with “strong” IP protection have to contribute to the innovative rent extracted by patent owners. ii) Another cost is represented by the local closure of certain activities, which may be obliged to shut down because of the changes in IP protection. iii) Finally there is the risk of abuse of patent protection by patent holders. In this case, competition policy provisions may be used to repair the damage, but this process is never simple to implement and is often very costly<sup>5</sup>.

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some transnational corporations (TNCs) in certain activities (Egypt, Thailand, etc.); finally the group in which there is no significant technological activity (El Salvador, Pakistan, Albania, etc.) (Lall, op. cit.).

<sup>5</sup> A recent, very perplexing example of ‘abuse’, illustrating how complex such situations can be, is provided by the case of Lamivudine (3TC) in China. Lamivudine is an ARV included in the therapeutic consensus for first line treatments against HIV in China. This ARV (for which the company GSK holds the patent) is patented but not marketed in China. As a consequence, it is not available in the local market. For a long time, the only

What conclusions can we draw from these elements? Three main points can be made.

1. It appears that a “strong” patent system can, under certain conditions<sup>6</sup>, prove favourable to innovation and wellbeing in countries with reasonably high levels of in-house innovative capabilities. But there is no reason to believe that the same holds true for countries with intermediate or low levels of technology. For these countries, the main risk (in the case of a “weak” IPR system) is that the multinationals won’t invest in them. However, this risk should not be exaggerated. In most low-technology countries, FDI is largely “cost-oriented”. In these zones of production, FDI is above all seeking *low labour costs*. The activities that multinationals relocate to these countries are usually segments with low technological content and low value-added. The lack of strong patent protection can hardly be a real obstacle to this kind of investment. If we consider what is happening in sectors such as clothing, textiles, toys or shoes (all located in countries with low costs and weak IP protection systems), we can see that the lack of IP protection does not seem to play an important role in the decisions of most of the powerful MNCs. All the more so since, in many cases, the lack of legal protection (in the form of IPR) does not necessarily threaten the exclusivity enjoyed by these large corporations. Their exclusivity may be founded on trade secrets or *savoir faire* - tacit or codified – which form part of corporate routine. These forms of appropriation are hard for outsiders to challenge, and they are widely used by large firms in many sectors of production<sup>7</sup>. For all these reasons, countries with low levels of “innovative capacity” would appear to benefit much more from “weak” patent protection systems than from “strong” systems aimed at encouraging very hypothetical foreign investment. In such countries, IP laws should

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formulation of 3TC available on the Chinese market has been the 150mg doses, recommended for Hepatitis B but quite inadequate for treating Aids.

For years, as a consequence of this difficult situation, Chinese patients were given a type of triple combination of drugs different that the one defined in the therapeutic consensus. This resulted in numerous side-effects for the patients, many of whom consequently gave up their course of treatment.

<sup>6</sup> This restriction is essential. Even for developed countries, there is a risk that the right balance might not be found between providing the incentive to innovate and favouring the diffusion of new knowledge. Likewise, the question of the definition of patentable objects has always been the subject of fierce debate. For a discussion of these points based on the pioneering articles of Arrow (1962) or Dasbugta and David (1994), see the debate maintained by Rai (2001), Jaffe and Lerner (2004), Merrill et al. (2004), Nelson (2004) as well as our articles Coriat and Orsi (2002), Orsi and Coriat (2005).

<sup>7</sup> On this point, see Cohen et al. (2000), who describes the multifarious methods used by firms (outside of IP) to protect and appropriate intellectual assets.

therefore be designed primarily to favour dissemination and “learning by imitation”, even at the risk of missing the opportunity to benefit from FDI<sup>8</sup>.

2. If such an orientation is followed, with a view to favouring the dissemination of knowledge and savoir faire within the fabric of the local economy whilst minimising the social costs attached to monopolies, IP Laws should be designed to incorporate high standards of patent criteria (above all as regards the definition of the “inventive steps” which lie at the heart of any patent system) and, likewise, high standards of information disclosure (including the disclosure of “best practices”). Moreover, IP laws should also make provision for protocols of pre-grant disclosure (as codified in European Patent Offices), so as to protect against the risk of the unwarranted patenting of discoveries submitted to patent examiners. Lastly, all the measures relating to the conditions of the granting of compulsory licenses should be thought out very carefully. This question is clearly crucial, and we shall return to it later.

3. Another complementary issue, involves the way in which Patent Offices should be designed. Here, two points call for attention. Firstly, it is of vital importance to build real technological expertise inside IP (and IP-related) Offices. Otherwise, local IP Offices will simply replicate the decisions and evaluations of their counterparts in the developed countries. The consequence of this would be the quasi-automatic granting of local patents to products or processes already patented in the developed countries. Secondly, IP offices should receive public funding, prohibiting the type of “pay as you go” funding methods recently introduced in the USPO (or the EPO). In a recent analysis, Jaffe and Lerner (2004) have shown how this reform in the mode of financing of the USPO was followed by very negative effects in terms of the relaxation of the criteria of patentability. The granting of a large number of “bad patents” and the rise in litigation costs are among the clearest consequences of this reform.

### **Compulsory licensing, Doha and the August 30 Decision of the WTO**

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<sup>8</sup> In every case, as the manifesto published by the group “Friends of Development” argues convincingly, the question of IPR regime is an issue that must be raised. For details of the arguments put forward by this group of countries, see United Nations University (2005).

Until now, we have only explored the implications of TRIPS in relation to the nature of the IP laws that should be introduced in Southern countries with a mid to low level of development. When we consider the domain of drugs and public health, which constitutes our main reference in this paper, this reflection can and should be extended to take into consideration the measures in the TRIPS agreement concerning the use of compulsory licenses.

We know that the measures covering this subject that were initially included in the TRIPS agreement (articles 28 to 31) proved to be impracticable and had to be amended. These measures only allowed for the use of such licenses for the production of generic drugs for “mainly domestic” purposes. For countries without the technical capabilities for drug production, it soon became apparent that the consequence of these measures (and particularly those contained in article 31f) was that they could *neither produce nor import generic drugs*. The poorest countries and those most in lacking in technical capacities were thus the most heavily penalised!

This state of affairs, which constituted a veritable institutional failure of the TRIPS agreement, was explicitly recognised at Doha in 2001, as Paragraph 6 of the Doha Declaration instructed the TRIPS Council to propose a solution to this problem.

In principle, this solution was provided by the TRIPS Council’s Decision of August 30 2003. However, there is a strong reason to fear that this “solution” will also prove to be inappropriate<sup>9</sup>, so severe are the restrictions it imposes on the import (or export) of generic drugs<sup>10</sup>. Indeed, 18 months after it came into force, this Decision has still not seen any concrete application.

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<sup>9</sup> This Decision assumes all the more importance since it is intended, as from December 6 2005, to be adopted as an Amendment of the TRIPS agreement.

<sup>10</sup> There are some positive and negative dimensions to the WTO Decision of August 30. On the positive side, it has to be noted that the Decision i) provides a legal basis for exports and imports of generic drugs and APIs; ii) it includes not only drugs, but diagnosis kits and other such medical materials. However, the decision suffers from serious limits. Namely, i) it requires the modification of national IP laws to incorporate the new provisions; ii) the decision implements a complex system of declarations and registration prior to any imports or exports; iii) last but not least, transactions have to be defined and specified one by one, and generic producers are only authorised to produce, batch by batch, the quantities specified in the compulsory licenses. This restriction clearly goes against the necessity to take advantage of economies of scale in order to produce at low and competitive costs (more on this issue in Van Puymbroeck, 2003).

On the purely legal level, however, it is still possible, if the political will exists, to overcome the current limitations of the August 30 Decision, in order to provide access to generics for the poorest countries. Coming back to the very spirit of the Decision, which aims to facilitate the issuing of compulsory licenses whilst controlling the international circulation of generic drugs to prevent the risk of their re-exportation to developed countries, a possible evolution of the Decision could consist in the implementation of the following triple principle.

i) DCs would be allowed to issue compulsory licenses (for generic drugs) *on a “once-and-for-all” basis* and no longer through a case-by-case mechanism. Ultimately, this would mean no more than following the avenue opened up by the *Amended Patent Law Act* recently passed in India. This Amendment authorises the continued production, beyond 2005, of all generic drugs already produced by Indian firms before this date. This authorisation was given in advance to permit the local production of those drugs which, through the “mailbox” mechanism, would be covered by patents after 2005.

The introduction of this type of measure would considerably lighten the bureaucratic requirements imposed by the August 30 Decision. By simple “decrees” (issued, for example, by the Ministry of Health of the country involved) in application of the “general” compulsory license granted on a once-and-for-all basis, orders could be placed with the importers as and when needed.

ii) In the same spirit, to enable generic manufacturers to mass-produce, they would no longer be required to produce in small quantities, batch by batch, as and when they received orders. To take advantage of economies of scale (and to pass this benefit on to their customers), they would be allowed to mass-produce, but they would then only be allowed to export on a batch-by-batch basis, following the orders received from importing DCs.

iii) Lastly, to guarantee control over the international movement and traceability of products, the rules concerning the prior declaration of all imports (or exports) to the WTO authorities would be maintained. Likewise, the obligation to “mark” generics produced in this way (to distinguish them from proprietary drugs) would also be maintained, in order to control their origin.

Concern for the control of the international circulation of generics produced within the framework of the Decision is perfectly legitimate. The advantage of the above system is that it would guarantee such control, without transforming it into a series of restrictions so severe as

to render inapplicable a Decision intended to provide a prompt solution to the problem of the import of generics by Southern countries.

Furthermore, in the perspective of technological capacity-building in developing countries, the benefit of such protocols for the use of compulsory licenses should not be restricted solely to the case of those licenses covered by the August 30 Decision. Remember that this decision deals exclusively with the import and export of generic drugs by the least developed countries. These measures could equally apply to licenses issued to ensure production for the domestic market by national firms (or firms established within the national territory) in order to deal with pandemics and, more generally, with all illnesses which represent a public health risk.

However, such measures, even if they were adopted, would only aim to promote favourable conditions *on a legal level* for the transfer and/or construction of local technological capacities. Of course, although such institutional conditions do matter, they are not sufficient in themselves: they are really no more than prerequisites. They must be accompanied and furthered by other dimensions of public policy to promote the building of local technological capabilities.

And it is to these dimensions of public policy, complementary to those involving the design of IP systems, that we shall now turn our attention.

## **II. IP, transfer of technology and technological capacity building**

Drawing on the lessons learnt from the experiences of several Southern countries in the construction of local technological competence in the production of generic drugs<sup>11</sup>, we propose a simplified model, a sort of “road map”, intended to facilitate the building of local technological capabilities.

### **Building local capabilities under the TRIPS Agreement: lessons from the field**

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<sup>11</sup> To the extent that the Aids epidemic represents the major public health challenge faced by Southern countries over the last twenty years, we shall examine their experiences in the production of ARVs.

The development of tri-therapies over the last decade represents a major advance in the fight against the HIV/Aids pandemic. With the appearance of an effective treatment against the illness in 1996<sup>12</sup>, public health policies took on a completely different dimension and scale.

Unfortunately, the price at which these treatments were marketed by Western pharmaceutical companies – 10 to 12,000 US\$ per patient per year - made it impossible for them to be distributed in the countries of the South, precisely where they were most desperately needed. At the same time, the worldwide enforcement of the TRIPS agreement made the production of generic copies of these drugs impossible (or at least very difficult). And until the signing of the TRIPS agreement, this had been the solution practiced by most of the countries of the South. Nevertheless, by exploiting certain flexibilities or loopholes in the TRIPS agreement, various DCs did engage in the production of generic ARVs. As we shall show, a series of lessons can be drawn from these experiences, as regards policies for the acquisition of technological capabilities. For the purposes of our present demonstration, it will be useful to distinguish between two types of policy: India and Thailand on one side, Brazil on the other.

#### *Lessons from Thailand and India*

A common feature of the policies deployed in these two countries is that the local production of generic ARVs was carried out without established links with public health programmes of access to ARV treatment. This meant that both countries were unable to take advantage of large-scale production to ensure price reductions. While a solution to this problem was gradually found in the Thai case, with the development of the public health programme<sup>13</sup>, for India, the need to export and to find affordable foreign markets remained and still remains of major concern to the local producers.

Another central feature of the experience of these two countries is that the range and type of ARVs produced locally has been highly dependent on domestic Patent Laws. This explains why a limited number of ARVs were produced in Thailand. In fact, Thailand complied with

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<sup>12</sup> These were the first tritherapies that enabled patients to continue living several years.

<sup>13</sup> Over time, Thailand slowly moved to create its own domestic market by providing ARVs and HIV care to a growing number of people.

the requirements of the TRIPS agreement even before its signing<sup>14</sup>. On the contrary, because India postponed its TRIPS compliance until 2005, there were no legal limits to the production of generic copies of existing therapeutic molecules. Historically, in fact, India has had two very different –not to say opposed – patent regimes. The patent regime from 1900 to 1970, largely based on the British one, guaranteed a high level of patent protection for both processes and products. The results in terms of incentives created for local producers were very disappointing. So, after serious discussions among policy makers and professionals, a new Patent Law was passed in 1970. Among the key provisions of this Patent Law are i) no patents on molecules ii) inclusion of a notion of “working patent” which allows for the legal local production of all products covered by patents but not produced locally; iii) the short duration of patent protection (7 years).

The consequence was a spectacular rise in the Indian pharmaceutical companies and industry: Cipla, Ranbaxy and Hetero Drugs amongst others were rapidly transformed into veritable “global players”, proof, if there is any, of what we argued in the previous paragraph, namely that a “weak” patent system can be extremely favourable for the development of technological capabilities in DCs. However, it should be noted that if the Indian pharmaceutical industry could enjoy such a boom, it was also because up until 1994 (date of the signing of the TRIPS agreement) there were no legal restrictions on the export of generics<sup>15</sup>, and that even after 1994, for most first-line ARVs, many countries of the South were not immediately constrained by application of the TRIPS agreement<sup>16</sup>. So for Indian firms, the limits of the domestic market (for ARVs) were compensated for by large export markets, a “window of opportunity” which they were able to exploit. Only time will tell whether, with the closing of this window (by the new Indian Patent Law and the TRIPS Amendment of December 6 2005), Indian firms will continue their expansion or become relatively less important on the world scene.

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<sup>14</sup> In fact, the Thai patent law passed in 1993 and later revised incorporates many so called “TRIPS Plus” provisions, such as “exclusive marketing rights” for many drugs not covered by patents and locally distributed. (Guennif and Mfuka, 2003).

<sup>15</sup> Except, of course, for exports to developed countries with “strong patent systems”.

<sup>16</sup> Remember that the TRIPS agreement extended the deadline for compliance for different groups of countries (2005 for intermediate countries, 2011 for the least developed countries).

***Building national capabilities through public health policy: The Brazilian experience***

The case of the Brazilian anti-aids policy deserves particular attention. It provides a unique case study of the types of contradiction raised by enforcement of the TRIPS agreement. It enables us to appreciate what can be done within the constraints of TRIPS and the limits that this agreement imposes on the public authorities in terms of public health policy, even when the authorities are strongly engaged in a health care programme.

A key feature of the Brazilian experience is that, beginning in 1996, Brazil implemented a public health programme with the aim of guaranteeing *free and universal access to antiretroviral treatments (ARVs)* and other related drugs for all people infected with HIV. It has to be noted, however, that at the same time, the country was pressurised by the US government into implementing a new patent law recognizing drug patents, to meet the requirements of the TRIPS agreement<sup>17</sup>.

Once committed to the policy of free universal access, the Brazilian authorities, driven by resource constraints and faced by the very high prices of patented ARVs marketed by foreign companies, chose to exercise price control through central purchasing and to mobilise local manufacturers to produce low-cost generic versions of some of these patented drugs. However, under the restrictions of the TRIPS agreement, Brazil could only produce those ARVs which had already been distributed before 1996 (the date of Brazil's TRIPS compliance), in other words a total of 7 ARVs out of the 17 used by the public health programme.

This experience showed that i) the price of locally-produced ARVs fell dramatically over time, whilst the price of imported ARVs remained almost stable during the same period; ii) in the case of imported ARVs, from 2001 on, the threat to foreign firms of the use of compulsory licenses in local production has been followed by sharp decreases in the price of some of the imported ARVs (see table 1).

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<sup>17</sup> Note that Brazil was not obliged to comply fully with the TRIPS agreement at this date, but in 2005, like the other developing countries. As has been well-documented, the Brazilian patent law amendment is largely due to US economic and political pressure, including the threat of using trade sanctions and retaliations. It is also important to note that this 1996 intellectual property law was subject to a US complaint at the WTO, claiming that article 68 of the Brazilian patent law defining the circumstances under which patented inventions can be subject to compulsory licensing violates the TRIPS agreements (fore more on this, see for example Oxfam, 2001 and t'Hoen, 2003). Although the US government finally withdrew its complaint, we should highlight the fact that Brazil is still on the so-called "Special 301 Watch list" (t'Hoen, 2003).

**Table 1**  
**Price comparison between ARVs produced in Brazil and ARVs imported from multinational companies**  
**(Unit price in \$US)**

ARVs produced in Brazil									Imported ARVs								
Drug	1996	1997	1998	1999	2000	2001	2002	Variation (%)	Drug	1996	1997	1998	1999	2000	2001	2002	Variation (%)
Zidovudine cap.100mg	0.56	0.53	0.45	0.21	0.18	0.11	0.13	-76.78	Ritonavir Cap.100mg	0.90	0.90	0.88	0.88	0.88	0.76	0.76	-15.55
Dinanosine pow.oral sol	*	*	60.2	37.8	38.8	29.76	31.44	-47.78	Nelfinavir Cap.250 mg	*	*	1.53	1.45	1.36	1.07	0.64	-58.17
Stavudine cap.30 mg	*	1.75	1.03	0.46	0.32	0.21	0.11	-93.71	Effavirenz Cap.200 mg	*	*	*	2.32	2.32	2.05	0.84	-63.79

\* ARV not made available by the Ministry of Health

Source: Brazilian Ministry of Health

Here, we should note that the local production of 7 ARVs has been possible because of previous public policies implemented since the 1950s, aimed at building national generic drug manufacturing capabilities, essentially through the establishment of a network of six public laboratories. These are currently responsible for more than 50% of the local production of ARVs<sup>18</sup>. Here again, as in the Indian case, the effective implementation of this active policy for the building of technological capabilities has only been possible because Brazil reformed its IP law in 1970 to authorise the legal copying of molecules by refusing to recognise patents on either processes or molecules.

Finally, the Brazilian programme has achieved a series of spectacular successes. First, it has implemented a unique programme (among DCs) *ensuring universal and free access to HIV care*, while at international level Brazil has played a key role in the reduction of many ARV prices. Moreover, taking advantage of the large domestic market created by the universal and free access policy promoted by the Ministry of Health, and thanks to efficient cooperation with the Indian firms producing the raw materials and active pharmaceutical ingredients (APIs) used for the production of drugs (Cassier and Correa, 2003), very significant improvements in local technological capabilities were achieved.

<sup>18</sup> Among these laboratories, we can cite the example of Far-Manguinhos, the State-run Institute of Pharmaceutical Technology which has played the role of a "Damocles sword" hung over multinationals' heads by strengthening its R&D activities and advising the Brazilian government about the alternative costs if full-scale production were to be carried out locally.

However, despite the successes, the programme is reaching its limits and is now facing serious problems. First of all, because of the TRIPS agreement, as already stated, the only ARVs locally produced are the oldest ones: those already commercialised before the enforcement in 1997 of the new Brazilian Patent law. Moreover, due to the lack of national capabilities to synthesize molecules, most of the chemical inputs have been imported from China and India<sup>19</sup>. This represents a serious threat to the future of the AIDS programme. The TRIPS compliance of these major suppliers of ARVs (India) and APIs (China) may jeopardize the whole architecture on which the Brazilian programme is based, by cutting the sources of cheap chemical imports. Secondly, most of the latest generation of ARVs, especially the whole second-line treatment, have to be imported. These imports are likely to grow fast in the future, as the new generation of drugs is completely protected by patents not only in Brazil but also in India, until now by far the largest provider of low-price ARVs in the world. The Table 2 (below) shows the huge difference between the prices of first line compared to second line ARVs

**Table 2 :**  
**Costs of 1<sup>st</sup> and 2<sup>nd</sup> lines treatments in Western and Developing Countries**

	3TC/d4T:NVP (1st line)	TDF+ddI+LPV/r (2 <sup>nd</sup> line)	2 <sup>nd</sup> line vs 1 <sup>st</sup> line
Western Countries	US\$ 8773/year	US\$ 13551/year	1.5 times more expensive
Developing Countries	US\$ 154/year Cipla Triomune	US\$3950/year Originator product	26 times more expensive
Reduction	- 98 %	- 70 %	

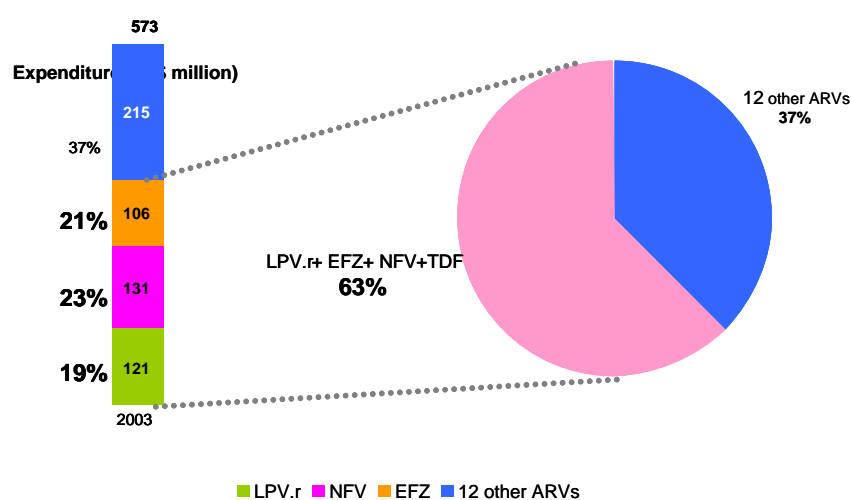
*Source : MSF*

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<sup>19</sup> In truth, a local capacity of synthesis did and still does exist. However, it was greatly reduced during the 1990s, when the liberalisation of foreign trade resulted in the closing of more than 1700 synthesis units in the country (because Brazil had to cut its customs barriers sharply). However, the surviving synthesis units have not benefited from the Aids programme. Small in size, they have not been able to rival the low prices offered by Indian and Chinese producers during the international calls for tender launched by the Aids programme. This policy of calls for tender was chosen in preference to a system of bilateral contracts with local firms for the procurement of APIs. It has the advantage of ensuring the low-cost procurement of chemicals, but it also has the disadvantage of failing to help local firms grow stronger by exploiting the large domestic market created by the programme of universal access. More on this in Orsi et al, (2003) and in Coriat and Orsi (2003).

As a consequence, already, 4 of the necessary ARVs, which are imported because they are protected by patents, represent about 57 % of the total cost of drugs distributed by the programme (see figure 1 below).

**Figure 1 :**  
**Expenditures of Brazilian Ministry of Health on ARV procurement (2004)**



Given the cost of entirely-patented second-line treatments, the consumption of which is growing fast, the future economic sustainability of the programme is clearly threatened. More audacious and “voluntarist” policies therefore need to be envisaged.

### 3. Looking ahead: scenarios for building national technological capabilities

In such conditions, more effective transfer of technologies policies and/or more effective use of compulsory licensing, combined with other elements of public policy aimed at strengthening local technological capabilities, are clearly at the top of agenda.

From this perspective, and remaining with the example of the pharmaceutical industry, we shall propose 2 variations – not necessarily contradictory – of the same scenario. The two variations deal with the acquisition of technologies and savoir-faire through the granting of licenses. The first variation explores the *voluntary* granting of licenses, while the second deals with the case of *compulsory* licenses, in the event that it has proved impossible to negotiate

the voluntary granting of a license. The difference between these two processes lies in the fact that the first relies ultimately on the “good will” of the holder of the technology, while the second is based on an initiative by the “recipient”, in other words the country or firm seeking to acquire the technologies it lacks.

This scenario has deliberately been constructed on a “realistic” basis. It is an extrapolation built up from situations envisaged by the Brazilian authorities to deal with the procurement of second-line drugs, at the very time when the price of some drugs was being negotiated with certain firms (with Abbott for Kaletra, in particular).

The Table 3 below presents the protocols draw up by the Brazilian authorities in relation with national producers.

**Table 3: Public Private Partnerships in the Brazilian Pharmaceutical Industry**

ARV	Synthesis of active ingredients		Formulation of ARVs	
	Prospective Brazilian institution	Estimated time to manufacture	Prospective Brazilian institution	Estimated time to manufacture
EFAVIRENz	NORTEC	- synthesis already achieved in laboratory - 4 months from the granting of the license, to go into mass production	LAFEPE	- 1 <sup>st</sup> quarter 2006 (registration with ANVISA of the 200 and 510mg presentations) - under negotiation with an Argentine firm for the production of the drugs - no manufacture of the oral solution
			FAR MANGUINHOS	3 months from the granting of the license
TENOFOVIR	GENVIDA	between 9 and 12 months from the granting of the license	FAR MANGUINHOS	8 months from the granting of the license
LOPINAVIR/r	CRISTALIA	3 months from the granting of the license	CRISTALIA	6 months (to carry out missing bioequivalence tests) from the granting of the license
			FAR MANGUINHOS	8 months from the granting of the license

Source: Compiled with data from the Brazilian Ministry of Health

Whichever case is considered (“voluntary” or “compulsory” licenses)<sup>20</sup>, the success of the transfer and/or local acquisition of technologies and savoir faire can only be ensured if they are conducted through certain specific protocols.

As Table 3 above demonstrates, one of the essential protocols for facilitating the acquisition of technologies consists in splitting the technology into sub-systems, with a distinct, specialised body being given responsibility for each sub-system. So, in the case of the pharmaceuticals considered here, the two main types of expertise involved – those relating to the *synthesis of molecules* and active ingredients and those relating to the *formulation of molecules* – are entrusted to separate bodies<sup>21</sup>. Formulation is entrusted to the network of public laboratories in Brazil which have recognised experience in this field, while synthesis is entrusted to private-sector firms. Note that the *import of molecules and active ingredients* can also be envisaged if none of the laboratories in Brazil present their candidature for acquisition of the technology.

We can then make an extrapolation from these scenarios. By taking into account the case described above, we can define some key “building blocks” which can be taken as a basis for the construction of a national policy for the acquisition of technologies by means of voluntary or compulsory licenses.

The model we propose is organised around the following steps<sup>22</sup>.

1. Whether we are dealing with voluntary or compulsory licenses, it is essential to the success of the project that the *initial* transfer should be made to a public institution or laboratory. This provides some guarantee that the knowledge being transferred will not be appropriated again, but distributed in a manner beneficial to public interest, ensuring the best possible dissemination of the knowledge. The aim here is to constitute a common knowledge base that will serve as a “community chest” from which designated operators or candidates to the acquisition and development of specific technologies and savoir faire can draw resources. In

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<sup>20</sup> In Table 2 above, the times to manufacture are given for the hypothesis of compulsory licenses. It may be supposed that these times would be shorter in the case of voluntary licenses granted to generic producers by the patent holders.

<sup>21</sup> With the exception of the firm Cristallia, which presented itself as a candidate for both the synthesis and formulation of Lopinavir/r.

<sup>22</sup> This model draws largely on the reflections proposed by Almeida (2004).

particular, the constitution of such a common knowledge base would make it possible, when deemed necessary, to transfer the knowledge not to one sole operator, but to two or three, so as to introduce a process of competition and thus increase the chances of success: the market could then be attributed to the operator making the best offer in terms of the criteria of cost, time and quality<sup>23</sup>.

2. When the initial license has been passed to a public institution, it is then possible to construct PPPs (Private-Public Partnerships). In the case of drugs, these PPPs are mainly constructed on the basis of a division of labour between the activities of synthesis and the activities of formulation, as envisaged in the scenario summarised in Table 2. But very different forms of arrangement are possible and can be envisaged. For example, synthesis in the laboratory (the “prototype”) could be performed in a specialised pilot unit (public or private) before entrusting the task of industrialisation to dedicated manufacturers<sup>24</sup>.

3. In many cases, such arrangements can and should cover not only the design and development of industrial technologies, but also the construction of markets to ensure that demand is solvent and production is economically viable<sup>25</sup>. The synthesis of AZT in Brazil was carried out following this protocol. When the firm Microbiologica worked on the synthesis of this molecule, the Brazilian public authorities did not contribute to the research effort (no subsidies or grants of any kind). They did, on the other hand, undertake to purchase all the AZT synthesised by the firm, on the condition that this was supplied below a previously agreed price limit. This incentive proved to be effective, and during several years a proportion of the AZT distributed by the public programme was bought from this firm. More generally, the existence of a guaranteed market appears to be one of the efficient conditions for the launching of research programmes by local firms tempted by the adventure of

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<sup>23</sup> In quite another context and domain, this is the type of policy implemented by the French authorities during the nineteenth century to acquire telecommunication technologies. The markets for the installation of networks were only attributed to the applicant firms (at the time, these were all foreign) on the condition that the patents corresponding to these networks were transferred (in the form of voluntary licenses) to a large public laboratory created for the occasion: the CNET (Centre National d’Etude des Télécommunications). This centre then served as the national platform for the accumulation of savoir faire, which was then transferred to the national firms who gradually entered the market. For a detailed presentation of this policy see Coriat (1993)

<sup>24</sup> In the case of French “grand programmes” involving complex technologies, it is most often a public laboratory which bears the essential costs up until production of the prototype. The technology is then transferred to specialised (public or private) firms for mass production (Cohen, 1992)

<sup>25</sup> Thus, in the case of the policy adopted by France for telecommunications described above, firms which committed themselves to the acquisition of technologies were, in the event of success (the development of technologies judged to be satisfactory in terms of cost and quality) guaranteed a large market.

technology acquisition. To maintain a sufficiently high level of incentive, one could also envisage a regular review of the minimum prices paid for locally manufactured products, lowering these minima as and when local firms gain experience and benefit from economies of scale.

4. Finally, to guarantee the long-term viability of these PPP policies, the development of manufacturing should be accompanied by a policy of quality certification for products and processes (WHO standards, ISO 9000 standards, etc.), so that local production remains consistent with the relevant international standards.

Essentially, of course, such policies concern countries which already possess a certain technological capacity. But if the technological segments chosen are suitable, more modest and capable of being split up into manageable sub-systems, there is no reason why these policies could not be applied by countries with low capacity, if they in turn wish to embark on the acquisition of technological capabilities.

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Developing countries face many obstacles on the road to the establishment of local technological competences. Nevertheless, we hope to have demonstrated, in this article, that if the permissive conditions are established in terms of IP, then the means do exist by which the current technological gap between North and South can be reduced.

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