Impact of Intellectual Property Rights on AIDS Public Health Policy in Thailand

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Key words: HIV/AIDS; TRIPS agreements; public health; industrial policy; intellectual property rights.

Abstract

After a committed policy to contain the spread of the HIV/AIDS epidemic in Thailand, another challenge must now be faced: that of providing accessible anti-AIDS treatment to those infected. This paper explores both the technical and legal aspects of a possible solution involving the provision of low-cost medicines by the Thai pharmaceutical industry. It shows that even if the efficient domestic drugs industry could participate in meeting this challenge, recent modifications in the intellectual property rights system hinder the large-scale local production of generic drugs. These institutional modifications can therefore be viewed as an obstacle to the continuation of public health policy as they impede the provision of affordable treatments.

Résumé

Après une politique volontaire menée pour infléchir le cours de l’épidémie du sida en Thaïlande, à présent un autre défi apparaît, celui de faciliter l’accès des personnes infectées aux antirétroviraux. Ce papier aborde les aspects techniques et juridiques de ce problème en examinant la possibilité de mobiliser l’industrie pharmaceutique domestique pour satisfaire cet objectif. Il montre que si l’industrie pharmaceutique locale est performante et peut aider à relever
ce défi, les modifications récentes intervenues dans le système de droit de propriété intellectuelle thaïlandais constituent un obstacle non négligeable. Ces modifications freinent la production large de traitements anti-sida et empêchent pour partie la poursuite d’une logique de santé publique en matière d’accès des patients à des antirétroviraux abordables.

Introduction

Since 1991, due to a strong political will, the public authorities have been active in controlling the epidemic. The public information program and the 100% condom campaign have brought about a significant increase in condom use among brothel-based sexual workers and their clients. For instance, condom use rose from 14% to 90% between 1988 and 1992 among brothel-based sexual workers. An estimated 2 million infections were thus averted.

Yet much more preventive action must be taken if public authorities want to influence the future course of the epidemic. Two population subgroups, streetwalkers and Injected Drug Users (IDUs), who display high-risk behaviour, must be urgently included in the prevention program, as they represent an important reservoir for infection and transmission of HIV/AIDS to the whole population.

Likewise, the number of infected pregnant women and infected children obtaining the AZT treatment is still low, due to the prohibitive price of the drugs. It costs 500 dollars per year to treat a woman and her child. Out of a population of 62,000 pregnant women requiring treatment in 1999, the Thai Red Cross provided only 2,891 courses of treatment.

Up until now, the low number of people living with HIV/AIDS (PLWAs) entering the symptomatic phase of the disease justified the Ministry of Public Health’s (MOPH) prevention policy. However, out of 755,000 PLWAs, about 70,000 are now developing the first symptoms of the disease. So they urgently need HIV/AIDS treatment in order to live more comfortably with the disease, to be able to keep on working and avoid a decrease in the household’s income.

Concerning the treatment issue, in 2000 the World Bank estimated the expenditure the MOPH may incur in facilitating people’s access to palliative care,

1. For a comprehensive presentation of AIDS public policy in Thailand, see [1, 2, 3, 4].
2. For the future, a quarter of new adult infections will be due to IDUs.
3. As Prescott said, to treat all infected pregnant women would require spending the whole AIDS budget.
4. In 1998, 73% of public funds allocated to the fight against AIDS was devoted to prevention.
opportunistic disease treatment and anti-AIDS drugs\textsuperscript{5}. Among other things, this report showed that the expenditure required to supply antiretroviral treatment ranged from a 66\% share of the AIDS budget up to 27\% of the health budget, according to the price level and number of patients to be treated. In particular, in order to treat 55,000 patients with the most expensive drug, the expenditure represents about 12 times the AIDS budget or 27\% of the health budget. Using generic drugs would cost about 3.6 times the AIDS budget or 8.1\% of the health budget\textsuperscript{6}. As a consequence, Thailand could use generic treatment to alleviate the health burden.

So the question is: “Does Thailand have the technical and legal possibilities to address the generic drug issue in order to ease health expenditure constraints and to facilitate as far as possible people’s access to anti-AIDS treatment?” In other words, can Thailand take advantage of an “industrial policy logic” to serve public health goals in a specific context, that of strengthening intellectual property rights (IPR)?

Due to a committed industrial policy, the domestic pharmaceutical industry has the formulation capabilities and equipment to produce generic drugs. The Government Pharmaceutical Organisation (GPO)\textsuperscript{7} has obvious formulation capabilities to produce anti-AIDS treatment. Nevertheless, it provides only a limited range of treatments and faces some difficulties in providing people with access to treatment.

This paper aims to demonstrate that the explanation for this apparent paradox lies in the successive modifications of the Thai Patent Act (TPA). The implementation of patent on product, the introduction of the Safety Monitoring Program (SMP) in 1992 and the ratification of the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreements in 1994 have brought about a new institutional environment. This environment prevents comprehensive mobilisation of the domestic pharmaceutical industry and especially reduces the GPO’s capability to foster health objectives such as facilitating access to AIDS treatment.

We briefly describe how, thanks to a favourable legislation on IPR (patent on process), Thailand has promoted the creation of an effective pharmaceutical

\textsuperscript{5} Through HIV, some diseases are again rising. Since the early 80s, in the north of Thailand, tuberculosis, pneumonia and cryptococcal meningitis have been particularly common among individuals infected with HIV/AIDS: 43\% have tuberculosis, 16\% pneumonia and 15.9\% cryptococcal meningitis [10].

\textsuperscript{6} Public authorities will have to spend about 70.8 bahts per year and per patient to provide low cost palliative care and treatment for opportunistic infections to only 10,000 individuals: 5\% of the AIDS budget for the 2000 tax year or 0.1\% of the health budget [8].

\textsuperscript{7} The organisation is in charge of the production of essential medicines for hospitals.
industry. We then list the successive IPR system modifications that have affected the current and future course of the Thai pharmaceutical industry. In relation to the production of anti-AIDS medicines, these modifications have provoked the withdrawal of domestic pharmaceutical firms (i). We describe the strategies the GPO has consequently implemented to circumvent IPR on products and provide anti-AIDS treatments at low cost. Recently, these strategies have permitted the formulation and production of the least expensive HIV/AIDS cocktail in the world. However, this treatment only partly solves the accessibility issue in Thailand (ii).

I

THE EVOLUTION OF THAI REGULATION:
A BRAKE TO GENERIC ANTIRETROVIRAL (ARV) PRODUCTION

From the 1992 Thai Patent Act
to the Safety Monitoring Program

Up until the end of the 80s, drug patents were forbidden in some developing countries; only process patents were granted. To reinforce this position, during the Uruguay Round in 1989, developing countries put forward industrial considerations. India consistently asserted that developing countries (like developed ones)\(^8\) have the right to follow an “Educational Protection”\(^9\) model [12]. In this way, developing countries could ensure the technological development of domestic industry through imitation of brand name drugs, provide medicines at low cost and avoid dependence on supply from multinational companies\(^10\).

8. For instance, in Europe, the first drug patent was implemented in the United Kingdom in 1949 followed by France in 1959 which introduced a “special drug patent”. Switzerland, home of one of the largest pharmaceutical companies, allowed drug patents only in 1977 [11].

9. According to List, when there is an industrial divide between countries, the only solution for the least developed countries is to protect their infant industry by erecting barriers to ensure their development. Through a period of “Educational Protectionism”, the country strengthens its competitiveness by promoting “learning-by-doing” [13] or “learning-by-copying” when there are no IPR. After that, international competition may be allowed. Empirical studies show that the lack of pharmaceutical IPR in Argentina, Costa Rica and Turkey enabled the local pharmaceutical industry to develop [14].

10. Thanks to process patents and a drug price control order, India has developed a powerful generic industry, which provides among the cheapest medicines in the world [15, 16]. In the same vein, due to their 14-year-old generic industry, Brazil is now implementing a research program promoted by the public laboratory Far-Manghuinos.
Following this argument, the first TPA was implemented in 1979 (Patent Act B.E. 2522) and only acknowledged patents on process. The lack of drug patents promoted “learning by copying”. Appropriating knowledge and core skills through “reverse engineering”, domestic firms achieved generic drug production such as Nucleoside Reverse Transcriptase Inhibitors. In 1997, the Thai pharmaceutical industry was composed of small and medium-sized enterprises (176 private companies) and a public firm (GPO)\(^{11}\). In summary, a positive correlation between regulation and industrial development was built up \(^{18}\).

1992 was a turning point for the Thai pharmaceutical IPR system. The 1979 Patent Act was revised in order to introduce product patents. Henceforth, all drugs discovered after 1992 could be patented in Thailand. Patent life is fixed at 20 years from the date of filing for patent\(^{12}\). During this protection period, no generic version can be produced.

Moreover, with the support of their national government, American firms put pressure on the Thai public authorities and obtained the implementation of the Safety Monitoring Program (SMP) in 1992. Officially, the goal is to increase the safety and effectiveness of products on the domestic market. In fact, this program grants “exclusive market rights” for 2 years to multinational companies. SMP covers new chemical entities, new combinations, new recommendations and new delivery systems.

Again in 1993, Thailand was the subject of “special 301” provisions under the US trade Act of 1974\(^{13}\). The Thai government was constrained to amend the law to extend the market exclusivity period. Firms could then ask for two successive extensions of one year of SMP. At the end of these extensions, firms have to collect data about the safety and effectiveness of drugs. These data are submitted to the Thai Food and Drug Administration (FDA) which may grant a drug registration certificate after 6 months. The FDA will approve the registration provided that the submitted data and reports are scientifically correct and complete. The drug can then be distributed through the market channels. The period of market exclusivity is eventually extended to 5 years.

\(^{11}\) In 1997, these firms produced generic medicines with a market share of about 60% in volume and 30% in value \(^{17}\)

\(^{12}\) In practice, due to the delay between patenting and marketing approval, the effective life of a patent is less than 20 years.

\(^{13}\) The “special 301” section is used as a market weapon against countries which don't respect the American market rules because this could be prejudicial to American interests.
After the Safety monitoring program expiration, generic drugs may be put on the market and can be imported or manufactured by local firms. Consequently, drug prices may decrease because of generic competition (Table 1).

Table 1: Brand name and generic price comparison in Thailand (in US$, 2001)

<table>
<thead>
<tr>
<th>Drugs</th>
<th>Brand name price</th>
<th>Generic price</th>
<th>% reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluconazole (200 mg caps)</td>
<td>6.20</td>
<td>0.26</td>
<td>95.8</td>
</tr>
<tr>
<td>Stavudine (40 mg caps)</td>
<td>2.60</td>
<td>0.10</td>
<td>96</td>
</tr>
<tr>
<td>Zidovudine (100 mg caps)</td>
<td>0.50</td>
<td>0.15</td>
<td>70</td>
</tr>
<tr>
<td>Didanosine (100mg tab/170 mg powder)</td>
<td>1.20</td>
<td>0.62</td>
<td>48</td>
</tr>
</tbody>
</table>

Source: Adapted from [19, 20, 21].

Until 1998, about 700 “new drugs” were controlled by the Safety monitoring program, including some ARVs. Patent owners’ interests were thus furthered at the cost of national generic producers. In fact, by strengthening the patent system, SMP constitutes a real entry barrier to Thai generic production.

In addition to the introduction of drug patents in the Thai IPR system, parallel importation was forbidden by the Thai government in 1992 because of the American threat to limit Thai textile imports. One year later, the Thai government was once again under American pressure: compulsory licences provided by the TPA (Patent Act, section 46) were suppressed. In return, the American government promised low customs duties on Thai gems and wood products.

The SMP plays a negative role in the industrial response to the AIDS epidemic. By delaying or even preventing generic production of ARVs, it obstructs the population’s access to vital medicines. For instance, didanosine (ddI, Videx™) was only released from the Safety Monitoring Program in 1998. Furthermore, discovered before 1992, stavudine (d4T, Zerit™) is out of patent in Thailand. Yet the implementation of the SMP allowed Bristol Myers Squibb (BMS) to obtain exclusive market rights for d4T. In 1999, d4T was released from the SMP. Upon expiry of exclusive market rights, generic production was implemented, enabling a substantial reduction in the price of the medicine (Table 1).
New strengthening of Intellectual Property Rights: Thailand ratifies TRIPS Agreements

The ratification of TRIPS means the introduction of IPR into international trade agreements. From now on, the signatory states must grant patents for 20 years (article 33, “Term of Protection”)\(^{14}\).

To convince developing countries to accept TRIPS agreements, developed countries argued that the lack of IPR is prejudicial to technology transfers and Foreign Direct Investments (FDI) in developing countries. On the contrary, TRIPS agreements favour technology transfers and local Research and Development (R&D), allowing developing countries to do their “catching-up” and provide people with the latest drugs.

The TPA was amended in 1999 (Patent Act n°3, B.E. 2542) to comply with the terms of TRIPS. Since 1992, Thailand had already been in compliance with the 20-year product patent. Now, parallel imports and compulsory licences have been reintroduced into the Thai patent system (articles 36 (7) and 51). Furthermore, in compliance with TRIPS (article 31), compulsory licences could be used not only in the event of a national emergency or other extreme circumstances such as public health emergencies (article 8.1), but also for public non-commercial use and to remedy anti-competitive practice. Therefore, according to articles 31 and 8 (paragraph 1), TRIPS provide for the exclusion of vital drugs from the patent system in order to allow generic production. Finally, the amendment of TRIPS in 1999 relaxes the law on IPR.

In spite of the public health emergency related to the AIDS epidemic, the compulsory licences measure has never been used in Thailand, as shown by the “GPO case”. Before TRIPS ratification, GPO succeeded in developing a generic version of ddI\(^{15}\). When the new TPA came into effect in 1992, BMS patented an improved formulation of ddI. The company was granted exclusive market rights and fixed its prices freely in compliance with the Thai pharmaceutical

\(^{14}\) In 1994, World Trade Organization (WTO) agreements clearly introduced a strengthening of the monopoly of multinational firms. If GATT allowed members to protect intellectual creations (article XX (d)), there was no obligation to adopt protection measures. IPR were allowed only if they did not lead to a reduction of international trade or a discrimination between members. The emergence of a knowledge-based economy promotes the critical role of IPR for developed countries. IPR is a strategic instrument in their rent-seeking dynamic.

\(^{15}\) The National Institute of Health (NIH), the US public research institution has been the patent owner of ddI since 1987. It has granted a licence to operate (production and marketing) to BMS who pays royalties: 5-6% of sales. This first version of the ddI was not patented in Thailand.
pricing system. Consequently, ddI was unaffordable for most patients\(^\text{16}\). Yet the new ddI was not a real innovation. It only offered a slight improvement compared to the ddI patented by the NIH\(^\text{17}\). Because of the BMS patent and SMP, GPO’s project for production of a generic ddI was stopped\(^\text{18}\). Nevertheless, in 1997, GPO made a request for a CL (for governmental use) to the Thai Patent Office under the cover of article 51 of TPA. According to this article, if GPO and BMS did not agree on a reasonable amount of royalties, the Thai Patent Office would take a decision. The GPO request led BMS to lobby for the intervention of the American government. The threat of commercial retaliation on Thai gems, wood and microprocessors dissolved the willingness of the Thai government to authorise national generic production of ddI. In the end, GPO was not allowed to market its generic version under cover of a compulsory licence. Finally, as the Thai government could not resort to TRIPS because of international pressure, part of the regulation was used as a barrier to generic and affordable production.

II

HOW TO RECONCILE PUBLIC HEALTH AND INDUSTRIAL LOGIC?

Regarding the modification of the TPA before 1994, with the implementation of SMP and the ratification of the TRIPS agreement in 1992 on one side, and the international commercial pressures the Thai government faced on the other, it clearly became difficult for Thailand to provide access to anti-AIDS treatments. However, thanks to GPO commitment, Thailand is trying hard to discover ways of reconciling public health logic and industrial logic through generic production that respects patents. Indeed, aware of the existing constraints of TPA, GPO has developed 3 strategies.

The first consists in identifying non-patented medicines or drugs discovered before 1992. At the present time, GPO produces many drugs at low prices (Table 2).

The second strategy is to produce a new formulation of patented drugs. Considered as an innovation, the medicine is covered by a “petty patent”. Provided by the TPA, petty patents cover minor innovations and provide 10-year protection.

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16. In spite of a “fair-pricing” clause provided by NIH in the licence.
17. The modification of the formulation consists of the addition of anti-acidity.
18. Based on a specific production process, GPO was about to market a generic version at a lower price in the country (25 bahts vs 45 bahts the tablet).
The last strategy is to combine non-patented molecules in a 3-in-1 tablet. Again, this kind of “invention” may be patented in Thailand under cover of a “petty patent”.

For instance, faced with the impossibility of obtaining a compulsory licence for the production of ddI, patented by BMS in a tablet form, GPO developed a new formulation of ddI (in powder) and asked for a “petty patent”. Likewise, developed in December 2001, GPO-VIR combines 3 ARVs not patented in Thailand: d4T, 3TC and Nevirapine. A two-dose daily treatment is prescribed for GPO-VIR, which means lower prices for PLHAs. Indeed, taken separately, the treatment costs $114 per month and per patient. Taken in a single pill, the cost falls to $27 per month and per patient, the lowest price in the world for this treatment19.

Table 2: GPO ARV drugs list

<table>
<thead>
<tr>
<th>LIST</th>
<th>BRAND NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zidovudine (AZT)</td>
<td>ANTIVIR™</td>
</tr>
<tr>
<td>Didanosine (ddI)</td>
<td>DIVIR™</td>
</tr>
<tr>
<td>Stavudine (d4T)</td>
<td>STAVIR™</td>
</tr>
<tr>
<td>Lamivudine (3TC)</td>
<td>LAMIVIR™</td>
</tr>
<tr>
<td>Nevirapine</td>
<td>NERAVIR™</td>
</tr>
<tr>
<td>AZT+3TC</td>
<td></td>
</tr>
<tr>
<td>d4T + 3TC + Nevirapine</td>
<td>GPO-VIR™</td>
</tr>
</tbody>
</table>

Source: [21].

With GPO-VIR, the government can hope to treat about 80% of people living with HIV/AIDS if the political commitment made in December 2001 to

19. The three ARV cocktail produced by CIPLA, an Indian generic firm, costs $350 per year (sale price for MSF).
provide ARVs to PLWAs is fullfilled\(^20\). Twenty percent of PLWAs display resistance to Nevirapine and have to switch to Efavirenz (Sustiva™). But the latter is patented in Thailand. It is still unaffordable. While one can be satisfied with GPO’s results, which have broadened PLWAs’ access to ARV treatments, new ARVs remain unaffordable for most Thai patients. In the event of a future radical innovation, \textit{i.e.} the discovery by multinationals of a more efficient anti-HIV drug, local producers and especially the GPO will not be allowed to produce a generic version, even if they have the technological know-how.

\textbf{Conclusion}

This leads to the conclusion that there is a need to make the IPR system more favourable for domestic firms. New public policies seem to be moving in this direction. Currently, the liberation of drugs from SMP is accelerating, and an amendment of SMP in January 2001 restricts the scope of exclusivity rights. Henceforth, exclusivity rights are granted only for drugs patented abroad between 1968 and 1991. In the same way, the National Drugs Committee has allowed the production of generic versions of patented drugs in order to begin bio-equivalence studies. Known as the “Bolar provision”, this measure allows their registration before the end of the exclusivity period and thus cuts the multinational exclusivity period by 2 to 3 years \([22]\).

Furthermore, we can observe that Thailand has been severely disillusioned on the question of technology transfer. Article 7, “Objectives”, of the TRIPS agreements stipulate that “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”. Furthermore, Article 66-2, “Least-Developed Country Members”, stipulates that “Developed Country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to Least-Developed Country Members in order to enable them to create a sound and viable technological base”.

\(^{20}\) Under the pressure of Non Governmental Organizations (NGOs), the New Health Insurance Policy was implemented under the slogan “30 bahts for curing every disease”. The objective was to extend cover to all Thai people and to decrease the burden on household expenditures. However, in practice, the introduction of ARVs is still problematic because of their price.
In fact, since the Thai Patent Act amendment in 1999, evidence of growth in technology transfer in the Thai pharmaceutical market is weak [23, 20]. According to Supakankunti et al. [24], 82% of directors in the R&D-based pharmaceutical industry believed that there was no technology transfer in the Thai pharmaceutical industry. From 1984 to 1998, the nationality of firms in the local market was Thai, leading to the conclusion that there were few foreign direct investments (FDIs) in the Thai pharmaceutical industry. Furthermore, since “working patents” allow both local production and importation of medicines, multinationals continue to import instead of producing drugs locally. In 1999, imported products represented 60% of the Thai medicine market. When production units of multinationals are actually installed in Thailand, their activities are limited to manufacturing finished products. Ultimately, FDI numbers have not increased in Thailand, despite significant modifications of the TPA. It appears that the disadvantages of the new TPA are clearly obvious, whereas the advantages remain questionable.

21. Similarly, The Thai boards of many R&D-based multinationals moved to Singapore in spite of the strengthening of the Thai Patent Act. The chief executive of the Pharmaceutical Producers Association, Professor Chitman, argues that Singapore is more attractive than Thailand because of many advantages like abatements, faster registration procedures and work permits for expatriates [22].
REFERENCES
