Introducing government use of patents on essential medicines in Thailand, 2006 - 2007

Policy analysis with key lessons learned and recommendations

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Preface

Intellectual property rights protection has two important roles in public health. On the positive side, this legislation framework aims to promote medicine discovery and innovation through two mechanisms: the provision of incentives to inventors, and the disclosure of information to facilitate technology transfer. On the negative side, the market exclusivity granted to patent holders and associated high prices of patented products are among the key barriers to pharmaceuticals and therefore, the health of the population. In the sense, effective use of the safeguarding provisions in the Agreement on Trade-related Aspect of Intellectual Property Rights (TRIPS) can help to improve access to essential medicines in developing and least-developed countries.

The Government of Thailand introduced public use of patents for 2 antiretrovirals and an anti-platelet drug in late 2006 and early 2007. This action prompted strong support along with opposition by key stakeholders around the world. The International Health Policy Program (IHPP) considered that the implementation of TRIPS flexibilities in resource-poor settings was rare, and that the development of such a policy in the past was not well documented and understood. For these reasons, an analysis of the Thai policy was conducted to shed light on the processes and the influences of political actors and context. As the IHPP is a semi-autonomous research arm of the Ministry of Public Health, we pursue quality, and strive for integrity in every area of our work. We are aware that although this study was not intended to serve a political purpose, parts of or the whole report may be used in such a way by some interests. Finally, we hope that lessons drawn on the Thai experience will be helpful for other countries and concerned organizations who wish to diminish the negative impact of intellectual property regimes on public health.

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Abstract

In late 2006 and early 2007, Thailand's administration announced its intention to introduce the government use of patents for 3 pharmaceutical products, including 2 antiretrovirals (ARVs): efavirenz and lopinavir/ritonavir combination and drug for heart disease: clopidogrel. According to the Ministry of Public Health (MOPH), this action, with the aim to ensure access to affordable medicines in the public sector, complied with the flexibilities of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS). The Thai move prompted rigorous protests and pressure from multinational drug companies and their national governments. At the same time, the use of public health safeguards was praised by international agencies and non-governmental organisations (NGOs). This study assesses the roles of key actors and contextual elements that shaped the processes of policy making and implementation.

This analysis suggests that despite continual advocacy by civil society organizations, the idea of enforcing TRIPS flexibilities for essential medicines in Thailand was heightened on the governmental agenda and adopted as a public policy when the new administration took office after a military coup in September 2006. To deal with the opposition from powerful parties, the Thai government sought collaboration with existing alliances of domestic and international NGOs, many of which had experienced campaigning for expansion of HIV/AIDS treatment, including those to encourage the use of TRIPS safeguards for public interests. Diverse strategies were employed by responsible government agencies and civic networks in order to alleviate political pressures and avoid trade retaliations. It could be observed that the government use policy often moved back and forth between the formulation and implementation stage, while limited groups of key stakeholders were involved. While international authorities, such as the World Health Organization (WHO), seemed to be reluctant to participate in the disputes between Thailand and the opponents to the government use policy, global

concerns about the unaffordable costs of patented drugs that hampered access to essential health care in the South was beneficial to the Thai action. The potential diffusion of this policy from Thailand to other developing countries triggered substantial tensions between the supporters and opponents of the government use enforcement.

The introduction of TRIPS flexibility for medicines in Thailand offers several lessons which may be helpful for resource-poor settings and health advocates coalitions, for example, the roles of public civic networks, relentless advocacy and collective learning among partners, as key factors of success. Policy recommendations derived from this study emphasize the needs for the commitment and leadership of the WHO, in collaboration with other parties, to bridge the gaps between the demands for and access to health products, by fostering intellectual property management frameworks which do not undermine health of the underprivileged.

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List of abbreviations

ARV	*Antiretrovirals*
ART	*antiretroviral therapy*
AZT	*Zidovudine (Azidothymidine)*
BMS	*Bristol-Myers Squibb*
CIPIH	*Commission on Intellectual Property Rights, Innovation and Public Health*
CL	*compulsory license*
CPTECH	*Consumer Project on Technology*
ddI	*didanosine*
DIP	*Department of Intellectual Property*
EC	*European Commission*
EFZ	*Efavirenz*
EP	*European Parliament*
EU	*European Union*
FDA	*Food and Drug Administration*
FTA	*Free Trade Agreement*
GMP	*Good Manufacturing Practice*
GPO	*Government Pharmaceutical Organization*
GSK	*Glaxo SmithKline*
GSP	*Generalized System of Preferences*
HAART	*Highly active antiretroviral therapy*
IGWG	*Intergovernmental Working Group*
IP	*intellectual property*
KEI	*Knowledge Ecology International*
MFA	*Ministry of Foreign Affairs*
MOC	*Ministry of Commerce*
MOPH	*Ministry of Public Health*
MSD	*Merck Sharp & Dohme*

MSF	*Medicin Sans Frontieres*
NGO	*non-governmental organisations*
NHSB	*National Health Security Board*
NHSO	*National Health Security Office*
NVP	*Nevirapine*
PHA	*People living with HIV/AIDS*
PhRMA	*Pharmaceutical Research and Manufacturers of America*
PWL	*Priority Watch List*
PReMA	*Pharmaceutical Research and Manufacturers Association*
R&D	*Research and development*
SMP	*Safety Monitoring Program*
TRIPS	*Agreement on Trade-related Aspects of Intellectual Property Rights*
TWN	*Third World Network*
UC	*Universal health coverage*
UNAIDS	*Joint United Nations Programme on HIV/AIDS*
USTR	*United States Trade Representative*
WHA	*World Health Assembly*
WHO	*World Health Organization*
WL	*Watch List*
WTO	*World Trade Organisation*

Introducing government use of patents on essential medicines in Thailand, 2006-2007

Policy analysis with key lessons learned and recommendations

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1. Introduction

Over the past decade, there has been a strong, collaborative effort from the global health community to alleviate the negative implications of intellectual property (IP) rights protection for access to essential drugs, especially in the developing world. Despite this dedication, market exclusivity, and the associated high prices of patented pharmaceutical products, remain crucial barriers to improved health and well-being of poor people (Messerlin 2005). This is in addition to the lack of research and development (R&D) of medicines for neglected diseases and the inadequacy of health care delivery systems. The magnitude of such problems suggests that existing frameworks to alleviate the adverse effects of IP regimes, i.e. the public health safeguards in accordance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration on TRIPS and Public Health, have so far been ineffective.

To be precise, the TRIPS flexibilities, including the definition of inventions and patentability criteria; bolar provision and other exceptions to exclusive rights, namely government use of patents, compulsory licensing (CL) and parallel importation, are not fully beneficial to resource-poor settings. Although these

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measures have been legitimately enacted as components of the national patent laws of most developing countries, they are not effectively implemented for several reasons. Among others, the lack of IP management capacity is a crucial factor for governments to use the TRIPS safeguards (Baker 2004; Lewis-Lettington and Munyi 2004). When we look at the details, it could be asserted, however, that the imbalance of power between developed and less-developed nations is another source of reluctance: the fears of objections and retaliations make the latter hesitate to enforce the flexibilities to protect public health (Steinbrook 2007). Opposition may be undertaken in many different forms, for example, threatening to impose countermeasures, cutting down on Overseas Development Administration support, reducing foreign investment, or downgrading foreign relations.

In late 2006 and early 2007, Thailand announced it would adopt a government use provision for three patented pharmaceutical products, namely efavirenz (EFZ), the lopinavir/ritonavir combination (LPV/r), and clopidogrel. This action prompted strong opposition from patent-holding pharmaceutical companies, a number of governments of industrialised nations, and international pharmaceutical industry associations. This research aims to analyse the policy process by which the government use of patents for the three medicines were implemented in Thailand in 2006 and 2007. The specific objectives of this study are:

(1) to describe the policy processes in the adoption, formulation and execution of government use provision;
(2) to identify key stakeholders who participated in the introduction of government use measure including the policy supporters and opponents, and assess their roles at each policy stage;
(3) to examine the influence of national and international contextual factors in the introduction of government use measures;
(4) to synthesize lessons learned for national and international audiences and to propose further actions by all national and international stakeholders for improving access to essential medicines.

Research methods

Document review, interview and personal communication with key informants and participatory observations were employed as major approaches for data collection. The analysis of all information gathered through these enquiries was guided by quality assurance strategies according to qualitative investigation principles such as triangulation and the verification of accuracy from other sources of information.

The documents reviewed include: government reports, minutes of meetings, notifications, letters and memoranda, newspaper articles, comments, analyses and reports made by concerned parties, research reports and other types of articles published in local and international journals, as well as relevant grey literature. The principal investigator attended several technical and policy conferences relating to the policy under study. Furthermore, this investigator participated, as an observer, in some sessions of government committees convened to enforce government use of the three medicines. In addition, as a Thai delegate, she was closely involved in the World Health Organisation (WHO)-sponsored international negotiations on public health, innovation and intellectual property. The researcher also communicated with knowledgeable persons to triangulate information on particular issues. The key informants in this study were those involved in the policy processes, such as senior officials of the Health Ministry, the National Health Security Office, the Government Pharmaceutical Organization; leaders of non-governmental organizations; and experts in drug policy.

This analysis covers the events concerning Thailand's policy to introduce government use provision that took place prior to the end of September 2007. Particular information relating to the government action in later phase has been added for better understanding on how the policy evolved.

Structure of this report

This report is organised into 11 sections as follows:

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2. Background information: International framework on medicine patents and the Thai experience

2.1 TRIPS agreement and public health

Inadequate access to essential medicines is a persistent aspect of ineffective health systems. As Hanson et al. (2003) have identified, the constraints in access to priority health interventions include the broad policy framework and governance, public policies across sectors, health policies and strategic management, health service delivery, and community and household factors. Regarding the provider side, inadequate infrastructure, health personnel and public finance are key barriers to basic health care in the developing world. Emphasising medicines, vaccines and other health-related products, the literature suggests that poor access involved a wide range of elements. According to the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) (2006), the problematic issues to be addressed in order to improve access to medicines can be categorised into 3 major areas of 'innovative cycle': new drug discovery, development of pharmaceutical products, and health care delivery.

The Commission's report (2006) also discusses the role of IP rights protection, i.e. drug patents in this case, which are enacted through the World Trade Organisation (WTO)'s international agreement on TRIPS. Patent protection mainly aims to provide an incentive, which is a time limited monopoly, to encourage inventions that will be beneficial for the society as a whole. It has been found that IP regulation is important to the private for-profit sector since it helps patent owners to obtain high returns from their investments (Mahoney and Krattiger 2007). However, the assumption on this function of IP is context-specific, as it generally holds true in developed countries and a few developing countries with sufficient capital, and scientific and innovative capacity (Commission on Intellectual Property Rights Innovation and Public Health 2006). As Messerlin (2005:1198) points out, *'The TRIPS agreement*

cannot guarantee such a positive outcome. Many developing countries-especially the poorest ones-will not be able to contribute to the development of major drugs (hence benefit from TRIPS-related revenues) for a long time to come.'

In those settings where the majority of the population are poor, the TRIPS agreement imposes negative effects for health, since market exclusivity rights over patented products can limit the affordability and therefore access. *'Since the TRIPS Agreement came into effect, many developing countries have been complaining about the growing monopolization of a few powerful titleholders'* (Lanoszka 2003:190). Inadequate access to anti-HIV drugs among large numbers of people in need of treatment in many parts of the world provides an obvious illustration that IP protection costs a lot of lives, and subsequent social insecurity (Gandy 2005). Generic production in Brazil, India and Thailand has considerably brought down treatment costs. However, access to these cheaper medicines is still hampered by political and diplomatic pressures from greater powers, including pharmaceutical firms. There are significant attempts by the pharmaceutical industry to secure stronger and longer patent protection through 'abusive practices', for example, by setting restrictive licensing conditions and establishing vertical control over distribution outlets to prevent product competition (Lanoszka 2003). Ever-greening patents and patents for 'me-too' products are filed in resource-poor settings, especially those which have a low capacity for IP management.

Linkage between potential profit and investment in medicine and vaccine development seems to be inevitable in a world dominated by market capitalism. One of the consequences is that many diseases that overwhelmingly afflict people in the developing world have been neglected due to the lack of market returns. This suggests that monopolistic right granted through current patent systems is commercially unattractive so that it fails to promote innovations in some areas of the public health domain (Centrale Sanitaire Suisse Romande 2006:16). Moreover, the unavailability of health technologies

for poor people reflects the urgent requirement for innovative financing mechanisms for R&D determined by true health needs, in order to replace the existing market-driven frameworks, including the TRIPS-fostering IP regime.

2.2 TRIPS flexibilities and the Doha Declaration on TRIPS and Public Health

Compulsory licensing is one of the flexibility provisions stipulated in the TRIPS Agreement. This aims to protect public interest from the undesirable effects of market exclusivity. These licenses are granted by national authorities, either administrative or legislative bodies, to a third party to exploit an invention under patent, without the patent holder's authorization (Correa 2007). As stated in Article 31(b) of the Agreement, however, there are a number of conditions to be met by proposed users prior to the introduction of such a public-health safeguarding measure. For instance, non-voluntary use is permitted only if proposed users, i.e. for commercial purposes by private entity in this case, have sought authorization from the right holders on reasonable commercial terms and conditions, and such efforts have not been successful within a reasonable period of time. Only when an attempt at negotiation and request has failed can the negotiator ask the regulating authority to issue a non-voluntary use of patent with appropriate terms and conditions. Nevertheless, such a requirement can be waived in the case of a *'national emergency'* or *'other circumstances of extreme emergency'* or *'public non-commercial use'*. In this connection, the government use of patents should have played a crucial role in promoting access to essential medicines and other health technologies. As Lee (2007) points out, the ability of a Member state to implement flexibility provisions to manufacture generic medicines in its own country is the most important safeguard in the TRIPS agreement.

Although flexibility instruments have existed since the start of the WTO and TRIPS in 1995, in not many cases, and in mostly industrialized countries, have had experiences of their implementation. In the US, government use of patents

or even government contractors use of patents have been widely issued (Correa 2007). These include the patents of pharmaceuticals, medical technologies and other inventions. Countries in the developing world such as Malaysia, Indonesia, Zambia and Zimbabwe have issued CL to promote access to affordable medicines, mainly antiretrovirals (ARVs). Meanwhile, Brazil have used CL to threaten pharmaceutical companies in drug price negotiations (Centrale Sanitaire Suisse Romande 2006) before this provision was introduced in 2007.

A significant body of literature suggests several factors discouraging the use of TRIPS safeguards. These involve mainly the lack of legal, administrative and technical capacities to implement such flexibilities, and also the fear of retaliation from more powerful trade partners (Kerry and Lee 2007). In some countries, IP laws are ambiguous and result in different interpretations by different stakeholders, including government officials (Lewis-Lettington and Munyi 2004). Furthermore, some governments prefer to surrender to the industry rather than to implement 'aggressive' measures, using the safeguards (Centrale Sanitaire Suisse Romande 2006). In the past, the limitation of CL to domestic production allowed this measure to benefit only countries with a domestic market and manufacturing capacity (Musungu and Oh 2006). This problem has been addressed by the decision of the WTO Council in 2003, which accepts the export of medicines produced under CL to other countries with inadequate manufacturing capacities. However, the difficulties of implementing this solution remain, and only a few resource-poor settings have made use of it. In addition, the fears of economic retaliation and trade repercussion by developed countries has been a major cause of hesitation to grant CL for medicines in most developing countries (UNCTAD-ICTSD 2005).

The growing numbers of people afflicted by HIV/AIDS, tuberculosis, malaria and other communicable diseases has raised substantial concerns over the IP regime as a major barrier to improving the health of the poor (Lanoszka 2003). Confrontations between the pharmaceutical industry and many developing

countries, especially the court case filed by 40 trans-national drug companies against the South African administration, were among focusing events (Gandy 2005). The need for the modification of the TRIPS Agreement to be part of the global action to address public health problems was discussed in the Ministerial Conference in 2001, in Doha. The key issues of discussion involved the effects of IP protection on the R&D of new health products, prices, and access to essential medicines in poor settings. The right of WTO members to implement flexibility provisions in such an agreement was reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health (World Trade Organization 2001). Paragraph 5(b) of the Declaration states that, *'Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.,'* and paragraph 5(c) states, *'Each Member has the right to determine what constitutes a national emergency or other circumstances of extremely urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.'* In addition, recognising that some WTO members have an inadequate manufacturing capacity to make effective use of flexibilities under the TRIPS Agreement, paragraph 6 of the declaration instructs the TRIPS Council to find a mechanism to expand the benefits of CL to these settings before the end of 2002. Owing to opposition from industrialised nations, it was not until August 2003 that the authority could reach an agreement that permitted legal importation of medicines produced under CL.

The Doha Declaration has been acknowledged as *'a giant victory'* and an important milestone in the fight for access to affordable medicines (International Center for Trade and Sustainable Development 2006). The Declaration also draws attention of the WHO to the implications of IP regulations in the health sector. Several forums and activities have been set up

to make use of such a ministerial agreement in order to ensure global public health through the improved access to affordable health products. For instance, the World Health Assembly (WHA) in 2003 appointed a panel of experts from different areas - the so-called Commission on Intellectual Property, Innovation and Public Health (CIPIH)-to analyse the relationships between IP protection and the health of people (Commission on Intellectual Property Rights Innovation and Public Health 2006). However, the Doha Declaration merely clarifies the rights of WTO Members to implement the TRIPS flexibilities, and as Lanoszka (2003:194) maintains, whether the Declaration is effective in expanding access to medicines will depend on the ability of developing countries to use the safeguarding measures.

2.3 Experiences of developing countries on the use of compulsory licensing for medicines

As mentioned earlier, Thailand was not the first WTO member to implement TRIPS flexibilities. Many developed and developing countries enforced either CL or government use provisions for medicines before Thailand did in 2006 (table 1). Love (2007) argues that CL in Africa has grown increasingly common, but is often not publicised. There were also attempts to issue CL in some other countries such as Cameroon, the Dominican Republic, Ecuador, and Korea, but the proposals were either pending or rejected. This section reviews the past experiences concerning CL introduction for medicines in some developing countries, namely Zimbabwe, Malaysia, Zambia and Indonesia. However, it has been found that the information on the involvement of stakeholders who supported or opposed the use of TRIPS flexibilities, the roles of contextual elements, as well as the policy consequences for improved access to medicines and cost containment in each setting, was limited.

Table 1: selected developed and developing countries with experience on the use of CL for medicines

Countries	Products under CL (year of enforcement)
Canada	Ciprofloxacin (2001), Oseltamivir (2006)
Eritre	HIV/AIDS medicines (2005)
Ghana	HIV/AIDS medicines (2005)
Guinee	HIV/AIDS medicines (2005)
Indonesia	Lamivudine and nevirapine (2004)
Italy	Imipenem/cilastatin (2005), Finasteride (2006)
Malaysia	Didanosine, zidovudine and lamivudine/zidovudine combination (2004)
Mozambique	Lamivudine, stavudine and nevirapine (2004)
Swaziland	HIV/AIDS medicines (2004)
Taiwan	Oseltamivir (2005)
USA	Ciprofloxacin (2001), Oseltamivir (2005)
Zambia	Lamivudine, stavudine and nevirapine (2004)
Zimbabwe	HIV/AIDS medicines (2002)

Source of information : Knowledge Ecology International (Love 2007)

Zimbabwe:

Zimbabwe was the first country to issue CL for the production of HIV/AIDS medicines. The Zimbabwean Ministry of Justice, Legal and Parliamentary Affairs (2002) declared a six-month period of emergency on HIV/AIDS in May 2002. This declaration enabled the government or government-authorized persons to produce, use or import any patented medicines including ARVs and other medicines indicated in the treatment of HIV/AIDS. This action was praised by international NGOs and other African countries: *'Zimbabwe's announcement marks the first time that a government has gone beyond using the threat of compulsory licensing as a negotiating tool, and actually declared that it will override patents to increase access to needed medicines when the prices are too high as a result of patent protection.'*

(MSF 2002). However, some parties criticized the policy decision as overdue, since the disease and its devastating effects had long existed in the country, resulting in over 2,000 HIV deaths per week (Health GAP 2002). Furthermore, it was noted by activists that the 6-month time limit issued for the state of emergency was too short to obtain the full benefits of CL on price reductions, and therefore should have been eliminated. As asserted by Maonera and Chifamba (Maonera and Chifamba 2003 quoted in Oh 2006), this short period was decided upon because of the concerns of the Ministry of Health and the Medicines Control Authority that the action would be opposed by the pharmaceutical companies. When there was no opposition from the multi-national pharmaceuticals industry, the declaration was amended to pursue a 5-year period of HIV-related emergency from January 2003 to December 2008.

Three Zimbabwean-registered companies were authorized by the government to manufacture and import HIV medicines under the declaration. As of 2006, one company had supplied 7 generic ARV products to health providers in the public and private sector (Oh 2006). These included, for instance, zidovudine (AZT)/lamivudine combination which would be sold to meet 75% of the government's needs at 15 USD per month. Meanwhile, the two other companies would import medicines under the CL from generic producers in India. As suggested by Oh (2006), however, the effects of the emergency declaration on access to medicines and price reductions required further assessment.

Malaysia:

The Malaysian government started its ART programme to provide free access to first-line regimens in 2001. At that time, highly active antiretroviral treatment (HAART) was freely available for limited groups of patients: HIV-infected mothers after delivery, children, profession-associated infection among healthcare workers, and patients infected through contaminated products/ blood transfusion. The idea to enforce government use of patent for ARVs

were generated in mid-2002, under pressure from civil society organizations, when the Health Ministry adopted the policy to extend the publicly-funded HAART initiative to cover around 10,000 people living with HIV/AIDS (PHA) with CD4 counts less than 400 (Oh 2006). In addition to the TRIPS safeguard, price negotiation with the patent-holding companies and the local production of medicines were planned to implement this policy. Nevertheless, despite the reduced prices offered by the drug industry, the medicines were still very expensive and unaffordable for the majority of the populace.

In October 2003, the Ministry of Domestic Trade and Consumer Affairs (2003) adopted the government use for didanosine (ddI), AZT and the AZT/lamivudine combination. A local company, Syarikat Megah Pharma & Vaccines (M) Sdn Bhd, was authorized to import generic versions from an Indian firm called Cipla and supply this drug for use in public hospitals during a two-year period, commencing 1 November 2003. This action was opposed by some government departments owing to the fear that it would hamper foreign investment. Actually, resistance from other public agencies had begun some years before the adoption of this policy, resulting in '*a lengthy and time-consuming decision-making process*' (Oh 2006). Moreover, complaints against the administration's action were made by the patent-holding companies, Glaxo SmithKline (GSK) and Bristol-Myers Squibb (BMS). One of them filed a court case over the authorization of the government use. However, the law suit is still on record but has not been activated. Following Chee (2006), the patent holders dropped their own prices as a result of the enforcement of government use measures. Other consequences of this policy included a reduction in the average cost of ART per patient per month by 80%, from 315 USD to 58 USD, and the increase in the number of patients being treated in public hospitals from 1,500 to 4,000.

Zambia:

Zambia was a least-developed country (LDC) that declared the use of TRIPS flexibilities for HIV medicines. In September 2004, the Ministry of Commerce,

Trade and Industry of Zambia (2004a) granted a CL to a local company, PHARCO, Ltd, to manufacture a triple-ARV formulation of lamivudine, stavudine and nevirapine (NVP), since the patent owners of the 3 medicine components had failed to reach an agreement to produce the combination. The government sent letters to notify the CL on these medicines to BMS and Boehringer Ingelheim on 30 September 2004 (Zambian Ministry of Commerce Trade and Industry 2004b; 2004c). However, as of 2006, there had been no further information on the actual implementation of this measure, or the medicines manufactured by the licensee or its public health benefits (Oh 2006). Furthermore, it is noteworthy that Zambia did not need to use the flexibilities, because as an LDC, it was permitted to delay the enforcement of medicine patents until January 2016.

Indonesia:

HIV/AIDS has been a major public health problem in Indonesia for a number of years. Although only 170,000 adults were reportedly living with the disease in 2006, it was believed the actual number was much higher. These patients could hardly afford ARVs at the price of 800-1,000 USD per head per month. Despite price negotiations with patent holders organized by academic institutes and NGOs, a very small portion of PHA could gain access to ART (Hanim and Jhamtani 2004). Civic coalitions encouraged the government to use TRIPS safeguards as a feasible, effective way to bring ARV prices down. On 5 October 2004, the Indonesian government issued a presidential decree authorizing the Ministry of Health to appoint a pharmaceutical manufacturer to produce two ARVs, lamivudine and NVP, on behalf of the government (President Republic of Indonesia 2004). The Indonesian Law No. 14 of 2001 on patents provided for the enforcement of government use for a 'non-commercial purpose'. As Hanim and Jhamtani noted (2004), the patent-holding companies did not made any comments on the Indonesian government policy, and one of them sent lawyers to pursue enquires from Patent Directorate officials, but did not take any follow-up action.

An Indonesian firm, Kimia Farma, was authorized to produce single-ARV formulations and fixed-dose combinations under government use. India was the source of raw materials. The price of the generic first-line combination of lamivudine, AZT and NVP was 38 USD per patient per month, while GSK's lamivudine was sold at 290 USD per 60 tablets and Boehringer Ingelheim's NVP was 96 USD per 60 tablets (Hanim and Jhamtani 2004). As the medicines supplied by Kimia Farma were significantly cheaper that the original versions, more PHA were able to gain access to ART: the portion of patients under treatment increased from 3.5% in 2003 to almost 50% in 2006. However, Kimia Farma operated at only 15-20% of its production capacity, and the amount of ARVs produced under the presidential decree could not meet the health needs of all patients in need.

2.4 Past effort to ensure access to medicines in Thailand

The effort of concerned parties to provide wide-ranging health care and medical treatment to Thai people has been observed for decades. This has included the instigation and continual development of health care delivery systems, disease control and health promotion programmes, and publicly-funded health benefit plans. As medicines played a crucial role in treatment and prevention of several diseases, like in other countries, strategies for proper management of pharmaceuticals were integrated into the National Health Development Plan since its first formulation in 1960s. In addition, the need for ensuring access to drugs necessary to solve public health problems was well recognised, and stated as an element of the National Drug Policy. Nevertheless, evidence suggested that the availability and affordability of essential medicines might be affected by public policies including laws and regulations in the non-health sectors. Among others, the implications of international and national frameworks on IP protection were substantial.

Confrontations between Thailand, governments of industrialized countries, especially the USA, with regard to IP protection and its undesirable effects on

public health took place several times prior to the first government use of drug patents in 2006. The attempt of some developed nations such as the USA, United Kingdom, Switzerland and France and their imminent pharmaceutical companies to strengthen the monopolistic status of medicines and vaccines can be traced back to late 1970s when the US administration pressured Thailand to amend its Patent Act. The withdrawal of the Generalized System of Preferences (GSP) along with a number of other trade sanction measures, using the Special 301 Trade Act, were raised to threaten Thailand as well as other developing countries in the demand for stricter protection of corporate interests (Oxfam GB 2001).

During the 1980s, the US demanded that the Thai administration amend the IP law to enact patent protection for both product and manufacturing process. For several times, the PhRMA filed GSP petitions, accusing Thailand as not providing effective patent protection for pharmaceutical products. In September 1992, the Patent Act number 2 was endorsed by the parliament, with many provisions that benefited multinational drug companies. For example, patents could be granted for products or ingredients which were previously not eligible for the protection. According to Markandya (2001), the amendment of the patent law was carried out even though the Thai Supreme Court argued that the country was not ready to do so. The Court's report also stated that, *'Thailand has been forced by countries who own technologies of producing pharmaceutical products to improve patent law for the exchange of trade benefits.'*

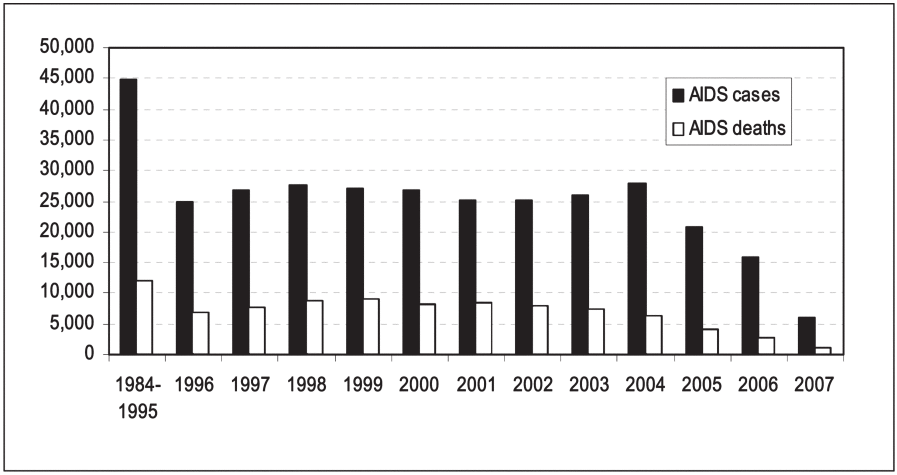
Note that under the Special 301 Act, the United States Trade Representatives (USTR) were entitled to take trade action against countries considered not to adequately protect the market exclusivity rights of the US patent holders. These countries might be named on either the Priority Watch List (PWL) or the Watch List (WL), according to the severity of patent violation as well as the extent to which government actions had been taken to curb such a so-called 'piracy' practice. Countries on the PWL were much more vulnerable to this 'punishment'. Like many other developing countries, Thailand's economy

depended largely on its exports to the US. Therefore, Thai government in the past had to avoid conflicts with the greater power counterpart. Despite this, the US administration placed Thailand on its PWL from 1989 to 1992, whereby the import tariff privilege under the GSP for agricultural goods exported to the US was cut (Maneerungsee and Arunmas 2007). It is noteworthy that during the same period, the US Trade Office was successful in pressuring Thailand to open up the tobacco market, by filing dispute to a General Agreement on Tariffs and Trade (GATT) panel (Vateesatokit 2003).

The demands of the US government and multi-national drug companies were occasionally far beyond the TRIPS stipulation. For instance, in 1987 the PhRMA began to ask, through the US Patent and Trademark Office, for the protection of 'products currently in the regulatory pipeline' (Markandya 2001). After 6 years of negotiations and a series of threats to introduce trade sanctions by the US counterpart, in 1993 Thailand established pipeline protection for medicines not eligible for monopolistic rights under the 1992 Patent Law. The Safety Monitoring Program (SMP) was instigated as an interim measure to grant original medicines for a 2 to 6 year market exclusivity. As the monopolistic rights granted by means of this administrative regulation did not involve a patent system, the introduction of flexibilities under the TRIPS Agreement did not apply, and as such did not protect the public health in such cases. Studies suggest that the SMP delayed generic competition, and therefore prevented substantial cost-savings from generic substitution in the country's health services. An example can be drawn on the case of fluconazole, a medicine indicated in the prevention and treatment of fungal infections normally afflicting HIV/AIDS patients. Manufactured by an American-based company, Pfizer, the original product was covered in the SMP. When the generic version of fluconazole was launched in Thailand in 1999, the price of the original version was 240 baht per 200 mg capsule, while its generic version was only 25 baht (Tantivess et al. 2002). Owing to generic substitution, it was estimated that the total cost saving for fluconazole capsules in the study, from both public and private hospitals, accounted for 71 million baht and 136 million baht in 1999 and 2000, respectively. Moreover, the generic availability substantially broadened access to this medicine.

Advocacy to promote access to essential health services, including medicines in Thailand, was significant in the area of HIV/AIDS. This country is one of those settings seriously affected by the HIV epidemic. Although the national prevention programme was able to curb viral transmissions, the disease had been transmitted to the general population (Bureau of Epidemiology 2003). As a consequence, the number of HIV-positive cases, and therefore demands for treatment and care, were very high. According to the Thai Working Group on HIV/AIDS Projection (2001), approximately 700,000 Thai people were living with the disease in 2003. However, only 317,000 HIV/AIDS cases reportedly sought care in health care settings in the same year (Deewong and Chitnumsub 2003). The number of newly-identified AIDS cases reported by health providers during the period from 1996 to 2004, ranged between 25,000 and 30,000, and then dropped to 16,000 and 6,000 in 2006 and 2007, respectively (figure 1). Meanwhile, AIDS deaths declined continually from 8,400 in 2001 to 6,200 in 2004 and 2,100 in 2007.

Figure 1: The number of newly-diagnosed AIDS cases and AIDS-related deaths reported by health facilities in Thailand, 1984-2007



Source: Bureau of Epidemiology, Ministry of Public Health

The need for HIV treatment and care, including prophylaxis of opportunistic infections and antiretroviral therapy (ART), has significantly increased since the mid 1990s (Kunanusont, Phoolcharoen, and Bodaramik 1999). At the same time, the effects of IP on drug prices became obvious. For instance, Pfizer's fluconazole enjoyed monopolistic rights granted under the SMP, and was sold at an unaffordable price until 1999 (Oxfam GB 2001). A joint mission carried out by the WHO and the UNAIDS in 2000 argued that the SMP was controversial and it might have negative implications on the ability to introduce generic HIV medicines (Velasquez and Jos 2000). Therefore, the mission recommended this drug safety promoting initiative should be reviewed by an independent team. At the same time, however, trade sanctions were employed by the US administration to threaten the Thai government when the latter planned to make arrangements to gain access to the generic version. A report from the International Centre for Trade and Sustainable Development (2000) points out that the fear of political and trade retaliations was the main reason why the MOPH was reluctant to implement TRIPS flexibilities for public health purposes. As reported in the same paper, the Director General of the Disease Control Department argued that, '*We must be very, very careful: considering the livelihood of our 62 million people, not just the 1 million HIV patients.*' This experience was also recorded by international NGOs as well as networks of local treatment advocates. According to Medicin Sans Frontieres (MSF) and Oxfam staff, when the government laboratory began to produce generic ARVs in 1999, the US ambassador in Bangkok informed the USTR, '*the Thai government certainly don't want to be the cause of a trade dispute which is what we have always told them would happen if compulsory licensing clause of the World Trade Organisation Agreement should be invoked*.' (Cawthorne and Dayal 2006). Personal communication with a former director of the Government Pharmaceutical Organization (GPO) Institute for R&D indicated that she was threatened not to pursue generic production. Owing to the threats posted by the more powerful nation, a senior official of the Ministry of Commerce (MOC) expressed similar concerns to the Disease Control Department Director.

The high cost of ARVs was a major constraint in treatment being scaled-up since the national initiative to provide AZT monotherapy to the poor was established in 1992 (Kunanusont, Phoolcharoen, and Bodaramik 1999). Because of the expensive drugs, the ART program could cover only a small fraction of the population in need. When HAART was proved effective in prolonging the lives of people in industrialized societies in the mid 1990s, NGOs and PHA networks began to play a crucial role in promoting treatment access (Kumphitak et al. 2004). With support from health professionals in MOPH hospitals and the Thai Red Cross, in 2000 a self-funded initiative, the so-called the Buyers' Club, was instigated in many areas of the country to prescribe HAART as well as other HIV care (Kreudhutha et al. 2005). In this programme, generic ARVs were purchased either from the GPO or from Indian companies. In addition, original EFZ was requested from Merck Sharp & Dohme (MSD) at a preferential price similar to that offered to sub-Saharan African countries. In 2002, around 1,000 PHA obtained medications from 21 Buyers' Club branches (Wilson and Ford 2004).

Civil society organizations, such as the Thai Foundation for Consumers, the Thai NGO Coalition on AIDS, the Thai Network for People Living with HIV/AIDS and MSF, were also involved in protecting public health from the negative effects of IP protection. In 1999 the coalitions campaigned for access to an ARV - ddI by providing support to the GPO when it requested a CL to produce a generic version of this drug (Ford et al. 2004). As the patent owner of this product was an American-based company - BMS, the civic groups submitted a letter to the US Presidency demanding that retaliations in the form of trade sanctions not be carried out when the generic version of ddI was locally produced. However, the Thai government refused to issue a CL, and started price negotiation for the original product instead (Wisartsakul 2004). Meanwhile, the GPO turned to producing ddI in a non-patented powder form.

In 2001 the NGO coalitions filed a lawsuit against BMS and the Thai Department of Intellectual Property (DIP) for intentional removal of the restriction on dose range of the initial ddI patent (Ford et al. 2004). Eventually, the Thai Central Intellectual Property and International Trade Court ruled this amendment by the DIP to be unlawful. This allowed the production of the generic ddI at different dosage ranges and also pressured the BMS to finally withdraw its patent on ddI. Nimit Tienudom, the Chairperson of the AIDS Access Foundation, has maintained however, that *'Didanosine is just an example of the whole problem related to patent monopoly and access to medicines. It's not the solution but it's the point from where you make the case. The ddI case is going to be a good example for other countries, as is this whole movement.'* (Tienudom quoted in Ford et al. 2004:562).

The radical change in Thailand's ART program in the early 2000s reaffirmed the crucial role of generic availability. When the UC plan was instigated in 2001, two treatments: ARV-based medications and renal replacement therapy, including hemodialysis and peritoneal dialysis, were excluded from the benefit package owing to their unaffordable costs when being provided to all patients in need (Ministry of Public Health 2001). In November 2001, however, the administration adopted the policy to provide free access to ARV medications to all needy people under the newly-established universal health benefit scheme. This considerable policy change was supported by several local and international factors. Among others, NGOs' campaigns for treatment expansion and the success in R&D of first-line ARV combination by the GPO played crucial roles (Tantivess 2006). Although the alliance of treatment advocates had put strong efforts into encouraging the government to broaden its ART delivery to meet universal coverage, it was not until October, when the GPO announced the success in generic manufacturing and substantial drug price reduction, that the MOPH paid serious attention to the NGOs' proposal. On the World AIDS Day Eve in 2001, the Health Ministry pledged to provide ART to UC beneficiaries, and gradually expand the service coverage.

Pre-grant opposition to Combid®, a fixed-dose combination of lamivudine and AZT, was another movement of civil society organisations in the intellectual property field. In October 1997, a British pharmaceutical company, GSK, applied for a Thai patent of this product. This application was strongly protested by AIDS activists and an NGO alliance, because this medicine was not qualified to be patented as it comprised existing anti-HIV ingredients and therefore, did not meet the criterion of inventive step and novelty, as stipulated in the Patent Act (Katanchaleekul 2007). The protests over this case continued for almost 9 years and involved not only the petitioning process at the Department of Intellectual Property and Patent Board, but also protests demonstrating in front of the GSK office in Bangkok and the Ministry of Commerce. As noted by the NGOs, they got strong support from the Public Health Minister Pinij Charusombut and officials from the Disease Control Department, FDA and GPO (Katanchaleekul 2007). In February 2006 the Minister signed an official letter asking the Ministry of Commerce to review the patent application for Combid® and postpone the granting of the patent right. Eventually, in August 2006, the company withdrew its controversial patent application.

This section suggests that IP and its implications on access to medicines are not newly-emerging problems in Thailand, but recognised and dealt with by several groups of government officials and health advocacy organisations. Confrontations between Thailand and industrialised nations over such issues had developed for many years before the introduction of the government use of patents for the three pharmaceutical products in 2006 and 2007. These events reflect the experience of civil society organisations in dealing with the hurdles to extend essential health care generated by IP protection.

2.5 Price negotiations prior to the government use of medicine patents in 2006-7

Given that reviewing how public policy evolved in the past can provide better insights into the current innovations of policy in particular domains, this

paper illustrates the attempt of Thailand's MOPH to pursue affordable medicines to meet its ultimate goal of providing free access to essential health services under the publicly-funded universal health coverage (UC) scheme, starting from April 2001, and the universal access to ARVs started in October 2003. The effort of the Health Ministry, the National Health Security Office (NHSO), and its affiliated agencies, including hospitals, to reduce drug prices can be traced back for many years.

Regarding ARVs, the need for cheaper medicines markedly increased when the government adopted the policy of offering universal access to ART in October 2003. According to Chokevivat (quoted in Kijtiwatchakul 2007b: 18-19), a former Health Ministry Senior Advisor on Disease Control, *'When we decided to include HIV/AIDS in the healthcare security programme, those involved knew full well that we had to use patented drugs too. Some patients suffered side effects from taking NVP, one of the three components of GPO-vir. We didn't succeed in negotiating the price of EFZ. We tried again in 2004.... But the negotiations came to nothing. So we had to look for an opportunity in the intellectual property laws. It was really our last resort.'*

Evidence suggests that the MOPH's Disease Control Department did seek cooperation from all research-based companies, including MSD and Abbott Laboratories, to reduce the prices of their ARVs prescribed in the national initiative (Ministry of Public Health and National Health Security Office 2007a). For instance, on 16 November 2004, the Department sent an official letter to HIV medicine producers to ask for discounts (Disease Control Department 2007b). Face-to-face negotiations of ARV prices were organised on 10 August and 29 December 2005. The attendants of such meetings included not only the representatives of drug companies, MOPH, NHSO and GPO but also HIV experts from different universities. During the fiscal year 2006, prior to the first enforcement of government use provision in late November, the price per

patient per month of Stocrin® (efavirenz 600 mg) decreased from 1,722.70 baht to 1,401.70 baht in July. Meanwhile, the price of Kaletra® (LPV/r) dropped from 17,547.84 baht per bottle to 11,877 and then 8,907.75 baht per bottle on 13 March and 23 November 2006, respectively. Abbott Laboratories also offered a free amount of Kaletra® which made the net price per bottle fall to 5,938.50 baht in November 2006. However, the MOPH did not accept the proposals, as the drugs remained much more expensive than their generic versions and also the budget implications of the programme were considered too high.

Price negotiation was also implemented through other channels. In April 2005, the Health Ministry appointed an ad-hoc working group, chaired by the Secretary General of the Thai Food and Drug Administration (FDA), to address the problems arising from the costly essential medicines under patent (Ministry of Public Health 2005). The implementation of the publicly-financed UC plan was stated as the rationale for appointing this working group. Emphasising three ARVs, namely EFZ, LPV/r and atazanavir, the working group asked for the price structure of these original drugs from the manufacturers: MSD, Abbott and BMS, respectively. Owing to the lack of cooperation from the industry and a lack of necessary information, price negotiations could not proceed (Ministry of Public Health 2007f). It was asserted that drug prices did not reflect only the costs of materials and production process, but also the expense on several operational procedures, including depreciation. The working group did suggest a list of priority drugs for further price negotiation and the possibility of introducing CL as a measure to strengthen the negotiation (table 2). It is noteworthy that drug price negotiations managed by this working group took place in parallel to the discussions between the Disease Control Department and drug companies that aimed to pursue the price reduction of HIV drugs as mentioned earlier in this section.

Table 2 : List of essential medicines to improve access through government use measures suggested by the MOPH's Working Group on Medicine Price Negotiation

I. Anticancer: rituximab, imatinib, gefitinib, bevacizumab
II. Antimicrobial: meropenam, imipenam+cilastatin
III. Anti-hyperlipidemia and cardiovascular drugs: atorvastatin; amlodipine, felodipine
IV. Anticonvulsant: gabapentin
V. Second-line and third-line ARV: atazanavir

Source: Working Group on Medicine Price Negotiation (2007)

3. The agenda setting and adoption of the Thai policy on government use of medicine patents

3.1 How the use of TRIPS flexibilities attracted policymakers

A substantial development took place when the Thai Rak Thai party-led government negotiated the issues of IP on pharmaceuticals as a component of the bilateral Thailand-US Free Trade Agreement (FTA) during the period 2004 to 2006. The *'new rule'* of IP protection according to this FTA proposal exceeded the standards incorporated in the WTO's framework and would seriously hamper the price reduction of, and improve access to, life-saving medicines (Kripke and Weinberg 2007). This was because the FTA provision would not only extend the market exclusivity period of patented products, but also restrict the use of public health safeguards in the TRIPS agreement as well as undermine the introduction of the Doha Declaration on TRIPS and Public Health.

As noted by an NHSO official Jamniendamrongkarn (2006), the IP protection measures proposed by the US side, which aimed to expand the course of market exclusivity to original pharmaceutical products beyond the elements adopted under WTO TRIPS-the so-called 'TRIPS-Plus', prompted notable

concerns within the public health community including NGOs and PHA networks. The potential implications of the Thailand-US FTA for public health, especially the provision of essential health services, including medicines to UC beneficiaries, as well as the need for effective solutions, were discussed in a meeting of the National Health Security Board (NHSB) in January 2006. A number of developing countries that had experience on the use of TRIPS safeguards were illustrated as examples.

> *'...the issue of Thailand-US FTA was raised to the discussion, owing to the fear that this agreement might severely afflict the universal health coverage scheme. This was, in particular, the proposal to include TRIP-plus measures as a component of the FTA. In the meeting, one of the Board members suggested that following the WTO's TRIPS agreement, Member states had the right to introduce the flexibilities to ensure access to medicines. So far, unlike some other developing countries such as Malaysia, Indonesia, Zambia and Mozambique, Thailand had never introduced any of the public health safeguards.'*
>
> (Jamniendamrongkarn 2006)

As this NHSO official noted in an interview in 2007, the Board member who initiated the exchange on the WTO public health safeguards maintained that while Thailand had never used even the existing flexibility provision of TRIPS agreement, the US's TRIPS-plus proposal might *'make things worse'* as it would totally abolish the chance to introduce such a measure to enhance access to medicines (Jamniendamrongkarn quoted in Kijtiwatchakul and Taechutrakool 2007:63). Note that the NHSB members consist of several influential NGOs and health advocacy experts. The Minister of Public Health Pinij Charusombut, who was the chairperson of the NHSB, the NHSO Secretary General Sanguan Nitayarumphong and Board members consensually agreed with the civic groups' suggestions that CL would be an effective mechanism to ensure the sustainability of the UC plan (Kijtiwatchakul 2007b). The NHSB

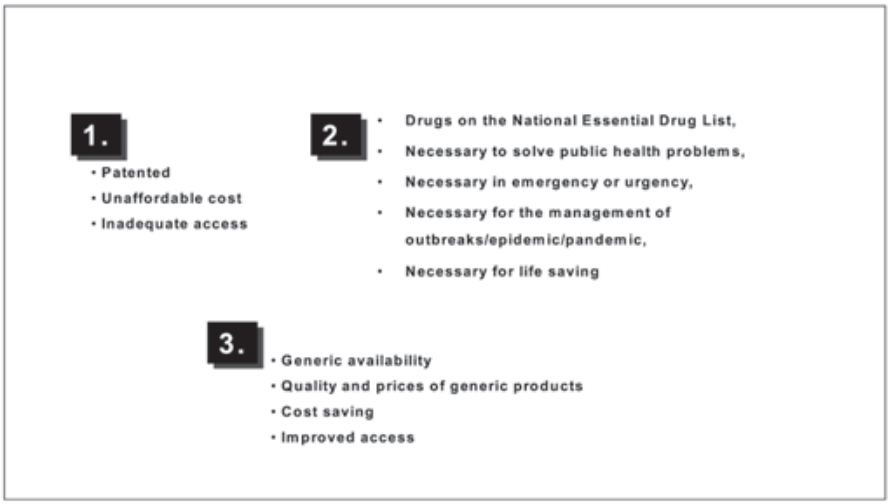
passed a resolution to assess the feasibility of implementing the public health safeguards as allowed by the WTO's rules. It was believed that in addition to the benefits of improved access to medicines, the use of public health safeguards might, to a certain extent, be able to hinder *'the US invasion through the FTA negotiation'* (Kijtiwatchakul and Tae-chutrakool 2007).

The NHSB established a subcommittee to consider and implement the government use of patents for medicines and medical devices in April 2006 (National Health Security Office 2006); exactly one year after the establishment of the MOPH's working group on price negotiation. Chaired by the Secretary General of the NHSO, this subcommittee consisted of senior officials from the Health Ministry's Departments of Disease Control and Medical Services, the FDA, GPO, DIP, and Council of State, as well as representatives from health and consumer-protection NGOs including PHA and cancer patient networks; Medical Education Consortium, the Lawyers Council, and individual experts. Apart from the GPO, however, the pharmaceutical industry, neither generic nor original, was included.

From March to May 2006, there were three meetings of this subcommittee. During this period, the subcommittee set up its framework and assigned experts to review existing evidence (Kijtiwatchakul 2007b). The agenda items comprised: the legal authority of the NHSO to enforce the government use provision, the criteria to select medicines to the government use programme; and royalty rates. Medicines were primarily selected if they were essential in dealing with the country's health problems, in either emergencies, an epidemic state or the normal situation, including those listed on the National List of Essential Drugs and life-saving medicines (Jamniendamrongkarn 2006). As shown in figure 2, the availability, quality and prices of generic products were also taken into consideration. Furthermore, the subcommittee established the conditions on which the government use of patents might be implemented. These conditions are (1) this measure must aim only for public, non-commercial use; (2) the patent holder would be granted royalty fees at an

appropriate rate; (3) when government use provision is implemented, the responsible agency has to notify the patent-holding companies without delay, and it was not necessary to inform the patent holders prior to the introduction of government use measure, and (4) the duration of any government use would not exceed a particular necessary period.

Figure 2: The criteria employed by the NHSB's Subcommittee on Medicine Selection to government use programme



Source of information: Jamniendamrongkarn, 2006

According to Jamniendamrongkarn (2006), the list of medicines considered by the NHSO subcommittee included: a number of ARVs: the lamivudine-AZT combination (Combid®), EFZ (Storcrin®), and LPV/r (Kaletra®); drugs for cardiovascular diseases (fibrinolytic agents and lipid-lowering drugs; and anticancer). The panel decided to take HIV medicines on board. The two ARV combinations, Lamivudine-AZT and LPV/r, were excluded because the former did not meet the Thai patentability requirements, and there was no generic version of the latter with acceptable bioequivalence quality. After a series of discussions, in May 2006, the government use of EFZ patent was decided. As the NHSO had no authority in accordance with the Patent Act to introduce a

government use measure, such an action was transferred to the MOPH. The royalty fee to be paid to the patent holder was set at 0.5% - the same rate paid by the Indonesian government when it issued the flexibility on this medicine.

In the draft Ministerial Notification, the rationale of the enforcement of government use for EFZ was narrated, including: the country's HIV situation, clinical importance and patent-associated high price of EFZ, the Doha Declaration on TRIPS agreement and Public Health, and the public-use provision according to the Thai Patent Act (Jamniendamrongkarn 2006). This draft Notification was sent from the NHSO to the MOPH for endorsement in July. However, since the political situation in mid 2006, where civil society networks and large numbers of the middle-class rallied to disprove Prime Minister Shinawatra and his cabinet, was not conducive to support such a considerable move, there was no action from the Health Ministry, as the NHSO's proposal was buried in the MOPH legal office, pending legal review. According to Jamniendamrongkarn (quoted in Kijtiwatchakul and Tae-chutrakool 2007:83-84), one of the obstacles was that the Health Minister at that time had had no background information on the effects of medicine patents and TRIPS safeguards; thus he hesitated to sign the Ministerial Notification, and kept consulting with the MOPH legal advisors and responsible officials in the NHSO. The actual process took substantial time and was briefly interrupted by wider political events. It was not until after the September coup de tat with the appointment of a new cabinet, including a new Health Minister, that this issue received political attention again.

As the new government took office, the NHSO re-submitted the draft notification on the public use of medicine patents to the Health Minister. All related documents were forwarded directly to the Minister, by-passing the MOPH Legal Office. A senior health official revealed that he was asked by the Minister to repeatedly review the legality of the matter (Kijtiwatchakul 2007b). A meeting was called among representatives of the DIP, the Council of State, the Lawyer Association, the NHSO, NGOs and the MOPH to discuss the

justification and process of enforcement of this TRIPS flexibility. The resolution drawn on this meeting was to suggest that the Minister have the notification signed by the Health Secretary or the Director General of the Disease Control Department - this action conformed with the provision in the Thai Patent Act, Section 51: any government ministries, bureaus and departments might exert the use of patents in order to carry out public services, or to prevent a severe shortage of food, medicines, or other consumption items. In such cases, the government had to pay a royalty to the patent holder and notify the company without delay.

On 29 November 2006, the Director General of the Disease Control Department announced the introduction of government use of EFZ patent as the first ever public use of medicine patents in Thai history (Ministry of Public Health 2006). The GPO was assigned to be the implementer of this policy. At that time, the GPO had been conducting R&D on EFZ formulation, and the products were under the studies of bioequivalence and shelf life. Therefore, in the initial phase of government use implementation, the EFZ product was to be imported from an Indian manufacturer, Ranbaxy, which was certified for Good Manufacturing Practice (GMP) standards under the WHO prequalification scheme (Disease Control Department 2006). After the announcement of the first government use of medicine patent, the selection process for other medicines to the scheme continued. However, it was not until early January 2007 that the NHSB subcommittee decided to adopt the government use for second-line ARV combination of LPV/r and an anti-platelet drug, clopidogrel (National Health Security Office 2007b). The notifications on the enforcement of the flexibility for these two products was publicised on 24 and 25 January 2007, respectively (Disease Control Department 2007a; Ministry of Public Health 2007d). All the licenses offered the royalty fee of 0.5% of the total sale value to the patent holders.

3.2 On what grounds the government use policy was adopted?

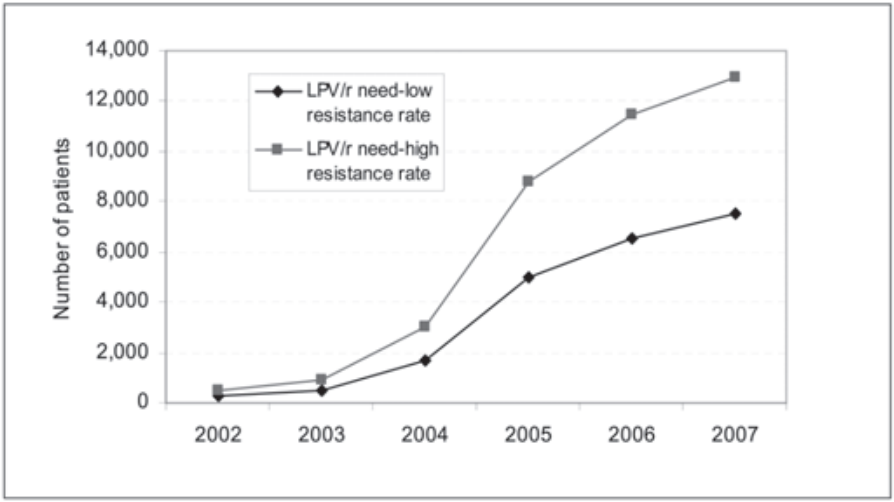
According to the MOPH and NHSO, the justification of issuing government use provisions for the three products was based on public health interests, i.e. to ensure access to essential medicines among Thai citizens. Since 2002, all Thais have been covered by one of the three national health insurance plans: the UC, Social Security, and the Civil Servant Medical Benefits schemes. Except for the Social Security plan, which was a tripartite system, the other two programmes were funded totally from general tax revenue. The beneficiaries under all three schemes are entitled to access to at least the drugs on the National Essential Drug lists. As the three drugs under government use programme would be prescribed only in the public sector for public services, and not for commercial use, the Thai action was in line with TRIPS article 31 (b) and the Thai Patent Act (section 51) as well as the Doha Declaration on TRIPS and Public Health (Ministry of Public Health and National Health Security Office 2007b). Furthermore, the exercise of this government use measure would help to maintain the achievement of the country's profound universal health care coverage initiative, as scientific evidence suggested that EFZ, LPV/r and clopidogrel were effective in and necessary for the treatment of diseases with a high prevalence in the Thai setting, namely HIV/AIDS, myocardial ischemia and cerebro-vascular accidents.

Since the three original products, namely Storcrin® (MSD, USA), Kaletra® (Abbot Laboratories, USA), and Plavix® (Sanofi-Aventis, France) were sold at unaffordable prices, the health system could not manage to provide free-access medication for all in need (Ministry of Public Health and National Health Security Office 2007b). Therefore, the market at that time consisted of those well-off patients who were able to pay out of their own pocket at private clinics or private hospitals, or some of those civil servants who were paid under the fee for service systems. Generic availability and price difference when compared to the original version were also taken into consideration. The price per month of the Indian generic EFZ was half that of

the patented product (650 baht vs. 1,300 baht). Regarding LPV/r, it was illustrated in the document considered by the NHSO's subcommittee to select medicines to the government use programme that the price per tablet of Kaletra® and the Indian-produced generic version was 33 baht and 22 baht, respectively. Meanwhile, a price reduction of 6 to 12 times was expected when the original clopidogrel was substituted by the generic version. The total cost saving for the three products would account for up to 800 million baht a year (Thai News Agency 2007b). Despite this substantial amount, the major purpose of the government use introduction in Thailand was not to reduce government expenditure on health services, but to improve access to essential medication among people in need. It was anticipated that, for instance, the half-price reduction of EFZ could allow an additional 20,000 PHA to have access to the less-toxic medicine, rather than taking risks of the adverse drug reactions of the NVP-based therapy, with a no increase in drug budget (Ministry of Public Health and National Health Security Office 2007b:14).

With regard to public health benefits, the government claimed that increasing access to the three medicines would contribute considerably to saving lives and also alleviate the suffering faced by large numbers of patients. This is true particularly for PHA, who needed effective ARVs with a low risk of severe adverse reactions. Replacing NVP with EFZ in first-line treatment protocols could lower the risks of side effects, ranging from hypersensitivity to hepatotoxicity, normally induced by the former, by 20% (Ministry of Public Health and National Health Security Office 2007a). Meanwhile, prescribing an affordable combination product of LPV/r would serve to meet the rising demand for second-line ART in the public sector. The Bureau of AIDS, Tuberculosis and Sexually-transmitted Infections estimated that 7,500 and 13,000 ART recipients required LPV/r in 2007. The resistance strains of HIV developed in two different scenarios, low resistance rate (10%) and high resistance rate (over 10%), respectively, depending on patient adherence to medication (figure 3). According to the MOPH, it was anticipated that the number of PHA in need of LPV/r would grow to 50,000 in the near future.

Figure 3 : Projection of the needs for LPV/r in two scenarios, 2002-2007



Source: Bureau of AIDS, Tuberculosis and Sexually-transmitted Infections, 2007

In a similar vein, owing to the high prevalence of coronary heart disease - an illness that afflicted 300,000 Thai people in 2007, the demand for anti-platelet therapy was considerable (Ministry of Public Health and National Health Security Office 2007a). In the prevention of coronary obstruction, clopidogrel was proven to be superior to conventional drugs like aspirin as the latter could be used in the case of applying coronary stent. Only approximately 30,000 patients could afford this expensive medication when the generic version of clopidogrel was not available in the country. As a consequence of generic substitution, the beneficiaries of the government-funded UC plan, especially the poor, would obtain equitable benefits to those with higher incomes.

In summary, the MOPH maintained that the three medicines under the government use programme were essential in treatment of major public health problems of the country, and the introduction of the TRIPS safeguards would result in improved access to these drugs among the population in need.

Table 3: Expected public health benefits of the enforcement of government use provisions for the three patented medicines

Medicine	Characteristics	Prices		Extended access
		Original product	Generic product	
Efavirenz	■ Less severe adverse reactions than nevirapine	1,300 baht per month	280-650 baht per month	20,000-100,000 patients
	■ Needed by 20% of PHA on ART			
Lopinavir/ ritonavir	■ Needed by 10% of PHA on ART in the first 2-3 years	6,000 baht per month	1,200 baht per month	8,000 patients
Clopidogrel	■ More effective than aspirin in preventing coronary obstruction	73 baht per day	7 baht per day	[currently, accessed by 10% of 300,000 needy patients]

Sources : Ministry of Public Health and National Health Security Office, 2007b

3.3 The motives behind the introduction of government use provision

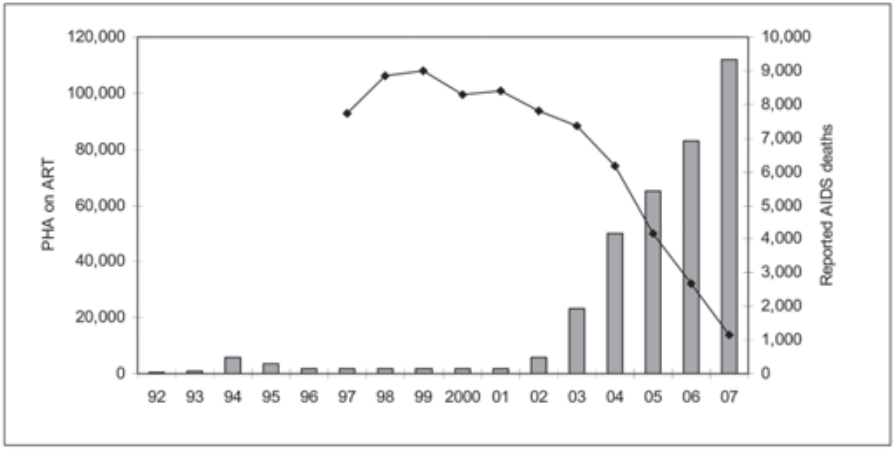
As mentioned in previous sections, the Thai administration implemented the public-use measure to overcome IP barriers to affordability and to ensure essential medicines for its people. On many occasions, the motivating factors of the government's actions were elaborated. Budget constraints, the public health need and humanitarian reasons were usually highlighted. As pointed out by Public Health Minister Mongkol Na Songkhla (quoted in Wong-Anan 2007), *'We have to do this because we have so many patients to treat with so little budget. We cannot watch our people die and their patents have been here for so long.'* According to the Minister, he did not want to *'upset the pharmaceutical industry',* but the use of TRIPS safeguards was unavoidable as the government put the health needs of the Thai people as its priority

(Treerutkuarkul 2007e). Na Songkhla (2007b) reaffirmed the rationale of this policy in his speech made at the WHA on 15 May 2007: '*...the fact remains that the patented products still cost much more than the generic products, and are unaffordable by the majority of people. Therefore, it is necessary for us to try to find some way so that the poor and needy can have access to these essential life-saving drugs at affordable prices.*'

The country's dire need to ensure access to affordable ARVs and other essential medicines, as the justification of the use of the WTO's public health safeguard, was confirmed by NHSO secretary general Sanguan Nitayarumphong. In an interview in February 2007, he defended the MOPH's decision to infringe patent rights on the three pharmaceutical products (Nitayarumphong quoted in The Nation 2007f). Moreover, he asked the multi-national medicine industry to sympathise with poor people, by arguing that, '*Pharmaceutical companies have reaped huge benefits from these medicines sold at high prices for some time. These companies should have compassion.*'

It cannot be denied that the rising demand for ARVs, especially second-line regimens, was a crucial factor stimulating Thailand's first introduction of a government use provision. In this country, HIV-related problems are substantial in terms of the size of the afflicted population and therefore, public health and socioeconomic consequences. ARV-based medication has been included in the UC benefit package since 2003. The number of ART recipients increased from 20,000 in 2003 to almost 120,000 in 2007 (figure 4). Meanwhile, the number of AIDS deaths reported by health care providers dropped significantly. It was predictable that treatment coverage would extend further to meet the growing needs.

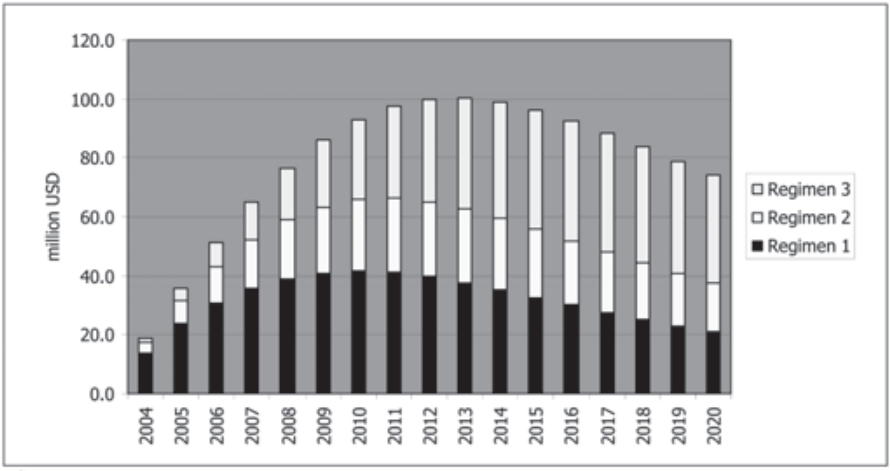
Figure 4: Number of PHA on antiretroviral therapy and reported AIDS deaths, 1992-2007



Source: Bureau of AIDS, Tuberculosis and Sexually-transmitted Infections and Bureau of Epidemiology

The difficulties in providing patented anti-HIV drugs to all people in need was anticipated when the government considered extending its ART initiative to meet universal coverage in the early 2000s (Tantivess and Walt 2006). This concern had been growing alongside the increase in numbers of treatment recipients, as it was generally recognised that the expansion of ART would inevitably result in the development of drug-resistance strains of the virus. A study by Lertiendumrong and colleagues (2004) suggested that the budget required to subsidize second- and third-line ARV regimens would be enormous in the near future (figure 5). However, the projected financial resources needed have been commented on as an underestimate. Despite rejection from previous Health Ministers, the campaigns for sustainable, efficient solutions, such as the use of TRIPS flexibilities, were maintained by NGOs, including PHA alliances. In late 2005, for instance, the Chairperson of the Thai Network for People Living with HIV/AIDS wrote a letter to the Minister of Public Health to ask for the issue of CL for HIV medicines (Kijtiwatchakul and Tae-chutrakool 2007).

Figure 5: Estimated budget required for ARVs in the national ART programme, 2004-2020



Source: Lertiendumrong et al, 2004

Thailand had been praised for its leadership in the fight against HIV/AIDS. The country's initiatives on this disease's prevention and treatment had caught the attention of the global health community. These initiatives included a publicly-financed programme to provide universal coverage for ART. In order to ensure the sustainability of this ambitious service, it was not only local treatment advocates but also international organizations that encouraged the Thai government to implement TRIPS safeguards as a policy alternative to the use of costly patented ARV products. In 2006, the World Bank released a research report on the policy options for effective HIV treatment in Thailand. As suggested in this paper, '*Because the drugs used in second-line therapy are patented, produced, and sold by multinational pharmaceutical corporations, Thailand must either pay the high prices demanded by those monopolies or exercise its rights under World Trade Organization treaties to grant a compulsory license for the manufacture of the drug, subject to negotiated royalties.*' (Revenga et al. 2006). The study also indicated that if the CL had been implemented, the patented second-line ARVs would be

substituted by generic products which were 90% cheaper, and the budgetary obligations of the national ART initiative would be reduced by 127 billion baht through 2025.

The use of public health safeguards for ARVs in HIV prevalent settings like Thailand seemed to be rational and acceptable, to some extent, even among opponents of this policy. In contrast, the circumvention of the Plavix© patent in January 2007 stirred debate on whether government use for chronic, non-communicable diseases conformed to the TRIPS flexibilities' conditions of pandemic, emergency or urgency of public health problems. According to a European Union (EU) official (quoted in Cronin 2007), *'In two of the cases where Thailand used CL, it was to deal with AIDS, which meets anyone's understanding of an urgent public health issue, while something like heart disease, perhaps does not meet the criteria.'* In the same vein, a spokesperson of Sanofi-Aventis noted that the company was surprised and disappointed by the Thai administration's action *'because Plavix benefits individual patients, and lack of access would not constitute a public health concern or an "extreme emergency" justifying a compulsory license.'* (Gerhardsen 2007). In response to these arguments, the MOPH maintained its commitments to provide universal coverage for all essential health care and medical services through the three publicly-financed schemes, whereby medications for not only communicable illnesses, but also non-infectious disorders, were included as benefits (Ministry of Public Health and National Health Security Office 2007a). The Ministry further noted that the WTO's IP framework did not contain any clause restricting the use of its public health safeguards to only communicable diseases.

The unmet need for clopidogrel was illustrated in the Health Ministry's White Paper. An estimated one-tenth of the 300,000 patients in need of this medicine had access to it, while the rest could obtain only a less effective drug, acetyl salicylic acid (aspirin) to prevent coronary obstruction (Ministry of Public Health and National Health Security Office 2007a). The MOPH's explanation

was supported by epidemiological information indicating a rising trend of chronic, non-infectious diseases. As shown in table 4, cardiovascular diseases, diabetes, and cancers of different organs were major causes of untimely deaths among Thai men and women in the year 2004 (International Health Policy Program 2007). This estimation also suggested the increasing need for affordable medicines which were indispensable in achieving universal coverage for such life-long treatments.

Table 4: Burden of diseases in Thailand (years of life loss - YLL), 2004

Rank	Male		Female	
	Disease	%YLL	Diseases	%YLL
1	HIV/AIDS	15.9	HIV/AIDS	10.6
2	Traffic accidents	13.8	Stroke	10.2
3	Stroke	7.0	Diabetes	7.1
4	Liver & bile duct cancer	7.0	Ischemic heart diseases	5.1
5	Ischemic heart diseases	4.3	Liver & bile duct cancer	4.7
6	Cirrhosis	3.5	Traffic accidents	4.5
7	Chronic Obstructive Pulmonary Disease	3.2	Lower respiratory tract infections	3.3
8	Bronchus & lung cancer	2.9	Cervix and uteri cancer	2.8
9	Drowning	2.9	Nephritis & nephrosis	2.8
10	Suicides	2.7	Breast cancer	2.3
11	Lower respiratory tract infections	2.6	Chronic Obstructive Pulmonary Disease	2.3
12	Diabetes	2.6	Bronchus & lung cancer	2.1
13	Homicide & violence	2.4	Cirrhosis	2.0
14	Tuberculosis	1.9	Tuberculosis	1.9
15	Nephritis & nephrosis	1.6	Drowning	1.7

Source: International Health Policy Program, 2007

From a different angle, the introduction of this government use measure might be motivated by the political need of this government to enhance its popularity. Although it is difficult to find substantive evidence to support such an argument, policy analysts should not deny its possible role in the policy development process. Mainly, this accusation was highlighted, among many others, by international drug companies and their allies, including the media. These included, for example, a report by Zamiska and Hookway (2007) published in the Wall Street Journal in April 2007 illustrating that, '*Some pharmaceutical executives question Thailand's real motives, suggesting the government's military-installed government, which took power in a coup last year, is using populist rhetoric and policies to curry favor with the Thai people.*' A similar claim was publicized in the Letter to Editor Section of a Bangkok-based English language newspaper in July, arguing: '*Taking on Western drug companies has proven politically popular for a temporary government in dire need of political successes... For political reasons, Thailand is more interested in continuing to fight big drug companies (otherwise the government may have to focus on more unpopular policies, such as the draft constitution, the crackdown on free speech and rapidly expanding military budget).*' (Attawut quoted in The Nation 2007b). Other have argued, however, that while domestic political pressures might had a role the urgency of public health need for extended access to ARVs and other essential medicines was more importance.

4. How the government use of medicine patents was put into operation

A key issue highlighted in this paper is the strategies introduced by the Thai government when it managed to enforce the government use provision. This policy stage developed after the announcement of the administration's decision to use the TRIPS safeguard for public health. In this period messy, reiterated policy processes, which involved both formulation and implementation activities undertaken by Thai policy makers and respective officials, were

observed. This complex development was enhanced by the fact that the introduction of TRIPS flexibilities was contentious - not agreed among key interests, especially the pharmaceutical industry and some industrialized countries' governments. Objections from these powerful actors required defensive measures to be devised, from time to time, by Thai officials. Meanwhile, actions to ensure access to essential medicines under the government use programme were carried out by responsible agents.

4.1 The MOPH's 'White Paper'

Criticism and political pressures from transnational pharmaceutical companies and some greater-power nations substantially mounted after the Thai government announced its decision to exert the rights over the patents for second and third medicines under its government use plan in late January 2007. The MOPH and NHSO were requested by stakeholders, both inside and outside the country, to provide information and clarification on several aspects of the decision to use this flexibility approach. On 17 February, the Health Ministry, in collaboration with the NHSO, launched a book-the informally labelled 'White Paper', which outlined the policy justification and addressed critics' concerns about the implications of this action (Ministry of Public Health 2007e). As asserted by a senior health official, it seemed that the paper was an important policy tool which aimed to mobilize support from the public: *'The stake of this game is very high... we are moving into a very dangerous area. We can not expect much support from other ministries. Therefore, we have to educate the public-this is why the White paper is publicised.'* (personal communication).

Jointly published by the MOPH and NHSO, this 80-page document, with a full title of 'Facts and evidences on the 10 burning issues related to the government use of patents on three patented essential drugs in Thailand,' was designed to combat criticism and pressures, by conveying *'effective and necessary'* messages to inform and educate the Thai and global society (Ministry of Public Health and National Health Security Office 2007a). The

content of this paper was framed to address ten questions frequently forwarded by vested interests as well as the public (table 5). Many related documents, such as letters and announcements of different concerned parties, were included in the annexes. Two thousand copies of the White paper were disseminated to a wide range of audience through different channels including the MOPH's website: http://www.moph.go.th/ops/ iprg/iprg_new/.

Table 5: List of issues concerning government use provision addressed in the MOPH's 'White paper'

1. What is the rationale behind the Government Use of Patents on the three drugs? Is this movement in compliance with national and international frameworks?
2. Why was there no prior discussion and negotiation with the drug companies?
3. Why has the MOPH turned down requests from drug companies to discuss and negotiate this issue even after issuing the Government Use of Patent?
4. What are the mechanisms and criteria used to determine which drugs to issue Government Use of Patent? Will there be additional Government Use for more drugs in the near future? Would these movements eventually lead to the failure of the IP systems?
5. The Government Use of Patents will save the government some funds but what are the benefits to the people?
6. What will the implications on the Thai export and economy and multinational industries be in Thailand?
7. Has the MOPH consulted with other ministries and why not let the cabinet decide this issue?
8. Will the issuing of Government Use result in a step backward for development in Drug R&D in Thailand?
9. What are the views of the WHO and other international organizations regarding this issue?
10. How can we be sure that the drugs derived from the Government Use of Patents will be equivalent in quality to the patented products?

Source: Ministry of Public Health and National Health Security Office (2007a)

4.2 The establishment of new government mechanisms

As mentioned earlier, when the first introduction of government use measure was announced in late November 2006, the NHSB's Subcommittee to implement Government Use of Patented Medicines and Medical Devices was the sole governmental mechanism for the formulation and implementation of this policy (National Health Security Office 2006). In January 2007, the Subcommittee suggested that two products, LPV/r and clopidogrel, be included in the government use programme. At the time, although the MOPH's Working Group on Medicine Price Negotiation still existed, it played no active role. In February and March 2007, the MOPH appointed 2 committees to facilitate the implementation of the public health safeguard, namely the Committee on Price Negotiation of Essential Patented Medicines and the Committee to Support Government-Use Implementation, respectively (Ministry of Public Health 2007g; Ministry of Public Health 2007h). This aimed not only to achieve the purpose of having access to affordable medicines under the government use programme, but also to respond to the growing pressures and protests against this policy. The creation of these institutional mechanisms to take forward the policy decision was a way of 'concretising' the measure. Meanwhile, the NHSB's subcommittee continued its role on medicine selection to the government use process. Following the MOPH's Order in February 2007, its ad hoc working group on drug price negotiation, established in April 2005, was terminated (Ministry of Public Health 2007g).

The Committee on Price Negotiation

The MOPH's Committee on Price Negotiation of Essential Patented Medicines invited representatives of the three patent-holding companies to discuss price reductions for their products under the government use scheme. This was in line with the MOPH's stated policy of building constructive, transparent and fair relationships with all pharmaceutical companies: *'The door for open constructive discussion was available before and after the announcement of the Government Use of Patent'* (Ministry of Public Health and National

Health Security Office 2007a). As argued by a health official (quoted in Gerhardsen 2007), the policy to negotiate with the patent-holding firms after the announcement of government use for medicines would work well: *'We have learned from our past experience that prior negotiation before announcing the use of the government use is not an effective way to bring the price down and reach better access. This is also the experience from all countries around the world that have done it.* Meanwhile, policymakers believed that they could know to what extent drug prices would be reduced only when they implemented the TRIPS safeguard which allowed generic competition; thus, the government use measure would be maintained even when the reduced prices of the drugs were agreed upon by both sides.

From March to June 2007, four meetings of the Committee and drug firms were convened. According to Siriwat Tiptaradol, the Secretary General of the Thai FDA, who chaired the Committee, the discussion with the companies were successful to a certain extent; all of them offered discount prices and/or other programmes to broaden access to medicines in the country (Food and Drug Administration (Thailand) 2007c). Moreover, the Chairperson asserted that the exchange of information during the meetings fostered a better understanding of the MOPH's medicine policy among the patent holders. He further pointed out that a positive impression from the corporate world was a key factor of innovative proposals to solve the problem of inadequate access to medicines in Thailand. However, as some have argued, all of these proposals contained the condition that the price discount and other offers from the drug industry would be effective only when the government use provision was not implemented. For example, in the case of Abbott Laboratories, in March 2007, the company cancelled drug registration applications of its 7 new medicines in Thailand in response to the MOPH's decision to use the patent for Kaletra®. After negotiations with the Thai administration and facing pressures from civil society networks around the world, in late April, the company offered to re-submit the application for marketing approval for the new tablet formulation of LPV/r, on the condition, however, that the public use of LPV/r patent would be revoked:

> *'Abbott has offered the above conditions in good faith and in exchange requests that the Thai government not pursue a compulsory license on the Aluvia tablet or source a generic copy. In this manner, the government will acknowledge the importance of supporting innovation and development of new medicines that will benefit Thai patients.'*
>
> (Masterson 2007)

In March 2007, Sanofi-Aventis offered the MOPH a 'special access programme' to provide a lower priced version of Plavix® to the beneficiaries of the UC and Social Security plans (Managing Intellectual Property 2007). Although at the time, the GPO had awarded a contract for two million pills of a generic clopidogrel product to the Indian drug manufacturer, Emcure, negotiations between the MOPH and Sanofi-Aventis continued. In June 2007, both sides managed to agree in principle on this programme (Baschiera 2007). According to the company's proposal, 3.4 million tablets of Plavix® per year would be provided free of charge to patients under the two schemes. Moreover, a tracking system including dispensing audits, drug utilisation evaluation and research grants for medical doctors through the Thai Heart Association, would be established if the Health Ministry agreed with the proposal and also stopped the enforcement of public use measure for this medicine. However, the two sides could not reach agreement and the intention to exercise public use of clopidogrel patent continued and was finally implemented.

In June 2007, the Health Minister suggested a benchmark. He suggested that the companies' proposal would be accepted if the net price of their patented products was not higher than 5% more than the available generic versions' (Food and Drug Administration (Thailand) 2007b). The Committee on Price Negotiation negotiated with the patent holders along this line. This reference point forced the industry to consider either reducing the price or offering complementary benefits to the MOPH. These benefits included, for example, training programmes for health workers and financial support for particular services relating to the diseases the drugs were prescribed for, such as diagnosis procedure. Meanwhile, the Committee insisted that the

announcement of government use introduction would not be cancelled, and if the companies' proposals were not satisfying, importation of generic products under the government use plan would be pursued (Treerutkuarkul 2007f). This principle was maintained when the MOPH decided to introduce government use measure for four anti-cancer drugs in early 2008.

It should be noted that in addition to the patent holders of the three medicines under the government use plan, a transnational company, Novartis, contacted the Price Negotiation Committee offering a price-reduction, along with a drug donation programme to extend access to its anti-cancer drug, Glivec® (imatinib), among the poor (Food and Drug Administration (Thailand) 2007b). According to a senior official, the company approached the Health Minister informally, and proposed the medicine at a low price; however, with a condition that the government had to shoulder the full cost during the first 3 months of therapy, and that the lowered price would be effective for patients in the 4th to 9th month of the treatment course. The company's proposal was not agreed to by the MOPH's Committee as it preferred to have an unconditional alternative. In January 2008, an agreement could be reached that the Health Ministry would announce the intention to introduce the government use of imatinib patent, but this measure would not be enforced as long as Novartis maintained its initiative, the Glivec International Patient Access Program (GIPAP), which allowed all UC beneficiaries whose annual household income was less than 1.7 million baht to get the medicine freely, without other condition (Ministry of Public Health and National Health Security Office 2008).

The Committee to Support Government-Use Implementation

Headed by Wichai Chokevivat, who also chaired the GPO Board, the Committee to Support Government-Use Implementation worked as the coordinator among the advocates of the TRIPS safeguards including a number of different agencies and related task forces under the MOPH and NHSO, other government ministries, NGOs, academic institutes and individual experts. Also, the Committee was the focal agent to deal with the actions of the policy's opponents. Mechanisms for building close collaboration and ensuring information exchange among the MOPH's and NHSO's respective committees and subcommittees were established. Many activities were

included in this Committee's strategic plan such as those concerning knowledge management including research, patient empowerment, and public communication. However, the main actions involved negotiations with international drug companies and their governments, as well as public information programmes, including press releases, international conferences and websites.

Table 6: Selected actions and outputs of the MOPH's Committee to Support Government-Use Implementation

- Policy recommendations concerning the following issues:
  - o withdrawal of new drug registration applications by Abbott Laboratories
  - o price formulaes for original products to be employed in price negotiation with patent-holding companies
  - o clarification of the purposes of the government use of medicine patents and related processes in response to medicine companies' and their governments' inquiries
- Establishment of the Public-Private Collaboration for Health System Development and Access to Medicines[4]
- Dialogues with Sanofi-Aventis and coordination with other public departments on the legality of the introduction of government use of clopidogrel
- Facilitating the registration process of generic LPV/r and clopidogrel in Thailand
- Cooperation with local and international partners to remove Thailand from the US Special 301 PWL

Sources: the Committee to Support Government-Use Implementation, minutes of different meetings, 2007

[4] This was one of the issues proposed by PReMA. After a series of discussion, on 4 June 2007 the MOPH's Committee agreed to establish an *ad hoc* subcommittee to improve access to essential medicines. Chaired by Wichai Chokevivat, the subcommittee comprised representatives from the MOPH, NHSO, GPO, international and local drug manufacturers, and NGOs. This subcommittee was responsible for the development of systems and mechanisms to enhance access to essential medicines among the Thai population. This was also to ensure the efficiency and sustainability of the UC plan. Capacity strengthening in research and development of medicines in the country also fell under the mandate of this panel. It was emphasized that the subcommittee's actions shall not delay the opportunity to access to essential medicines, and that the subcommittee shall not be involved in the decisions on the government use of patents.

4.3 Networking with local and international partners

While the three panels were assigned as the major policy venues, through which the government's decisions concerning the government use provision developed, it appeared that the MOPH, in collaboration with the NHSO, other ministries and civil society organizations, had to work extremely hard to get this public health safeguard into practice and at the same time, had to work to mitigate the arising undesirable consequences of this policy. Networking, to build institutional alliances, was among the key strategies employed by the Thai government. In addition to local and international coalitions of NGOs strongly supporting the Thai actions, the government created collaborations with other developing countries, international organisations and philanthropic foundations through different channels. For instance, the Public Health Minister sought support for the use of TRIPS flexibilities from WHO Member States at the WHA in May 2007, where he made a speech on the issues of IP protection as barriers to essential medications in the developing world and the needs for public health safeguards (Sajirawattanakul and Saengpassa 2007). The Minister revealed before he left Bangkok that a number of *'friendly states'*, mainly from Asia, Latin America and Africa, had contacted him for *'a talk on the sidelines'* of the WHA.

It should be noted that the 2007 WHA passed a resolution on public health, innovation and IP which encouraged the WHO Director General to provide technical and policy support to Member States who wished to implement TRIPS flexibilities to improve access to medicines (WHO 2007c). The resolution, in part, reflected substantial agreement over the use of public health safeguards, as permitted in the WTO's framework, among the members of this international health body. At the Assembly, through Thailand's close working with the representatives of other developing countries, led by the Brazilian delegation, in the drafting process of this resolution, a strategic alliance was maintained in proceedings. The Health Ministers of the two

countries subsequently declared a common stance to expand access to medicines among poor people (Ministry of Public Health 2007k). Thereafter, alliances between Thailand and countries in Latin America were continually strengthened. A notable development was achieved when the Health Ministers of Thailand and Brazil planned to sign a health cooperation agreement in the near future. Medicine manufacturing and the technology transfer of influenza vaccine production were among the elements of collaboration. A similar partnership on public health and pharmaceuticals was created between Thailand's and Argentina's Ministries of Health, with an aim of enhancing the capacity of both countries to produce affordable medicines to meet the needs of their populations (Ministry of Public Health 2007j).

During a trip to Washington, D.C. and New York in May 2007, the Health Minister and other senior health officials met representatives of the US administration, legislatures and business associations. Although the exchange with these key players failed to settle disputes over the use of TRIPS safeguards in Thailand, the Minister won support from groups of congressmen (National Health Security Office 2007a; The Nation 2007i). After meeting with the Thai Minister of Public Health on 21 May, Democratic representative Henry A Waxman[5] (2007) issued a statement to urge the US administration to *'show compassion and provide support'* to Thailand rather than retaliate against this country over its decision to introduce a public health safeguard (figure 6).

[5] Waxman had long been an advocator of global public health such as tobacco control and the Framework Convention on Tobacco Control (FCTC). He supported the Thai government when it faced pressure from the US Trade Office to open the tobacco market in late 1980s.

Figure 6: Selected section of the statement of US congressman Henry A Waxman on making HIV/AIDS drugs more affordable, 21 May 2007

> Mr. Mongkol assured me that the Government of Thailand is committed to the principle of balancing the peotection of innovation and access to medicines. In this regard, the Government of Thailand is particularly sensitive to intellectual property concerns and maintains that it will only use compulsort licenses in compliance with WTO rules.
>
> Accordingly, the U.S. should show compassion and provide support to our longtime friend rather than impose punitive actions such as the U.S. Trade Representative' s recent announcement that Thailand has been put on the agency's 'Priority Watch List.'"

Source: Waxman (2007)

Apart from the use of flexibilities under the TRIPS Agreement, the Thai administration introduced other measures to make affordable medicines available to its people. Participating in a bulk-purchasing scheme of anti-HIV drugs, managed by the Clinton Foundation, was among those policies implemented to try to achieve the Thai government's ultimate goal. On 9 May 2007, Thailand and 16 other developing countries agreed to join an initiative for wider access to HIV drugs, whereby the Foundation would help in price negotiations with the drug industry, including patent holding companies (Ministry of Public Health 2007a). The medicines in this pricing agreement included both first and second-line ARVs. The benefit of joining this drug purchasing scheme included not only the lowered-priced medicines, but as this foundation was chaired by Bill Clinton, former president of the US, the invitation to Thailand to participate in this collaboration, to a certain extent, could enhance the country's image over its commitment to its people's health. Importantly, Clinton strongly backed Thailand's use of TRIPS flexibilities, which made the Thai move more legitimate. As reported in US newspapers, the

former president *'forcefully endorsed recent decisions by Thailand and Brazil to break patents held by American pharmaceutical companies that are charging prices Mr. Clinton described as exorbitant, but that drug company officials said were reasonable.*' (Dugger 2007). Clinton also maintained, *'No company will live or die because of high price premiums for AIDS drugs in middle-income countries, but patients may'.*

In addition to the formal collaborations sought by the Public Health Minister, many officials in the Health Ministry and NHSO put efforts into obtaining support from their international friends and colleagues. For instance, a senior advisor to the Minister revealed that when the Thai action was strongly opposed and criticised as unlawful, he made contact with people in international NGOs and academic institutes: *'...I emailed our allied networks overseas asking this question. Prior to the CL announcement, we didn't communicate much with these networks. With the increasingly vociferous opposition, I contacted Martin Khor of Third World Network, Dr Carlos Correa of the University of Buenos Aires, and James Love of the Knowledge Ecology International.*' (Kijtiwatchakul 2007b:33-34).

4.4 Importation and distribution of medicines under the government use programme

Among key policy actors are those involved in translating policy prescription into practice. The GPO, as the sole MOPH agency with drug manufacturing expertise and experience on importing pharmaceutical products, was assigned to be the implementation unit of the government use scheme. Given that the GPO's EFZ was under assessment of bioequivalence and shelf-life, in order to get the medicine before the stock ran out in February 2007, the GPO ordered a generic version of EFZ from an Indian company Ranbaxy, which met the WHO prequalification scheme's standard. As of June 2008, almost 8 million EFZ tablets (600 mg) and 900,000 EFZ capsules (200 mg) had been imported under this programme (table 7).

Table 7: Importation of ARVs and clopidogrel under the government use scheme, as of June 2008

Medicine (producer)	Date	Quantity	Price
EFZ 600 mg tablets (Ranbaxy)	Jan-May 2007	66,000 x 30 tablets	684 baht/30 tablets
	Sep-Dec 2007	100,000x30 tablets	571 baht/30 tablets
	Mar-Jun 2008	100,000x30 tablets	547 baht/30 tablets
EFZ 200 mg capsules (Ranbaxy)	Jan-Mar 2008	10,000x90 tablets	670 baht/90 capsules
LPV/r tablets (Matrix)	Jan-Mar 2008	8,000x120 tablets	2,457 baht/120 tablets
Clopidogrel tablets (Cadila)	Apr 08	2 million tablets	159 baht/100 tablets

Source: Government Pharmaceutical Organization

During 2007 the movement to import generic LPV/r and clopidogrel was not very pressing as there was still a large quantity of these drugs remaining in stock. The GPO decided to purchase generic LPV/r from Matrix, an Indian medicine producer. The drug produced by this firm had the highest potential to gain approval from the Thai FDA, and was also recommended by the Clinton Foundation. The MOPH's Committee to Support Government-use Implementation urged the firm and the GPO to promptly pursue drug registration in Thailand (Manager 2007a). Meanwhile, the Thai FDA set up a fast track to facilitate the drug approval process, since access to the medicines under the government use plan was regarded as a national priority. Nine-hundred and sixty thousand tablets of generic LPV/r arrived in Thailand during January to March 2008.

With regard to clopidrogel, the GPO organised bidding in September 2007, whereby an Indian company Emcure proposed the lowest price of 1.01 baht per tablet, as compared to 70 baht per tablet for the patented drug Plavix® (Sathitphattarakul and Treerutkuarkul 2007). However, as of December 2007, the company had failed to get its product approved by the Thai FDA. According to a health official, in addition, owing to the threat of legal actions

taken by Sanofi-Aventis, Emcure hesitated to further the registration process. Eventually, another Indian manufacturer, Cadila got market approval for its generic clopidrogel and became supplier of this medicine under the government use initiative. In April 2008, 2 million tablets of clopidogrel were imported into the country. Health providers had to order the drug directly from the GPO, at the amount to meet the needs of patients under the three public health benefit schemes in each health care setting, which meant that this generic product would not be prescribed to out-of-pocket patients who could afford to pay for the patented Plavix®. This arrangement was dissimilar to the anti-HIV products EFZ and LPV/r, as the generic version would be purchased from the GPO by the NHSO and then distributed to particular health care settings through the National ART programme. The distribution of ARVs would be arranged by the GPO, using a Vendor Manage Inventory System (VMI). Importantly, none of the generic products imported under the government use programme would be available for patients in the private sector, or to those who chose to pay out-of-pocket for medical services in public health facilities.

4.5 Seeking support on the use of TRIPS flexibilities from the WHO

While the Thai administration was facing opposition to its government use enforcement, the policy processes regarding IP and public health had notably developed at the WHO. The work of the Intergovernmental Working Group (IGWG) on Public Health, Innovation and Intellectual Property addressed the inadequate access to essential health products in poor settings by taking into account not only the effects of IP protection but also the implications of wide-ranging factors, for example, innovative incentives for the R&D of medicines for neglected diseases, as well as the limitations of health service delivery in the developing world (WHO 2007a; WHO 2007b). The IGWG's global strategy and plan of action was endorsed by the WHA in May 2008. However, in the 2007 WHA, the WHO Secretariat was put under enormous

pressure by a number of middle-income countries such as those in the Latin American and African regions and Thailand, because there was no significant progress of the IGWG's action plan and there were signs of bias towards some developed nations with strong pharmaceutical industry. Headed by the Brazilian delegation, developing countries jointly supported a draft resolution to press the WHO and IGWG Bureau to improve their performance.

According to the WHA resolution 60.30, dated 24 May 2007, the WHO Secretariat was urged to provide financial and technical assistance to the IGWG, as well as related intersessional activities including regional consultations, so that its tasks could be accomplished by May 2008. Importantly, the Director General was also asked to provide technical and policy support to Member States that decided to introduce TRIPS flexibilities for public health safeguards:

> *'To provide as appropriate, upon request, in collaboration with other competent international organizations, technical and policy support to countries that intend to make use of the flexibilities contained in the agreement on Trade-Related Aspects of Intellectual Property Rights and other international agreements in order to promote access to pharmaceutical products, and to implement the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments;'*
>
> (WHO 2007c)

This WHA resolution reflected the need of resource-poor countries to obtain full support from the global health body in employing the TRIPS safeguards for public health. The resolution also indicated that the WHO leadership had been lacking in providing support to developing countries to achieve their public health purposes, even though the flexibility provisions and the Doha Declaration had existed for a long time. In addition, it cannot be denied that the enforcement of government use in Thailand and its political consequences

played an important part in the development of this policy at the WHO, as such a recent experience suggested there were significant impediments in the use of TRIPS flexibilities for public health purpose in developing countries. When raised to discussion, this evidence could help to justify the WHA resolution which mandated the WHO to have an increasing role in the area of health-related IP. It is noteworthy that the US representatives protested this health need driven resolution by walking out of the WHA meeting room.

Thailand was the first country to make use of WHA resolution 60.30. In the letter, dated 17 July 2007, the Health Minister requested that the WHO Director General, in collaboration with other international organisations, consider providing technical and policy support to Thailand, in view of the fact that the Thai government had announced its intention, in November 2006, to use CL on 3 essential medicines (Ministry of Public Health 2007c). As stated in the correspondence, the Minister requested, in particular, *'sending competent experts to provide technical support, including assessment of the system for implementation as well as the impact.*' Furthermore, the WHO and other international organizations, such as the United Nations Conference on Trade and Development (UNCTAD), the World Intellectual Property Organization (WIPO) and the WTO, were requested to develop guidelines for introducing TRIPS flexibilities *'in such a way to strike a balance between access to medicines and incentives for innovation.'*

It took a considerable period of time for the MOPH to receive a response from the WHO regarding this matter. Personal communication with respective officials indicated that they often followed up the case and felt uncomfortable with the delay. It was not until late January 2008 that an expert team, let by the Director of the WHO Secretariat on Public Health, Innovation and Intellectual Property, visited Bangkok. The team members comprised experts in public health, development and IP-related laws from the WHO Office for the South-east Asia Region, the WTO, and UNCTAD. According to the Terms of Reference (WHO 2008), the mission would provide:

- relevant materials and guidelines for the implementation of TRIPS flexibilities and suggest possible indicators for future assessment by the Thai authorities of the measures;
- advice on the practical aspects and procedures for the use of TRIPS flexibilities: compulsory licensing and government use in particular; and
- factual information regarding other countries experiences of the use of TRIPS flexibilities to protect public health.

During the visit, the mission talked with the officials and representatives of many organisations involved in, or affected by, the government use policy. These included the DIP, the NHSO, the Ministry of Foreign Affairs (MFA), MOPH committees on government use enforcement and price negotiation, the Disease Control Department, the GPO, multi-national drug companies, NGOs, PLHA networks and cancer patient groups. As noted in the report of the mission, the discussions aimed to facilitate an understanding of the context and circumstances related to the granting of CL in Thailand, and identify the appropriate technical and policy support required on the use of TRIPS flexibilities (Velasquez et al. 2008). It should be noted that this mission also met, at their request, with economic and trade advisors from the Embassies of Australia, Brazil, Switzerland, and the USA, along with the EU Office and several Bangkok-based UN agencies.

On 15 February 2008, the mission submitted its report to the MOPH. The 34-page report titled 'Improving access to medicines in Thailand: The use of TRIPS flexibilities' was comprised of 5 sections: (1) Cost-containment mechanisms for pharmaceutical products; (2) Non-voluntary licenses for government use: practical aspects and procedures; (3) Other important TRIPS flexibilities to promote access to medicines; (4) Information on country experiences with the use of TRIPS flexibilities to protect public health and access to medicines; and (5) Guidelines and tools on the use of TRIPS flexibilities to promote access to medicines (Velasquez et al. 2008). Importantly, it was

emphasised that this report *'is not intended to make any evaluation or assessment of the use of TRIPS flexibilities in Thailand.*' On this basis, none of the sections of this paper provided obvious comments on particular domestic policy. However, some officials interpreted that it was clear from the report that the Thai action on CL was perfectly consistent with TRIPS requirements.

The WHO Mission completed their tasks on 6 February 2008, which was the first day in office for the newly-elected government[6]. The Mission's report was summarized into a 4-page Thai paper and distributed to the new Health Minister, the Health Secretary, the Deputy Health Secretary in charge of TRIPS flexibility issue, and the Director of the International Health Office. Moreover, an electronic version of the full report was posted on the MOPH website (http://www.moph.go.th/hot/THAIMissionReport%20FINAL 15feb08. pdf).

5. Interplay between local stakeholders

While the political pressures from industrialized countries over Thailand's decision to circumvent medicine patents and the crucially supporting role of HIV NGOs and PHA coalitions were explicit, the expression and movement against this policy among local stakeholders, including public organizations and private businesses, could not be easily observed. As public policy scholars have asserted, a government is not a homogeneous institute, since what we call 'government' structurally consists of several departments (Walt 1994). Even individual officials in the same division may have different perceptions and positions towards particular problems and the ways to solve them. This is because organizations and individuals differ in terms of missions, historical and/or professional background, experiences and interests. The case of government use initiatives in Thailand confirms these arguments. This section reviews the positions towards, and roles played, by key domestic actors of the Thai government use policy in late 2006 and 2007.

[6] Under the 2007 Constitution, a national election was organised in late December 2007.

Some government ministries might hesitate to support the decision of the MOPH and the NHSO to share patents held by multinational medicine companies. A common reason was simply that these state agencies were worried about worsening relationships with powerful nations as well as subsequent retaliation. According to a report by Agence France-Presse (2007b), *'Thai officials (in interview) were concerned that the dispute could create political disputes between the two governments if the issue was not settled in a timely and appropriate manner. They pointed to the American pharmaceutical lobby, deemed quite influential in the US.*' Such concerns were understandable, because Thailand, as a developing country, had had an unpleasant experience concerning the threat of trade retaliation, through the legislation called 'Special 301', imposed by the USTR when the country resisted enacting and amending its Patent Act as had been desired by this more powerful country since the late 1980s and early 1990s (Arnold 2006). The lesson recurred when ART advocates raised the use of TRIPS flexibilities to the government agenda in late 1990s. It is noteworthy that at the time, health activists sought to introduce public health safeguards which had already been endorsed in international and national IP laws. The use of such flexibilities was, nevertheless, objected to by the government. As a result, these measures were never implemented. An illustration can be drawn on the assertion of an official of the MOC in 1999 when NGOs and PHA networks called on the government to implement CL for HIV medicines: *'If a compulsory license were to be issued, just one million people will benefit, while the rest of the country's 61 million people will have to pay the price if the US retaliates.'* (Cawthorne and Dayal 2006). Maintaining good relationships with powerful nations was considered crucially indispensable among Thai policymakers and bureaucrats, especially those in the Commerce and Foreign Ministries. The major concern was due to the fact that the Thai economy depended on the export of goods to the US, which accounted for 10-12% of the total economic value of Thai exports at that time. A 10% reduction of exports to the US could result in the loss of 1% to 1.2% of the Thai economy including several hundreds of thousands of job losses.

With regard to the issuance of government use provisions in 2006 and 2007, inter-ministerial tensions generated over the MOPH's action were reflected in some newspaper articles, government meetings, confidential correspondence and informal communication among government officials. As Pananda (2007) pointed out, since the government use policy was implemented while the international trade and investment community was in the midst of confusion regarding Thailand's economic direction because of the adoption of the sufficiency economy as a guide to national development, *'the Health Minister's controversial decision has exacerbated international jitters as to where the country is heading.'* In this sort of political climate, the Foreign and Commerce Ministries had to shoulder huge burdens.

It seemed that cabinet members had neither been consulted nor informed about this MOPH policy prior to the announcement of the first government use of medicine patent. This was what a columnist argued, *'With pressure building on Health Minister Mongkol to reverse a policy that appears to have caught his cabinet colleagues by surprise...'* (Schuettler 2007). The ill preparedness for the negative policy consequences of two key agencies responsible for foreign relations, international trade and IP protection, might have been a reason for tensions between ministries. This analysis is supported by the evidence of the MOPH's effort to improve policy engagement with a wider range of stakeholders when external political pressures had been rising substantially. After the introduction of a second government use measure in January 2007, the MOPH sent an official letter to inform the Prime Minister about the justification and crucial elements of this policy (Ministry of Public Health 2007b). In the letter, the Health Minister maintained that the action was in line with the WTO's IP framework, the Doha Declaration and the Thai Patent Act, and that prior discussion with patent holders was not required. At the end, the Minister pledged to 'mindfully' continue to implement this policy,

by ensuring stakeholders' engagement, constructive dialogues, and compliance with international and national regulations.

Evidence suggests that foreign trade and industry lobbyists tried every effort, via official and unofficial channels, to seek clarification about the MOPH's government use policy and its 'true' intentions (The Nation 2007c). Not only the MFA and MOC in Bangkok, but also Thai embassies in major capitals around the world experienced *'a deluge of questions'* about the government use of medicine patents and the country's trade policy (Panananda 2007). Concerns about political pressures were often raised by officials in other agencies in discussions with the MOPH and NHSO. For instance, in a consultation among government agencies and NGOs on 24 August 2007, representatives of the MFA suggested that the MOPH should take into account the potential long-term implications, on both the positive and negative sides, of the government use enforcement including those of international relations, and use this measure as a last resort (Ministry of Public Health 2007i). In this forum, MFA officials also echoed the concerns of the US and EC that the government use measure might be 'systematically' introduced in Thailand and that other developing countries might follow the Thai steps which would then seriously impact on research drug companies. Personal communication with a Thai diplomat in late 2007 suggested that the MFA had no reason to oppose the use of TRIPS flexibilities for public health purpose. As she pointed out, however, her office, as well as Thai embassies, felt some difficulties in relation to the government use enforcement because the MFA had never got the necessary information and explanations from the MOPH. This lack of information, especially in the early phase, meant that this ministry, and its representatives in other countries, were unable to respond to the criticism and pressure in a timely manner. All these arguments might reflect part of the reasons why officials of the MFA felt uncomfortable with the MOPH's government use policy, while the differences in the interests of the two ministries as a major factor of their conflicting policy stances could not be neglected.

Meanwhile, the Health Minister contended that the use of TRIPS flexibilities was the *'right thing to do',* and was therefore strongly supported by the Prime Minister, Surayud Chulanont. After a meeting with representatives from the US Chamber of Commerce and the EU on 19 March 2007, the Minister revealed that he was aware that mounting political pressures from the US and EU were not only put on the MOPH but also considerably transferred through the MOC and the MFA; thus, he truly sympathised with the two counterpart agencies for any difficulties caused (Manager 2007b). He further pointed out, *'there was a mutual understanding that all concerned ministries would be informed if the MOPH decided to issue the next CL on medicines, so that they could prepare well for the aftermath.'* According to a reliable source in the MOPH, the Prime Minister confirmed several times that he agreed with the policy to introduce the TRIPS safeguard. In April 2007, for instance, the Premier maintained that *'Although we got strong protest from the US, we have to do this [enforce the government use provision-ST] as it is necessary for our people.'*

It was not until May 2007 that the Prime Minister openly talked about his position concerning the government use initiative to the public. In a press conference on 3 May, he stressed he *'stood by his government's decision'* to introduce the public health safeguard, by maintaining that, *'we have reasons to explain to the world. We are confident that relevant parties will understand our needs.*' (Chulanont quoted in The Nation 2007m). He emphasised, *'We will now focus on how to make others understand our need to enforce the breaking of the patent.'* (Chulanont quoted in Sajirawattanakul and Saengpassa 2007). It is worth noting that at that time, Thailand's trade status had already been downgraded as a result of being added to the US PWL over IP violations, and policymakers in the MOC and MFA were aware of the risk that the GSP privilege for Thai exports to the US would be

cancelled. The Prime Minister assigned the MOC to work with the US Embassy in Bangkok to devise a plan in order to remove the country from the USTR's PWL. One of the reasons quoted was the concern about the transparency of the TRIPS flexibility implementation. At the same time, he revealed to news reporters that his government would address these problematic issues by classifying them into two groups: one on the infringement to the Patent Law, including the piracy of commodity goods, and the other on the use of TRIPS flexibilities:

> *'Thailand will abide by requirements that will remove the country from the list... We will try to work out a solution with the right balance and compromise. In areas where our flaws exist, we will try to solve the problems. But in other areas, we will stick to humanitarian reasons.'*
>
> (Chulanont quoted in The Nation 2007n).

Only a few days after the Prime Minister's expression of his position regarding the government use introduction, the MFA clarified Thailand's position on the issue by reaffirming that the government use of patented medicines was allowed under the WTO's framework (The Nation 2007d). Since there had been misunderstandings reported in the foreign media and misplaced accusations made by certain organizations on the MOPH's government use enforcement on 3 life-saving drugs, the Ministry stressed that these misconceptions had *'underscored the need to set the facts straight.'* Clarification statements on 9 elements (table 8) were posted on the Ministry's website on 14 May (Ministry of Foreign Affairs 2007). As noted by an English newspaper columnist, *'This is the first time that the ministry stepped in to join the defense over the decision to use CL.'* (The Nation 2007d).

Table 8: Key elements excerpted from Thailand's positions and facts on the introduction of government use of medicine patents, as illustrated on the Ministry of Foreign Affairs' website

(1) The CL decision is primarily concerned with the issue of 'access to life-saving medicines' and their affordability. The announcements by the MOPH to use CL on the three drugs are permissible under the TRIPS agreement and the Thai Patent Act and are not contrary to the patent regime of developed countries in general.

(2) Public health is a top priority for the government, which has been making great efforts to ensure universal access to essential healthcare. Currently, every Thai citizen is covered under one of the three public health benefit schemes. However, the high prices of some life-saving patented drugs resulted in their inaccessibility.

(3) Thailand's CL decision is strictly for public, non-commercial purpose. Generic drugs will be imported under CL only for those patients under the three public health insurance plans. So, the market for the high-price patented products will practically not be affected.

(4) Thailand is not among the poorest nations, but this does not mean that its health budget is unlimited. Many of the less well-off people cannot afford the high-priced patented essential medicines, which have to be received without interruption for the patients to stay healthy.

(5) Looking at the actual situation, of the three medications announced for CL measures, Thailand has so far imported only EFZ. LPV/r and Clopidogrel are still in the process of negotiation and have not yet been imported.

(6) It had taken the MOPH more than two years of discussions with drug companies before the CL announcements were made. After the announcement, the MOPH continues to discuss and negotiate with patent holders and all stakeholders with a view to achieving constructive agreements on good-quality essential medicines at the lowest possible price.

Table 8: Key elements excerpted from Thailand's positions and facts on the introduction of government use of medicine patents, as illustrated on the Ministry of Foreign Affairs' website *(Continued)*

(7) It is untrue that the GPO will benefit from CL through the commercial manufacture of generic drugs. In ensuring access and affordability for patients under the three public insurance schemes, the government plans to either produce or import generic drugs. The Thai government will continue to give priority to dialogues and consultation as a way to find mutually acceptable solutions.
(8) Establishing linkages between the CL and Thailand's political change in September 2006 or current economic status should be viewed as a misinterpretation of our true policy objective and an attempt to politicize the issue with the intention to discredit Thailand and the Thai government.
(9) Thailand is not the first country to announce the intention and use the CL for public purposes. Many developed and developing countries had successfully expressed their intention or implemented their CL to increase the access to medical as well as other essential technologies for the greater public interest.

Source: adapted from Ministry of Foreign Affairs (2007)
Note: on this website, the word 'compulsory license (CL)' was used in the same meaning as 'government use of patents'.

At official level, a good relationship between the MOPH and the MFA was gradually created as representatives of the two agencies were assigned to work together at several international forums on public health and health-related aspects of IP protection. It should be noted that the Thai government use policy developed while the issue of IP effects on health was a priority on the global health agenda. The work of the WHO-sponsored CIPIH and IGWG on Public Health, Innovation and Intellectual Property, and related discussions at the WHA, as well as WHA resolutions, were important

political contexts of the Thai movement, and also helped to accelerate mutual recognition among MOPH and MFA officials. An illustration could be drawn on the fruitful collaboration between MOPH officials in Bangkok and the Permanent Mission to the UN and other International Organizations in Geneva. Based on the feeling of true partnership, both sides exchanged helpful information, learned from one another, and jointly devised proper negotiation strategies. On many occasions, Thai diplomats were consulted, both formally and personally, by their health official counterparts as the latter party respected the international relations expertise of the former.

Modest-path, diplomatic interventions involving a balance between public health benefits and IP rights protection seemed to be a normative position of MFA officials. Ambassador Sihasak Puangkatekaew of the Geneva-based mission, for instance, called for the cooperation of the research drug industry as a key player in solving the problem of unaffordable medicines in the developing world. He maintained in an interview in October 2007, *'Certainly, it is our right to use CL when considered truly necessary. We can go ahead with this policy as long as we are able to explain to the global community how badly needed this action is, and to ensure that this approach is employed only for non-commercial benefits.*' (Puangkatekaew quoted in Matichon 2007a:21). In his opinion, Thailand needed to convince all concerned parties that the country should not be left alone in the midst of political pressures over its action to protect public health. According to the ambassador, this would be an opportunity to create intergovernmental and/or public-private collaborations to solve the rising problems within different international frameworks.

The MOC was closely monitored by NGOs and PHA networks for their policy stance towards the enforcement of the government use provision. These included, in particular, the DIP and the Department of International Trade Negotiation, which might either be implicated or affected by the MOPH's government use policy. As some health activists put it, *'over the past ten years in the fight against industrialized nations, with the aim to broaden coverage*

for HIV medications, the roles of these two departments have been suspicious... we doubted if they really worked for the benefit of Thai people or only to protect the interests of the great powers.' (personal communication). There was a perception that developed nations were able to take advantage of Thailand in almost every negotiating forum on trade-related IP protection. The amendments of the Patent Act and patents granted for particular ineligible medicines, such as ddI, were raised by NGOs and PHA leaders as examples of their unpleasant experiences with various MOC departments. The position of the MOC was understandable as its responsibility was to enhance the country's economy through national and international trade. To be fair, it might have been the imbalance of negotiating power comparing to trade counterparts like the USA that allowed Thailand only a very few policy choices. However, the assertions of the civic coalitions reflected the distrust in government agencies and officials.

The MFA and the MOC were often urged by civil society organizations, including autonomous public institutes, not to surrender to the political pressures placed by the US and other developed nations (Sajirawattanakul and Saengpassa 2007). When the pressures over the government use initiative were rising considerably in May 2007, local HIV NGOs, such as the Aids Access Foundation and the Thai Network of People Living with HIV/AIDS, released a joint statement to encourage all government agencies to be united (The Nation 2007k). This testimony targeted the two key state organisations: *'... the Foreign Affairs and Commerce Ministries should fully cooperate with the Public Health Ministry in explaining that the compulsory-licensing process has been in line with Thai law and international rules... don't alienate the Public Health Ministry.'* To a certain extent, this reflected the civic groups' perceptions towards the two state agencies. Such an argument also indicated that the supporters and the opponents of the government use policy might have different interpretations of what health needs in term of the life-saving and urgent nature of particular conditions were qualify for TRIPS flexibilities.

As the Human Rights Commission criticised, government trade negotiators were unreasonably afraid of deteriorating foreign trade relationships due to the government use introduction (Manager 2007e). In addition, trade officials were encouraged to stop '*conservative thinking*' that would make the country's future depend on the US GSP 'gimmick'. The NGOs' distrust of the MOC could also be observed when Tilleke & Gibbins, legal consultants for MSD, the holder of the EFZ patent, filed a petition to the DIP on whether the MOPH had breached patent laws in February 2007 (Pratruangkrai 2007). In response to the industry's movement, HIV alliances, led by the AIDS Access Foundation and the MSF, rallied at the MOC to pressure the IP authority not to accept complaints from pharmaceutical companies that opposed the introduction of government use of medicine patents. As reported in newspapers, the NGOs were afraid that the DIP would consult the Patent Committee asking if the MOPH had the authority to impose this TRIPS flexibility. This was because the Committee members comprised pharmaceutical industry representatives. However, it was the Council of State that the DIP asked for legal advice. The activists urged the MOC department to clarify if it had attempted to rule over the Health Ministry's action. The Director General denied the interfering row, but said that the department was reviewing the legal arguments of the medicine industry and *'would mediate if the Public Health Ministry and multinational drug companies could not settle the issue.*' (Treerutkuarkul 2007c).

Since the US government retaliated against Thailand by employing trade sanctions, such as placing the country on the PWL and reviewing the list of Thai products under its GSP, local industry and associated business were among groups of stakeholders under threat. Therefore, it was not surprising that a discussion concerning the negative implications of the government use provision openly developed in the private sector. As reported in a Bangkok-based English newspaper on 19 June 2007, *'...the state policy on compulsory*

licensing has sparked concerns in the business sector over the possible withdrawal of hundreds of Thai export products from the US GSP list after the US reviews the list on July 1' (Treerutkuarkul 2007b). Some experts suggested that Thai exporters might lose large amounts of trade revenue. As asserted by a member of the Board of Trade of Thailand, the incomes earned in the export sector accounted for 65% of GDP, while the value of exported goods to the US in 2006 was 4.3 billion USD, 3.3% of which was obtained through the GSP-related privileges. He went on to suggest, *'The business community is concerned about the impact of the shock announcement of these compulsory licenses without any attempt by the MOPH to consult with the companies about the perceived problem of access to medicines, and possible price reductions or other solutions.'* In a similar vein, Pornsilp Patcharintanakul, the deputy secretary-general of the Board of Trade, said he was disappointed that a public policy could become a trade barrier, and encouraged both the Thai and US governments to negotiate and settle problems (Maneerungsee and Arunmas 2007).

Apart from the financial loss, this business group considered that the MOPH's policy of using patent rights for essential medicines was an '*embarrassing*' action. In a presentation on the social and economic perspectives of the government use introduction, Wongsilchote (2007) discussed 5 issues of *'Government Embarrassment'* (table 9). The reduction of healthcare expenditure, the increase in the defence budget, the GPO as a profit-making enterprise, and the non-emergency state of the country's HIV epidemic were not only misunderstandings, but also somewhat the echoes of the Pharmaceutical Research and Manufacturers Association (PReMA), the representative of the multi-national drug industry. It was not the case that the GPO was a for-profit enterprise, but rather the GPO would not make any profit from selling ARVs and other medicines under the government use programme, as it was this government action aimed for public, non commercial interest.

Table 9: The embarrassment of the Thai administration stemmed from the enforcement of government use for medicines in view of business sector in Thailand

- The government cut healthcare spending by 12million USD in 2006, while also increasing their pay by $9M and increasing defence spending by 1.1 billion USD
- The GPO is a for-profit entity, which earned profits of 25 million USD in 2005
- How can the claim of "not having the money to pay for the people's healthcare needs" be legitimate?
- Zimbabwe is only other country that has used public health safeguards as a "first strike," rather than seeking dialogue and negotiation with pharmaceutical companies
- A 1% HIV infection rate in Thailand vs. 10% in certain African countries. Is this a comparable "emergency?"

Source: Wongsilchote (2007)

The assertion on the potential economic loss owing to the abolition of GSP privileges was counter-argued by other trade specialists. Sutthichai Iam-charoenying, Social Venture Network Asia (Thailand), representing a group of private entrepreneurs, pointed out that most Thai people get incorrect information about the government use of medicine patents and its implications (Manager 2007g). According to a projection, the country would lose only 142 million USD (approximately 4.8 billion baht) in 2006 if the GSP benefit for Thai goods was lifted. Iam-charoenying also maintained, *'Most of the time, the total amount of Thai-to-US export value, 4.3 billion USD, was underscored in public discussion on CL issues. On the other hand, the true cost of GSP-revocation of 142 million USD was rarely emphasised.'* He further noted that the effects of the use of TRIPS safeguards on the business sector was really very minor, comparing it to the consequences of other elements such as the strong Thai currency and economic recession in some

developed nations. Moreover, Iam-charoenying believed that the GSP tax waiver was not as important as that of the lives of HIV-positive people which could be saved due to the policy on universal coverage for ART and the use of TRIPS' public health safeguards (Treerutkuarkul 2007b). He urged the government and local industry to work in collaboration to strengthen the country's economy without relying on the US GSP, because as he forecast, this type of privilege would certainly be cancelled sooner or later.

6. The roles of international organisations

The use of TRIPS safeguards for medicines in Thailand was commended by international health organisations. This expression of strong support might be in part based on the fact that this action was expected to set a precedent for other developing countries to follow. The lack of access to essential medicines had long been recognised as a crucial impediment to pursuing the good health and well-being of people in resource-poor settings. As mentioned earlier, such problems became obvious when the numbers of PHA in the developing world rose significantly, yet only a small fraction could obtain proper treatment including ARV medication (UNAIDS 2004). The restricted availability of generic medicines, owing to IP protection, was identified as an important factor. As the Thai initiatives on HIV/AIDS had been successful and regarded as good practice (Dhanarajan 2001), there was no doubt that the government would be lauded for their intention to use public health safeguards. However, many HIV NGOs and developing country governments believed international health organizations should take a clear public health stance and be more supportive of countries which planned to introduce the flexibilities.

The Joint United Nations Programme on HIV/AIDS (UNAIDS) was the first global organisation that expressed a clear policy stance, supporting the use of private patents by the Thai administration. The Health Ministry's decision to import a generic version of patented medicines as a means to provide access to ART was praised by Peter Piot, the Executive Director of UNAIDS, as

'strong and steadfast' efforts and *'a good example of commitment'* (Piot 2006a). In his letter to the Thai Public Health Minister dated 26 December 2006, he stressed that, *'it is also a sign of the need to urgently and consistently lower the cost of ART in developing countries so that it not only becomes more affordable but also financially sustainable.' The UNAIDS'* position concerning the Thai policy of enforcing government use of medicine patents was reaffirmed in the ASEAN Summit on HIV/AIDS. Piot (2006b:6) argued in his address to this Special Session that a great, long-term challenge faced by countries in the region was to ensure the sustained availability of life-saving commodities such as ARVs and a future AIDS vaccine at an affordable cost, through extended regional production capacity and the 2001 Doha Declaration on TRIPS agreement and Public Health. He went on to assert that, *'I would appeal to you to make full and effective use of TRIPS flexibilities to secure medicines at affordable cost to the infected populations in your countries.*' Furthermore, the UNAIDS Executive Director applauded the Thai move: *'In this respect the bold step taken recently by Thailand in issuing a compulsory license for an ARV drug is highly commendable.'*

The Thai poliey to increase medicine access was applauded in other forums on HIV/AIDS. For instance, the International Congress on AIDS in Asia and the Pacific, addressed the decision to issue TRIPS flexibilities as *'one of the most critical political commitments'* to combat HIV/AIDS, and also a good example for other countries heavily affected by the epidemic to follow (Sathitphattarakul and Treerutkuarkul 2007). In this conference, Prasada Rao, the director of the UNAIDS regional support team asserted, *'It's the right thing to do because we just can't provide those who need with only the first-line drugs because of the high cost. I urge countries in Asia and the Pacific region to use the WTO flexibilities to do more and show more commitment to AIDS response.'*

The WHO's formal response to the Thai action came late, and in the beginning, was heavily criticized as being controversial. It was also not appreciated among AIDS activists and NGOs. On 1 February 2007, Margaret Chan, the WHO Director General, who had just taken office in January 2007, visited Bangkok as an honorary guest of an international conference to mark the 15th anniversary of the Prince Mahidol Award. During her visit, she was invited to the NHSO, where she made a speech admiring the effort and commitment of the Thai government to improve the health of its people by increasing the public budget allocation to national health security services, including health promotion programmes. It was reported in newspapers that the Director General suggested that the MOPH negotiate with pharmaceutical companies before introducing the government use for medicines (Treerutkuarkul 2007g). This article also stated that the Director General encouraged the Health Ministry to improve its relationship with the drug industry to strike the right balance in having access to medicines.

As one Thai civic group put it, the viewpoints of WHO had caught the public by surprise, and was disappointing to many people. The Director General's statements created confusion about whether the Thai administration's decision deserved *'flowers'* or *'stones'* (Prachathai 2007). Promptly, after the Director General's remark, representatives of humanitarian organizations, and experts on patent law and public health, both inside and outside Thailand, joined a press conference. Each of the panel members was critical of, and outraged by, the Director General's position (Hong 2007). It was reported by the Inter Press Service, a civil society news agency, that these NGOs condemned the new chief of the WHO for her support for the interests of the transnational pharmaceutical industry, instead of tackling the difficulties of poor people in the developing world (Macan-Markar 2007). The detailed comments made by NGO leaders and experts, namely MSF's Ellen T'Hoen, Knowledge Ecology International (KEI)'s James Love, the AIDS Access Foundation's Nimit Tienudom,

the Third World Network (TWN)'s Martin Khor, and Carlos Correa, Director of the University of Buenos Aires' Science and Technology Policy Programme were illustrated publicly via the internet and other channels. As reported in the media, the panel members strongly supported the MOPH's decision, by arguing that :

> *'The new Director General of the WHO should have stood up for the poor. This is a bad start. She needs to educate herself about intellectual property rights'* (Love quoted in Macan-Markar 2007).
>
> *'The WHO has to look more closely at its role in the global public health campaign. It must be able to stand up to the threats of big pharmaceutical companies.'* (Tienudom quoted in Macan-Markar 2007).

Similar observations from different parts of the world about the role of the WHO were distributed through the Internet. For instance, the Delhi Network of Positive People (2007) argued that, *'These comments, if accurate, not only represent an attitude which is not in conformity with WHO's mandate to attain, for all peoples, the highest possible level of health, but also reflect a deeply flawed understanding of the compulsory licensing mechanism and its indispensability in promoting access to essential medicines.'*

On 7 February 2007, the WHO Director General wrote a letter to the Thai Minister of Public Health arguing that her comments at the NHSO were misinterpreted by columnists and *'have caused embarrassment to the government of Thailand'* (Chan 2007). This correspondence emphasised that the Director General neither opposed the use of TRIPS flexibilities nor suggested negotiations with patent holding companies before using public health safeguards. Chan asserted that the decisions to introduce the govern-

ment use measure were countries' prerogatives, and *'it is entirely appropriate and necessary for the government of Thailand to find means of reducing these costs to ensure sustainable financing of health care.*' This letter clearly reflected, for the first time, WHO's policy stance regarding the use of TRIPS flexibilities as public health safeguards: *'WHO unequivocally supports the use by developing countries of the flexibilities within the TRIPS agreement that ensure access to affordable, high quality drugs. This includes the use of compulsory licensing, as described in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*'. The Director General further pointed out, *'There is no requirement for countries to negotiate with patent holders before issuing a compulsory license.'* At the same time, however, she underscored the right balance between the immediate need to provide adequate access to affordable medicines to needy people and the need to provide incentives for the R&D of new medicines. Finally, she again argued that, *'...prior negotiations with industry is a pragmatic approach that may ensure countries have access to high quality medicines at affordable prices.'*

However, despite this explanation, it seemed that the Director General's comments had generated a persistent, difficult-to-change, negative impression of HIV NGOs and other health advocates. According to Wong (2007)'s interpretation, *'the WHO persuaded the Thai government to negotiate with drug firms before issuing a compulsory license.'* In the same vein, Mabika and Makombe (2007) noted that, *'Chan's statement created the impression that there was something wrong with compulsory licensing that needed to be corrected through negotiating with pharmaceutical companies.'* They went on to remark *'If the comments were meant to shock and awe, they achieved exactly that!'* Others such as the Third World Network understood that Chan obviously gave warnings to Thailand (Hong 2007). Meanwhile, the opposition to the Thai government use policy, such as Roger Bate, a resident fellow at the American Enterprise Institute for Public Policy Research in Washington, D.C.,

thought that the Director General's criticisms of the Thai action were legitimate ones (Bate 2007). In his analyses, Bate claimed that Chan's letter to the Health Minister of Thailand had resulted from humanitarian groups' *'coordinated condemnation'* of her statements at the NHSO.

Among others, a group of HIV NGOs, including the MSF, the AIDS Access Foundation, the Thai Network of People Living with HIV/AIDS and a drug policy specialist responded to the WHO Director General, arguing that her comments were *'misplaced'* and casting the question: *'Is WHO's Director-General more concerned about the needs of patients or the interests of industry?'* (Cawthorne et al. 2007). As stated in the Lancet, the Thai government *'does not need to be advised'* to negotiate, and negotiation with patent holders was not required as a pre-condition when a government decided to issue the flexibilities in accordance with the TRIPS agreement.

The civic groups further asserted that the *'balance'* mentioned by the WHO Director General might refer to the industry's claim that patent protection and the associated high prices of medicines were important means to pursue the cost recovery of their innovation; however, the medicine companies had never made it clear how much they had really invested in R&D, while this sort of business earned a huge sum of money, as much as several billion dollars annually (Cawthorne et al. 2007). In addition, the authors of this article pointed out that it should not be the role of the WHO Director General to protect industry benefits or neglect public health. The *'inaction'* of former WHO Directors General, when Thailand faced pressure by the US government over its IP laws in the mid-1980s, was cited as an illustration of the 'suspicious' mission of this global health agency. These NGOs welcomed Chan's clarification that WHO definitely supported the use of TRIPS flexibilities, and urged her organization to provide *'active'* technical and political support for the Thai move.

The intensive opposition to the Director General's remarks might be fostered by the fact that she made this policy statement at a crucial time, when Thailand had declared its intention to use the TRIPS flexibilities, and the country was in the midst of facing serious pressure from policy opponents (Macan-Markar 2007). As analyzed by an NGO columnist, AIDS and public health activists had been anticipating that Chan's statements at the Prince Mahidol Award Conference, and at other events during her visit, would enhance the Thai government use initiative to improve access to medicines for the people. Furthermore, Macan-Markar (2007) pointed to the coincidence that at the time the WHO was under scrutiny by civil society organizations. The author noted that NGOs and health advocates *'fear that the WHO is selling out to the pharmaceutical industry given the pressure imposed on it by the US government'*. This internet article also provided an example of the case of William Aldis, WHO representative to Thailand, who had been removed from his position after publicly cautioning the Thai government to be aware of the potential negative implications of the TRIPS-plus proposal under the Thailand-US FTA in January 2006.

Both the WHO and UNAIDS were urged to play an increasing role in providing support to broaden access to medicines in developing countries by solving IP-related impediments. For instance, Paul Cawthorne, a health advocate at the Bangkok-based MSF, maintained in an interview in March 2007 that both agencies were in relevant positions to do so, *'despite facing pressure from pharmaceutical companies'*, since it was the two organisations' mandate to deal directly with the world's population and health issues (Cawthorne quoted in Treerutkuarkul 2007h). In addition, the humanitarian NGO stressed, *'It is the WHO's job to find cheaper versions of the expensive drugs for poor countries'*. This might be the NGO's slightly-inaccurate interpretation of the WHO's role in providing support to policies which promote access to medicines.

7. Pressing movements of drug companies, their representatives and country governments

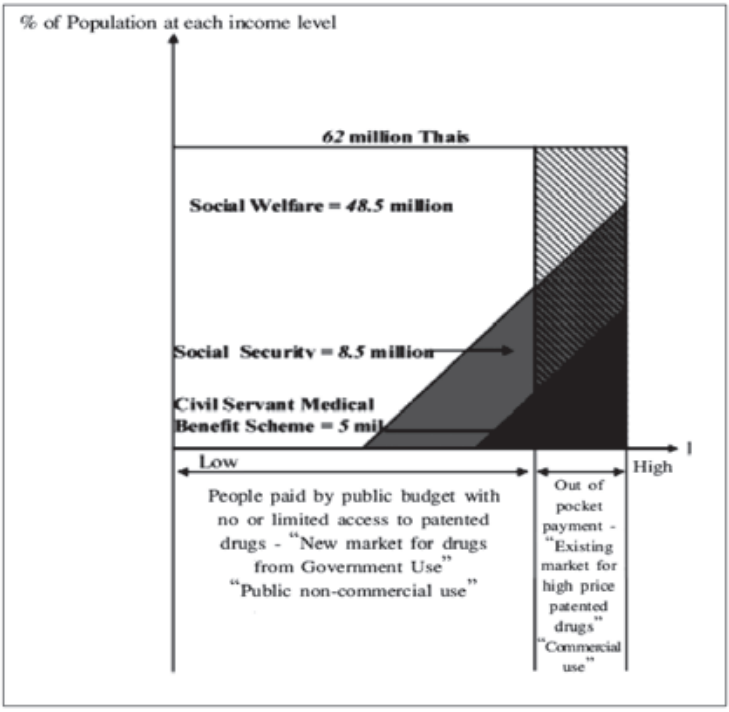
The introduction of government use of medicine patents in Thailand prompted strong opposition from pharmaceutical industry, especially the patent holding companies of the three medicines, and their country governments. These policy opponents employed different strategies not only to protest against the Thai action but also to convince the MOPH to revoke the use of this TRIPS flexibility measure. This section reviews the motives underpinning the opposition to the government use enforcement and the involvement of the drug companies and some developed countries' government in the policy processes.

7.1 The motives of the opposition to the government use policy

To understand the position and role of political actors, either for or against a public policy, ones need to get insight into their interests including the benefits they would gain or loss from the implementation of such a government action (Varvasovszky and Brugha 2000). The extent to which the interests of a group of stakeholders contradict to those of others is a driving force of policy participation. Taking these concepts into account, it can be argued that the potential profit loss among the patent holders was the key motivation of the opposition to the use of TRIPS flexibilities. It was because the public use of patents would terminate the market exclusivity rights granted to patent holders and therefore, allow competition of lower-priced generic medicines. Although the MOPH maintained that the generic products would be prescribed only in the public sector so that it would only slightly affect the

existing market of the patented, original versions (figure 7)[7] (Ministry of Public Health and National Health Security Office 2007a), the policy opponents might feel that the business loss was substantial.

Figure 7: An illustration to support the MOPH's argument on the minor effect of the government use of medicine patents on the existing market size of patented products



Source: Ministry of Public Health and National Health Security Office (2007a:7)

[7] Following the Health Ministry and the NHSO (2007a), almost all of the patients having access to patented medicines included the well-off who could afford to pay out of their pocket. This market, mostly existed in the private sector, would not be considerably affected by the government use provision, since the generic products imported under this plan would be prescribed to only beneficiaries of the three publicly-subsidised benefit schemes: the Social Welfare (UC), the Social Security and the Civil Servant's. Given that the majority of these people had not been able to receive patented products, the generic launch would create new market for particular drugs.

At the same time, the medicine industry and its supporters maintained that the Thai action and the subsequent reduction in market returns would discourage investments in research and development of pharmaceuticals in the future. In addition, this policy might create a chain of impacts on the industry and related business. For instance, a group of US congressmen pointed out that IP protection was critical not only for further development of new drugs but also for millions of employees in this sector (Kind et al 2007). Similar to other commercial enterprise, pharmaceutical companies are for-profit organizations. Profit maximization is pursued through different marketing, pricing, investment and public relation strategies. Being unprofitable means negative effects for stock values, investments, and market share, which subsequently implicate senior executives, workforces and company as a whole (Turner 2006).

Concerns about spill-over effect of the Thai policy into other countries and a wider range of medicines might have a role in stimulating the policy opposition. An official of the Thai MFA argued in a meeting at the MOPH in August 2007 that the US administration was not concerned about the loss of revenues on the medicines under the government use programme in the Thai market, but the 'domino effect' of the policy in other developing countries (Ministry of Public Health 2007i). As noted by some economists and drug policy analysts, the reactions were generated because other countries in the developing world tended to follow the suit. Following Gustav Ando (quoted in The Nation 2007a), an analyst for an American economic-forecasting firm, *'The drug industry is very well aware of what this means. If one country does it that means any country can do it. This is the front-line battle at the moment. It's not going to stop there.*' In the same vein, Steve Brozak (quoted in Thai Associated Press 2007), an analyst with WBB Securities, asserted that the use of TRIPS flexibilities might be extended to a wide variety of medicines: *'It's a problem that will only increase. The question becomes: Today HIV drugs, tomorrow, what?*'

In this context, the effort of international drug companies to intimidate Thailand over the enforcement of TRIPS flexibilities might reflect the intention to dissuade other resource-poor settings from following the Thai course of action. As argued in a newspaper article, the actions undertaken by the policy opponents aimed to bully Thailand for *'daring to take advantage of a WTO agreement on intellectual property rights.,'* and *'The message to the rest of the world was clear: Issue a compulsory license, and be punished.'* (Bangkok Post 2007a). In addition, as law professor Baker (2007) asserted, the protests against the Thai administration for the use of clopidogrel patent took place because *'the medicine industry would like to draw a boundary around Africa and around AIDS drugs and declare a regional and disease-specific cease fire in its ongoing Pharma Wars.'* He pointed out further that research drug companies wanted to eliminate the use of TRIPS flexibilities and also discourage the development of a robust generic industry that would compete with regard to newer, more broadly patented medicines.

7.2 Reactions of some industrialized nations

US Trade sanctions

After the Thai administration announced its policy regarding the public, non-commercial use of the EFZ patent, held by the US company, MSD, in November 2006, the Washington government, the research drug industry, diplomats, parliament members, academics and NGOs, all had different positions and responses to this action. Many of these political actors were apparently opposed to the use of TRIPS flexibilities, while others hailed the use of the public health safeguards. Nevertheless, some analysts, including Wall Street Journal columnists, observed that the US administration *'has mostly stayed on the sidelines during the dispute'* (Zamiska and Hookway 2007).

A first move was undertaken on 10 January 2007 by 22 US Congress members, led by Sander Levin, who sent a letter to USTR's Susan Schwab to suggest that the US administration respect the Thai decision to enforce

government use provision for anti-HIV EFZ (Levin et al 2007). The letter argued that it was necessary for Thailand to use this measure to ensure access to affordable medication among needy populations - an action which was in line with the WTO's TRIPS agreement and the Doha Declaration. It was also emphasised that developing countries need not negotiate with the patent holder in advance, since EFZ produced or imported under the government use programme would be prescribed for non-commercial use by its national programme. In this letter, these Congressmen pointed out that the US government might be *'attempting to intervene'* in Thai policy. Finally, they asserted that the Trade Promotion Authority Act of 2002 mandates that US trade policy respect other countries' public health initiatives under the Doha Declaration.

On 17 January, Schwab responded to the above correspondence by sending a reply to Levin, emphasising that the US administration was fully committed to the TRIPS flexibilities and the use of public health safeguards to *'address effectively public health emergencies'* (Schwab 2007a). She admitted that Thailand had not failed to comply with any particular national or international rules. At the same time, the letter indicated that *'it would be appropriate for the Thai authorities to respond to any requests for direct discussions by concerned stakeholders, including, among others, the patent holder.'* However, as she maintained in her letter, *'...we have not sought to insert the US government into any such discussions.'*

Along with the above policy direction, an American diplomat in Bangkok said in an interview in early February that the US administration would not object to the right of the Thai government to introduce TRIPS flexibilities if it was considered necessary (Agence France-Presse 2007b). However, the embassy's spokesperson went on to suggest, *'We would strongly urge, as a matter of sound public policy, that senior Thai officials meet with relevant stakeholders, including the patent-holders, to discuss Thai government concerns. Those concerns might well be resolved in a mutually satisfactory manner through*

dialogue.' Furthermore, on 9 February, a senior economic officer at the American Embassy in Bangkok assured the Thai DIP Director General, and other MOC officials, that the US government would not link the circumvention of pharmaceutical patents with its annual revision of unfair trade practices by its trading partners (The Nation 2007o). At the time, relevant data and information on the extent of the progress made by the Thai government to suppress IP rights violation were collected by American trade officials in Bangkok to submit to the USTR. The trade status of Thailand, as an American trading partner, would be reported on 30 April.

The policy stance of the US government was reaffirmed by its trade representative officer. The USTR's Schwab, in her letter to the Thai Commerce Minister, Krikkrai Jirapaet, dated 6 March 2007, urged Thailand to find a balance between *'practice'* and *'philosophy'* in introducing its policies to ensure access to medicines, by taking into account the importance of new drug development through the active protection of IP (Schwab 2007b). Schwab expressed official disappointment as the Thai government did not choose to talk with pharmaceutical companies before announcing the sharing of certain drug patents. She went on to maintain that the US administration was concerned about the effects of the government use initiative on the overall investment environment in Thailand. Moreover, as discussed in this correspondence, the Thai actions could deter the future investment in the development and manufacture of products in Thailand. Finally, the trade representative encouraged the Thai administration to pursue public health *'without creating the appearance that Thailand disregards the value of intellectual property and its role in promoting the development of new, innovative medicines.'*

Movements of other groups of congress members in March reflected different opinions concerning the Thai government use of medicine patents among the policy elite in the US. On 15 March, 12 lawmakers, headed by Ron Kind, wrote a letter to the USTR, because, as argued by the authors, it appeared that

Thailand might expand its government use programme to cover many more medicines developed by US companies (Kind et al 2007). As claimed in the correspondence, the Thai government intended to include '*nearly a dozen*' medications for life-style diseases such as high cholesterol and other illnesses which obviously did not meet the conditions of public health urgency as stated in the TRIPS agreement. The congressmen expressed their concern that, *'Thailand's proposed actions may constitute a new governmental policy to expropriate patents on all manner of innovative medicines not used to address significant public health needs.'* As further asserted in the letter, without an appropriate response by the US administration, the Thai policy might inspire other countries around the world to disregard IP rights. Also, it was maintained that strong protection of IP was necessary for further development of life-saving medicines, and that the US medicine industry was vitally important, as more than two million workers were employed in this sector.

One week before the USTR report was publicized, Ralph Boyce, the US ambassador to Thailand, urged the Thai administration to negotiate with the pharmaceutical industry for the price reduction of patented medicines, instead of introducing government use provision (Bangkok Post 2007d). On 23 April 2007, the ambassador met the Public Health Minister, Na Songkhla, and other senior health officials for an hour. The US officer insisted after the meeting that, although Thailand had the right to use the permitted public health safeguards in accordance with the TRIPS agreement, the concerned parties should try to reach a common ground on reasonable drug prices through constructive dialogue.

As many had predicted, the US government put Thailand, along with 9 other developing countries[8], on its PWL. According to the 2007 Special 301 report, the change in the country's trade status was owing to the concern over the

[8] Argentina, Chile, Egypt, India, Israel, Lebanon, Turkey, Ukraine, and Venezuela

overall deterioration in the protection and enforcement of IP rights in Thailand (Office of the United States Trade Representative 2007). In addition, piracy of trademarked products like footwear, books, business software, cable and signals were cited. As also stated in the report, Thailand had insufficient penalties for violations, and there were indications of a *'weakening of respect for patents*' and a *'lack of transparency and due process.'* The report noted that the US government would consider all possible measures including initiation of dispute settlement consultations with the countries which failed to adhere to the TRIPS agreement.

Although the link between the Thai government use of medicine patents and USTR's treatment of Thailand had been officially denied, Ambassador Boyce admitted in a press conference, on 1 May 2007, that the use of TRIPS flexibilities was a reason for the US' sanction: *'True, compulsory licensing in Thailand is one of the concerns, but it is not the main reason for Thailand being placed on the Priority Watch List'* (Boyce quoted in Maneerungsee and Treerutkuarkul 2007). As the US ambassador emphasised, that the Thai effort to protect IP had been weakened over the past years was the US' main concern, while the other trade and economic policies of the Thai administration, such as the Foreign Business Act amendment, the capitol control measures and the Retail Act, were other reasons for the downgrading.

The US' decision to place this developing country onto a more severe PWL states stirred protests in Bangkok and Washington, D.C. Quoting an international trade source, Thailand had not done any better or worse than in previous years in terms of its overall record on IP protection (Maneerungsee and Arunmas 2007). It was, therefore, suggested that the true reason for the US sanction might have been be to retaliate against this country as it had *'outraged the politically powerful and deep-pocketed pharmaceutical industry'.* by sharing patents on block-buster medicines. In a demonstration in front of the US Embassy in Bangkok on 3 May 2007, one of the AIDS activists announced, *'We are here to condemn the US government for caring more*

about the money it receives from drug companies than humanitarian causes and the plight of patients.' (Tienudom quoted in Sajirawattanakul and Saengpassa 2007). The HIV treatment advocate also pointed out that *'hostile and aggressive retaliation'* by the US and the drug industry apparently contradicted WTO' IP frameworks and set a *'dangerous precedent'* for other developing nations who wished to implement the TRIPS safeguards. At the same time, others such as IP law expert Jade Donavanik maintained that the enforcement of the government use measure did not violate the TRIPS agreement. As Donavanik (quoted in Maneerungsee and Treerutkuarkul 2007) further put it, *'It is unfair to interfere with another country's sovereignty by taking unilateral trade action like this.'*

A campaign to protest the USTR Special 301 report was organised by a group of US senators. Henry Waxman and 34 other members of congress signed a letter dated 20 June to call on the USTR to re-examine the decision to downgrade Thailand to the PWL, and to stop any retaliation for Thailand's public health efforts (Waxman et al 2007). The lawmakers put in their letter that the US' sanction was a punishment for Thailand's use of TRIPS flexibilities: *'It is difficult to interpret this decision as anything other than retaliation for Thailand's recent actions. It sends a troubling message not only to Thailand, but the whole world, that the exercise of recognised public health flexibilities in trade obligations is frowned on by the United States'.* In addition, this letter pointed out that the sanction could be viewed as *'a warning and threat'* to other countries that were considering undertaking similar action. Also, the congressmen urged the USTR to respect the rights of WTO members to freely exercise public health safeguards under TRIPS and the Doha Declaration.

The move of 35 Congress Members was supported by many health advocate organizations, both inside and outside the US. For instance, Robert Weisman, the director of a Washington-based NGO, Essential Action, issued a statement arguing that the letter by these lawmakers suggested a *'growing sentiment'* in the legislation body that the US policy on access to medicines needed to be

changed (Ashayagachat and Treerutkuarkul 2007). This civic group agreed with the assertion in the Congress members' letter that the US administration placed Thailand on the PWL as a sort of retaliation. As Weisman (quoted in Ashayagachat and Treerutkuarkul 2007) argued, the *'USTR's retaliatory placement of Thailand on the priority watch list was designed to punish the country for prioritizing public health over the interests of Big Pharma.'* The NGO leader added that the trade sanction aimed to send a threatening message to other developing countries that they might be punished for the use of flexibilities available in the WTO rules.

While US pressures over Thailand's use of TRIPS flexibilities were growing significantly, the Public Health Minister, Na Songkhla, insisted that the introduction of government use for medicines was not violating WTO rules, and that this measure would be carried out only when it was necessary. In May 2007, before attending the WHA in Geneva, the Minister and other senior health officials visited several government agencies, NGOs, humanitarian organisations and individual key persons in Washington to clarify the justification for the Thai policy (The Nation 2007j). Apart from positive responses from civil society, philanthropic foundations and some members of the US Congress, the Thai Minister of Public Health admitted that the trip to the US had won very little support from the US administration (The Nation 2007i). Also, he revealed that the US Commerce Secretary and his high-ranking staff *'seriously asked'* Thailand to stop the action.

Irrespective of the association between the Thai government use of patents and the country's trade status according to the Special 301 provision, some Thai products were removed from the US tariff exemption scheme for exports from developing countries in 2007. Effective from 1 July, the US government ended the GSP of three products exported from Thailand, namely gold & jewellery, flat panel televisions and polyethylene terepthelate (US Commercial Service 2007). Meanwhile, it granted Thailand a renewal of competitive need limitations to export pneumatic radial tires, which allows the industry to

continue exporting under the GSP programme. As argued by the American Embassy in Bangkok, the removal of GSP privilege for the three exports was unrelated to the *'controversial'* public use for medicines in Thailand. It was suggested further that the US administration had made the decision in accordance with *'statutory-based guidance regarding product competitiveness'* and *'was not retaliation of any kind'.* The Embassy also claimed that Thai industry had the ability to effectively compete in global markets, and that this competency was a successful outcome of the US GSP programme in helping to foster competitive industries in Thailand.

The European Union's action

The exchange of deliberation between the EU and the Thai government on the latter's use of TRIPS safeguards is an interesting case study. Opposition to this policy was expressed by the European Commission (EC) and some member countries promptly after Thailand announced that they were going to circumvent the pharmaceutical patent of a heart medicine, Plavix®, a patented product from France's Sanofi-Aventis. In July 2007, the European Parliament (EP) adopted a resolution on TRIPS agreement and access to medicines in resource-poor countries. More lessons can be drawn on the action of a European Trade Commissioner in mid 2007 as well as its consequences.

Like other countries, where drug companies had patents that were shared by the introduction of TRIPS safeguards, the EC established dialogues with the Thai administration. Senior officials from the EC delegation in Bangkok visited the Ministries of Commerce, Public Health and Foreign Affairs to express their concern over the government use of patents for HIV and heart medicines. On 16 March the EC Ambassador met the Minister of Commerce to discuss the policy justification and future development (Thai News Agency 2007a). On the same day, in a meeting with Vichai Chokevivat, Chairman of the Committee to Support Government Use of Medicine Patents, the Ambassador

sought clarification on the legality and rationale of the use of TRIPS flexibility, especially for Plavix® (Manager 2007d). One of the questions was about whether the escalation in defence spending had resulted in health budget constraints and a subsequent demand for access to cheaper medicines by employing a government use approach. Another query was the potential of this policy to discourage innovation and new drug development. Furthermore, the EU wanted to ensure that medicines under the government use initiative would not 'leak out' and be prescribed in private practices. According to Chokevivat, the EU delegate appreciated his explanation on all elements and well understood the country's need to have increased access to affordable drugs.

When Thailand implemented the TRIPS safeguards in 2006 and early 2007, the EP did not issue any particular policy statement to address the Thai move, but dealt with the problem of trade-related IP protection as an impediment to essential medicines and public health in the developing world in general. The EP had been considering ratifying an amendment to the TRIPS agreement, which would facilitate access to patented drugs by helping poor nations to manufacture and import medicines at affordable prices. However, some members of this parliament explicitly supported the Thai action. For instance, the EP socialist group noted that government use of patents was an effective measure to counter *'the crisis of access to essential medicines.'* (McKay 2007). They stressed the need to encourage countries to *'make the Doha Declaration a reality'*, and to prohibit the public health threats of the pharmaceutical lobby and industrialised countries protecting their interests.

On 12 July 2007, members of the EP passed a resolution identifying policies necessary to promote access to medicines in the developing world. Among other elements, two emphasized the actions closely related to the flexibilities entitled by WTO's TRIPS and the Doha Declaration on TRIPS agreement and Public Health (The European Parliament 2007):

> *'8. Asks the Council to support the developing countries which use the so-called flexibilities built into the TRIPS Agreement and recognized by the Doha Declaration in order to be able to provide essential medicines at affordable prices under their domestic public health programmes;*
>
> *9. Encourages the developing countries to use all means available to them under the TRIPS Agreement, such as compulsory licences and the mechanism provided by Article 30 thereof.'*

This also included the demand for the EC to stop seeking IP protection beyond the measures stated in the TRIPS agreement in trade negotiations with poor countries. Nevertheless, the resolution was not agreed to by all Parliament members, especially the Trade Committee. The discordant arguments on the connection between the TRIPS agreement, public health safeguards and access to affordable medicines had been distributed by different levels of government in the EC a few months before the resolution was adopted (ICTSD 2007).

The disagreement concerning IP protection and flexibilities to promote access to medicines in resource-poor settings could be observed only two days before the EP passed its resolution: on 10 July 2007, Peter Mandelson, a member of the European Commission, wrote to Thailand's Ministers of Commerce, Public Health and Foreign Affairs (Mandelson 2007a). It was suggested that the EU was concerned by some indications that Thailand might be introducing another measure to improve access to medicines, as the government had stated that *'if drug companies wish to do business in Thailand, they should offer their drugs for no more than 5 percent above the generic cost.'* As Mandelson maintained, this approach would undermine the patent system, as well as the R&D of new drugs. As a result, this might force pharmaceutical companies to abandon their patents and could lead to *'the isolation of Thailand from the global biotechnology investment community.'* In addition,

Mandelson (2007a) pointed out that TRIPS flexibilities were *'exceptional measures'* to expand access to essential drugs, and should be introduced as the last resort. According to his letter, either the TRIPS agreement or the Doha Declaration does not justify *'a systematic policy of applying the government use of patents wherever medicines exceed certain prices.'* He went on to suggest that the EC encourage the Thai government to engage in direct discussions with the patent holders, as he thought that constructive dialogues and public-private partnerships were promising policies to pursue the long-term benefits of populations in need of medicines.

In response, the Ministers of Commerce and Public Health replied to Mandelson (Managing Intellectual Property 2007). According to the Commerce Minister, the introduction of government use measure for medicines was consistent with the country's obligations as a WTO member and complied with the TRIPS agreement (Jirapaet 2007). Moreover, the MOPH's Committee on the Negotiation for Increasing Access to Essential Patented Drugs was discussing price reductions with the patent holders of the drugs under the government use programme. The negotiation between the two parties was so constructive that fruitful and satisfactory outcomes could be expected. At the same time, the Health Minister asserted in his official letter that in implementing the public health safeguard, it set the royalty payment for patent holders at 0.5% - a figure that no company was interested in negotiating (Na Songkhla 2007a). Meanwhile, the 5% credit suggested that if the producers of original medicines agreed to sell their products to the government at a price of not more than 5% over the lowest generic price, the government use measure would not be enforced, and the patented products would be purchased by the publicly-funded health plans. As the Health Minister put it, *'This increase from 0.5% to 5% royalty is to show our gratitude to the patent holders when they show their commitment to serve the public at large.'* Furthermore, the Minister reiterated that it had tried to negotiate with drug companies prior to the announcement of the government use provision. However, the negotiations failed owing to a lack of interest and cooperation from the patent holders. The

Minister of Public Health also noted that as the EU members had often implemented TRIPS flexibilities, especially CL, he asked Mandelson whether these countries were affected by the so-called *'isolation from the global biotechnology investment community.'*

The action of this Trade Commissioner generated disproval from both inside and outside the EU. It is noteworthy that Mandelson's letter became public in August, as the UK's Financial Times had a report on the content on 10 August. Manuel Lobo Antunes, the EU Council's Secretary of State for European Affairs wrote in his 6 August letter to the President of the EP recalling that the Council supported the flexibilities of TRIPS agreement and the Doha Declaration, and it *'is certainly concerned about the coherence of EU policies and the consistency of its external actions.'* (Lobo Antunes 2007). Moreover, when Mandelson attended a meeting of the EP's Trade Committee on 11-12 September, he was heavily criticized about the correspondence with the Thai Ministers, as many committee members thought the EC should not put pressure on any developing countries to discourage their effort to introduce TRIPS flexibilities (Managing Intellectual Property 2007). According to the ICTSD (2007), '*...committee members were only partially satisfied with the commissioner's explanation that his letter had been misinterpreted.'* Helmuth Markov, the German EP member who chaired the International Trade Commission maintained that it was not the right time to send this letter to the Thai government, and he would send a written complaint to Mandelson for the action that contradicted the concerns raised by the EP (Cronin 2007). Meanwhile, other members, including Carl Schlyter from Sweden, pointed out that the Commission misunderstood the purpose of the TRIPS flexibilities that it was intended to be used by least-developed countries according to the United Nations, but not those classified as poor or middle-income countries. Quoted in Cronin (2007), Commissioner Schlyter also argued that *'the EU should be happy that Thailand has been making use of the flexibilities applying to TRIPS.'*

Unsurprisingly, Mandelson's letter prompted objection from civil society organisations. Oxfam and the MSF protested the calls for Thailand to stop the attempt to introduce government use for medicines, and negotiate with the patent holders instead. Following their joint letter, the two humanitarian organizations reminded the Commissioner about the EP resolution of 12 July 2007, which called on the Council to support the use of TRIPS flexibilities in developing countries (Pruett and von Schoen-Angerer 2007). The NGOs noted that Mandelson's request for Thailand to discuss with patent holders *'blatantly ignores basic public health safeguards incorporated into the WTO TRIPS Agreement and reaffirmed in the Doha Declaration...'* Furthermore, the letter raised evidence shown in the report by the WHO's CIPIH indicating that an increase in patent protection in developing countries did not encourage innovative medicines for diseases that primarily affected people in these settings. Finally, Oxfam and the MSF urged the EC to support the efforts of resource-poor countries to ensure access to medicines for their people, and requested the EC not to exert pressure on Thailand or other developing countries that were introducing public health safeguards to protect their citizens. In the same vein, Alexandra Heumber, an MSF campaigner, urged the EP to react immediately to Mandelson's letter; otherwise *'the consequences will be quite worrying*.' (Cronin 2007).

The ACT UP-Paris and AIDES were two other civil society organisations that took part in the campaign against the Commissioner's action. Their joint letter asserted that the Thai policy to introduce government use measure was in agreement with international law on IP, and that Mandelson's correspondence with the Thai administration was *'clearly in a complete contradiction with the Parliament's resolution.'* (Chateau and Spire 2007). The NGOs wrote: they were impressed that the Commissioner had amended the international IP protection framework to suit *'the interest of the brand pharmaceutical*

industry, regardless of the consequences this has on the patients.' They further criticised Mandelson for intimidating Thailand, not only through his assertion about the risks of isolation from the biotechnology investment community, but also by taking no action towards Abbott when the company withdrew their new medicine registration dossiers from the Thai FDA in April as a means of retaliation against the government use of medicine patents. As suggested by the ACT UP-Paris and AIDES, *'It is extremely shocking to see a European Commissioner adding to the already unbalanced relationships of power between developing countries and drug companies.'*

It seemed that 'systematic' or 'routine' use of TRIPS safeguards was the key concern of Mandelson. As a Commission official argued, Mandelson's letter was misinterpreted and unfairly criticized (Cronin 2007). This official went on to point out that Mandelson only sought explanation of whether Thailand was planning to circumvent patents systematically when the country regarded the unaffordable costs of particular medicines. On 10 September, Mandelson (2007b) responded to the Thai Ministers, maintaining that government use of patents should be enforced *'in the spirit of the Doha Declaration and in the respect of the conditions of the TRIPS agreement...'* Importantly, as he repeated, this public health safeguard should not be systematically introduced as a *'standard way of doing business'*, since it would undermine the patent system, which would then be detrimental to innovation and the development of new medicines. He emphasized that this was the reason why the Commission encouraged negotiations to pursue voluntary agreements between potential licensees and patent holders. In this letter, Mandelson also stated that he welcomed the clarification that *'the Thai government is not engaged in a systematic policy to apply compulsory licenses wherever medicines exceed certain prices.'*

The issue of the systematic implementation of government use of patents for medicines was also highlighted in Mandelson's letter to NGOs. The ACT UP-Paris and AIDES were informed that the use of TRIPS flexibilities was

merely one among many approaches to solving the problem of inadequate access to medicines in poor countries, and that this problem needed to be addressed by *'a comprehensive package of national and international actions'*. (Mandelson 2007c). Mandelson confirmed that in bilateral and regional agreements with developing countries, the EC would not ask for provisions which could undermine TRIPS flexibilities and affect access to medicines. As Mandelson further asserted, *'it is in the interest of developing countries themselves to adopt appropriate patent protection in order to attract investment and develop their own production capacities.'* In view of some NGOs, this letter was disappointing since there was no answer at all on Thailand-related questions (Martin 2007). Meanwhile, others, such as Wilbert Bannenberg (2007), a moderator of an emailing discussion group on essential drug issues-so called E-drug, appreciated the pledge the EC had made that it would not seek to include TRIPS-plus in any of their agreements with developing countries. He observed that this was *'in sharp contrast to the USA which tries to make TRIPS-plus conditions in almost all of its Free Trade Agreements.'*

7.3 Pressing movements of the multi-national drug industry

As the introduction of government use provision would undermine the monopolistic right commanded by patent holders and therefore, result in a reduction in the profit gained, the riposte from the drug industry was not a surprise. As IP lawyer Ed Kelly (quoted in Schuettler 2007) put it, the use of TRIPS flexibilities in Thailand was *'a punch in the nose'* for drug companies, as the investors needed to ensure that they would not lose control of their *'world-class technology'* either to pirateers or in this case, a public policy to *'nationalise foreign assets'*, While the Thai government was praised by NGOs, humanitarian organisations and international health agencies, drug manufacturers condemned the action and tried different tactics to discourage its use. As Schuettler (2007) argued, the industry *'talked tough'* in the public domain, accusing the Thai government of *'stealing intellectual property'*, and also put every effort into *'negotiating a way out'*.

The role of PReMA as a multi-national drug industry representative

The Pharmaceutical Research and Manufacturers Association (PReMA)-a Thai-based foreign industry umbrella group-was one of the local actors that promptly reacted to the implementation of the public health safeguard. PReMA acted as the agent of foreign pharmaceutical firms to oppose the government use of medicine patents. Teera Chakajnarodom, President of PReMA, argued that the government use of patents was not legitimated as this action infringed on the WTO TRIPS, because it did not meet the conditions of urgency or emergency, and the MOPH did not negotiate with the patent holders prior to the policy enforcement. As he incorrectly understood, *'the law allows such actions with pharmaceutical products only in cases of extreme national emergencies, or during wartime, and only after negotiation with the companies concerned.'* (Chakajnarodom quoted in Medical Patent News 2007). He also asserted that this action seriously damaged the country's image in the global business community (Agence France-Presse 2007b), and might deter foreign investment as the investors would feel that the government could not guarantee the safety of their assets (Ahuja 2007). Chakajnarodom (quoted in Pratruangkrai 2007) suggested that the MOPH's decision might have negative effects on access to new medication among Thai people: *'Individual pharmaceutical companies will consider the very significant risk this policy poses when deciding whether to bring their latest medicines to the Thai market. Far from providing poor patients with the best medicines, the compulsory licence policy might block access to new treatments in Thailand'.* From different angle, ones might argue that without the use of TRIPS flexibilities, Thailand and other developing countries would not have access to these new treatments. Furthermore, this representative of multi-national drug companies pointed out that the industry might petition the Administrative Court to revoke the license (Banchanont 2007).

On 25 December 2006, the Chairman and a number of staff members formally met the Health Minister Secretary to discuss a number of issues. As recorded by the Secretary (Health Minister Secretary 2007), the summarized exchange was as followed:

(1) As the NHSO Secretary General had declared in early December that the government would introduce TRIPS safeguards on medicines for some illnesses, such as cardiovascular diseases and cancer, PReMA asked the authority if there was any future plan to do so. They were worried about the implications of the Thai government's action for drug companies, collaborations between Thailand and international institutes on R&D of medicines, and patent applications of Thai inventors in other countries.

(2) PReMA encouraged public-private partnership by offering to play a mediator role in transferring information and establish a discussion/negotiation between the MOPH and multi-national drug companies. This was because both PReMA and the pharmaceutical industry had the good intention of cooperating with the Thai government to improve the country's health system. PReMA asked the MOPH to consult patent holders and negotiate prices with drug manufacturers prior to the use of TRIPS flexibilities in the future so that consumers could get original medicines at preferable prices. It was believed that the two parties would be able to reach an agreement after negotiation.

(3) PReMA proposed that the Health Ministry revoke the government use of patents on MSD's EFZ (Stocrin®) because the company had already offered the Disease Control Department a low price.

(4) PReMA expressed its concerns on the quality of Indian medicine that might be poorer than the original product. This would affect the effectiveness and therapeutic results, as well as an increase in the development of drug resistance strains of the virus. Moreover, the operational costs might be higher when introducing the Indian medicine compared with the MSD product, since the original company provided better after-sale service in terms of logistics, supply and drug exchanges.

(5) PReMA presented two examples of countries that cancel the use of public health safeguards after announcement, namely Canada and Malaysia. According to PReMA, the reason for the former case was the fear of undesirable implications at a national level, and the need for high-quality original products for the latter.

One month later, PReMA sent a 'most urgent' letter, dated 24 January 2007, to the Minister of Public Health to suggest alternative strategies to TRIPS flexibilities, since it anticipated that this policy might *'negatively implicate Thailand in general aspects.'* (Pharmaceutical Research & Manufacturers Association 2007a). It was asserted that although the government use of patents was legitimated according to the Thai Patent Act, the main principle, which was internationally well-accepted, endorsed the introduction of this measure only when it met the conditions of emergency or national crisis, in the absence of other options. The letter reiterated the discussion with the Health Minister Secretary on 25 December 2006, emphasising the collaboration between government and patent holders as the prime strategy to achieve national public health goals. PReMA also maintained that the government use of patents would deter the R&D of new essential medicines as well as undermine innovation and technology transfer in the country. Following the PReMA's analyses, the enforcement of public health safeguards might generate problems in international trade.

Although the MOPH and NHSO provided an explanation of every issue of doubt for foreign drug producers and their local representatives, it seemed that such an information measure was not effective, and the pharmaceutical industry intended to fight back. In April 2007, PReMA published an A-4 sized, 40-page book entitled 'Partnering for Better Health' to illustrate the industry's perspective (Pharmaceutical Research & Manufacturers Association 2007b). This book repeated both PReMA's and the multi-national drug manufacturers' points of view on a number of issues. That the government use policy was introduced without consultation with the patent holder companies and that

such a government use approach was not sustainable, but tended to restrict access to essential therapies were underpinned as main assertions. In this paper, PReMA selected a number of arguments from the Health Ministry's 'White paper' to discuss, such as the quality of original and generic products, budgetary constraints as policy justification, and the public non-commercial use of medicines under the government use initiative. As pointed out on page 30, *'The MOPH has consistently argued that it would only use compulsory licensed products for "public non-commercial use". However, it tends to make these medicines available through Thailand's GPO, a government owned, for-profit enterprise that competes against generic and research-based companies.*' In this section, there was a table showing that the GPO had made a profit of 989.02 million baht (25 million USD) in 2005.

Moreover, this book publicized the findings of an analysis concerning the future plans of the Thai government regarding the introduction of TRIPS flexibilities. This analytical exercise was based on the fact that the MOPH appointed 3 committees to consider price negotiations and facilitate the implementation process of the public health safeguards (Pharmaceutical Research & Manufacturers Association 2007b). According to PReMA's interpretation, this suggested that the Health Ministry would continue to enforce the safeguarding measure on a routine basis. In other words, the Thai administration would *'institutionalize'* a government use approach. At the same time, there is a small paragraph containing comments on *'extensive powers', 'very broad criteria', 'no appeal mechanism available'* and *'a high risk of making arbitrary decisions'* with regard to the operation conducted by the three committees. As noted by PReMA, it was believed that *'this is the most worrying aspect of Thailand's recent actions on compulsory licensing'*. It appeared that these observations triggered a serious reaction by an EU trade commissioner and caused some difficulties to the Thai government, which will be discussed later.

PReMA maintained its active role as the representative of the transnational drug companies by continually encouraging the Thai government to establish public-private collaboration for health system development and ensuring access to medicines. In some instances, this business association called for meetings with senior officials in the MFA and MOC. For instance, PReMA's members met with the Deputy Minister of Commerce in August 2007 to express their concern about the MOPH's preparation to announce the public use of patents for two more medicines, which from PReMA's perspective would significantly undermine the country's image and enhance the distrust of foreign investors (Osathanond 2007).

Responses from the multi-national drug industry

As mentioned earlier, multi-national drug companies voiced strong opposition to the enforcement of the government use of medicine patents in Thailand, and at the same time, tried to negotiate with the Health Ministry. Abbott Laboratories, the patent holder of LPV/r, were relatively aggressive, comparing with the other two patent holding companies, in their stance against the Thai government's policy.

In response to the Health Ministry's decisions, at the beginning, networks of international pharmaceutical companies announced that they would withdraw their investments in Thailand (The Nation 2007e). Very similar assertions to PReMA's were raised to convince the Thai administration to give up the patent circumvention. The three pharmaceutical companies criticised the government on their overruling of patent rights without prior negotiation (Thai News Agency 2007b). They urged the MOPH and NHSO to consider other policy options to ensure access to medicines, rather than continuing to override drug patents. MSD offered to sell EFZ at a lower price or provide a voluntary license for a generic version, as they had implemented in South

Africa (Steinbrook 2007). A price-reduction scheme was also proposed by Sanofi-Aventis for its product, Plavix® (clopidogrel) (Matichon 2007c). According to this proposal, patients under the UC plan would have access to 3.4 million tablets of Plavix® for the same price as that of 1 million tablets. While the three patent-holding companies negotiated with the relevant governmental committees to reduce the prices of their products, the pharmaceutical industry association employed complementary measures. Several meetings between representatives of medicine companies, international trade associations and the MOPH and other ministries were convened for different purposes. On some occasions, the industry sought clarification from, and bargained with, the state agencies. In many instances, however, representatives of the industry visited ministry offices to put pressure on government officials (personal communication). On 31 January 2007, for example, former American ambassador Darryl Johnson, as a member of Abbott convoy, met Deputy Prime Minister and Finance Minister MR Pridiyathorn Devakula and Commerce Minister Krirkkrai Jirapaet to discuss the public use of drug patents (The Nation 2007c). The main concern of Johnson's was that the public health safeguard would affect the US as it is one of the world's major medicine producers. However, Johnson (2007) noted in his letter to the Thai Ambassador to Washington, that he would accompany the Abbott delegation to Bangkok, *'to facilitate these meetings and to help both sides reach a new level of understanding'.* According to Bass (2007), the former ambassador was employed as a lobbyist for American pharmaceutical companies, who did not want to lose the business they would have to give up if Thailand were able to obtain affordable generic products and stop importing the patented versions from the US. Bass also argued that Johnson's conduct was *'highly inappropriate',* and urged the Thai officials to assess if his role was in line with US government regulations regarding present and former government employees.

Another intervention to discourage generic competition under the government use scheme was that the patent-holding companies threatened generic manufacturers. This tactic was employed by Sanofi-Aventis, owner of the Plavix® patent. On 25 August, the company reportedly sent a letter to the Indian drug producer, Emcure, claiming that Thailand had not introduced government use of patent for clopidogrel (The Nation 2007l). The letter threatened to sue the generic firm for civil and criminal offences under the Patent Act if it supplied Thailand with its clopidogrel product. In the same vein, a warning letter was sent by legal representative of Sanofi-Aventis to Bioscience Co. Ltd, sales agent for the Indian drug manufacturer in Thailand. They suggested that the Thai government had not yet enforced public use provision for clopidogrel, and those who infringed the drug patent would be subject to a criminal sentence as well as a civil action lawsuit (Kelly 2007). In this regard, the Thai FDA responded by sending letters to confirm the effective legal status of the government use for clopidogrel in Thailand to both Sanofi-Aventis and the Indian generic manufacturer (The Nation 2007l).

Abbott case

Similar to other patent holders, Abbott argued that the MOPH's decision to share medicine patents undermined their ability to fund the R&D of new products that ultimately benefit all patients. Unlike MSD and Sanofi-Aventis, however, Abbott introduced an 'unbelievable' strategy, as it cancelled applications to market seven of its medicines in Thailand in response to the government use policy (The Nation 2007a). These included anti-arthritis drugs and anti-hypertensive drugs, along with medicines for other conditions (table 10). Importantly, one of the applications was for Aluvia®, a heat-stable version of LPV/r which required no refrigeration. In addition, Abbott threatened not to register any of its new medicines in Thailand in the future. The company's officers said they had made such a decision because Thailand has *'chosen to break patents on numerous products, ignoring the patent system'* (Athersuch and Waldron 2007). This 'unprecedented' move by Abbott was criticized as

'cold-hearted' by treatment advocate groups around the world (Zamiska and Hookway 2007). As argued by Baker (2007), an American professor of law, *'The stakes of this boycott are death. It's hard to understand why a company that makes $1.1 billion a year from Kaletra sales is willing to kill people to secure more profits.'*

Table 10: List of Abbott's registration dossiers withdrawn from the Thai FDA in March 2007

Trade name	Generic name	Indications
1. Aluvia	Lopinavir-Ritonavir (fixed-dose combination)	HIV infection
2. Humira	Adalimumab 40 mg/0.8ml	Osteoarthritis, rheumatoid arthritis
3. Clivarine	Reviparin sodium	Thrombosis, thrombo-embolism, anti-platelet aggregation
4. Tarka	Trandolapril-Verapamil (fixed-dose combination)	Idiopathic hypertension
5. Zemplar	Paricalcitol	Hyperparathyroidism in chronic renal disorders
6. Brufen	Ibuprofen (suspension)	Fever and pain
7. Abbotic	Clarithromycin (granule for oral suspension)	Upper and lower respiratory tract infections; acute otitis media; cellulitis; folliculitis

Source: Food and Drug Administration, Thailand

On 10 April 2007, Abbott offered to cut the price of Kaletra by more than 55%, to 1,000 USD per patient a year, for 40 developing countries-this decision which was welcomed by patient groups and activists (Agence France-Presse 2007a). According to drug policy analysts, this intervention was introduced since Abbott came under fire after it decided to withhold the registration files of its 7 medicines in Thailand. It seemed that the WHO Director General, Margaret Chan, was a key player in this development. In the company's press document, the Director General and her role were highlighted:

> *'Abbott and WHO Director-General, Margaret Chan, have agreed on a balanced approach to provide Kaletra/Aluvia (lopinavir/ritonavir) capsules and tablets to more patients in the developing world, while supporting continued long-term biopharmaceutical research and development. In the interest of international public health, Director-General Chan approached Abbott to discuss how to improve affordability and access while maintaining incentives to support developing new medicines.'*
>
> (Abbott Laboratories 2007)

In Thailand, however, this offer was on the condition that the Thai administration revoked the government use of patent for its LPV/r product. A spokesperson for Abbott insisted, *'We are willing to have discussions to come to a solution, but we have not backed down on protecting intellectual property'* (Brotz quoted in Zamiska and Hookway 2007). It appeared this strategy could not resolve the dispute with the Thai government, as the proposal was not agreed to by the MOPH, because the Ministry considered that price reduction was not a sustainable solution for the HIV/AIDS problem. In addition, the company still refused to resubmit the applications to sell Aluvia® and other new medicines to the Thai FDA. From an AIDS activist's perspective, *'It's just a business tactic to make them look better.'* (Phurahong quoted in Zamiska and Hookway 2007). In the same vein, an MSF leader noted, *'Abbott's move was just another 'trick'* and *'there was nothing to guarantee that Thais could have access to the lower-priced drugs.'* (Cawthorne quoted in The Nation 2007a).

As part of worldwide protests against Abbott, on 26 April 2007, demonstrations run by NGOs, PHA groups, health professional associations and academic supporters, were organized in front of Abbott office, the American Embassy and the MOC, as well as in some business areas in Bangkok (Arunmas and Treerutkuarkul 2007). Thousands of copies of pamphlets were distributed to inform the public about the problem of unaffordable medicines in the country, and a campaign to boycott medicines and other products from Abbott was

launched in response to their action. Moreover, the protestors submitted a petition to the Internal Trade Department to investigate if the company's reaction had violated the Trade Competition Act, since the withdrawal of drug application dossiers without appropriate an reason might affect the opportunity of Thai patients to access new medicines.

The Thai activists' campaign against Abbott was supported by international and regional NGO alliances. Rallies to protest the drug firm's action took place, on 26-27 April 2007, in many countries, including the US (table 11). Petition letters calling for a boycott of Abbott's products was circulated via the Internet and other channels. The MSF (2007) asserted on its website on 11 April that it was *'increasingly frustrated by the crisis faced by people living with HIV/AIDS in Thailand and throughout the developing world who need vital second-line medicines.'* Many humanitarian organizations communicated directly with the company's administrators and shareholders. Among others, Health Action International (HAI) Africa, Ecumenical Pharmaceutical Network (EPN) and their partners sent an open letter dated 26 April to Abbott's shareholders in their annual meeting (HAI Africa and EPN 2007). These civic groups expressed their concern and their disappointment regarding the company's decision to withdraw the registration of its new drugs, including Aluvia,® in Thailand. Through this letter, sentimental information and messages were conveyed to the investors, for example:

> *'Indeed Abbott made a heart-stopping $1.1 billion on sales of Kaletra®, is a thrilling return on your investment. But if actions such as those by Abbott in Thailand are what go into making that profit and you consider the people whose lives are adversely affected by it, it really isn't so thrilling at all. We believe that by owning shares in a pharmaceutical company, not only do you want a sound investment, but you also want the assurance that the medicines produced are of benefit to all humanity irrespective of social and economic status. This noble aim is being lost on the altar of profit.'*
>
> (HAI Africa and EPN 2007)

Table 11: Protests against Abbott Laboratories around the world, 26-27 April 2007

Country	Events and activities
Thailand	The Thai network of people living with HIV/AIDS, the AIDS Access Foundation and allied organisations and individuals marched to the Thai MOC and through the streets of Bangkok. TNP+ has also initiated a global boycott of Abbott's products.
Argentina	There was a march in front of the US embassy (19 April) using the opportunity of the AIDS Forum.
Brazil	Activists protested in front of the U.S Consulate in Recife.
Canada	Activists held a demonstration against Abbott's policies in downtown Toronto sponsored by AIDS ACTION NOW! Toronto and Friends of Treatment Action Campaign North America.
China	AIDS activists faxed in hundreds of petitions in protest.
France	Act UP-Paris launched a campaign of protest against Abbott investors as well as an online effort to target Abbott. Thou sands of people simultaneously visited Abbot's website, making it unavailable for most of the day. Act Up-Paris received, in the afternoon, a fax from Abbott's lawyers threatening them with a lawsuit for "service denial".
Germany	Doctors and 8 major NGOs across the country kicked off a campaign to sign up their fellow physicians to refuse to meet with marketing representatives of Abbott.
India	There were various actions in Bangalore, Mumbai and several other regions. There were demonstrations outside the Abbott offices by PHA, lawyers, and doctors. In New Delhi, a large rally congratulated the Thai ambassador on the issuance of the Compulsory license.
Indonesia	A demonstration was held in front of the Abbott office in Jakarta.

Table 11: Protests against Abbott Laboratories around the world, 26-27 April 2007 (continued)

Country	Events and activities
Japan	The network of PLHA (Jan+) along with other Japanese civil societies sent a letter to the Abbott office in Japan and the USA and held a press conference.
Nepal	The National Association of PLHAs in Nepal held a protest, with support from its allies, in front of the US Embassy in Kathmandu and handed over a letter to Embassy officials.
South Korea	Seven groups of Korean activists gathered together in front of the Abbott office in Seoul, sending funeral flowers to Abbott in an act of grief and rage at the people killed by the greed of pharmaceutical companies.
Switzerland	The Ecumenical Advocacy Alliance (EAA) began distributing an "action alert" to all members in Europe and worldwide to ask that Abbott change its policies.
The United Kingdom	At Abbott's UK headquarters in Maidenhead, students Kingdom and supporters of the Stop AIDS Campaign assembled to tell Abbott that the 'games it is playing with people's lives' makes them sick.
The United States	Students, PHA, doctors, and other activists held protests States across the country. Protests were also staged in Washington DC, Texas, Chapel Hill and other communities across the US.
Chicago	Massive demonstration with activists from Chicago and Thailand protesting Abbott's withdrawal of drugs from Thailand.
New York	Members of Act UP-New York Magic Johnson, a spokesman for Abbott, at an event in Brooklyn. Johnson applauded the activists and promised to talk to the company.

Source: adapted from http://www.abbottsgreed.com index.php?title= Days_of_Action

The cancellation of new drug applications in Thailand and its consequences then provoked protests from the company's shareholders. In late March 2007, Christian Brothers Investment Services, and 13 other faith-based institutional investors, with approximately $35 million in Abbott Laboratories holdings, requested that the drug company immediately reverse its decision (Mitchell 2007). The investors argued, *'To our knowledge, no pharmaceutical company has before withdrawn AIDS drugs in response to a pricing or licensing dispute. By keeping life-saving medicines like Kaletra off the shelves in Thailand, Abbott Labs is threatening the health of Thais who need access to these drugs for survival.'* According to the shareholding organisations' statement, they were disappointed that the company could not reach any agreement with the Thai administration which would enhance access to affordable products among Thai PHA. The group further emphasised, *'We believe that Abbott's actions are creating a precedent for pharmaceutical industry behaviour which we can not endorse.'*

Signed by the 14 religious institutional shareholders, a letter to Miles White, Abbott's Chief Executive Officer, dated 16 April 2007, pointed out that the management's sanctions over Thailand *'could damage the company's reputation and hurt business prospects in developing countries'* (Agovino 2007). It was also argued that the price reduction of Kaletra in 40 developing countries, including Thailand, though constructive, would have a limited impact (Gozen et al 2007). These organisations expressed their concerns about a number of unresolved issues including the dispute on the withdrawal of drug dossiers in Thailand, and recommended that the registration of all Abbott products in this country resume. This group of shareholders also urged the Chief Executive Officer to actively carry out the promising agreement with the WHO in order to meet the needs of stakeholders, including patients in resource-poor settings.

Eventually, on 24 April 2007, Abbott's Chief Executive Officer, Miles White, announced that his company would reinstate the registration dossier of Aluvia®

in Thailand (The Nation 2007a). A new price for the drug, which was lower than any generic version, would also be offered. Nevertheless, the company still asked the Thai Health Ministry not to enforce the government use provision on its product: '*...in the name of access for patients, we offered to resubmit Aluvia® at our new price, which is lower than any generic, provided they wouldn't issue a compulsory licence*' (White quoted in The Nation 2007a). The company's proposal was not accepted by the MOPH, and the importation of generic products under the government use plan would be pursued.

USA for Innovation

Although a group of business lobbyists - the so-called the 'USA for Innovation' -defined themselves as an NGO, evidence regarding their role and activities suggested that these actors had a close relationship with the multinational pharmaceutical industry[9]. As asserted on its website, *'USA for Innovation is a non-profit organization dedicated to the protection of intellectual property and continued innovation around the globe. USA for Innovation educates decision makers, the media and general public about threats to innovation.*' The main action of this lobby group was the dissemination of information against the public use of medicine patents in Thailand via the internet, at http://www.usaforinnovation.org, and other public media.

On 10 May 2007, USA for Innovation launched its advertising campaign, accusing Thailand over its *'theft of American and European medical technology*' which would negatively affect poor and sick people in the country (Asia Net News 2007a). The full-page advertisement in two Bangkok-based English newspapers, The Bangkok Post and The Nation, criticized the actions of the

[9] The literature suggests that NGOs in the health sector are not-for-profit and concerned with public interests. Industry associations are not NGOs in this sense. The term 'non-profit' is somewhat questionable in such case. On some occasions, organizations of this type are funded by industry and may strictly not make a profit but represent profit-making bodies.

Health Minister by saying that they would undermine jobs, and risk investment and access to safe medicines for the Thai population. In late April, a similar ad was also published in the Wall Street Journal, claiming, among other things, that Thailand *'stole'* three medicines produced by American and European companies (Maneerungsee and Arunmas 2007). In addition to the newspaper ad, USA for Innovation introduced an internet programme on the website ThaiMyths.com (http://www.thaimyths.com) (Asia Net News 2007b). During the period 7 to 18 May 2007, the website released information regarding the ten *'myths'* by the Thai Health Minister, with the aim to *'draw attention to the deceit in Thailand's decision to steal American and European innovation.'*

In addition, USA Innovation sent an open letter to the US Secretaries of State, Commerce and Health in order to get the administration to place pressure on Thailand to desist patent violation. The letter also suggested that the Washington government should introduce economic and military sanctions over the Thai government use of drug patents (Manager 2007h). The business lobbyist group, as stated in its letter to USTR's Susan Schwab, on 23 April 2007, was concerned about the Thai action, stating that it was inconsistent with their obligations under the TRIPS agreement (Adelman 2007). It was maintained that:

> *'While the government of Thailand's inability to enforce intellectual property protections is troubling enough, the Minis try of Health has taken a sharp turn for the worse in announcing its intentions to issue government-use compulsory licenses ... The important distinction between theft of American assets on the streets of Bangkok and theft of American assets in Thailand's public health care system is that the latter is sanctioned, endorsed and promoted by the government of Thailand.'*
>
> (Adelman 2007)

When the USTR's 2007 Special 301 report was released on 30 April 2007, the USA for Innovation issued a statement welcoming the US government's decision to downgrade Thailand to the PWL, as this developing country was a 'global abuser' of American intellectual property rights (USA for Innovation 2007).

Figure 8: Complete text of the advertisement of the USA for Innovation, 10 May 2007

The Wrong Prescription for Thailand

Thailand is refusing American and European medical technology at the expense of the poor and sick of Thailand. These actions hurt jobs and investment in Thailand.

Thailand is now the only country in Southeast Asia on the U.S. Government's PWL.

Investor confidence in Thailand has plummeted since the announcement to compulsory license American and European drug patents.

Groups in the United States have demanded tariffs and sanctions on major exports from Thailand such as shrimp and gems.

Even worse, these actions hurt Thai patients. Most of Thailand's AIDS patients will not have access to the world's best medicines. Instead, the Thai government will provide locally manufactured drugs that have not even been approved by the WHO.

A 2005 study by Mahidol University found that GPO-vir, a copy HIV treatment made by GPO, had between 39.6% and 58% resistance. This is one of the worst cases of HIV drug resistance in the world. The people of Thailand deserve safer medicines and better public health policy from their leaders.

We Urge the Leadership to Protect the People of Thailand.

Source: Asia Net News, 10 May 2007

The advertisement, publicized by USA Innovation, stirred opposition from health advocates, who supported the use of TRIPS safeguards, such as the MOPH; NGOs and experts, who condemned the information as being inaccurate and misleading. As GPO administrators argued, for instance, the assertion that owing to the poor-quality production processes of the GPO, the use of GPO-Vir caused a high resistance of between 39.6% and 58%, making it *'one of the worst cases of HIV drug resistance in the world'* was wrong, since scientific evidence suggested that a resistance rate of only 20% had developed among patients receiving the medication (Treerutkuarkul 2007a). Wichai Chokevivat, chairperson of the GPO's Executive Board, believed that this lobbyist group *'intended to mislead the public by mixing up information to convince the public that the rate of resistance is among all people living with HIV in the country'* (Chokevivat quoted in Sathirawattanakul and Hongthong 2007). Chokevivat told the press that he and the GPO's legal team were considering taking legal action against USA Innovation as its campaign had distorted some information and damaged the GPO's reputation.

According to experts on pharmaceutical policy, the dissemination of misleading information through English-language newspapers by the lobby group aimed to target well-educated audiences, including some business entrepreneurs, especially shrimp and jewellery exporters who obtained tariff privileges from the US GSP (Treerutkuarkul 2007a). As asserted by a leader of the AIDS Access Foundation, however, there was a positive point in the USA for Innovation campaign: *'Read it carefully, you will see the advertiser's self-interest. It pretended to be concerned about Thai Aids patients but intended to provoke them into using its brand-name drugs.'* (Ungpakorn quoted in Treerutkuarkul 2007a). Moreover, the lobby group's advertisement played an important role in spurring responses from different institutions, both inside and outside the country. Among others, 16 health advocate organizations and consumer protection groups wrote an open letter to support the Health Ministers of Thailand and Brazil and urge the pharmaceutical industry and its representatives to stop abusing their power (Kijtiwatchakul

2007a). In addition, public relations campaigns and official dialogues with the media and the lobbyist group were instigated by the Thai MFA to counter the false claims (Ministry of Foreign Affairs 2007).

According to one AIDS activist, the executive director of USA for Innovation, Ken Adelman, was a senior adviser to Edelman Public Relations. This activist further claims that this company, Edelman Public Relations, was used by not only the patent-holding companies of three products under government use programme in Thailand: MSD, Abbot and Sanofi-Aventis, but also the ousted Prime Minister Thaksin Shinawatra (The Nation 2007k). However, as this health advocate argued, there was no evidence of a relationship between the ex-premier and the *'misleading'* campaign on the Thai action. Actually, the suspicion about the true objectives of USA Innovation was originally raised by an internet watchdog, 2Bangkok.com, as the lobbyists' website addressed some political issues which were strange for a group that was concerned with pharmaceutical patents (2Bangkok.com 2007a). These included, for instance, the articles focusing on 'Slouching towards Burma'; 'Radical new regime'; 'Military Dictator'; and 'targeted disappearance in the deep South'. Moreover, this website had scarcely released any press information before April 2007, although it was claimed that the date of establishment was in 2005. As the 2Bangkok.com put it, *'USA for Innovation was the fake lobbying site set up by PR company Edelman to pressure the Thai military junta. The site pretended to have a long history with many press releases on an on-going mission to target Brazilian and Thai compulsory licensing'* (2Bangkok.com 2007b). Finally, both USA for Innovation and its sister, ThaiMyth.com, websites disappeared in late May 2007.

8. Non-governmental organisations as key players

The introduction of government use provision in Thailand was welcomed by both the local and global health communities. Patient and caregiver groups, health and HIV/AIDS NGOs, human rights advocates and health care

specialists applauded such a 'brave and correct' decision. As mentioned in an earlier section, NGOs have played a crucial role in HIV/AIDS policy, including access to ARVs and medicines for opportunistic infections in Thailand, for a long time before the enforcement of public health safeguards in 2006-2007. International and domestic NGOs, including PHA networks, humanitarian organizations, philanthropic foundations and expert alliances, remained key players when government use provisions were introduced in this middle-income country.

As suggested by public policy scholars such as Hajer and Wagnaar (2003), to address globalisation and increasingly fragmented sources of political power across societies, the government and non-governmental actors need to exchange and share policy resources with each other. In the introduction of government use for medicines in Thailand, civil society organizations possessed different sorts of resources which were insufficient or not available in the public sector. By this, the supporting roles of NGOs in this public health policy, as well as their contributions, were substantial. It was evident that the civic coalitions participated in the policy processes in a number of ways. First, NGOs and academic networks were key players in the policy agenda setting. It was the civic members of the National Health Security Board that raised the issue of public health safeguards under the TRIPS agreement to be discussed in the meeting in January 2006 (Jamniendamrongkarn 2006). It could not be denied that the NGOs' arguments drew the intensive attention of other Board members to the problem of inadequate access to medicines in the country, as well as the use of TRIPS flexibilities as a potential solution.

Second, the civic networks helped to legitimize the use of TRIPS flexibilities. Letters, statements, assertions and different forms of information campaigns could contribute to a better understanding of the justification of the Thai action among the general public. Given that IP, international trade agreements and public health safeguards were complex and usually confusing for lay people who were not familiar with the intentions, contents and interpretations

of related rules and regulations, without NGOs' interventions, the public could have accessed only the information from the opponents of the TRIPS flexibility provision. The civic groups' interpretations of the government use of patents for ARVs and drugs for heart disease, for example, *'as evidence of the government's commitment to tackling the AIDS crisis'* (American Jewish World Service 2007) and *'Thailand has shown the world what it means to place public health over commercial considerations'* (Weisman quoted in Ashayagachat and Treerutkuarkul 2007), was also helpful in enhancing the image of the Thai government and its policy to ensure access to essential medicines.

Third, NGOs' movements provided direct and indirect moral support to the Thai administration. The announcement to implement the government use measure prompted an expression of appreciation among international and domestic NGOs and PHA networks. For instance, an MSF officer, Ellen Hoen, (quoted in Agence France-Presse 2007b) said at a press conference in Bangkok in early February 2007, *'We fully support Thailand's decision. What Thailand is doing is exactly what WTO members agreed in 2001.'* In addition, James Love, from the US-based KEI, hailed the Thai decision: *'Thailand's government is trying to do something for people who need treatment. We expect Thailand will issue other compulsory licences for medicines in the future'*. The Clinton Foundation also expressed its support for the use of TRIPS safeguards to ensure more access to affordable anti-HIV medicines, and also pointed out that *'...in the worldwide market for antiretroviral drugs, patent holders derive roughly 90% of sales from high-income nations, largely in America and Europe.'* (Magaziner 2007). In the same vein, local NGO leaders, such as Wirat Purahong (quoted in The Nation 2007g), chairman of the Thai Network of People Living with HIV/Aids, maintained, *'The government's compulsory-licensing move wins our full support. This is a move to manufacture life-saving medicines. Thailand needs to move on, because this is the hope of countries all over the world'*.

When the pressure, from pharmaceutical companies and governments from powerful nations, on the Thai Minister of Public Health was rising notably, *'health activists are riding to his defence'* (Schuettler 2007). It was also reported that NGO leaders and staff visited government offices on several occasions. For example, PHA coalitions, led by the Thai Network of People Living with HIV/AIDS, called on the Public Health Minister after Thailand was placed on the US' Special 301 PWL on 30 April 2007 (The Nation 2007g). When Abbott withdrew the registration applications of new medicines from the Thai FDA in March 2007, representatives from the MSF and British-based Oxfam met senior health officials to show their support for the ministry's drug access policy (Treerutkuarkul 2007h). Moral support was also offered to the Thai administration by regional NGOs. On 25 April, the Working Group on Intellectual Property (GTPI) and the Brazilian Network for the Integration of Peoples (REBRIP), together with 80 health advocates organizations, issued an open letter to express their solidarity with the people of Thailand:

> *'It is time to unite all those who have always defended the use of TRIPS' flexibilities, which can be invoked in the name of protect ing public health, as is the case of compulsory licenses. Together, we must publicly denounce Abbott's grave attitude that is harmful and disrespectful to the Thai people.To provide unlimited support for Thailand on this issue means to support the urgent need of all countries to put health before the profits of multina tional pharmaceutical companies.'*
>
> (GTPI and REBRIP 2007)

Fourth, civil society organizations, including academics in the fields of law, health and pharmaceutical science, contributed technical expertise to policy development and implementation. Evidence-based arguments, campaigns and demonstrations organized by NGOs and individual experts around the world, were crucially beneficial to the Thai policy. As discussed earlier, the WTO's

regulatory frameworks on IP protection and related agreements on international trade were complex and not well understood among the public. This was true even for health officials involved in the use of safeguarding measures. Almost every time the MOPH was attacked by patent-holding companies, lobbyists and their governments questioned the legitimacy and legality of the use of TRIPS flexibilities, while NGOs and law specialists delivered counter information through press releases and other channels, including the Internet. Illustrations could be drawn when the Thai administration was accused by PReMA, Abbott Laboratories, USA for Innovation, and the EC Trade Commissioner. In particularly, letters from American professors of Law to provide clarification concerning several controversial elements raised by the medicine industry and their lobbyists (Baker 2007; Flynn 2007) were influential. At the same time, the roles of experts from Thailand and other developing countries, for example, Chulalongkorn University's Jiraporn Limpananont, Wollongong University's Jakkrit Kuanpoth, and the University of Buenos Aires' Carlos Correa, were very relevant, not only in the government use of medicines in Thailand, but also in many other health-related IP forums.

Fifth, health activists and civil society networks organized demonstrations, public discussion and different sorts of campaigning activities at local and international levels. As argued by health officials and NGO leaders, these movements contributed considerably to the use of TRIPS flexibilities in Thailand, as they were effective in fostering an understanding of the difficult issues and mobilizing support from a broad range of stakeholders both inside and outside the country.

Apart from disseminating messages on their position to support the use of TRIPS safeguards, in some instances, these civic alliances communicated directly with particular actors, for instance leaders of international

organizations; politicians, legislators and public officers of industrialized countries; drug companies; and the media, for a variety of different purposes. For instance, in December 2006, the Consumer Project on Technology (CPTECH) and the MSF asked the US Secretary of State and the USTR to refrain from any opposition or interference with the Thai efforts to exercise their rights in accordance with the WTO agreements (Cawthorne 2006; Love 2006). As argued in the CPTECH's correspondence, *'The United States should not pressure Thailand on the issue of issuing compulsory licenses on patents for AIDS drugs. It should accept the fact that Thailand, like all WTO members, has an obligation to take measures to promote access to medicines for all.'* Furthermore, in March 2007, health advocacy groups, led by MSF officer Paul Cawthorne, urged the WHO and UNAIDS to take action in support of poor countries to broaden access to essential medicines via the enforcement of government use measures, despite pressure from the pharmaceutical industry and the governments of industrialised nations (Treerutkuarkul 2007h). The group members expressed their dismay over the lack of a clear policy stance and inadequate assistance from the two leading health agencies on this issue. Recently, in September 2007, over 100 organisations of consumers, labour, fair trade, health advocacy and religious groups urged the US Congress to support resolutions which reaffirmed the US commitment to international agreements that promote access to medicines in developing countries (Silverman 2007b).

Finally, domestic NGOs and PHA coalitions had a role in monitoring and, to a certain extent, overseeing the moves of Thai government agencies involved in international relations, trade and IP. These included not only some departments under the MFA and MOC, but also the MOPH and the NHSO, which were responsible for the implementation of TRIPS safeguards. Frequently, these civic groups urged the MFA and MOC to provide strong support to the Health Ministry's efforts to enhance access to affordable medicines for the Thai people, and not to surrender to pressure from

industrialised nations and multi-national drug companies (The Nation 2007k). In addition, these activist and PHA networks *'kept an eye on'* the MOPH's and NHSO's governmental committees regarding the selection of essential patented medicines for the government use programme, drug price negotiations with patent-holding companies, and decisions to import generic products from particular medicine producers (Treerutkuarkul 2007b).

9. Immediate benefits of the enforcement of government use measure

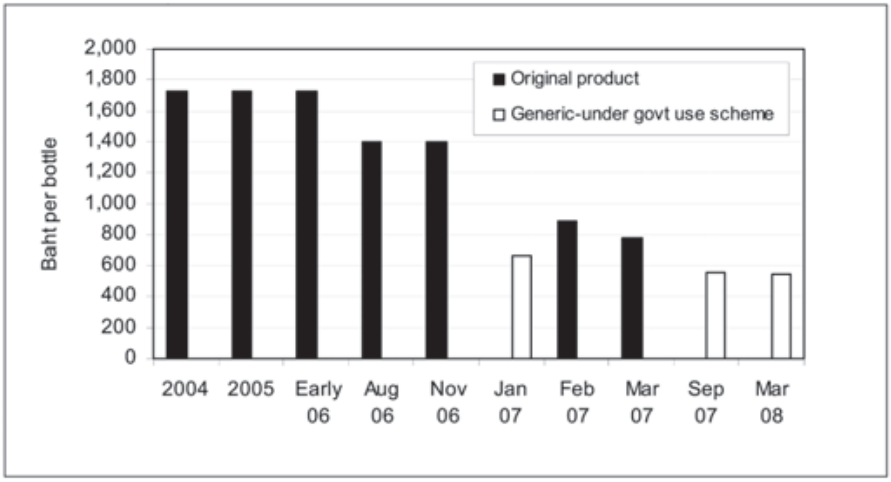
The introduction of government use provision for medicines in any settings is aimed for improving access to particular products among people in need. The public health goal of using TRIPS safeguards can be met through the alleviation of monopolistic right granted to patented medicines, enhanced accessibility to affordable, generic versions and associated reductions in the medication costs. In many instances, however, a public policy is not translated into action as effectively as policymakers have expected, so that its beneficial implications cannot be achieved. This section discusses the immediate, desirable consequences of the enforcement of the public use provision by the Thai administration, including the direct and spill-over effects of such a government action.

9.1 Beneficial implications for Thailand's health systems

As mentioned in section 4, by June 2008, significant amounts of generic EFZ, LPV/r and clopidogrel had been imported from three Indian manufacturers, namely Ranbaxy, Matrix and Cadila, under the government use initiative (see also table 7). Price reductions for the three medicines were offered by the patent-holding companies: after the policy to use the TRIPS safeguard was announced, the three multi-national firms met with a MOPH committee, where several rounds of price negotiations regarding the original drugs were undertaken (The Nation 2007h; Treerutkuarkul 2007d). However, the decrease in drug prices could be observed before the government use provision was

introduced. Prices of Stocrin® purchased by the Thai Disease Control Department dropped from 1,723 baht per 30 tablet bottle in early 2006 to 1,400 and 777 baht per 30 tablet bottle in August 2006 and March 2007, respectively (figure 9). Despite this, generic EFZ imported by the GPO during 2007 was cheaper than the patented product. Figure 10 shows the price evolution of original and generic EFZ distributed in developing countries during 2002 to 2007 comparing to those purchased by the GPO under the government use initiative in 2007. This suggests the lower cost per patient per year of the Indian EFZ tablets than when Stocrin® was prescribed. The cost of the generic product under the government use plan dropped from 179 USD per patient per year in January 2007 to 161 USD per patient per year in March 2008- slightly lower than those of the WHO-prequalified generic EFZ.

Figure 9: Prices of EFZ 600 mg tablets, original product purchased by the Department of Disease Control, and generic version purchased under the government use scheme (baht per 30-tablet bottle)

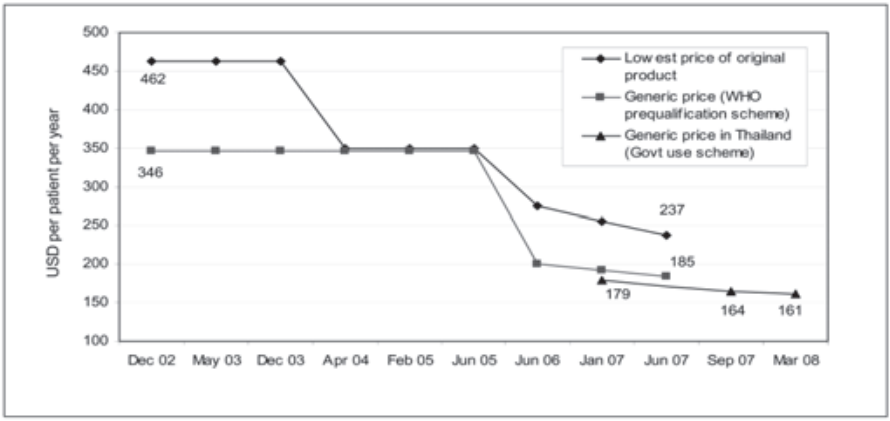


Sources:

(1) Department of Disease Control, Ministry of Public Health [on the prices of original product]

(2) Government Pharmaceutical Organization, Thailand [on the prices of generic product purchased under the government use scheme]

Figure 10: Prices of generic and original EFZ 600 mg tablets distributed in developing countries, comparing to those purchased under the Thai government use scheme, 2002-2008 (USD per patient per year)



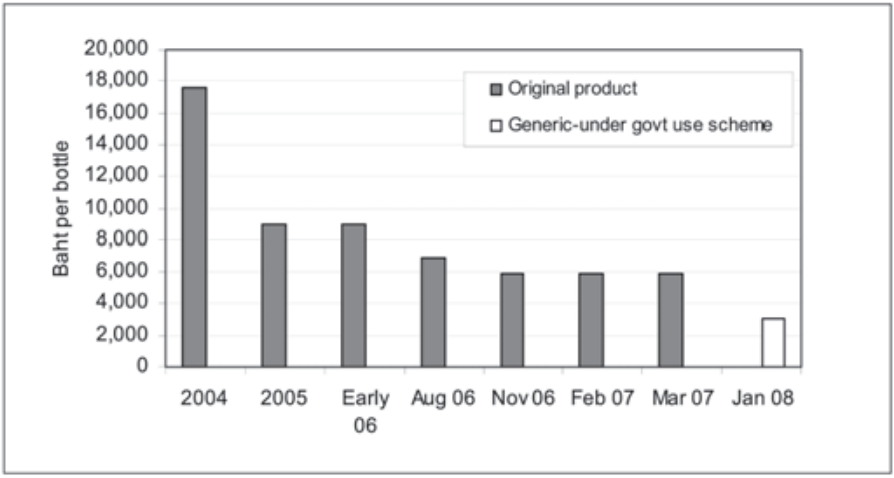
Sources:

(1) *Medicins Sans Frontieres. Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries 10th Edition, July 2007 [on the lowest prices of original product and prices of generic products purchased under the WHO prequalification scheme]*

(2) *Government Pharmaceutical Organization, Thailand [on generic prices under government use scheme in Thailand]*

In similar vein, the introduction of government use policy resulted in the price reductions of LPV/r prescribed in the national ART initiative. Price of Kaletra® purchased by the Disease Control Department in November 2006 was slightly lower than that in August of the same year (figure 11). As the negotiations between the MOPH and Abbot continued, lower prices of the patented medicine were offered on the condition that the MOPH would cancel its government use policy for this drug (figure 12). However, the company's proposal was not accepted, and the generic product was imported from Matrix in January 2008, at a half price of its original.

Figure 11 : Prices of LPV/r capsules, original product purchased by the Department of Disease Control, and generic version purchased under the government use scheme



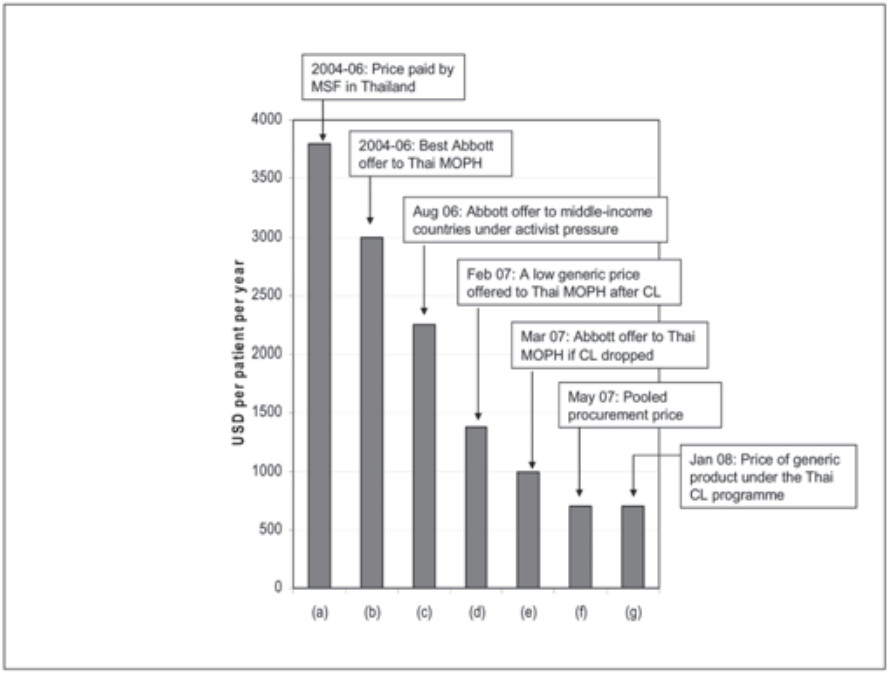
Sources:

(1) *Department of Disease Control, Ministry of Public Health [on the prices of original product]*

(2) *Government Pharmaceutical Organization, Thailand [on the prices of generic product purchased under the government use scheme]*

Note: Original product: one capsule contained 133.3 mg of LPV and 33.3 mg of ritonavir, and one bottle contained 180 capsules; generic product: one capsule contained 200 mg of LPV and 50 mg of ritonavir, and one bottle contained 120 capsules

Figure 12 : LPV/r costs per patient per year in middle-income countries including Thailand, 2004-2008



Sources:

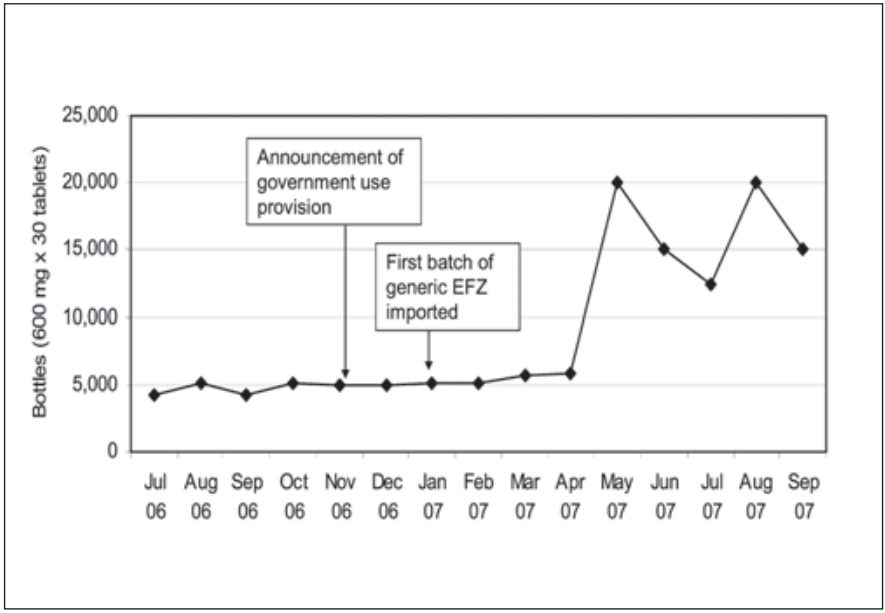
(1) *Medicins Sans Frontieres. Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries 10th Edition, July 2007 [on (a) to (f)]*

(2) *Government Pharmaceutical Organization, Thailand [on (g)]*

The volume of EFZ 600 mg tablets distributed through the three major health benefit plans rose from 5,000 bottles (30 tablets) per month in 2006 to 12,500-20,000 bottles per month between May and September 2007 (figure 13). The increase in the quantity of LPV/r capsules requested by hospitals to be prescribed through these publicly-financed schemes could also be observed, even during 2007, before the importation of generic product under the government use initiative. This was because health providers recognized the

changes in the national ART policy that allowed the use of this second-line regimen in eligible cases, and that this previously expensive medicine would become constantly accessible. According to the NHSO's report on 15 May 2008, approximately 15,000 to 18,000 PHA were receiving these EFZ products in public health care settings, and the number of those obtaining LPV/r accounted for 1,400.

Figure 13 : Volume of EFZ distributed through the 3 major publicly-subsidized health benefit plans, before and after the introduction of government use provision



Source : National Health Security Office 2007
Note : the quantity of EFZ shown in this figure refers to the volume requested, in particular months, by hospitals for the beneficiaries of the 3 health benefit plans

The above information on the price reductions, increased volume of EFZ and LPV/r distributed through publicly-financed health benefit plans, and rising number of patients receiving the medicines indicates, to some extent, the

broadened access to the two ARVs as a consequence of the government use provision. However, these figures provide only a brief picture of the immediate, positive effects of the Thai action. Further research should be carried out for better understanding of these implications, for instance, by employing methodologies in particular disciplines such as health economics, financing and pharmaceutical management to explain the real changes in medicine prices, distribution and accessibility. Moreover, studies to provide empirical evidence on other associated health and economic benefits such as those in terms of survival, quality of life and productivity of medication recipients will be helpful to inform policy development in the future.

9.2 Spill-over effects of the Thai action

Apart from the direct implications on the broadened access to the three medicines, the announcement of the intention to use TRIPS safeguards generated some positive spill-over effects. These included:

- Price reductions of Stocrin® and Kaletra® worldwide;
- The increasing attention of stakeholders and the public to the issues of IP and access to medicine; and
- Inspiring other developing countries to follow suit.

MSD and Abbott offered discount prices of their products. In mid-February 2007, MSD cut the price of EFZ by 14.5%, to 65 cents per day, or 237.25 USD per patient per year, from 0.76 USD per day, for Thailand and other developing countries with high HIV prevalence (Merck & Co. 2007). Following the Financial Times' analysis, such an action aimed to convince the Thai MOPH to stop imposing government use provisions for the importation of the Indian-made generic EFZ. The company offered this new price to the Thai Disease Control Department, however, with several conditions. For instance, there would be no Vending Management Information system implemented; purchased drugs could not be returned to the company; payment must be issued within one month; and the drug had to be ordered 4

months in advance. With regard to LPV/r, on 10 April 2007 Abbott announced that the prices of Kaletra® and its heat-stable version, Aluvia®, would be cut by over 55%, to 1,000 USD per patient per year, in 40 developing countries, including Thailand (Abbott Laboratories 2007). By offering this, the company hoped to reach a deal on price with the MOPH, and at the time preserve its patent (Zamiska and Hookway 2007). Although this move of the company did not settle the dispute with Thailand, as the Thai government disagreed with the condition to cancel the government use of patent for LPV/r, the price reduction would contribute to substantially increase access to LPV/r in many HIV-afflicted settings.

The enforcement of government use measure in Thailand also had other positive repercussions for other resource-poor settings, not only in terms of a price reduction of the two ARV products. It was believed that the Thai move might bring attention to the issues of IP, drug costs, inadequate access to drugs and TRIPS flexibilities among developing countries, as well as other stakeholders, including the WHO, NGOs, and the pharmaceutical industry. After the government use policy was announced by the Thai administration, some middle-income countries, such as the Philippines, Kenya, Malaysia and Indonesia, began to work out plans to contain drug costs by employing different means including debating or implementing legislation that would permit overriding patents in particular circumstances (Silverman 2007a; Zamiska and Hookway 2007). The Thai Health Minister revealed that Brazil and five other developing countries had asked him for information on how the MOPH had managed to introduce the government use provision (Arunmas and Treerutkuarkul 2007). A senior administrator of the NHSO (quoted in Kijtiwatchakul 2007b:35) maintains that the international attention drawn to IP and health issues rapidly transformed into solidarity among supporters of the Thai policy: '*...the impact was, as expected, not limited to a national level. But the positive side of it was the emergence of the solidarity of the global*

community. Previously, I had expected some support for our compulsory licensing efforts, but had never thought it would be this extensive.' This is an illustration of how globalization can be harnessed for the good of public health.

Furthermore, the use of TRIPS flexibilities in Thailand was an important test, not only of the TRIPS agreement and Doha Declaration, but also of the WHO's stance and leadership to provide support to developing countries that had implemented public health safeguards and been retaliated against by powerful vested interests (Bangkok Post 2007c). In several forums within WHO, such as the meeting of IGWG on Public Health, Innovation and Intellectual Property, and the WHA, the enforcement of TRIPS safeguards in Thailand was raised as an illustration of the inefficient mechanisms of the current WTO system and requirements for interventions to fulfil public health needs. Thailand's bravery was also highlighted by health activists to encourage other developing countries to follow suit. For example, it was argued in a newspaper article, directly sending a message to African nations:

> *'The AIDS epidemic will constitute the single greatest loss of life in modern history. It is impossible for us in the West to conceive of death on such a scale. Far more difficult to understand, however, is the arbitrary nature of this holocaust: The drugs exist, why can't people have them? African countries should find the resolve to follow Thailand's example and grant compulsory licenses when they see fit. In so doing, they would put an end to a drug monopoly whose human cost brings shame to us all.'*
>
> (Santoro 2007)

As of November 2007, Brazil had been the sole developing country that invoked TRIPS safeguards after Thailand enforced its government use policy. On 4 May 2007, the Brazilian government authorised the country to sanction the CL on EFZ (Shashikant and Tayob 2007). This decision was made after the

failed negotiation with MSD. The company offered to lower the price per tablet from the current 1.59 USD to 1.1 USD (BBC 2007). However, Brazil wanted a price of 0.65 USD per tablet, which was similar to the price proposed to Thailand. Brazil would import a cheaper generic version at the price of 0.45 USD from an Indian drug producer. Brazil was in a very similar situation to Thailand: the country had a domestic pharmaceutical industry and provided universal access to treatment to PHA (Steinbrook 2007). Also, generic, first-line ARVs were produced by a number of government laboratories. Price negotiations, backed by the threat to impose CL and local generic production, had been the main strategy used by the Brazilian government to lower the price of patented ARVs, from approximately 4,350 USD per patient in 1999 to 1,517 USD in 2004 (Ford et al. 2007). As of June 2006, an estimated 186,000 Brazilian people received ART (Steinbrook 2007). The cost of ARV medication in the country had increased substantially, which reflected the needs for costly second-line medicines. Brazil had threatened several times to break patents, but had always reached agreements with drug companies (Silverman 2007a). The use of CL for anti-HIV medicine in Brazil caused *'profound disappointment'* to MSD, and sent a *'chilling signal'* to the research-based drug industry which might be discouraged to undertaking 'risky' research on diseases that affected the developing world. Meanwhile, the US Chamber of Commerce pointed out that the Brazilian's move would likely cause investment in innovative industries that relied on IP to go elsewhere (Silverman 2007a).

10. The way forward

As stated in the introduction of this report, the focus of this study is the first-ever use of TRIPS safeguards for essential medicines in Thailand in late 2006 and early 2007. The analysis includes the policy processes and related factors from the first phase through until the end of September 2007. However, as the introduction of TRIPS flexibilities in this middle-income country, and its consequences, continue beyond the study's timeline, this section provides initial discussion on the future development of the Thai government use policy.

10.1 Anticancer: medicines in the government use pipeline

While the Thai administration was busy with the tasks of devising and undertaking different activities to counter the obstacles in enforcing the public use of patents on EFZ, LPV/r and clopidogrel, the NHSB's Subcommittee on the Selection of Medicines to Government Use Programme still functioned. The profiles of many drugs necessary to solve the country's health problems were reviewed by physicians and expert members of the Subcommittee. In August 2007, the NHSB appointed a new panel to select essential drugs and medical devices with problems of inadequate access among beneficiaries of the three public health benefit schemes (National Health Security Office 2007c). This Subcommittee superseded the existing one. The medicines selected by the new panel would pass through any effective channels, not only the government use programme, to enhance access to them.

Although the members and missions of the new Subcommittee differed slightly from the former, its work was not interrupted. In a meeting on 20 September 2007, four medicines for the treatment of cancer were recommended to the NHSB and MOPH (table 12). From October, meetings to discuss price reductions with the drug producers were convened by the MOPH's Committee on Drug Price Negotiation. Pooled procurement, voluntary licensing, donation schemes and other possible measures to bring the prices down were taken into account (Food and Drug Administration (Thailand) 2007a). As of the end of November 2007, the Committee had not yet agreed on the prices and conditions proposed by the drug companies. However, the prices of the four products, as offered by the industry, became significantly lower, when compared to their initial prices (Tunsarawuth 2007).

Table 12: List of anticancer medicines suggested by the NHSB's Subcommittee as essential, inadequate-access medicines, September 2007

Medicine	Trade name and producer of the original product	Indication	Price (baht)	
			Original product	Generic product
Imatinib tablet	Glivec/Novartis	Leukemia, Gastro-intestinal Stromal tumor	917 per 100 mg tablet	50.20-70.00 per 100 mg tablet
Docacetel injection	Taxotere/ Sanofi Aventis	Breast and lung cancer	25,000 per 80 mg vial	4,000 per 80 mg vial
Erlotinib tablet	Tarceva/Roche	Lung cancer	2,750 per 150 mg tablet	736.00 per 150 mg tablet
Letrozole Tablet	Famara/Novartis	Breast cancer	230 per 2.5 mg tablet	6.00-7.00 per 2.5 mg tablet

Source: Minutes of the Subcommittee to Select Essential Medicines and Medical Devices with Problems of Inadequate Access in Public Health Benefit Plans, 20 September 2007

Seemingly, the Thai administration had indicated plans to negotiate with the pharmaceutical industry, as it decided to pursue affordable medicines through negotiations prior to the introduction of government use of patents. According to an MOPH source, although the government could bypass negotiations with the patent holders and immediately announce the government use provision on these drugs, it intended to provide an opportunity to the companies to cooperate (Manager 2007c). If, at the end, the proposed prices remained unaffordable in view of the Committee, the Ministry would introduce the government use of the patents, by importing generic products from India. It is noteworthy that for these anticancer drugs, the MOPH would accept the original products at prices of not over 30% higher than the generic versions' a much less stringent position than the existing 5% benchmark set for other medicines. It was not until January 2008 that the Health Minister, Na Songkhla, signed a Ministerial Notification to declare the intention of imposing

government use of patents for the four anticancer medicines on the list suggested by the NHSB Subcommittee (Ministry of Public Health 2008a; 2008b; 2008c; 2008d).

10.2 Government's plan on local drug production

In parallel to the implementation of government use for the first three medicines, the Thai administration tried different ways to ensure long-term access to essential drugs for the population. The Public Health Minister said in an interview in February 2007 that the medicines under the government use scheme had to be imported from India, and *'when everything is ready*' the country would produce the drugs itself (Gerhardsen 2007). The capacity of the state laboratory, the GPO, was strengthened as an element of the intergovernmental collaboration with Brazil and Argentina, in accordance with the agreement signed in August 2007.

In addition to the partnership with other state governments, there were plans for a technology transfer from private drug producers in India. In October 2007 the GPO sought collaboration with Hetero Drugs, an Indian pharmaceutical company, to improve its anti-HIV production plant in order to meet the requirements of WHO GMP standards (Eawphan 2007). In addition, the government laboratory planned to receive production technology for other medicines, including clopidogrel, influenza vaccines and heat-stable LPV/r through voluntary licensing deals with two other Indian firms, Emcure and Matrix, in late 2007 (Manager 2007f; Matichon 2007b).

10.3 Looking beyond the 2007 general election: will the government use policy continue?

An interesting question relating to the use of TRIPS flexibilities as a mean to ensure access to affordable medicines in Thailand was asked regarding the sustainability of this public policy. This query was drawn from the fact that

the introduction of government use provision was decided when the country was ruled by a temporary, military-installed, government. Several factors, such as pressure from the international drug industry and industrialized nations, and concerns about the country's image, made health advocates and their networks believe that this policy might be terminated when the new cabinet took office after the national election in December 2007. Furthermore, there were no political parties in Thailand that had taken a clear policy stance towards the issues of IP protection, its implications on public health, including the use of TRIPS flexibilities, and in particular the continuity of public health safeguard enforcement (Post Today 2007).

In August 2007, NGO and academic coalitions began to urge these parties to back the government use policy and include this TRIPS safeguard as part of the national agenda to provide access to cheap medicines (Sarnsamak 2007a). According to Achara Eksaengsri, deputy director of the Research and Development Institute of the GPO, it would be easy for the new government to issue CL for other medicines, since it had a model to follow and the policy had been proved successful in pursuing lowered-price drugs. Civic groups also asked politicians to spell out explicitly, during the election campaign, what their policies would be if they were elected and became administration or legislative body members (Post Today 2007). As Tienudom (quoted in Post Today 2007) stressed, *'We are monitoring closely if any political party pays attention to further the CL to ensure people's access to essential services.'* He further argued that, *'The point is, any new government must ensure it spends money to guarantee access to healthcare; the high price of drugs is a big issue for patients in this country.'* (Sarnsamak 2007b).

At a public forum held by NGOs in October 2007, a number of major political parties presented their proposals on health and welfare policy. The party representatives pledged to ensure peoples access to essential health services

and medicines; however, they expressed different view points on the means, particularly the use of CL (Bangkok Post 2007b). The Democrat party, the oldest political party in Thailand, vowed not to obstruct the implementation process of CL for *'truly'* essential drugs. Although the party stated that CL would be implemented as *'a way to solve the problem of high-cost medicines'*, this measure would only be taken as a last resort, and public hearings would be held to assess public opinion towards the issue. Meanwhile, the People Power Party personally supported the adoption of CL, but stated that the policy had to be agreed to by every party that formed the coalition government. In the same vein, a representative of the Chart Thai party, who was a former Health Secretary, pointed out that, *'I cannot promise whether the party would carry on with the CL policy. If the party is not in the government, it would be difficult to achieve it. Any decision by the party would be tied to national interest.'* (Bangkok Post 2007b).

After the general election in December 2007, a new coalition government, led by the People Power Party, came to power. On their very first day in office in February 2008, the new Minister of Public Health, Chaiya Sasomsub, informed the public that he would revoke the government use programme for the four anticancer medicines-an announcement that prompted strong opposition from NGOs and patient networks both inside and outside the country (Sarnsamak 2008; Sathitphattarakul 2008). Meanwhile, such a policy shift was supported by multi-national drug companies and those members of the local industry which had export ties with US trade counterparts (Arunmas 2008). The fear of the US trade sanction of Thailand being downgraded from the current PWL to the worst status of Priority Foreign Country (PFC) was raised to justify the new initiative. However, the public debates on the use of TRIPS safeguards for anticancer drugs ended in March 2008 as the Health Minister decided to continue the existing policy (Treerutkuarkul 2008).

11. Discussion, lessons learned and policy recommendations

The enforcement of government use provision for medicines in Thailand in late 2006 and early 2007 was a crucial policy innovation, not only in the country's health domain, but also in the global health arena. As only a few developing countries dared to share the patents held by powerful multi-national drug companies, several lessons can be drawn on the Thai experience regarding the aspects of public health and public policy.

11.1 Agenda setting and policy adoption

The move of Thailand's Health Ministry to enforce public health safeguards to address the unmet need for medicines might not happen in the absence of three supportive factors. First: the legal status of, and social support for, the use of TRIPS flexibilities. Evidence suggests that the effects of IP rights protection were one of the key barriers to essential health products in the developing world. At the same time, the movements to support the application of the existing solutions: the TRIPS flexibilities and the Doha Declaration on TRIPS and Public Health, had risen onto the global agenda. Member states of the WHO and WTO agree that public health interests must come before trade. Moreover, campaigns to broaden access to essential treatments run by NGO coalitions, especially in the HIV/AIDS field, had long been well established at international level and in many developing countries. In such circumstances, it could be anticipated that the introduction of government-use measures on the three patented medicines would gain wide support from the global community. Furthermore, the past experiences, with some successes, of local HIV NGOs overcoming IP-generated impediments in scaling up ART coverage might have fostered confidence among the civic networks as well as policy makers and respective health officials.

Second: the political commitment and demand for universal access to essential health care. As an integral part of national political reform, which was ensured by the Constitution of 1997, the rights of Thai people to fundamental public

services had been translated into many populist programmes over the past 5 years. This included the instigation of the UC scheme, one of the most popular policies of a previous government led by the Thai Rak Thai party. The rights to essential health care, and the responsibility of the administration to meet the rightful needs of its citizens, helped to justify the governmental action of introducing the TRIPS flexibilities.

Third: the political change after the 19 September 2006 coup de tat. The newly-installed, temporary government comprised non-politician ministers, selected not only for their expertise in particular fields, but also on good image, including reputation. The Health Minister, Na Songkhla, who also chaired the NHSB, was a former Health Secretary and rural doctor, with a record of being strong-minded, a sharp decision maker and dedicated to the well-being of people. It was his decision to rapidly promote the public health safeguard policy that prompted the corresponding actions of respective officials in two agencies: the MOPH and the NHSO. In addition, the Minister and his senior staff, as well as the Secretary General of the NHSO, had had long-term experience of the issue of IP and also good relationships with civil society organisations, including NGOs and PHA networks. All of these factors helped to facilitate the policy decision to pursue affordable medicines by implementing the flexibility measure.

The Thai government's decision to enforce government use for medicines was an unusual event, given that only a few developing countries had introduced this public health safeguard owing to the fear of retaliation by powerful industrialised nations. As Kingdon (1984) suggests, a considerable policy change takes place only when *'the window of opportunity opens'*, that is to say, at the time that problems are recognized, particular solutions are available, and the political atmosphere is conducive to a shift in policy agenda items. On many occasions, two of the three *'streams of problems'*, policy and politics, are brought about by the persistent effort of some interest actors-the so-called *'policy entrepreneurs'*. Although the problem of inadequate access to patented

medicines and its corresponding solution: safeguarding provisions according to the TRIPS agreement, had existed for many years, such a flexibility measure had not been implemented in Thailand before 2006. The introduction of government use of medicine patents in this lower middle-income country was decided by the new administration, after a sudden change in the political system. This is in line with Kingdon (1984) as he argues that new group of policy makers, including public committees and officers who possess different ideologies from the former ones, may raise novel policy options on to a governmental agenda, and therefore new policies are likely to be adopted. In the same vein, Baumgartner and Jones (1991) maintain that the shift in the policy making arena that allows new policy elites to dominate the policy decisions may lead to policy innovation. This is because these new interests have particular perceptions towards the problems and policy alternatives, which differ from previous governments.

11.2 Policy formulation and implementation

Public policy scholars assert that although policy studies require the simplification of policy processes into the four stages of agenda setting, policy adoption, formulation and implementation, policies in real life are so complex, dynamic and repetitive that they cannot be divided into distinct phases (Hill 1997). Thailand's policy to implement government use of medicine patents resembles this assertion, as its formulation and implementation activities were carried out back and forth in the same period.

It could be seen that the measures to facilitate the introduction of government use policy were devised while the policy was being translated into action, which illustrated iterative loops of formulation and implementation. Responsible authorities, including the three governmental committees constantly worked out new strategies to counter emerging pressures generated by the opposition to the use of the TRIPS safeguards. The messy policy processes were notable, especially in the beginning phase of the initiative,

which illustrated the *'contingency'* or *'trial and error'* approaches employed by the Thai administration. Responses to the objections by patent-holders and industrialised country governments became systematic when the MOPH appointed 2 committees to facilitate the policy implementation in February and March 2007. Apparently, it was the allocation of clear responsibilities to these two committees, and the existing NHSB's subcommittee on medicine selection to the government use programme, that made the strategies to introduce the TRIPS flexibilities well-organised. As maintained by Hogwood and Gunn (1984), unambiguous tasks and lines of commands are among the most crucial factors of effective implementation of public policies.

From a different angle, the attempt to systematically strategise the responses to the policy opposition suggested that the decision makers in the Health Ministry and NHSO were learning to draw lessons on their fresh experiences, even though they had not been well-prepared for the introduction of these TRIPS flexibilities, nor for their negative consequences. Such a practice was in line with what the policy learning model argues: to address arising problematic issues, policy makers usually look for existing policy choices in their organisations or foreign settings, rather than commission new research, as the studies would not deliver timely findings to inform policy decisions (Rose 1993). These lessons will then be assessed against a particular set of criteria and adapted to fit the political context before adoption. Although lesson drawing does not always ensure desirable policy development and outcomes, learning from past experience can encourage policy makers and their supporters to be cautious and provide them with the ability to avoid repetitive mistakes.

Aiming to legitimize the actions for or against the use of TRIPS flexibilities, public relations and information campaigns were introduced, not only by the Thai administration, and its health advocates alliance, but also by the multi-national drug industry and its lobbyists. It seemed, however, that the government use of patents for the three medicines did not gain significant

attention from the general public, but was discussed intensively within restricted policy communities, encompassing the government and concerned parties. The limited participation of lay people in public policy is normally observed in highly technical areas such as health and biomedicine (Barker 1996). Indeed, the issues of international trade and intellectual property are difficult to understand, even among many of the policy elite and health professionals. The nature of the health and intellectual property elements of the public, non-commercial use of drug patents in Thailand might discourage the public from policy engagement.

Despite the messy processes of the policy under discussion, one could claim that the use of TRIPS flexibilities by the Thai government was relatively successful. Such an achievement, reflected in the positive consequences immediately emerging in 2007, was determined by 3 main factors. First, the experience of state actors: key actors in public agencies, who drove the formulation and implementation of the government use policy, had long been involved in important events in the countrỹs drug systems, including those regarding medicine patenting. Some had previous experience at the Thai FDA, from the late 1980s to the early 1990s, whereby they obtained basic knowledge and experiences concerning IP laws, an understanding of the pressure from the US administration, including the USTR office, an understanding of the positions of other government ministries and a clear idea of appropriate strategies to counter threats. During the enforcement of the TRIPS safeguards in 2006-2007, this background had a crucial role in fostering confidence among themselves and the Health Minister.

Second, connections between state actors: the introduction of government use of medicine patents started with the selection of medicines to the programme by the NHSB's subcommittee. Then, the generics needed to be registered with the Thai FDA, imported or produced by the GPO. These agencies had to set the public health safeguard policy as their priority and also worked well with each other. A delay or blockage at any step would hamper the translation of

the policy into action. It appeared that in practice, there was no significant hurdle, which reflected the partnerships between the leaders of all of the responsible agencies. Anecdotal evidence suggests that the connections among these state actors might stem from their concerted campaigns against the military regime in mid-1970s, and in the Rural Doctor Society since the early 1980s.

Third, connections to knowledge-based civil society organizations, both within and outside the country: placing health officials at the centre, these actors had created close collaborations with many knowledge-based NGOs, especially those that dealt with trade and IP issues, for example, the Drug Action Group, KEI, TWN, Oxfam and MSF. Many of the documents shown in the MOPH's white paper were recommended and offered by these organizations. The public-civic connections provided not only wisdom to guide the policy implementation in the right direction, but also strong legal background and justification of the policy.

11.3 Policy networks: exchanges of resources and their contributions

One of the critical features of Thailand's government use policy in 2006 and 2007 was the active participation of civil society organisations in the policy processes, despite the lack of involvement of the general public. As mentioned in section 2.4, the activism alliances of domestic and international NGOs and PHA networks played a crucial role in promoting extended access to HIV medicines in Thailand since mid 1990s, through which the government use of private companies' patents, including enforcement of government use for medicines, was advocated. The civic coalition continued its campaigns for the use of public health safeguards in accordance with the TRIPS agreement until they were successful in 2006, when the policy issue reached the governmental agenda and was subsequently adopted. The importance of these policy entrepreneurs was lasting throughout the formulation and implementation of

this policy. It can be asserted that networks among health officials, as well as public-civic collaborations, as mentioned in the previous section, were influential elements that drove the use of the TRIPS flexibilities in a desirable direction.

Public policy literature suggests a modern form of governance developed through the partnerships between state and non-state actors. Although the analysis of policy networks was initially used for the assessment of the sharing of power between the public and private sectors, the emphasis has been extended to government-civil society collaborations (Rhodes 2006). Policy networks are created as the network members share common values and policy interests, and realize that they are interdependent. Following Rhodes (1988), both government and non-government actors require support from each other: the former can achieve specific policy goals with assistance from the latter, while the non-state side can take part in policy making to pursue their goals. The existence and roles of policy networks in different stages of policy processes are operated through the exchange of resources possessed by each member of the network, and also resource mobilization from external sources (Hajer and Wagenaar 2003). As Stone (2003) puts it, policy resources can be finance, workforces, information, knowledge, expertise, technologies as well as management capacity.

Policy network concepts fit to explain the interrelationship between the Thai administration and civil society organizations, and their contributions to the use of TRIPS flexibilities in this country. A common ideology and goals to ensure access to medicines among populations in need was the major driving force of network establishment, maintenance and operation. The exchange of resources possessed by each party through collaboration was crucial: while the MOPH commanded the authority to adopt and implement government use policy by employing certain strategies, their civic counterparts had

practical experience in campaigning and mobilizing support from a broad range of academic and political organizations at both a national and international level. This paper illustrates substantial contributions of civic members to the government use policy networks alongside policy development. Without these collaborations, the MOPH and NHSO would have had to deal with the huge pressures from policy opponents alone, with their limited resources. If this were the case, the course of policy formulation and implementation might have developed undesirably. Existing studies suggest that the networks of public health agencies and civil society organizations in Thailand were not just instigated when the MOPH implemented government use of medicine patents in 2006 and 2007. On the other hand, however, such a policy network had played an important role in HIV/AIDS prevention and treatment programmes in this setting for decades (Tantivess 2006). Wider public-civic collaborations could be observed in other public health areas in Thailand, such as tobacco control policies, since the 1980s (Supawongse 2005), and the national health system reform during the 2000s (Jindawatthana et al. 2006). Long-term partnerships and trust among members of these networks were beneficial to the collective work undertaken in the following phase.

Although the roles of networking between the Thai government and NGO coalitions were prominent in the policy under investigation, it does not mean that intergovernmental partnerships were less important. The pursuit to widen access to affordable health products and services was a common responsibility of governments in the developing world, but only a handful of countries were able to overcome the IP-generated impediments. This lack of government capacity tended to deter the benefits from partnering among nations in the South. However, concurrent developments concerning public health, innovation and intellectual property at the global level was a conducive context in which to enhance the advantages of the South-South networks. That the governments of developing nations expressed appreciation to the Thai

administration for its brave action to use the TRIPS safeguards for public health purposes, and also spoke in one voice at international meetings and conferences concerning the undesirable effects of IP and the grave need for effective interventions reflecting the solidarity among the governments of developing nations, to a great extent, helped to legitimate the Thai public health safeguarding policy.

11.4 Looking at Thai CL policy through the lens of power

In many instances, policy analysts explain the processes of a particular public policy by examining the uneven distribution of power across networks of policy actors in a policy domain. Elitist theories argue that only small numbers of actors, the so-called policy elite, who command high levels of power, dominate agenda setting, decision making and policy changes (Walt 1994). At the same time, however, multiple interest groups, who are not elite, often challenge the leading partisans in order to pursue their policy goals. According to Galston (2006), the ability of an organised interest to achieve what it demands depends not only on their personal resources but also on the conflicting intentions of other parties. As he further points out, the feasibility and success of introducing a public policy depend on how powerful the policy entrepreneurs are. Elitist theories also suggest that power is based in several different types of resources such as wealth, technical expertise, connections with other powerful actors, and legitimate authority (Buse, Mays, and Walt 2005).

The concept of power can be employed to shed light on the implementation of government use of patents for medicines in Thailand. The reluctance of developing countries' governments to introduce TRIPS flexibilities to widen access to essential health products reflects the awareness of the relatively weaker power they command, when compared with industrialised nations

and multi-national drug industry. As mentioned earlier, Thailand's actions, which challenged the world's great powers, developed concomitantly with the mobilisation of resources, and therefore power, through public-civic networks. It cannot be denied that the strong support received from both domestic and international partners considerably strengthened the power of the Thai administration, as well as the whole health advocate network, in dealing with more powerful countries. The evidence indicated, however, that the political power possessed by the government use policy networks was not comparable to that of the well-established economies, including the US, the EU. and other countries in the North. The trade retaliation meted out to Thailand by the Washington administration offered an illustration of the disparities in the power wielded by the policy advocates and that of their powerful opposition.

Throughout the processes of introducing the policy to override medicine patents by the Thai government, little was heard from international organizations, including the WHO. Although the WHO had a mandate to protect the health of the global population, there was no concrete intervention by this public health agency when Thailand faced tough pressure from more powerful countries. Such negligence existed even though the Doha Declaration on TRIPS and Public Health assured that the action by the Thai administration complied with the WTO's framework on intellectual property protection, and that similar policies should be encouraged among other resource-poor settings in order to narrow the gaps between the need for, and the access to, essential medicines. It was definitely clear that the WHO had no legal authority to settle the disputes between Thailand and the more industrialized states over the enforcement of TRIPS flexibilities. However, many assert that laws and authority are not the sole sources of power (Hudson and Lowe 2004), while others point out that political will and commitments are equally important in improving national and global health governance, as well as the way it works (Dodgson, Lee, and Drager 2002; Menon-Johansson 2005).

11.5 Why Thailand's government use initiative generated serious tensions: the matters of interests and awareness of potential policy transfer

One of the key elements to be addressed in an analysis of public policy is the interests of particular groups or individual policy participants (Walt and Gilson 1994). This is because a public policy may affect stakeholders in different ways, either positive or negative. To maintain or pursue their interests, actors put their efforts to influencing the course of policy decisions and implementation. The positions and roles of governments, elites and organised interests are guided by their preferable consequences of the policies (Hill 1997). As discussed above, it was the common interests shared by groups of actors that fostered policy networks and partnerships (Rhodes 2006). Following Walt and Gilson (1994), however, practice and behaviours of participants in certain policies are also moulded by the context in which the policies develop.

Why the use of TRIPS safeguards for medicines in Thailand resulted in intensive opposition is an interesting question. Apparently, the loss of interests owing to generic competition and a reduction of profit were the primary reasons for the multi-national drug industry to oppose this policy. However, one may argue that the value of business loss due to the Thai action would not be significant, when compared to the total market size of the global drug industry. As discussed earlier, the rigorous protests against the Thai administration might be driven by the concern of spill-over effects of the government use implementation in this middle-income setting (see section 7.1). It is noteworthy that a caveat of policy imitation was perceived by the drug industry when the Malaysian administration enforced government use of ARV patents in 2004: *'Both companies used the threat of reduced foreign investment in the country, and one of them also expressed concerns that Malaysia's action would create a precedent internationally.'* (Chee 2006:14).

According to the policy transfer model, policies can be transferred across time and space, i.e. effective policies implemented in the past or in one setting may be adopted, with or without adaptation, by current policy makers, or leaders in other organisations (Dolowitz and Marsh 1996; Rose 1993). Several types of policies in one country can diffuse across borders and be adopted in foreign settings. Elements of transfer include political ideologies, policy goals and objectives, benchmarks, management, whole programmes, strategies, guidelines and activities. This suggests that in the Thai government use policy, potential lessons learned and emulated by governments of other developing countries comprised not only the use of TRIPS safeguards in those settings but also the adoption of ideologies which underpinned the Thai move as well as the introduction of a number of tactics. The enforcement of the government use of the EFZ patent in Brazil, in May 2007, offers an illustration of the transfer of ideologies and policy action. Meanwhile, protests against the Gleevec® patent, in December 2007, in India, whereby NGOs urged medical doctors and consumers to boycott the patent-holding company Novartis (The Hindu 2007), are an example of strategy diffusion in the pre-grant opposition to medicine patents.

The above analysis suggests that the government use policy in Thailand might be more persuasive to follow than the introduction of this flexibility in other settings in the past. Putting the use of the public health safeguard into context, this argument may be sensible. First, the Thai policy to use medicine patents for public interest was translated into action while the global health community realised that IP protection was a crucial barrier to access to essential medicines among people in resource-poor settings. At the same time, developing countries had been repeatedly learning about the importance of patents and the effects of market exclusivity on drug prices and people's health. Several disputes and court cases between pharmaceutical companies and poor countries like South Africa and India became prominent lessons. Second, Thailand was one of the key actors that had a leading role in international forums, including the WHA and the WHO-sponsored IGWG, to

counter the problem of inadequate access to health products, especially those associated with medicine patents and market exclusivity. Thailand had also created strong networks, not only with other developing nations, but also with civil society organisations, all of which were actively involved in devising effective solutions to such problematic issues.

Third, many countries in the developing world had instigated public programmes to provide ART and other expensive HIV medicines. To make these initiatives sustainable, it was inevitable that national governments had to consider appropriate policy alternatives to lower drug prices. The success of the Thai government in introducing the government use provision for 2 ARV products, and the significant reductions in medicine costs, would inspire other resource-poor nations to adopt a similar solution. Finally, the MOPH's appointment of two committees, one to negotiate drug prices, and the other to facilitate the implementation of TRIPS flexibilities, in early 2007, reflected that the Thai government intended to establish a system to circumvent the patents of many other medicines in the future. This might be an alarming signal for international drug companies that they should not underestimate Thailand's action and its potential implications; if they did, their market privileges and interests would be substantially undermined.

The high stakes of the conflict between Thailand and multinational drug companies, and the reason why the latter tried every effort to stop the introduction of TRIPS flexibilities, were recognised by NGOs and health advocate alliances. Concerned reactions by civil society organisations around the world to alleviate the industry's pressure on the Thai administration could also be observed. As Athersuch and Waldron (2007) maintained, '*If Abbott's pressure on Thailand proves successful, it sets a dangerous precedent where developing countries will avoid using provisions designed to protect public health, for fear of illegal retaliation from Abbott and others in the pharmaceutical industry.*' This argument was shared by others, such as MSF activist Paul Cawthorne (quoted in Schuettler 2007): '*If this brave attempt*

fails, the multinational companies will have a stranglehold on the lives and well-being of millions of poor people, and no other developing country will dare use their right to issue a compulsory licence.'

To sum up, the awareness, by both proponents and opponents of the Thai government use program that their interests were being challenged by others, and that a particular action and its consequences in one country can be used as models and inspiration by policy advocates in other settings, was an important factor in encouraging tough reactions against Thailand.

11.6 Lessons drawn on the government use of medicine patents in Thailand

For the purpose of improving access to essential medicines, the use of TRIPS flexibilities for affordable medicines in Thailand in 2006 and 2007 provides many lessons which may be helpful for other resource-poor countries and public and civic health advocate organisations. They are as follows:

(1) Despite enduring technical, political and economic impediments, the use of TRIPS safeguards to protect public health in developing countries is feasible, and is likely to result in desirable outcomes including drug price reductions and expanded access to essential medicines. These challenges can be overcome with clear and sus tained high level commitment to this goal.

(2) In the introduction of government use measures, like other TRIPS flexibilities, South-South partnerships and collaborations between governments and NGOs are critical factors for success. Given likely opposition from powerful vested interests, it may not be possible for a single country to unilaterally push these policies forward. Mobilising broad based support from other countries and actors, to form supportive policy networks, was critical.

(3) Although the adoption and implementation of government use policy

is difficult in resource-poor nations, the Thai case illustrates the key role of the determination and perseverance of local and interna tional civic alliances, as policy entrepreneurs. It was their experience and expertise, developed throughout the past decades, that substantially benefited the current administration when a window of opportunity opened.

(4) The enforcement of TRIPS flexibilities to ensure access to essential health products in the developing world requires strong leadership and the commitment of governments to improve the health of their people, especially the underprivileged. Despite facing robust opposition from influential parties, the systematic learning and networking carried out by policy makers and health officials is helpful in achieving policy objectives. Solidarity among public agencies is indispensable when a country adopts a policy that challenges the interests of more powerful economies. The Thai government use enforcement indicates that communication, information exchange and collaboration between ministries need to be strengthened.

(5) To ensure access to affordable medicines for a needy population, diverse strategies which complement each other should be employed. It is noteworthy that although Thailand could obtain essential medicines at significantly lowered prices through its government use programme, in parallel, the Thai administration undertook negotiations with patent-holding companies and also promoted R&D in order to foster the local production of generic medicines. However, there is still a need for strong technical expertise in trade laws including those relating to IP which is not generally available to ministries of health and the public health community. Building capacity to understand and apply these legislation frameworks, for the benefit of public health, is essential.

11.7 Policy recommendations

An analysis of the introduction of government use measure in Thailand in 2006 and 2007 provides us with recommendations which may be helpful for policy makers and concerned parties at different levels, given the desperate need to improve access to essential health products and related services in the developing world. First, the WHO should observe WHA resolution 60.30 that urges the Director General to provide technical and policy support to countries that wish to make use of TRIPS flexibilities, and other international agreements, to promote access to pharmaceutical products. As most resource-poor countries may not feel confident to introduce these public health safeguards, the WHO, in collaboration with other international organizations, needs to take a proactive role to strengthen the IP management capacity of government officials in these settings. Capacity strengthening schemes may include, for example, the development and dissemination of practical guidelines, good practice models and lessons drawn on relevant case studies. This issue offers an opportunity for the WHO to demonstrate strong leadership based on public health principles.

Second, not only education and information programmes on IP management and the impact mitigation of patent-related market exclusivity for policy makers and public officials need to be established. Trade law is outside usual purview of health policy makers and specialist expertise was needed to enable Health Ministries in the developing world to argue accurately and effectively. Appropriate frameworks to translate empirical evidence regarding the successful implementation of TRIPS flexibilities in one country into real-life policies and actions in other settings with different contexts are also required. This suggests that political strategy to take forward a public policy is as important as its technical reliability. To achieve this, the creation of pertinent mechanisms to foster close collaborations between the WHO, country governments, civil society organizations and experts in particular fields, is vital.

Third, the WHO and other global agencies should establish clear policy positions and take intensive actions to facilitate the use of TRIPS flexibilities for public health purposes in developing countries. These organizations should not hesitate to be actively involved and should make timely interventions when disputes relating to the IP and health issues develop between countries in the North and the South.

Finally, with the WHO's leadership, the global strategy and action plan to foster the discovery, development and delivery of health products for diseases that overwhelmingly affect people in the South, adopted by the 61st WHA in 2008, should be immediately implemented as a global health priority issue. This includes, among others, new financing mechanisms recognising the need for health-driven R&D of medicines and diagnostics. Concomitantly, effective monitoring and evaluation systems should be in place to ensure timely reporting of the outputs and consequences of the initiatives to member states and other concerned parties.

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Policy analysis with key lessons learned and recommendations

'The Doha Ministerial Declaration on the TRIPS Agreement and Public Health confirms that the agreement does not and should not prevent Members from taking measures to protect public health. The declaration, while reiterating commitment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), affirms that the Agreement can and should be interpreted and implemented in a manner supportive of the rights of WTO Members to protect public health and, in particular, to promote access to medicines for all.'

(Global Strategy on Public Health, Innovation and Intellectual Property, the World Health Assembly resolution 61.21, May 2008)

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