

Chapter 12

Support for Access to Essential Drugs and Compulsory Licensing of Drugs

1. Introduction

The Thai patent law that is now being enforced is the Patent Act, B.E. 2522 (1989), and its amendment No. 2 of B.E. 2535 (1992) and amendment No.3 of B.E. 2542 (1999). The Act authorizes compulsory licensing or government use of patents on any patented products including patented drugs in two instances, one by any ministry, sub-ministry or department of the government according to Section 51 and the other by the Prime Minister with the Cabinet's approved during a state of war or emergency in accordance with Section 52. The exercise of power for both instances mentioned above is in accordance with Article 31 of the Agreement on Trade-Related Aspect of Intellectual Property Rights (TRIPS Agreement), which was adopted by the Doha Declaration on TRIPS and Public Health by members of the world trade Organization (WTO) at the WTO ministerial conference held in Doha, Qatar, on 14 November 1999.

There were efforts to urge the government to exercise such a right in Thailand in 1999 by a group of HIV-infected people led by Mr. Jon Ungphakorn, requesting that MoPH issue a compulsory licence for antiretroviral drug "ddI", but did not succeed. That was because the government was afraid that such a practice would affect the trade relationships in regard to the Generalized System of Preferences (GSP) and that a trade retaliatory action might be taken according to Article 301 of the U.S. trade law. As a result, Thailand had to bear the burden of unreasonably high prices of such a drug under the patent law, especially the Patent Act, Amendment No.2 (1992), which also covered pharmaceutical products, whereas the previous law covered only a manufacturing process. Such a law amendment in Thailand was undertaken 8 years before the time frame specified by WTO and 13 years before least-developed countries, including India. But finally, Thailand had a pressing need to exercise the compulsory licensing from late-2006 until early 2008 for a total of seven patented drugs, of which two were antiretroviral, one for heart disease and four for cancer treatment.

2. Background

In the 1997 Constitution of Thailand, there were two sections directly on public health as follows:

Section 52: A person shall enjoy an equal right to receive standard public health service, and the indigent shall have the right to receive free medical treatment from public health centres of the State, as provided by law.



The public health service by the State shall be provided thoroughly and efficiently and, for this purpose, participation by local government organisations and the private sector shall also be promoted insofar as it is possible.

The State shall prevent and eradicate harmful contagious diseases for the public without charge, as provided by law.

Section 82: The State shall thoroughly provide and promote standard and efficient public health services.

In the 2007 Constitution of Thailand, which is the first constitution of the country that passed a public referendum and is currently enforced, also contains the two sections on public health with some modifications as follows:

Section 51: A person shall enjoy an equal right to receive standard public health service, and the indigent shall have the right to receive free medical treatment from State's infirmary.

The public health service by the State shall be provided thoroughly and efficiently.

The State shall promptly prevent and eradicate harmful contagious diseases for the public without charge.

Section 80: The State shall act in compliance with the social, public health, education and culture policies as follows: ...(2) promoting, supporting and developing health system with due regard to the health promotion for sustainable health conditions of the public, providing and promoting standard and efficient public health service thoroughly and encouraging private sector and the communities in participating in health promotion and providing public health service, and the person having duty to provide such service whose act meets the requirements of professional and ethical standards shall be protected as provided by law.

Basically, according to the intent and provisions of the 1997 Constitution, the Parliament passed the 2002 National Health Security Act aimed at providing universal health care for all Thai citizens on an equitable and efficient basis with high quality. In particular, Section 5, paragraph 1 of the Act prescribes that "The Thai population shall be entitled to health services with such standards and efficiency as prescribed in this Act".

Besides, the Royal Decree on Criteria and Procedures for Good Governance, B.E. 2546 (2003), specifies that state agencies have to implement their respective functions to achieve seven goals as per Section 6 of the law as follows:

- (1) Resulting in maximum benefits for the people.
- (2) Resulting in achievements of state missions.
- (3) Being efficient and worthwhile for state missions.
- (4) Not having too many operating steps other than essential ones.
- (5) Modifying state missions in accordance with changing situation in a timely manner.
- (6) Being convenient for the people and responsive to their needs.
- (7) Having performance evaluations on a regular basis.

To achieve the goals prescribed in the Constitution, the National Health Security Act and the Royal Decree on Good Governance, the National Health Security Commission and the National Health Security Office (NHSO) have decided to use the capitation financing method as the most economical capitation rate can be calculated. In the beginning, the rate was 1,202 baht per capita per year, which was the lowest, compared with the capitation rates under the Social Security Fund (SSF) and the Civil Servant Medical Benefit Scheme (CSMBS). With the capitation budget, NHSO has been able to manage and achieve the objectives quite effectively.

However, one of the big problems hindering people's access to essential drugs or medicines is the drugs' high prices especially patented drugs with monopoly and arbitrarily set prices of drugs. Thus, unavoidably, there was a need for the government to issue compulsory licences on certain essential patented drugs according to the Thai patent and international rules.

3. Procedures for Operation

The first drug, according to the country's needs, that would be considered for compulsory licensing was an antiretroviral drug (for HIV infection).

According to the 2002 National Health Security Act, the eligible persons will have access to drugs in the National List of Essential Medicines (NLEM) except for antiretrovirals in the first year of the universal healthcare scheme due to budgetary constraints. But in the following year, the government issued the policy on access to antiretrovirals for all, beginning on 1 October 2003, according to the humanitarian principles and the provision of the Constitution: "Every person shall enjoy equal rights to receive appropriate and standard public health services".

For the universal access to antiretrovirals policy to be implemented in an economical and efficient manner, it is necessary to use the cheapest drug regimen, i.e. GPO-VIR of the Government Pharmaceutical Organization (GPO) which contained nevirapine, an antiretroviral that could not be tolerated and cause adverse drug reactions among a number of patients. So, the regimen had to replace the drug with another expensive patented drug efavirenz. Besides, a certain number of patients would naturally develop drug resistance and another expensive patented regimen would have to be used instead, i.e. a combination of ritonavir and lopinavir.

Efforts were made continually to negotiate with drug patent-holders after MoPH had issued Order No. 360/2548 (2005) appointing an ad hoc working group on negotiations of patented drug prices, chaired by the Secretary-General of the Food and Drug Administration and comprising representatives of non-MoPH agencies including the Patent Office and the Internal Trade Department of the Ministry of Commerce. The negotiations were undertaken on 3 antiretrovirals, i.e. efavirenz of Merck Sharp and Dohme (MSD), ritonavir/lopinavir of Abbott Laboratory and atazanavir of Bristol-Myers Squibb (BMS) Company. But, according to the working group's report, "the negotiations with the drug companies were preliminarily not successful, no cooperation was received from the companies...."



Before that, the Department of Disease Control sent a letter No. MoPH 0424.4/7/6673, dated 16 November 2004, requesting price reduction for drug efavirenz of MSD and another letter No. MoPH 0424.4/7/6692 on the same date for drug ritronavir/lopinavir of Abbott Laboratory. But the requests were rejected.

Later on, NHSO issued Order No. 4/2549, dated 19 April 2006, appointing a Subcommittee on Government Use of Patented Drugs and Medical Supplies, chaired by the Secretary-General of NHSO and comprising representatives of health professionals, AIDS and cancer patients, the Office of the Council of State and the Intellectual Property Department of the Ministry of Commerce. The subcommittee later made a recommendation on the government use of patents on all the patented drugs, which were later on under compulsory licenses, with the endorsement of NHSB prior to submission to MoPH.

It is noteworthy that the compulsory licensing actions at a later date were reviewed by relevant agencies and taken after considerable negotiations with the patent-holders.

4. Announcements of the Government Use of Patents for the First 3 Drugs

The announcements or notifications of compulsory licensing or government use of patents of the first three patented drugs, including two antiretrovirals (efavirenz, ritronavir/lopinavir) and one cardiovascular drug (clopidogrel), were undertaken pursuant to Section 51 of the Patent Act. The announcements for the antiretrovirals were issued by the Director-General of the Department of Disease Control on 29 November 2003 and 24 January 2007, while the one for clopidogrel was issued by the Permanent Secretary, MoPH, on 25 January 2007.

In addition to issuing the announcements and notifying the patent-holders, the notification was also made to the Director-General of the Intellectual Property Department. And the import of all the three drugs was undertaken by the Government Pharmaceutical Organization.

The justification for compulsory licensing of the three drugs was clearly stated in the three announcements. For example, in the case of efavirenz, the justification includes legal authority and resources/necessity and conditions as follows:

It is generally accepted that the HIV/AIDS epidemic is one of the most grievous public health problems. Approximately, more than one million Thai people have been afflicted with the HIV. More than 500,000 of this number are still alive and eventually need long-term uses of HIV antiretroviral drugs to maintain their productive lives. The budget allocated for health services of the people who have been infected with HIV as well as AIDS patients under the national health security system for the fiscal year 2006 is only 2,796.2 million baht for the target group of 82,000 patients.

Even now there are many effective HIV antiretroviral drugs which are capable of extending life span of HIV-infected persons and the Royal Thai Government has launched, since 1 October 2003, a policy to promote access to HIV antiretroviral drugs for all HIV-infected persons and has also allocated budget for this purpose, but the accessibility to some kinds of HIV antiretroviral drugs which are effective and having low level of side-effect is still difficult in spite of an inevitable necessity for the HIV-infected persons. This due to the fact

that all those antiretroviral drugs are under patent protection in accordance with the law on patent which enables the patent-holders to dominate market without competition. The prices of such antiretroviral drugs are, as a result, very high and a hindrance for the State to acquire the drugs for distribution to all HIV-infected persons.

Efavirenz has already been proved so far to be one of highly effective and safe antiretroviral drugs with very low side effect. It has also been placed in the National System for Secured Accessibility to Antiretroviral Drugs. This antiretroviral drug, however, is subject to patent protection which deters the Government Pharmaceutical Organization or other manufacturers from manufacturing and importing this specific drug for sale in the market. The price of efavirenz in Thailand is twice the price of the same drug which is generic drug in India. The budget allocated by the government is therefore sufficient to provide only some patients with efavirenz, while the rest has to use non-patent drugs with higher level of side-effect than efavirenz because of their lower prices.

According to the Doha Declaration on the TRIPS Agreement and Public Health, each member country has the right to protect public health, in particular, to promote access to medicines for all in case of emergency and for public benefit, especially accessibility to those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics. In this regard, the Thai law on patent empowers ministries, sub-ministries and departments to exercise the right under any patent without prior authorization of the patent-holders so as to provide public service as mentioned above.

Therefore, the Department of Disease Control, the Ministry of Public Health, hereby notifies, by virtue of section 51 of the Patent Act, B.E. 2522 (1979), as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999), that it is now exercising the right under drug patent of the drug under trade name "Stocrin" (generic name: efavirenz). In this regard, the Department of Disease Control entrusts the Government Pharmaceutical Organization to exercise the right in its name in accordance with section 36 paragraph one of the Patent Act, B.E. 2522 (1979), as amended by the Patent Act (No. 2), B.E. 2535 (1992) and the Patent Act (No. 3), B.E. 2542 (1999), subject to the following conditions:

- (1) the right shall be exercised from now on through 31December 2011;
- (2) the exercise of the right is limited to annual provision of drug having the aforesaid generic name to not exceeding 200,000 patients who are entitled persons under the 2002 National Health Security Act and the insured persons under the 1990 Social Security Act, and persons entitled to medical benefits for civil servants and government employees scheme;
- (3) a royalty fee of 0.5 per cent of the total sale value of drug having the aforesaid generic name by the Government Pharmaceutical Organization shall be paid to the patent-holder.

The Department of Disease Control, Ministry of Public Health, shall notify the patent-holder and the Department of Intellectual Property for information without delay.



5. Procurement of Drugs under Compulsory Licenses

As Thailand was forced to amend its patent law to cover pharmaceutical products in 1992, ever since no drug companies have invested in research and manufacturing of generic drugs whose patents are still valid. So, the purchase of such drugs had to be made from other countries, especially India which has been manufacturing a lot of generic drugs with good quality and low prices. In India, the patent law's provision on drug manufacturing process was observed especially with regard to the timeframe established by WTO; until 2005, the law was amended to also cover pharmaceutical products. Over the past decade, India has developed its pharmaceutical industry on a leap scale; and it has been able to produce medicines according to the standards of WHO and other developed countries such as the USA and European countries. Pharmaceutical products can be exported to almost all over the world; and importantly, there are a lot of pharmaceutical plants that are able to produce pharmaceutical ingredients for domestic use and export at a reasonable price.

Prior to the compulsory licensing for patented drugs, the Thai MoPH had examined the list of generic drugs that should be imported for use in lieu of high-priced patented drugs. After the issuance of compulsory licences on certain patented drugs, GPO has been able to procure the drugs under compulsory licenses accordingly. However, to ensure the good quality of such drugs and to follow the country's legal requirements, the import of the drugs under compulsory licenses have to be strictly undertaken according to the Thai FDA requirements, including drug registration and quality assurance of the Department of Medical Sciences or other foreign agencies for the case that cannot be done by the Department of Medical Sciences. So, it takes a rather long time for each imported drug to reach the patient.

It is a pleasure, anyway, that the price of each imported drug is markedly lower than that of the patented drug, especially heart-disease drug clopidogrel whose patented drug price per tablet is 70 baht (approx. US\$2.33), while the GPO-purchased drug was only 1.06 baht (approx. US\$ 0.0353).

6. Retaliation from Patent-holders

After the government's compulsory licensing of patents, three patent-holders responded and retaliated in different aspects.

Merck Sharp and Dohme (MSD) responded in a creative manner by reducing the price, but not to the level set by the **Committee on Support for the Government Use of Patent**, i.e. the patented drug should not be more expensive than the generic drug by more than 5%. This is to allow generic drug industries to compete in the procurement process for the promotion of the people's better access to essential drugs. Accordingly, the compulsory licensing for efavirenz of the drug company was in effect.

For Abbott Laboratory, the retaliation was rather strong with the withdrawal of seven new drugs from the FDA. Besides, there were retaliations from various agencies, blaming Thailand's compulsory licensing measure. For example, the Pharmaceutical Research and Manufacturers Association (PReMA, Thailand), the

Pharmaceutical Research and Manufacturers of America (PhRMA) and the United States-ASEAN Business Council (USABC) reasoned that Thailand's action was the impediment to research on new drugs; and there would retaliate by stopping or reducing investments on other businesses in Thailand. Moreover, the U.S. Trade Representative (USTR) also expressed its negative position on Thailand's measure and later on raised Thailand from their Watch List to Priority Watch List in relation to trade retaliation. The then US ambassador to Thailand asked for a meeting with the Thai Minister of Public Health to express concerns and suggested ways of negotiation with patent-holders in lieu of compulsory licensing of patents even though he had known or should have known that MoPH had used the negotiation method considerably but failed to reach any satisfactory result.

Later on, an agency called USA For Innovation opened a website and put advertisements on a full page of Thai and English newspapers strongly attacking the Thai government, especially, MoPH and GPO, on this matter as well as the government having been established by the 19 September 2006 military coup. But the investigation conducted by the Royal Thai Embassy in Washington, D.C., revealed that the agency's location did not actually exist. The foreign mass media that continually attacked Thailand's compulsory licensing of patents was The Wall Street Journal.

As for Sanofi Company, the owner of clopidogrel, its legal action was undertaken by a law firm, Tilleke & Gibbins, informing GPO and all concerned including the Indian drug company that MoPH's issuance of compulsory licences for its patented drug was illegal and that such an action be discontinued otherwise a legal action would be taken.

7. International Perspectives

The international perspectives on Thailand's compulsory licensing of patents were all positive from individuals, agencies or organizations within and outside the USA such as Medicins Sans Frontieres (MSF, or Doctors Without Borders), the US-based Consumer Projection Technology, the William J. Clinton Foundation, and the Knowledge Ecology International (KEI). Importantly, 22 U.S. congressmen signed a letter to USTR, informing USTR not to intervene in Thailand's compulsory licensing of patents. Later on, a legal expert of American University prepared an analysis of this matter and concluded that Thailand's compulsory licensing of patents is legal and in accordance with Thai law and the TRIPS Agreement. And after the USTR had raised Thailand to The Priority Watch List, 35 U.S. congressmen sent a letter to USTR indicating their objection to such a matter. As for the case of Thailand's being deprived of the GSP privileges for gold jewellery, two key congress commissioners also sent an objection letter to USTR.

In other counties, the Department for International Development of the United Kingdom sent a letter, dated 22 May 2007, supporting Thailand's compulsory licensing of patents and the European Parliament passed a resolution on the protection of developing countries' access to essential medicines on 12 July 2007.

In addition, international organizations clearly supported Thailand's action: the Joint United National Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) sent letters of



support to the Minister of Public Health on 26 December 2006 and 7 February 2007, respectively.

8. Explanation of Thailand

In addition to periodically answering the questions of the press by the Minister of Public Health and relevant health officials concerned, there have been public relations efforts through various tools and mechanisms as briefly described below:

1) Issuance of “white paper “on” Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand”. The 16-page paper contains 10 questions and answers, systematically explaining various facts and evidences in all key relevant aspects with references as appendices in a reliable manner with a simple, concise and clear language. The publication of the paper could be done within a short period of time in February 2007, only a few weeks after the issuance of the government use of patents or compulsory licences on the first three patented drugs. It is regarded as the extremely good practice of a public relations effort as, in addition to publication for a wide-scale distribution, the paper was also posted on the MoPH website. Describing the justification and righteousness of the government use of patent related to essential drugs to the general public, the paper has created a good understanding among all public health personnel throughout the country.

The paper was later on translated into English with a clearer explanation on certain aspects in accordance with the changing situation; its hard copies were widely distributed and its electronic file was posted on the Internet for worldwide distribution which helped create a good understanding for Thai and global citizens, especially in efficiently counter-attacking the claims of the benefit-losers.

Another white paper of this kind was prepared after the issuances of the government use of patents related to four anti-cancer drugs, entitled “The 10 burning questions regarding the Government Use of Patents on the Four Anti-Cancer drugs in Thailand”, published in February 2008.

2) Overseas trips to the USA. Two trips were taken to build up alliances and clarify the facts on this matter; the first one was to hold a joint press conference with former president Bill Clinton at the William J. Clinton Foundation in New York City and the second one to give a briefing to relevant persons and agencies in Washington, D.C., especially those who were supportive of, or against, MoPH’s operations on this matter. The Thai delegation also met with key figures in the USA such as Congressmen, (both the government and opposition sides), the U.S. Secretary of Commerce, the Pharmaceutical Research and Manufactures of America, the U.S.-ASEAN Business Council, office of the U.S. Trade Representative, and the Office of the Washington Post. At the end of each day of the 2-day visit, a press briefing was held at the Royal Thai Embassy in Washington, D.C., where proactive public relations efforts could be effectively undertaken. Both trips to the USA were efficiently supported by the Royal Thai Embassy in Washington, D.C., which also provided excellent background information about the negotiation partners.

3) After Thailand had been put on the USTR’s Priority Watch List due to vague reasoning of Thailand’s government use of patent, the Thai Minister of Public Health bravely declared that Thailand was

retaliated because of the drugs' compulsory licensing, rather than being blamed for taking incorrect actions, making Thailand being in a difficult situation. On the contrary, the mass media and the general public praised the courage and were displeased with the USA's action persecuting Thailand with its power.

4) When the USA For Innovation opened its website and issued a full-page advertisement in Thai and English newspapers, strongly blaming Thailand with true and false information, the GPO responded immediately by filing a legal action against such an agency, but not against the advertising newspapers. As a result, the newspapers discontinued the advertisement and the USA for Innovation disappeared.

9. The Second Wave of the Government Use of Patents

During the late stage of the Surayud Chulanont government, despite being pressured by the US government and the Thai Ministry of Commerce, the Thai Minister of Public Health decided to issue the government use of patents for four patented anti-cancer drugs: docetaxel, letrozole, erlotinib and imatinib, with the conditions that the patent-holders agree to give one of the drugs to Thai patients under the universal healthcare scheme free of charge, but the use of the other three drugs would be in accordance with Section 51 of the Patent Act, B.E. 2522 (1979), as amended, after unsuccessful negotiations because the patent-holder agreed to reduce the prices with the conditions that were hard to follow, and thus unacceptable.

The compulsory licensing or government use of the four aforementioned patented drugs began when the Subcommittee on Selection of Essential Medicines and Medical Supplies with Difficult Accessibility under the Health Insurance System submitted a letter No. NHSO 05/013521, dated 25 September 2007, to the Minister of Public Health and the Committee on Supporting the Implementation of the Government Use of Patents passed a resolution at its meeting No. 7/2550, on 2 October 2007, requesting the Minister of Public Health to issue the government use of patents as per its memorandum No. MoPH 0100/TST/special, dated 19 October 2007.

After more than 10 negotiations with the drug companies conducted by the Committee on Price Negotiation of Patented Drugs, chaired by the FDA Secretary-General, the Minister of Public Health signed the notifications on the government use of patents for the four patented anti-cancer drugs, but its implementation was delayed, pending further negotiations. After another round of negotiation with Novartis (imatinib's patent-holder), the company agreed to donate the drug to the patients under the universal healthcare scheme; and thus the MoPH notification on government use of patent for imatinib was repealed. Accordingly, a new notification with conditional government use of patents was issued instead on 25 January 2008, which also cancelled the delay in the implementation for the other three drugs.

10. Implementation of the Change in Government

After the general elections on 23 December 2007, the People's Power Party won the majority seats and the new Minister of Public Health issued a policy to review the implementation of the government use of patents on patented drugs; but the move was widely apposed by the Rural Doctors Society and groups of



patients. In this connection, the Public Health Minister issued orders transferring the then FDA Secretary-General to another position and removing the GPO Board of Directors. In this regard, some members of the Board filed a petition to the Administrative Court and the Central Administrative Court issued an injunction reinstating all the Board members, but later on the Supreme Administrative Court reversed the order, resulting in the removal of all the Board members. Some time later, as a result of the political change, the newly appointed cabinet endorsed the reappointment of the former chairperson of the GPO Board of Directors.

It is noteworthy that, during the one-year period after the general elections, there were changes in membership of the GPO Board of Directors as the post-election Cabinet had policies that were clearly different from those of the Surayud Chulanont government, especially on the government use of patents. There were criticisms that the decision had been made arbitrarily, especially for the anti-cancer drugs, taking the opportunity while being the caretaker government. But because there was no official order for GPO to delay the implementation of the policy directed by the Surayud government, the importation of the generic drugs under the government use of patents has been carried out continuously.

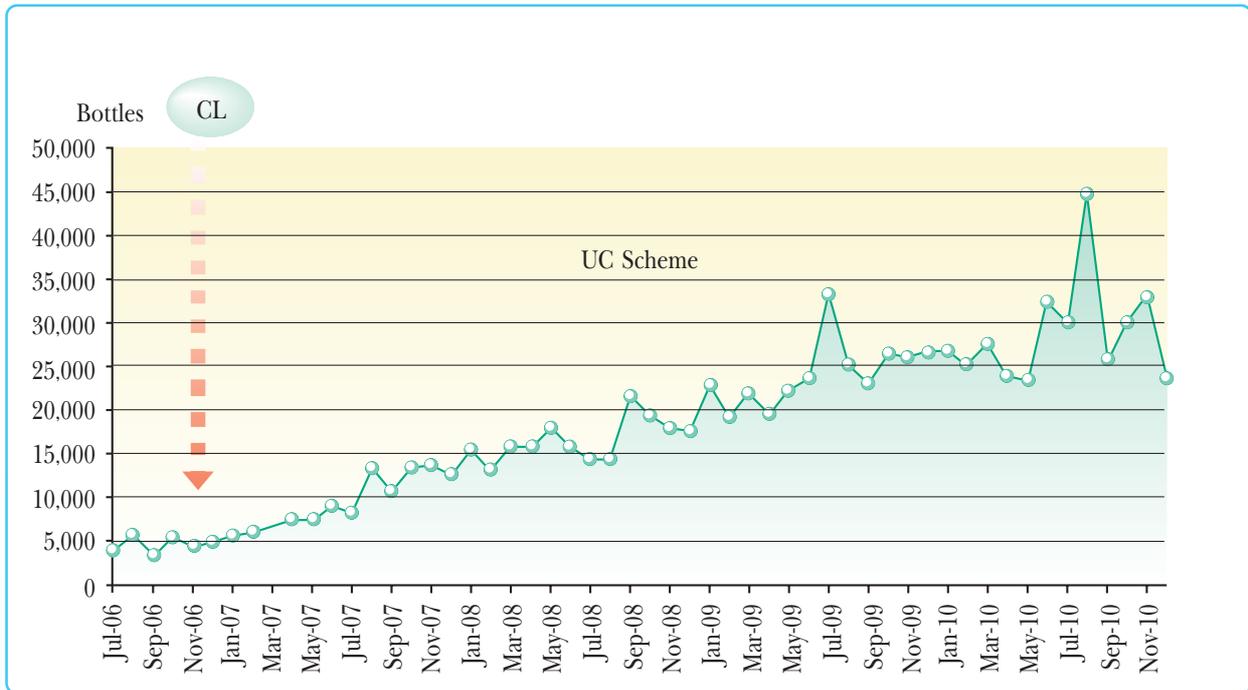
11. Results of the Operations

Between January 2007 and 14 February 2011, GPO imported five generic drugs under the government use of patents, but the other two drugs were not imported; the first one, imatinib, was not imported as it is under the conditional government use of the drug patent and there had been no conditions for such importation and, for the other drug (anti-cancer erlotinib), it was not imported as there was no generic drug with the results of bio-equivalence study in the blood according to the FDA criteria. Totally, the value of drug imports during the period was 1,077.7 million baht.

12. Increase in the Access to Patented Drugs

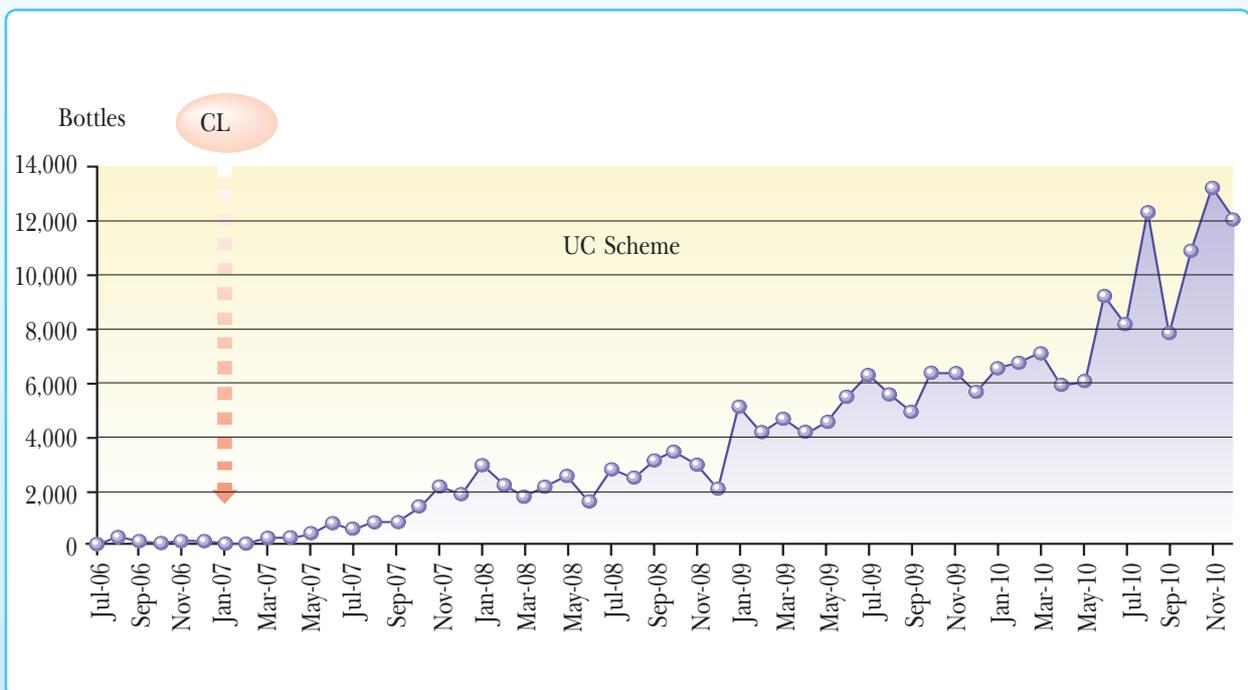
After the issuance of notifications of the government use of patents and the importations of generic drugs, it has been noted that patients' access to essential drugs has increased considerably in both the universal healthcare and social security systems, especially for two antiretroviral drugs: efavirenz and lopinavir/ritonavir (Figures 12.1 and 12.2).

Figure 12.1 Use of antiretroviral efavirenz (600 mg) under the universal coverage (UC) of healthcare scheme, 2006–2010



Source: Suwit Wibulpolprasert, 2011.

Figure 12.2 Use of antiretroviral lopinavir/ritonavir (200/50 mg) under the universal coverage (UC) of healthcare scheme, 2006–2010



Source: Suwit Wibulpolprasert, 2011.



13. Systematic Monitoring and Evaluation

To make it apparent to the world community that the government use of seven drug patents was correct, justifiable, transparent and accountable, according to World Health Assembly resolution 60.30, MoPH requested the WHO Director-General to send a group of experts to examine and give advice on MoPH's operations. In response, the expert team comprising representatives of WHO, WTO, the U.N. Conference on Trade and Development (UNCTAD), and the UN Development Programme (UNDP) came to review the system and procedures for the government use of patents on patented essential drugs in Thailand from 31 January to 6 February 2008. The team did not find any operation that was not transparent or inconsistent with the WTO rules. However, the team recommended that Thailand deploy the TRIPS flexibility measures for more Thais to get access to the essential drugs, particularly the pre-patenting measures that have been used effectively in India.

Regarding the impact assessment, the Health Intervention and Technology Assessment Program (HITAP) conducted a study on the government use of drug patents in Thailand, but with a limited timeframe of 2006–2008, the study did not cover the four anti-cancer drugs as their patent use was imposed at a later date. The study briefly reveals the following:

“Regarding health, the compulsory licensing measure has considerably increased the number of patients having access to essential drugs, particularly antiretrovirals. But for clopidogrel and the four anti-cancer drugs, during the study period there were no imports of such generic drugs, the researchers had to make an assumption that there would be the imports of such generic drugs from 2009 onwards. It was found that the numbers of patients with access to each of such drugs had increased at a high to low level for clopidogrel, letrozole, docetaxel, imatinib and erlotinib, respectively.

In terms of economic impact, the measure has resulted in a greater number of patients having access to such drugs, better quality of life and, a longer lifespan, worth US\$ 132 million. Even though the relation between Thailand's compulsory licensing measure and USA's revocation of GSP on three Thai products was unclear, the study has revealed that such a trade retaliation 'has no impact on the country's overall exports and investor's confidence in the short run'. However, there should be a further study to monitor the impacts of such a policy in the long term.

In assessing the socio-psychological impact, data collection has done using a questionnaire for Thai and foreign respondents; most of them agreed to the compulsory licensing measure for antiretrovirals. The positive impacts that most Thai and foreign respondents agreed to was the cheap prices of drugs. As for the negative impact, most Thai respondents viewed that technology transfer from developed to developing countries would decline, while most foreign respondents said that the major negative impact was the blame on Thailand by the international community.

Under this study, the researchers have proposed six factors for use when selecting patented drugs if the compulsory licensing measure has to be deployed in the future; and there are needs for the development of an information system for the health system, the health insurance project and intellectual property right

protection; the dissemination of knowledge and the creation of correct understanding for the general public particularly in relation to the flexibility according to the TRIPS Agreement and compulsory licensing; and the selection of measures for resolving the problem of inaccessibility to essential drugs in a suitable manner, based on empirical evidence.”

14. Conclusion

The government use or compulsory licensing of patents for seven essential patented drugs is the correct operation in accordance with all principles and justifications: humanitarianism international rules, the country’s law and good governance. The operations, including the preparation, have been undertaken with prudence and step-by-step procedures, with the participation of all relevant persons, and by the agencies directly responsible for this matter, not deferring it for cabinet’s consideration. Wherever there were retaliations or objections from the benefit-losers, there were systematic and adequate clarifications at the national and international levels.

The implementation of such a measure has resulted in the significant reduction of unsuitable expenses as such patented drugs are unreasonably expensive. The major target has been achieved, i.e. the substantially increased number of patient with access to essential drugs; and there has been no impact on international trade as expected.

In the future, there should be studies and preparation on using other measures to increasingly improve patients’ access to essential drugs such as pre-patenting measure recommended by WHO’s team of experts.

