การเมืองและระบบราชการเบื้องหลังการประกาศใช้สิทธิตามสิทธิบัตร (ซีแอล) โดยรัฐบาลไทย

นางสาว กมลรัตน์ โชติสูงเนิน

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาศิลปศาสตรมหาบัณฑิต
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POLITICS AND BUREAUCRACY BEHIND THAI GOVERNMENT'S ISSUANCE OF COMPULSORY LICENSING (CL)

Miss Kamolrat Chotesungnoen

A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Arts Program in International Development Studies
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กมลรัตน์ โชติสูงเนิน: การเมืองและระบบราชการเบื้องหลังการประกาศใช้สิทธิตามสิทธิบัตร (ซีแอล) โดยรัฐบาลไทย. (POLITICS AND BUREAUCRACY BEHIND THAI GOVERNMENT'S ISSUANCE OF COMPULSORY LICENSING (CL)) อ. ที่ปรึกษาวิทยานิพนธ์หลัก: ดร. พวงทอง ภวัครพันธุ์, 141 หน้า.

งานวิจัยฉบับนี้มุ่งศึกษาปัจจัยที่เป็นตัวกำหนดการประกาศใช้สิทธิตามสิทธิบัตรโดยรัฐ หรือ ซีแอล ในสมัยรัฐบาลรัฐประหาร พลเอก สุรยุทธ์ จุลานนท์ (ตุลาคม 2549-มกราคม 2551) โดยมุ่งพิจารณาสองประเด็นหลัก ประเด็นแรกเป็นปัจจัยทางการเมือง ซึ่งเกิดขึ้นหลักจากการเกิดรัฐประหาร 19 กันยายน 2549 ประเด็นที่สองเกี่ยวข้องกับระบบราชการของกระทรวงสาธารณสุข

ผลการศึกษาพบว่าการเมืองระดับประเทศเป็นปัจจัยที่กำหนดการประกาศซีแอลของรัฐบาลไทย งานวิจัยฉบับนี้ใช้กรอบการวิจัยที่เรียกว่า โครงสร้างโอกาสทางการเมือง เพื่อวิเคราะห์มิติทางการเมืองที่เปลี่ยนไป ซึ่งช่วยให้ข้าราชการกระทรวงสาธารณสุข สามารถรวมกลุ่มผลักดันและสามารถประกาศซีแอลในที่สุด ผลการศึกษาการเมืองไทยระหว่างปี 2541 – 2549 ชี้ให้เห็นว่ารัฐบาลที่ผ่านมาและส่วนราชการที่เกี่ยวข้องจ่ายอมให้กับแรงกดดันและผลประโยชน์ทางการค้าระหว่างประเทศ การเข้าถึงยาจึงไม่ถูกจัดเป็นนโยบายเร่งด่วนในขณะที่เศรษฐกิจของประเทศถูกครอบงำโดยโลกาภิวัฒน์เสรีนิยมใหม่ ผลการศึกษาพบว่ารัฐประหาร 19 กันยายน 2549 ได้เปิดโอกาสทางการเมืองที่นำไปสู่การประกาศซีแอล คือ ทำให้เกิดการเปลี่ยนแปลงโครงสร้างรอยปริรอยแยกทางการเมือง และโครงสร้างสถาบันทางการเมือง

ระบบราชการของกระทรวงสาธารณสุขเป็นอีกปัจจัยสำคัญที่กำหนดประกาศซีแอลของรัฐบาลไทย กรอบการวิจัย โครงสร้างการเมืองการบริหารจัดการ ทำให้เห็นความสัมพันธ์และการต่อรองในบรรดาข้าราชการซึ่งรวมทั้งข้าราชการการเมืองและข้าราชการประจำ และระหว่างข้าราชการกับตัวแสดงที่ไม่ใช่รัฐ ได้แก่ภาคประชาสังคมและบรรษัทยาข้ามชาติ ผลการวิจัยพบว่าลักษณะเชิงวัฒนธรรม โครงสร้างและหน้าที่ของระบบราชการกระทรวงฯ เป็นปัจจัยกำหนดการประกาศซีแอล ลักษณะเชิงวัฒนธรรมแยกออกเป็นสองประเด็นหลัก ได้แก่ ปรัชญาของกระทรวงฯ และ การยอมรับเป็นลายลักษณ์อักษรว่าคนไทยมีสิทธิในการได้รับบริการสาธารณสุขและการเข้าถึงยาทั้งในระดับประเทศและระดับหน่วยราชการที่เกี่ยวข้อง สำหรับลักษณะเชิงโครงสร้างและหน้าที่ พบว่ามีการปรับเปลี่ยนข้อจำกัดเชิงโครงสร้างให้กลายเป็นนโยบายที่มีพลวัตร และมีนัยยะสำคัญสี่ประการที่นำไปสู่การประกาศซีแอล ได้แก่ หนึ่ง การกระจายอำนาจ สอง การจัดตั้งคณะทำงานให้ขึ้นกับรัฐมนตรีสาธารณสุขโดยตรง สาม ไม่ผลักอำนาจการตัดสินใจไปที่รัฐสภา สี่ กระทรวงฯ ใช้ยุทธวิธีประสานกับภาคประชาสังคม

งานวิจัยฉบับนี้เสนอให้ประเมินปัจจัยพื้นฐานสามประการ ได้แก่ ความสามารถ อำนาจหน้าที่ตามกฎหมาย และความเป็นอิสระในการตัดสินใจ พบว่าความเป็นอิสระในการตัดสินใจเป็นปัจจัยที่แท้จริงในการกำหนดการประกาศซีแอล

สาขาวิชาการพัฒนาระหว่างประเทศ ลายมือชื่อนิสิต.....
ปีการศึกษา 2550 ลายมือชื่ออาจารย์ที่ปรึกษาวิทยานิพนธ์หลัก.....

#4981301124: MAJOR INTERNATIONAL DEVELOPMENT STUDIES
KEY WORD: THAI GOVERNMENT'S COMPULSORY LICENSING/ NATIONAL POLITICS/ MINISTRY OF PUBLIC HEALTH'S BUREAUCRACY
KAMOLRAT CHOTESUNGNOEN: POLITICS AND BUREAUCRACY BEHIND THAI GOVERNMENT'S ISSUANCE OF COMPULSORY LICENSING (CL). THESIS PRINCIPAL ADVISOR: PUANGTHONG PAWAKAPAN, PH.D., 141 pp.

This research seeks to elaborate and identify the determining factors that led to the Thai government's issuance of CL during the military-installed government of General Surayud Chulanont (October 2006 - January 2008). This research places an emphasis on two contexts: 1) national politics that provided political opportunities following the September 19, 2006 coup d'état; and 2) the Thai Ministry of Public Health (MoPH)'s bureaucracy and its key features.

Research findings revealed that national politics was a determining factor. The conceptual framework of "Political Opportunity Structure (POS)" was applied to analyze the changed dimensions of the Thai state that provided incentives for MoPH bureaucrats to undertake collective action and to eventually bring about CL. It found that previous Thai governments and concerned authorities, particularly during the period of 1998-2006, had been submissive and could not withstand international pressure and trade sanctions. Thus the issues of access to medicines was not taken as a priority, and was even swept aside when the country was under increasing domination of neoliberal globalization and international trade interests. Research findings showed that the September 19 coup opened up political opportunities for the Thai government's ability to issue CL. The political opportunities include the reconfiguration of national cleavage structure and institutional structure.

Research findings showed that the MoPH's bureaucracy was another determining factor. This research applied the framework of "Politico-Administrative Structure (PAS)" to characterize the relationship and bargaining among bureaucrats (political and civilian) as well as between bureaucrats and non-state actors (civil society and drug TNCs). It elaborated that cultural and structural/functional features of the MoPH's bureaucracy were accountable. *Cultural* elements were manifested in two aspects: 1) the MoPH's philosophy; and 2) institutional perceptions on the right to access to healthcare and medicines at both the national level and the level of the MoPH. *Structural* and *functional* dimensions also significantly contributed to the issuance of CL by transforming structural limitations into an active (functional) administrative policy. The success of CL issuance derived from four major implications: 1) decentralization and authority dispersion; 2) putting a panel under the direct supervision of the MoPH Minister; 3) not deferring the final decision to the cabinet; and 4) using the prevailing strategy of "highly coordinated" in dealing with health civil society.

Lastly, this research built on preceding analysis and offered a reassessment of capacity, authority, and autonomy behind the Thai government's issuance of CL. Among these three fundamental aspects, research findings proved that autonomy was a determining factor.

Field of Study: International Development Studies
Academic Year 2007

Student's Signature: Kamolrat C.

Principal Advisor's Signature: P. Pawakapan.

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I completed my Master's degree during the time in which Thailand was facing a crisis with a political instability, shortage of rice, unresolved southern conflict, and rising costs of living. I intend to return to my professional world and to make contribution to a better society as much as I can.

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LIST OF ABBREVIATIONS

AFTA	ASEAN Free Trade Area
AFPF	Armed Forces Pharmaceutical Factory
APEC	Asia-Pacific Economic Cooperation
CHW	Community Health Worker
CL	Compulsory Licensing
CSMBS	Civil Servant Medical Benefit Scheme
CSR	Corporate Social Responsibility
Drug TNC	Drug Transnational Corporation
DSG	Drug Study Group
EU	European Union
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FTA	Free Trade Agreement
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GPO	Government Pharmaceutical Organization
HCP	Health Consumer Protection Programme
H&DF	Health and Development Foundation
IP	Intellectual Property
IPR	Intellectual Property Right
LDC	Least Developed Country
MoC	Ministry of Commerce
MoF	Ministry of Foreign Affairs
MoU	Memorandum of Understanding
MoPH	Ministry of Public Health
MSF	Médecins Sans Frontières International
NHRC	National Human Rights Commission

NHSO	National Health Security Office
NLED	National List of Essential Drugs
NME	New Molecular Entity
OECD	Organization for Economic Cooperation and Development
PAS	Politico-Administrative Structure
PCT	Patent Cooperation Treaty
PLHA	People Living with HIV/AIDS
PMA	Pharmaceutical Manufacturers Association
POS	Political Opportunity Structure
PReMA	Pharmaceutical Research and Manufacturers Association
R&D	Research and Development
SMP	Safety Monitoring Program
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
SSS	Social Security Scheme
TBT	Agreement on Technical Barriers to Trade
TNC	Transnational Corporation
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UC	Universal Coverage of healthcare
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
VHC	Village Health Communicator
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

CHAPTER I

INTRODUCTION

1.1 Rationale

Thailand made its strike on international headlines right after the bloodless military coup ousted the elected Thaksin Shinawatra government on September 19, 2006. Only a few months later Thailand once again came into the limelight and remains so with the Ministry of Public Health (MoPH) granting Compulsory Licensing (CL) for seven life-saving drugs since late 2006.[1] A *Compulsory License* is an authorization given by a "national authority" to itself or a third party for the exploitation of such the subject matter as drugs protected by a patent without the prior consent of the patent title holder (Correa, 2007, p. 274). It is usually required to allow parallel importation[2] and local production of substantially cheaper generic drugs as well as use of a patented technology for research within a specified term. Issuing CL will ultimately increase sizable access to medicines among patients. Based on a report by the World Bank (2006, p. 169), by exercising CL, Thailand would reduce the cost of second-line therapy for AIDS patients by 90 % and the government would save its future budgetary obligations by 127 billion Baht (US$3.2 billion) discounted through the year 2025. For example, imported generic anti-retroviral *Efavirenz* from India costs less than half the price of the patented version (615-650 Baht per bottle versus 1,400 Baht) (MoPH & NHSO, 2007, p. 8). An additional 20,000 AIDS patients will

[1] Thailand' issuance of CL was carried out in two major batches during the term of the coup-installed Public Health Minister Mongkol Na Songkhla (October 2006 - January 2008). With a 0.5% royalty rate of the total sale offered to patent holders, the first batch covers three CLs on two antiretroviral drugs for HIV/AIDS and one blood thinner for heart medication, i.e. *Efavirenz* (or Stocrin®), a combination of *Lopinavir* and *Ritonavir* (Kaletra®) and *Clopidogrel* (Plavix®) respectively. For full details of the MoPH notifications, see MoPH & National Health Security Office (NHSO) (2007, pp. 38-46). The second batch is to treat breast, lung, pancreatic and ovarian cancer, namely *Docetaxel* (or Taxotere®), *Letrozole* (Femara®), *Erlotinib* (Tarceva®), and *Imatinib* (Glivec®). For full details of the MoPH notifications, see MoPH and NHSO, (2008, pp. 27-34).

[2] For example, two batches of imported *Afavirenz* were ordered from an Indian generic manufacturer. A pool procurement of *Kaletra* with coordination from the Clinton Foundation was undertaken. Meanwhile, the Government Pharmaceutical Organization (GPO) is preparing for local production under the consideration that local production should be more cost-effective than importation.

receive this drug while the government does not have to increase its budget (MoPH & NHSO, 2007, p. 8).

Debates over CL in Thailand are not new, yet never conclusive. Local civil society has a long fight against the US's pressure on the amendments of Thai Patent Act that, to Intellectual Property (IP) scholars, poses severe negative effects on the development of local pharmaceutical industry and access to medicines. However, CL markedly became intense around 1998 when HIV/AIDS networks started to look at CL as a key strategy to gain access to anti-retrovirals essential for AIDS patients (Weeraboon, 2004, p. 25). Since then, a number of milestones have been achieved, including the battle to revoke the Thai patent on ddI (anti-retroviral Didanosine) during 1999-2004 in which CL proposals were aborted but health civil society turned very strong and united networks; the inclusion of anti-retrovirals in the universal health care scheme in 2003; the successful protest halting the US-Thai FTA's sixth round negotiation (with negative consequences on IP and public healthcare) in 2006; and the withdrawal of *GlaxoSmithKline*'s patent application on the key anti-retroviral "COMBID" in 2004.

Thailand's issuance of CL is an undoubtedly serious issue in the context of neoliberal globalization. Trade liberalization has dominated the global political economy, and international trade imperatives are very appealing to nation-states (Held & Mathias, 2003). Thailand is no exception, as it has persistently geared its economic policies toward trade liberalization. What is problematic is that international trade rules and regulations have been excessively elevated due to combining them with more stringent IPRs protection. This brings about the conflicting roles of nation-states as economic maximizers versus caregivers, in particular when it comes to the matters of international trade standards and domestic health care[3]. Often, it is not an easy task for a nation-state to reconcile these two roles.

[3] Robert D. Putnam coins it "two-level games" (1988, pp. 427-460) to refer to the fact that governments have to reconcile international interests with domestic interests.

Therefore, Thailand's historic move on CL has provoked a range of national and international debates. The decision is also believed, if not explicit and formal, to have led to Thailand's downgrading by the US government's "Priority Watch List" (PWL) of countries that the US deems do not have adequate and effective IPRs protection (Office of the United States Trade Representatives (USTR), 2007b, para. 17). Critics[4] of Thailand's decision to issue CL strongly believe that Thailand's CL is against IPRs ideology and ruins trade competition climate, using the argument that CL discourages pharmaceutical research and innovations (*Bangkok Post*, 2007, March 21; *Reuters Thailand*, 2007, January 25). CL is unjust for pharmaceutical industries that need to recoup a huge cost of pharmaceutical R&D and therefore deserve a monopolistic market. Affected drug companies allege that the Thai government did not negotiate with them prior to Thailand's issuance of CL. Some critics go further to question the legitimacy of the coup-backed government and place blame on the country's notorious corruption. In retaliation, Abbott, one of the affected drug firms, announced it would no longer register new seven drugs for sale in Thailand. In disapproval to such boycotts and criticisms, policy makers and proponents[5] stand firm on the humanitarian principle of putting human life before trade. CL, as a lawful measure in compliance with both national and international binding laws, fully respects the protection of human rights (rights to life and rights to health). A range of scholars even echo the repercussions of global patent system and pharmaceutical IP. They propose that the system be replaced by new constructive frameworks that reconcile innovation and access to medicines such as medical prize fund, patent pool, and voluntary licensing.[6]

Looking closely at drivers of the issuance of CL, policymakers reiterate that Thailand is in need of essentials medicines and that CL is the last resort. Budget constraints is a major factor, as Health Minister Mongkol na Songkhla of the General Surayud Chulanont government stated, "We have to do this [issue CL] because we don't have enough money to buy safe and necessary drugs for the people under the

[5] See Jakkrit, 2007a; Kannikar, 2007; Khor, 2007; Korthorn, 2007; Love, 2007a; MoPH & NHSO, 2007; MSF, 2007; Oxfam, 2006; World Bank, 2006.

[6] Read more in Shiva, M. (2007) and Love (2007b)

government's universal health scheme" (*Bangkok Post*, 2007, October 31). Giles Ungpakorn,[7] a local prominent activist, asserted that it is a "disguise", if not function, of "sufficiency economy" immensely promoted as fundamental to national development. However, critics including Simon Montlake (2007) believe that there must be "political calculations". According to Montlake, after seizing power in the 19 September coup d'tat, the military-installed government has tried to rebrand as much as possible Thaksin's legacy, yet cannot escape from "populist" policies. For example, the new MoPH quickly abandoned the requirements to pay 30 baht for the health care scheme and renamed it universal health care. A local newspaper (*Matichon*, 2007, March 17) believes that the reshuffle in the government and the MoPH's ministerial team constituted the most important driver, arguing that their pro-poor idealism has simply been manifested in Thailand's CL.

Existing arguments center on whether Thailand -- a middle-income country long considered a pupil of neoliberalism -- made the right decision in accordance with various political economy ideologies and disciplines. They are mainly concerned with legitimacy and impacts of CL, trade, IPRs protection and access to medicines. Substantially lacking is the literature that analyzes the windows of opportunities (and lack thereof) and mobilizing process that have led Thailand to arrive at this controversial policy.

Apparently, it is important to study Thailand's CL in hopes that insightful lessons will be drawn for bureaucrats, policy makers and the public. No matter how long CL takes the role of supporting "access to medicines for all", at least this time CL was not superseded by commercial values. It is interesting that the surrounding political environment of Thailand's CL is neither restricted to democratic/ authoritarian milieus, nor concerned with pleasing constituency orientations in preparation for an election. Paradoxically, CL as possibly called a "populist" public policy was executed by the coup government. The preceding elected Thaksin government did not issue CL even though it called itself unabashedly "populist". To

[7] See Wittayakorn (October 31, 2007). Interview with Giles Ungpakorn: Politics, coups, elections and the left. *Prachathai*.

civil society's disappointment but without surprise, vested conflict of interests for policy-making politicians and bureaucrats triumphed. Fear of trade retaliation by the American superpower and Thai-style "*krengjai*" as "didn't want to bother the US" were more prioritized.

This research seeks to elaborate how Thailand came to the decision of issuing CL by addressing a central question: *What are the determining factors, particularly in the Thai politics and the MoPH's bureaucracy during the military-installed government of General Surayud Chulanont (October 2006 – January 2008), that led to Thailand's issuance of CL?* In identifying the determining factors that are casual and prone to different interpretations, this research postulates they should be directly associated with policy making process and authority. Therefore, it will explain Thailand's issuance of CL from two key factors: political opportunities that came after the September 19 coup and key features of the Thai MoPH's bureaucracy. This research is not intended to make evaluation or assessment of the Thailand's issuance of CL.

1.2 Overview/ literature review

This section surveys articles and sources that further contribute to the understanding of the rationale discussed above and the formulation of the research questions to be put forward in the following section. This section is divided into two parts and focuses on a period of 1998-2006 during which the issue of CL became intense. The first part provides an overview of existing assessments on factors that drove Thailand to issue CL. A number of scholar sources use this component issue to supplement a larger context, making directly relevant sources limited. Therefore, this part draws on a broader range of perspectives by including non-scholar work such as news, articles, and interviews. It also examines accounts as to why Thailand was unable to issue CL in the past despite the predominantly public support and available legal options. The second part discusses a literature review on the leading roles of civil society in the Thai state and public healthcare.

1.2.1 Factors that led to Thailand's issuance of CL

Existing literature that offers some understanding of factors that drove Thailand to issue CL can be made into two camps as per authors' credentials. CL proponents provide positive factors while opponents give negative ones. Then a third camp of literature discusses obstacles that made Thailand unable to issue CL in the past.

1) Antagonistic assumptions are diverse and unsympathetic.[8] Apart from political calculations (to legitimize the coup government and to rebrand Taksinomics), some authors believe that Health Minister Mongkol Na Songkhla intended to issue CL in order to gain popularity in the coming election. Public opinions exchanged on internet blogs including those on the popular *pantip.com and* on the Buddhism-based *larndham.net* illustrate widely polarized viewpoints even among Thais. Comments read that there must be "conflict of interests" for the Health Minister and his support team. A controversial website, *thaimyths.com* (2007), suspects that the interim government of General Surayud Chulanont shifted health budget to the military and it has to implement CL to compensate for the loss. The website is sponsored by the *USA For Innovation* claimed a non-profit American organization dedicated to the protection of IP and continued innovation around the globe. In coincidence, an increase in defense spending nearly quadrupled in the wake of the September 19 coup. The Thai military raised its budget to 115 billion baht from 29 billion baht in the previous year ("Thailand's military-installed government on Wednesday unveiled a 1.66 trillion baht (48.5 billion dollars) budget for 2008, including a hefty 24 percent increase in defense spending.", *Manager Online*, July 5, 2007). An editorial of the *Wall Street Journal* ("ABBOTT's Bad Precedent", April 30, 2007) bluntly claims that Thailand would like to make profits "Bangkok intends to seize the patents and ship

[8] Some of these views were recapitulated in the keynote speech titled "Strong political will, social supports, adequate wisdoms and good coordinated management make the impossible possible: The case of Thai Compulsory Licensing" (Mongkol, 2007, paras. 2-3). It was given by Health Minister Mongkol Na Songkhla in the opening of the international conference on *Compulsory Licensing: Innovation and Access for All*, held on November 21-23, 2007 at Asia Hotel, Bangkok.

them to the Government Pharmaceutical Organization, a *for-profit* state-owned company".

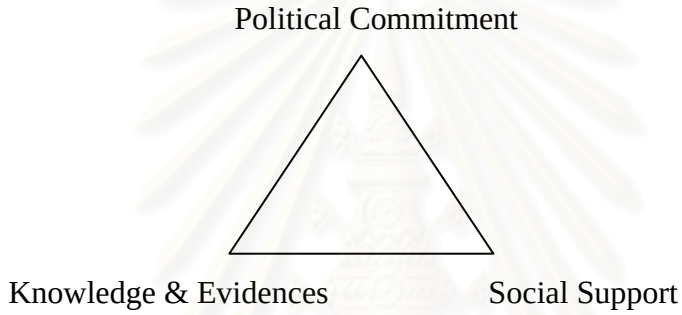
2) By contrast, CL advocates hold on that the stance and roles of Public Health Minister Mongkol Na Songkhla and his team are the determining factors. It is their "*udomkarn*" (commitment) to the humanitarian principle that determined their decision. Their commitment has been cultivated from once serving as rural doctors who experienced first-hand grievance of the poor and the disadvantaged. A statement is put by a NHSO official *"the success of Thailand's use of compulsory licensing did not result from a rash and self-satisfied decision of the military-backed government"* (Kannikar, 2007, p. 25). This administration of veteran former bureaucrats could do this because it has a minister named Dr. Mongkol Na Songkhla, whose support team is already well-versed in this issue. Relatively more radical views hinge on the discourse on "national sovereignty" (*Manager*, March 12, 2007). Thailand has its right to implement CL so as to secure public health and national interests. Thailand will not give up to pressure put by financially influential nations.

Conceptually, the "Triangle that Moves the Mountain" tends to the most cited model in an assessment of determining factors for Thailand's CL (Kannikar, 2007; Vichai, 2007). This model has been introduced and promoted widely by Professor Prawes Wasi, the highly respected guru of the Rural Doctor Group. The model (Figure 1.1) combines social mobilization with knowledge creation and political engagement in addressing complex national problems concerning politics, economy, socio-cultural aspects, environments, etc. The Mountain means a big and very difficult problem, usually unmovable. The model has been applied to many national issues including the Health Systems Reform in 2000, the rewriting of the Constitution 1997 for political reform, and the social movements on 1,400 million baht corruption of medicines and medical supplies in the MoPH in 1998. Professor Prawes explained how each component supports one another:

> *"Creation of relevant knowledge through research is very crucial, but not adequate by itself; it must interact with social movement or social learning. Without relevant knowledge, social movement cannot go very strong or may deviate to something else. Knowledge derived from*

> *research must be translated into forms and languages that can empower the public. Many academicians shun politicians, thinking that they are bad people and do not wish to do anything with them. But politicians have authority over utilization of state resources and in law promulgation, which are very often needed in development. Thus without political involvement the working structure is not complete. Politics without knowledge and social movement will not do. In developing countries, and sometimes even in developed countries, the lack of this "triad" leads to failure in solving difficult problems"* (2000, pp. 106-107).

Figure 1.1 The Triangle that Moves the Mountain



The Triangle model was in line with an article in a local business newspaper *Prachachat Thurakit* (May 20, 2007, p. 6). In similarity, the article called the pattern of CL campaign "Tripartite Fight for Patients' Rights" and detailed agents of each component (cited in Kannikar, 2007, pp. 48-49):

- *The state:* through the MoPH, NHSO, GPO, FDA, DIP and Council of State.
- *Public stakeholders:* the TNP+ had the longest experience in insisting and demanding that commercial interests take into account patients' benefits and physical health promotion, which underpinned national and economic development. This fight for CL rights is leading to the emergence of new networks of patients with chronic kidney diseases, heart diseases and cancer.
- *Civil society:* comprising the medical, pharmaceutical and law academics that have ceaselessly monitored this issue since 1985 such as the Drug Study Group, Social Pharmacy Action Research Unit, Consumer's Health Protection Program of Chulalongkorn University, Rural

> Pharmacists Foundation, Rural Doctors Foundation, Law Society of Thailand, NGOs working on AIDS and consumers' rights, AID ACCESS Foundation, Center for AIDS Rights, Thai NGO Coalition on AIDS, Foundation for Consumers and Health and Development, as well as the FTA Watch Group monitoring free trade negotiations.

In "The Right to Life", a book timely published in November 2007, the author expanded the Triangle model with a "globalized" aspect (Kannikar, 2007, pp. 47-50). Upon using narratives and incorporating quotes of authorities and respected figures, the author stressed the importance of health networks on a global level that "it [Thailand's CL] was also a phenomenal collaboration of global significance, with the participation of several national and international sectors" (Kannikar, 2007, p. 47). She pointed out that there was a remarkably high level of coordination across boundaries. For instance, the Thai and Brazilian MoPHs kept very close contact for experience and data exchange. Medical, pharmaceutical and law academics used networks in many countries. So did international health NGOs such as MSF, Oxfam, Focus on the Global South, the US-based Knowledge Ecology International, Third World Network, Health Gap and Essential Action (Kannikar, 2007, p. 49). This work was integrated with mass media and local networks of civil society such as AIDS Access Foundation, TNP+. All aforementioned coordination constituted the determining factor that let to Thailand's CL.

3) Why was Thailand unable to implement CL even though it has been proved lawful and supported by vigorous public campaigns? Assessments are concordant and well-evidenced: lack of political will. Former MoPH Minister Korn Thapparansi (ministerial period of 1998-2001) decided to allow only the production of ddI in power form instead of tablet form. Health activist Kannikar exclaimed "but things were simply forgotten" (2007, p. 19) when recalling Mrs. Sudarat Keyuraphan (MoPH Minister during 2001-2005) took no further action after ordering the Department of Disease Control and the FDA to negotiate the prices of essential drugs. A feasibility study of compulsory licensing was about to be conducted after finding that the health system was short of *Efavirenz*. A similar view was exerted by a NHSO

board member who reflected the reason why Public Health Minister Mongkol's team could implement CL whereas the previous Minister Pinij Jarusombat's could not. To him, Minister Pinij's team spent a lot of time since they knew nothing about the matter and "had to restart from square one" (Kannikar, 2007, p. 25). Therefore Minister Pinij missed the opportunity to sign his name.

Lack of political will is due to fear of retaliation measures taken by developed-country trade partners, reaffirmed a respected Thai law professor Jakkrit Kuanpoth (2007b). He lists two more drawbacks as to why Thailand and developing countries are hesitant to exercise CL (Jakkrit, 2007b, p. 12): lack of effective management system such as dispute settlement measures regarding remuneration and lack of "know-how" to produce patented drug because of sophisticated processes unspecified in a patent application. Furthermore, the World Health Organization (WHO) upholds that the TRIPS Agreement contained ambiguity regarding implementation of flexibilities. In response to the rising social movements for clarifications, the Doha Declaration on the TRIPS Agreement and Public Health was adopted at the WTO's Ministerial Conference in 2001 (WHO, 2006, p. xxi). The Declaration clarified and reaffirmed the flexibilities available under the TRIPS Agreement. It proclaimed that the Agreement does not and should not impede Members from taking measures to protect their respective public health. As well, the Agreement shall be translated in a manner which contributes to the members' right to protect public health and particularly to promote "access to medicine for all" (WHO, 2006, pp. 1-15). Members can exercise their right, to the full, to issue CL with freedom to determine relevant grounds.

Dr. Pakdi Pothisiri, former FDA Secretary General, once explained some other reasons in the proceeding from the national technical consultation on the implications of FTAs and IPRs on access to medicines (United Nations Development Programme-UNDP, 2005, pp. 17-18). There are: 1) lack of confidence due to insufficient intellectual property literacy and management, which leads to a fear of consequences if IP laws are used incorrectly; 2) lack of experiences among relevant government agencies for Access to Medicines; 3) lack of interdepartmental coordination and

cooperation; and 4) public health situation appears stable without utilizing these flexibilities.

The above assessments leave some missing gaps as they are inconclusive and serve their purposes. The assessments on factors (or lack thereof) that have led to Thailand's issuance of CL are self-explanatory. It is not beyond expectation that these assessments are diverse in terms of provenance and objectivity as Thailand's CL has created both winners and losers. Therefore pertinent information (e.g. defense spending versus public health budget) might be considered or ignored in proving authors' point. For negative factors, this research agrees that some of them have been disproved including the accusation in which the Public Health Minister Mongkol Na Songkhla would have liked to please constituency. Following his ministerial termination, the minister has not entered the political arena. For positive factors, this research judges that the model of "The Triangle that Moves the Mountain" is most convincing in that all encompassing elements are taken into consideration. In addition, at least an alternative interpretation can be made by citing a statement on the different working nature of two ministers. They have different degree of political will.

For an outline on the barriers against Thailand's possible issuance of CL in the past, this research notes a dominant view on the lack of political will. Yet it recognizes that other barriers are well grounded and contribute to our understanding. Lack of effective management, know-how to produce generic drugs, and interdepartmental coordination are all rational. Only a reason given by Dr. Pakdi Pothisiri, Secretary General of the Thai FDA, is rather outdated and no longer convincing. He claims that Thailand did not issue CL earlier because public health situation appears stable without utilizing CL. Above all, the consensus is most likely in relation to political commitment, be it an alternative interpretation, a dominant barrier against CL and a component of the Triangle model. This research places it focus on this linkage and takes it as departure point.

As this research deals with Thailand's issuance of CL from two key factors: the political opportunities that came after the September 19 coup and the working

culture of the Thai MoPH's bureaucracy. The following section briefly reviews dominant roles of civil society in the Thai state and public healthcare.

1.2.2 The roles of civil society in the Thai state public healthcare

The Thai state has changed a great deal politically, socially, and economically, over the past few decades. State power was no longer monopolistically in the grip of the military-civilian bureaucracy as a team of scholars used to argue for.[9] The student-led topple of the military government in 1973 led to another great change in the Thai state and its political landscape.

Teerayuth Boonmee (1993) and a succession of social movement scholars observed an expansion of civic organizations and civil society as non-state actors that brought about significant changes throughout the last three decades. They believed that popular movements have dispersed and penetrated various sectors of the Thai state. Many popular movements are characterized by a participatory process rather than a centralized and top-down approach as in the past. Social movements have largely empowered community initiatives and non-state actors including private sector associations, professional associations, and NGOs. Teerayuth argues that political ideology, once confined to state-building and state nationalism is withering away. Instead, the institutionalizing of civil society will eventually elevate Thai politics to a sustainable standing. He suggests four phases in building a healthy civil society: 1) the emergence of a civic mind; 2) the emergence of civil society institutions; 3) the distilling of a civil mind and the transformation of national ideology; and 4) the institutionalization of civil society as a core social institution. According to Theerayuth, Thailand is in the third phase (Komatra, 2005, p. 40).

[9]Influential American political scientist Fred W. Riggs (1966) developed the term "bureaucratic polity" in describing the Thai political system as from the 1960s as essentially dominated by the military and civil bureaucracy. The model was warmly welcomed by a camp of national political scientists including Chai-anan Samudavanija, Sukhumphan Boripat and Sujit Boonbongkarn (Anek, 1996, p. 11). It was used to analyze the transformation of the Thai political system with an appearance of democracy and general elections accompanied by a legislative process through representative parliament and executive process through representative government. However, to Riggs, real political power was still clustered within a newly constructed "official" class of bureaucrats that covers both decision makers at the top and policy implementers below (1966, pp. 312-313).

Due to the nature of public health that directly involves people, a number of literature on public health stresses the dominant roles and scope of health civil society. The mushrooming of health civil society (to name a few, HIV/AIDS movements, non-smoking campaign, Drug Study Group, and Friends of Cancer) is due to several contributing factors including an expansion of global civil society, national socio-economic development with a growing number of educated and politically active people, as well as mounting complex domestic problems (Penchan, 1996; Suwit, 1996; Komatra, 2005). An important change is also observed in the way health bureaucrats work with civil society; the top-down approach is largely replaced by a more horizontal approach to empower people. It is notable that the MoPH became the first ministry granting financial support to health civil society since 1992.[10] Health civil society has evolved and new forms of people participation have been developed with a range of objectives. Nevertheless, critics argue that the influence of health civil society is still limited in that civil society also mobilizes under an assimilative and integrative framework rather than challenges and disrupts the public sector.

The above theoretical explanations toward the contemporary Thai state and its linkages to civil society are well grounded and rational. By the early 2000s, most scholars hailed the victory of democracy and civil society in describing post-1970s Thai politics (e.g. Teerayuth, 1993; Pasuk, 2002; Yoshinori, 2002). Policy bargaining power has evolved and non-bureaucratic forces have greatly contended over this power, even though the Thai state and bureaucracy still hold firm policy-making power. Political scientist Chai-Anan Samudavanija accepted that the Thai civil bureaucracy has been capable of adjusting itself to maintain its policy-making power despite the alarming growth of societal forces (cited in Medhi, 1997, p. 8). However, state-society relations are successively marked by shifting patterns and interdependence. Bureaucratic and non-bureaucratic interests may become strategic

[10] At that time, the MoPH started to allocate some budgets (around $US 1 million) to support civic organization for health development. The budget increased to around $US 2 million in 1992. After the economic crisis it was reduced to less than $US 1 million (MoPH, 2004, p. 454).

partners or hostile rivals, depending on policy orientations and political regimes (Medhi, 1997, p. 8).

1.3 Research questions

What are the determining factors which led to Thailand's issuance of CL? Do the national politics and the bureaucracy of the MoPH, in particular during the military-installed government of General Surayud Chulanont (October 2006-January 2008), account for such factors? If yes, how they are account for and in what context? What is the working relationship between civil society and the MoPH in pushing for the issuance of CL?

1.4 Objectives

1.4.1 To analyze how the change in the Thai government from the elected ones to the coup one in September 2006 constituted opportunities for Thailand's issuance of CL

1.4.2 To understand how the key features of the MoPH contributed to the success of CL issuance

1.4.3 To examine the collaborating between civil society groups and the MoPH officials and its impacts

1.5 Hypotheses

Global trade and IP system have negatively impacted national capabilities to ensure access to medicines. In Thailand, policy advocacy movements for CL to improve access to essential medicines have taken place for at least a decade. Preparations and proposals were made and decisions were repeatedly dropped in previous governmental/ministerial terms. The possibilities existed but had not been taken. This research hypothesizes that national politics which is receptive to global trade and IP regime, coupled with the MoPH's bureaucracy which is receptive to national politics, have blocked such attempts.

By looking at Thailand's historic issuance of CL starting from November 2006 – January 2008, this research hypothesizes that Thailand's ability to issue CL was due to political opportunities. That is, opportunities were opened up for the passing of CL after the 19 September military junta brought in the militarily-installed government of General Surayud Chulanont (October 2006 – January 2008) and the reshuffle within the MoPH.

In addition to political opportunities, this research also hypothesizes that Thailand's ability to issue CL has strong implications within the bureaucracy of the MoPH. Key figures and administrative properties within the MoPH must contribute to determining factors for the issuance of CL.

1.6 Conceptual framework and research scope

Two major cross-cutting conceptual frameworks are used in this research.

First, this research views that Thailand's CL is possibly treated as political opportunities. Therefore, it modifies a conceptual framework which explains the components, variables and setting of an institution called **"Political Opportunity Structure (POS)"[11],** a model from the new social movement theory. By POS, this research means changed and stable dimensions of the political environment within the Thai state that provided incentives for MoPH bureaucrats to undertake collective action and to eventually bring about Thailand's CL. The structure is initially conceptualized based on four components: national (and local) cleavage structure; institutional structure; prevailing strategy; and alliance structure.[12] This research,

[11] Leading social movement scholar Sidney Tarrow initially refers to the concept as the "consistent - but not necessarily formal, permanent or national - dimensions of the political environment that provide incentives for people to undertake collective action by affecting their expectation for success or failure" (1994, p. 85).

[12] In his previous work, social movements scholar Sidney Tarrow (1988, pp. 421-440) summarized key variables in the models of political opportunities which increase our understanding about the structures, strategies and outcomes of a social movement (in this context Thailand's CL as issued by the MoPH): (1) degree of openness in the polity, (2) stability and instability of political

however, focuses on the first two properties (cleavage structure and institutional structure) for the POS framework and shifts prevailing strategy and alliance structure to another framework which will be discussed below. Hence, this framework begins by briefly discussing the characteristics of previous governments (Chuan 2 and Thaksin Shinawatra) that limited Thailand's possibilities to issue CL. Then it presents analysis of how the September 19, 2006 coup opened up political opportunities specifically during the military-installed government of General Surayud Chulanont (October 2006 – January 2008). Changed cleavage structure and institutional structure are discussed in this section. As well, variables to be discussed include reorientation of agendas of the coup government, policymaking capacity and autonomy, characteristics of the coup government, etc.

Even though the POS corresponds with Thailand's issuance of CL to a certain extent, the concept does contain some obscurity and this research proposes to adjust the concept from the onset. First, the political opportunities to be applied in this research do not explain their *direct* impact over the mobilization of social movements, but rather explain their direct influence over a policy change manifested as one form of social movement (MoPH and NHSO, 2007, p. preface). Nor do the political opportunities in the context of CL impinge directly on social protests or demonstrations, but on configurations of state power and particularly the MoPH bureaucracy. Second, as Tarrow (1988, p. 430) notes, political opportunities contain a subjective component. Actors have to *perceive* the opportunities before taking advantage of them. Third, there is a further need to define the "challengers" to cover drug TNCs and allies, rather than typically social movements in hostile of state.

Second, this research speculates that no single framework suffices in explaining the formation and dynamics of ideology and policy-making process related to Thailand's CL. Hence, it bridges the POS with another framework **"Politico-Administrative Structure (PAS)**". The PAS is generally offered in a public administration framework that characterizes a realm where a political executive

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alignments, (3) presence or absence of allies or support groups, (4) divisions within the elite, and (5) policymaking capacity.

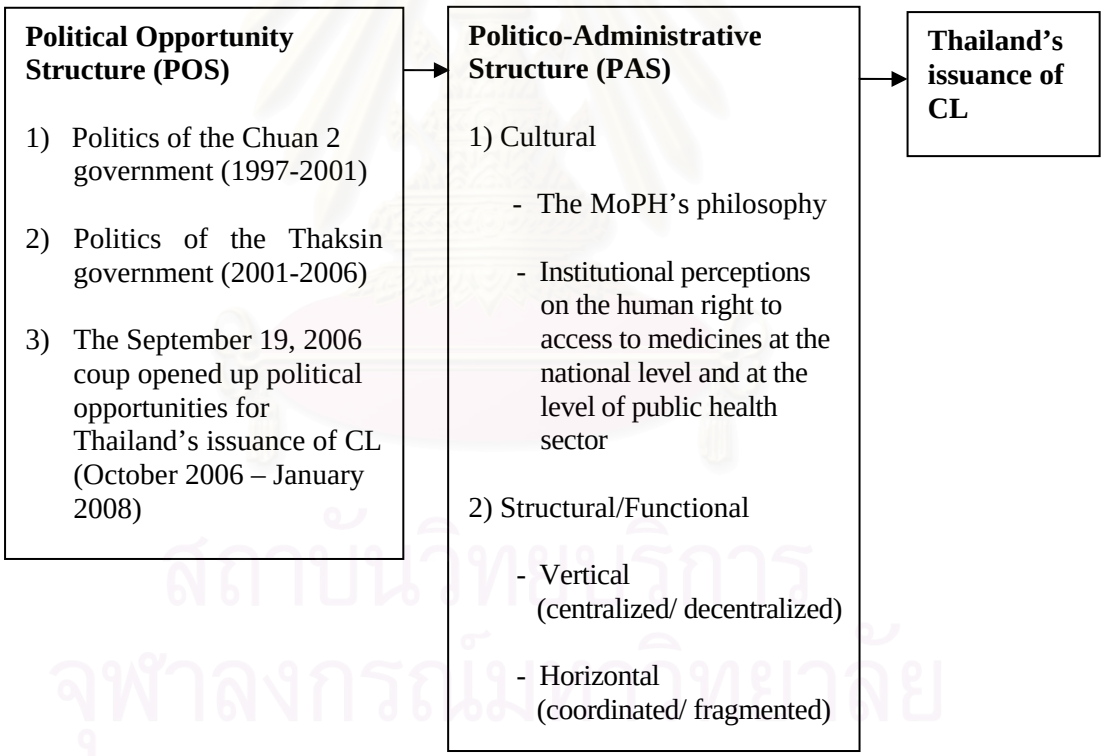
(minister) bargains with a top bureaucrat (permanent secretary) or where political management corresponds to or collides with bureaucratic administration (Pollitt & Bouckaert, 2004, p. 41). In this research, the PAS is extended to a broader context in which relationship and bargaining space are not confined to state actors (minister versus bureaucrats), but integrate non-state actors, particularly civil society groups and drug TNCs (Transnational Corporations). This research applies three key features originally suggested as most likely to affect the process of a management reform: *cultural, structural, and functional.* These three features are linked.

Cultural elements of the MoPH bureaucracy may be realized in their dominant administrative culture. These elements are mentioned as the "expectation of staff" of an organization about what is "normal" and "acceptable" or as the context of ethical consideration in the public sector. This research places its focus on *cultural* elements which are viewed in: 1) the MoPH's philosophy as its dominant administrative culture that could mount to the issuance of CL; 2) the overriding perceptions on the human right to access to medicines as institutionally recognized in Thailand.

Structural and *functional* elements are decoded from specific forms within the MoPH's bureaucracy in relation to the issuance of CL. Such forms are depicted by the set-up of concerned administrative bodies and by at least three sets of relationship (MoPH minister vs MoPH bureaucrats, MoPH minister vs other ministers and cabinet, and MoPH minister and bureaucrats vs non-state actors (mainly health advocate groups and drug TNCs). In general structure and function may be viewed in, but not limited to, two basic dimensions: *vertical* and *horizontal.* The former refers to the degree of authority dispersion, centralized or decentralized. That is how far authority is shared among different groups/ levels. Alliance structure is also discussed in this section. The latter concerns the degree of *horizontal* coordination in which the MoPH central executives (minister and top bureaucrats) are able to get their acts together in order to ensure that all concerned ministries, the central government, beneficiaries and affected parties pull together in the same direction. Horizontal coordination can be broadly conceptualized as *highly coordinated* or *highly fragmented.* Thus prevailing strategy is applied in this regard.

In sum, this research first assesses in what context the September 19, 2006 coup opened up political opportunities for Thailand's issuance of CL. Then it examines key features within the MoPH's bureaucracy that contributed to the issuance of CL. Subsequent results form an integral part in analyzing and identifying factors in the politics and bureaucracy of the MoPH particularly during October 2006 – January 2008 that determined Thailand's issuance of CL (see figure 1.2 conceptual frameworks).

Figure 1.2 Conceptual frameworks to identify determining factors in the national politics and the MoPH's bureaucracy that led to Thailand's issuance of CL



1.7 Research methodology

Based on an inductive approach, this research employs a qualitative research method with a synthesis of primary and secondary data.

Primary data was collected from interviews and personal communications with key informants (see Appendix A for a complete list of interviewees and Appendix B for sample semi-structured interview questions). Interviews were conducted in Thai during a three-month period of December 2007 – February 2008. Interviewees were strategically selected from CL's designated administration and implementation bodies in the MoPH. This is to reflect their perspectives, roles, and experiences. Another set of informants was drawn from health civil society, which has played a significant role in conjunction with public sector, to provide external viewpoints. In sum, interviewees comprise of seven (7) high-level public health officials and two (2) reputable NGOs staff and leader. Included also was some non-participatory observation by the researcher in three events related to Thailand's CL held between June and November 2007 (see Appendix C for a description of events): 1) the movie festival with talks and exhibition; 2) the launch of biography of the MoPH Minister Mongkol Na Songkhla, and 3) the international conference.

Secondary data in both English and Thai was primarily based upon:

- relevant international agreements and obligations (TRIPS Agreement, the Doha Declaration on the TRIPS Agreement and Public Health, the Declaration on Human Rights, etc.);
- national laws (Constitutions, Patent Act, National Health Security Act, National Drug Policy, National List of Essential Drugs, etc.);
- official documents (communications from the MoPH, USTR, etc.);
- existing studies and reports from notable organizations (e.g. WHO, World Bank, MSF, Oxfam, etc.);
- academic articles;
- news archives;
- books;
- and seminar proceedings pertaining to Thailand's CL.

Secondary data cover major issues from the global and national context of Thailand's CL. The global context includes institutional arrangements, international obligations, and foreign experiences. The national context covers political and cultural

accounts in Thai bureaucracy and in focus the MoPH bureaucracy which determined Thailand's issuance of CL. This part also sheds light on rationale, timeline, formality and architect of Thailand's issuance of CL.

The literature review places an emphasis on two issues. It first provides an overview of existing assessments on factors that drove Thailand to issue CL. It draws on a broader range of perspectives by including non-scholar work such as news, articles, and interviews. It also examines accounts as to why Thailand was unable to issue CL in the past despite the predominantly public support and available legal options. The second part discusses emerging roles of civil society in the Thai state and public healthcare.

1.8 Significance of research

1.8.1 This research helps identify determining factors in the national politics and a public sector's bureaucracy that lead to national policy formation and implementation. The research will explain configurations and strategies of a state in bringing about a policy change and mobilizing a society.

1.8.2 Results of this research assist in national policy making which is challenged by the clash between trade imperatives and national welfare benefits. This research argues that bureaucrats/policy makers should take into consideration all comprehensive accounts (1.8.1) in implementing an economic and welfare policy.

1.9 Ethical considerations

1.9.1 *Academic purpose:* The researcher adheres to an ethical rule that this research was conducted to contribute to academic and constructive purpose, without intention to harm reputation of concerned institutions and individuals. Participants were assured that process, given

information and findings of this research are of such consistence and post no risk to them.

1.9.2 *Voluntary participation:* Each key informant was informed on the nature and objectives of this research. Each was asked for one's consent and willingness to participate in this research.

1.9.3 *Anonymity and confidentiality:* Personal and sensitive information of participants will be treated anonymously and confidentially. The researcher asked permission from informants before starting audio recording interviews and informed them on their right whether any part or entirety of the information would be put off record for this research.

1.10 Outline of research

Chapter I The first chapter sets out background and explains why politics and bureaucracy behind Thailand's issuance of CL are important. It also reviews existing arguments regarding factors that led to Thailand's issuance of CL. Further, it provides academic notions on dominant roles of civil society in the Thai state and public healthcare. Next, it discusses what this research intends to contribute and thereby introducing research questions, hypothesis, conceptual framework, methodology, significance, and ethical considerations.

Chapter II This chapter assesses how and to what extent global trade liberalization and IP protection are associated with access to medicines at the national level. It provides: 1) an overview of the nature and dynamics of global trade and the IP regime as one single package; 2) impacts of pharmaceutical IP on access to medicines in terms of price, availability, and manufacture capability which revolve issues on FDI, technology transfer and R&D; 3) flexibilities laid down in the TRIPS Agreement and the Doha Declaration that enable countries to take measure to procure their access to medicines; 4) an illustrative example of Thailand's experience with regard to characteristics of its

pharmaceutical industry and the TRIPS-Plus that may devastate its ability to secure access to medicines.

Chapter III This chapter presents a mix of overview, research findings and analysis. It provides an overview of major policy advocacy movements to improve access to medicines in Thailand during the period of 1998-2006. An emphasis is placed upon the national politics and the MoPH's bureaucracy which were accountable for constraints rather than opportunities for those movements preceding Thailand's issuance of CL in 2006. Thereafter, it assesses how the September 19, 2006 coup d'état opened up political opportunities for Thailand's issuance of CL.

Thereafter, two conceptual frameworks of Politico-Administrative Structure (PAS) and Political Opportunity Structure (POS) are applied to the policy-making process of Thailand's CL. These applications elaborate and in turn identify the determining factors that led to Thailand's issuance of CL.

Chapter IV This chapter draws conclusion on determining factors in the national politics and the MoPH's bureaucracy that led to Thailand's issuance of CL. It also suggests subject matters for further research.

CHAPTER II

INTELLECTUAL PROPERTY AND GLOBAL TRADE: OVERVIEW OF KEY CONCERNS REGARDING ACCESS TO MEDICINES

2.1 Introduction

This chapter addresses the hypothesis of this research by delineating how and to what extent global trade liberalization and intellectual property (IP) protection are associated with access to medicines at the national level. By focusing on the three main themes of trade, IP and access to medicines, this chapter provides basic socio-economic, political and legal perspectives rather than strict theoretical considerations. It is crucial to understand this body of knowledge as backdrop behind analysis to be made in the following chapter, which deals with the national context of Thailand when it exercised CL to safeguard access to medicines.

This chapter is divided into four sections. The first section sets out with an overview of the nature and dynamics of global trade and the IP regime as one single package. The second section examines the impacts of pharmaceutical IP on access to medicines in terms of price, availability, and manufacture capability which revolve issues on FDI, technology transfer and R&D. This section examines major concerns over the WTO's TRIPS Agreement which serves as a dominant driver of the global trade and IP regime. Discussions are later presented in a broader context of impacts that are imposed by the pharmaceutical IP on access to medicines. The third section switches from limitations to opportunities laid down mainly in the TRIPS Agreement and the Doha Declaration so that countries can take measure to procure their access to medicines. The fourth section provides an illustrative example of Thailand. It discusses Thailand's characteristics of pharmaceutical industry by focusing on its research and manufacture capability. It also discusses the new trends of bilateral free trade agreements (TRIPS-Plus) that tend to restrict national opportunities from gaining access to medicines in Thailand and elsewhere.

2.2 How do trade and IP make a global access to medicines an issue?

This section describes how trade and IP make a global access to medicines an issue. It first points out the dynamics of neoliberal globalization and economic growth. Then concepts of IP and international obligations are briefly examined. Lastly it addresses the implications of the triple-track doctrine of multilateralism, bilateralism and unilateralism with regard to access to medicines.

2.2.1 Dynamics of neoliberal globalization and economic growth

Neoliberal globalization became a key context for the study of world population health since the second half of the 20th century. Neoliberal policies geared toward trade liberalization, deregulation, and privatization have been coupled with an unprecedented pace of scientific advancement, communications and cross-border movement of capital, goods and labor. In fact, the links between international trade and health have long been recognized, as exemplified in the Black Plague and international trade route in the 14th century as well as the holding of the first international sanitary conference in Europe in the 19th century (Bettcher, Yach & Guindon, 2000). However, neoliberal globalization has considerably changed external conditionalities for countries when it comes to counterbalancing world economic integration and domestic public health care.

Trade liberalization as perhaps the most familiar element of neoliberal globalization became dominant across the global economic order. The value of world trade grew two-fold from 24% of the world gross domestic product (GDP) in 1960 to 48% in 2003 (Labonté & Schrecker, 2007, p. 2). A major impetus has been the nine rounds of multilateral trade negotiations held for nearly six decades and the transformation of the General Agreement on Tariffs and Trade (GATT) into the establishment of the WTO in 1995. The WTO became the principal institution for the management of about 90% of world trade volume. Since then, international trade rules have been re-engineered through scaled-down tariff measures and trade barriers as

articulated in the WTO's two frameworks of Multilateral Trade (in Goods) Agreements (MTAs) and General Agreements on Trade and Services (GATS). On the other hand, much non-tariff barriers have been scaled up to protect intellectual property rights (IPRs) and the interests of producers and traders as mandated in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These three multilateral agreements (trade in goods, trade in services, and IPRs) are considered as a single package and must be accepted as a binding treaty to all WTO members. This situation is different from previous arrangements under GATT in which members could choose only preferred agreements to adhere to. For the first time in global trade history, trade rules and IPRs regulations are tightly coalesced, binding and enforceable at the national level.

Whereas concerns of WTO's the TRIPS agreement is particularly raised for global health implications, the emergence of regional and bilateral free trade agreements in the early 1990s has exacerbated such concerns. These trade agreements include comprehensive chapters on IP going far beyond TRIPS ("TRIPS-plus"). More dominant are bilateral free trade agreements (FTAs) which involve two nation states that enter negotiations and conclude deals on trade barrier reduction, reformation of trade and investment regulations, and most importantly enforcement of stringent IP standards. The trend comes from attempts by countries, in particular economic powers, to use such a "fast-track" option to facilitate trade liberalization and economic growth. It is also coupled with the stagnation of the multilateral trade negotiations at the WTO Ministerial Meeting 2003 in Cancun. According to the World Bank (2004), the number of agreements in force has surpassed 250 and has arisen six-fold in just two decades.

In fact, economic growth could offer a range of concrete contributions worldwide to health, with accurate reference to an increase in: the wealth index, health indicators (e.g. child mortality rate and maternal health), and breakthroughs of medical sciences. Globalization of trade can enable countries to better utilize information technology and increase the importance of international standards and

legal instruments to achieve sustainable globalization and promote the health of the global population. In this sense, globalization is often equated with trade liberalization accompanied by commercialization of health systems. Notably, it appeals to comparative studies under the sponsorship of the World Bank which concluded that by the 1990s the economies of the "globalizers" grew greater than the "non-globalizers", thereby expanding the resources at their disposal to improve access to health services, markedly through the reduction of extreme poverty (Dollar, 2001).

While the economic benefits of global market integration have been studied empirically and well-documented, these studies have not yielded convincing solutions for the health of the global population. To take the issue of access to medicines as a key determinant of public health, in 2005 alone, nearly 30 million[1] people died worldwide from leading but treatable burdens of heart disease[2], AIDS and cancer for which, medicines existed but were inaccessible, particularly for the poor. Economic growth by itself has not been sufficient in improving population health, nor have collective action on health rely on the market to address public health concerns. Neoliberal globalization fails to address multiple asymmetries in society and provides very little guidance for national public health safeguards and implementation. Economic growth leads to increasing inequality and unequal distribution of health services both within and across national borders. Global trade policy scholar Nancy Birdsall observed that "globalization, as we know it today, is fundamentally asymmetric…in its benefits and its risks, it works less well for the currently poor countries and for poor households" (2006). Interlocking drivers and effects of globalization and health are thus identified and described on many fronts, in particular trade liberalization and commercialization of health systems, which are the focus of this chapter; global reorganization of production and labor markets and urbanization;

[1] The figure constitutes 17.5 million deaths of cardiovascular diseases (WHO, 2008b), 7.6 million cancer (WHO, 2008a), and 3.1 million AID-related diseases (UNAIDS & WHO, 2005, p. 2).

[2] To use precise terminology, "cardiovascular disease" that is caused by disorders of the heart and blood vessels, and includes coronary heart disease (heart attacks), cerebrovascular disease (stroke), raised blood pressure (hypertension), peripheral artery disease, rheumatic heart disease, congenital heart disease and heart failure" (WHO, 2008b).

financial liberalization, debt crisis and economic restructuring; and natural resources and environmental exposures (Dollar, 2001).

2.2.2 Concepts of IP and international IP obligations

1) Concepts of IP

IP is intangible and refers to creations of the mind, be it inventions, literary and artistic works, and symbols, names, images, and designs used in commerce (WIPO, 2007). It is distinguished from tangible assets such as homes, land and computers. Unlike the latter case, an IP owner is not entitled to withhold one's ownership endlessly, but has to transfer or reinstate it to a society after a given period. In other words, IP is a reconciliation of two ideologies (Gorman, n.d.; May & Sell, 2006). Advocates of a proprietary model argue that promising material reward for individual ownership encourages an inventor to create innovation and novelty. Proponents for the "commons" stand firm that these collective rights inherently belong to the society from which they derive and should be thus shared with the society.

Out of far-reaching IP laws,[3] this section singles out patents as not only one of the most original and obvious forms of IP, but also as an inseparable aspect of pharmaceutical IP. A patent is a legal monopoly given to inventors as an incentive to innovate. Inventions are awarded for products or process under three basic criteria worldwide: novel, utility and inventiveness. That is, an invention must be new and useful, inventive-step engaged, and industrially applicable. Discoveries are not patentable. A patent is a trade-off. After a patent is granted, its patent documents or its

[3] IP laws confer a bundle of exclusive rights designed to protect different forms of subject matter, although in some cases there is a degree of overlap. IP laws are divided into two categories (WIPO, 2007): 1) industrial property (inventions or patents, trademarks, industrial designs, and geographical indications of source; and 2) copyright (2.1 literary and artistic works such as novels, poems and plays, films, and musical works, 2.2 artistic works such as drawings, paintings, photographs and sculptures, and architectural designs). Rights related to copyright cover those of performing artists in their performances, producers of phonograms in their recordings, and those of broadcasters in their radio and television programs.

IP are made publicly available. Without a patentee's consent, others shall not make, use and sell that patented product or process. The patentee is also granted the right to license "proprietary technology" to others; those who wish to use a protected patent have to pay royalties to the inventor. For this reason, on the one hand, the state has to secure its role in giving privileges to the inventor. On the other hand, the state has to balance diverging public interests including consumer welfare, the right of other inventors to use technology, and the right to developmental and environment protection (Khor, 2002, p. 203).

Conceptions of patents are based on two theories -- natural rights theory and economic theory. Natural rights theory is largely influenced by world philosophers like John Locke[4] (1632-1704). It articulates that if an individual invest knowledge, time and expenses to create an invention worthwhile for a society, the individual should be entitled to ownership granted by the society. Ownership is in turn an enticement for the inventor because it assures that, firstly, resources and time spent during research and development will be eventually compensated in the form of monopoly right. Secondly, jurisdiction under a patent is to safeguard a patentee's creativity from being ripped off without consent. In accordance, economic theory believes that patents are to encourage invention and disclosure of secrets analogous to technology transfer. Patents are part of the economic infrastructure of states, both developed and less developed.

2) International IP obligations

Prior to radical changes of global IP protection in the 1990s, major international bodies on intellectual property were contained in four conventions (La Croix, 1995, p. 2):

- The Paris Convention 1883 acknowledged inventions, trade names, trademarks, service marks, industrial designs and so on;

[4]Locke views that ownership of property is created by the application of labor. Property precedes government and government cannot "dispose of the estates of the subjects arbitrarily (Cohen, 1995).

- The Berne Convention 1886 covered the protection for copyright;
- The Rome Convention 1961 specified the protection for sound recordings; and
- The Washington Convention 1989 covered the protection for layout designs of integrated circuits.

These four Conventions lacked efficient mechanisms of binding, enforcement and dispute settlement. According to IP scholar Peter Drahos, during the 1960s and 1970s, developing countries began questioning the international IP standards, particularly the two prominent Conventions, the Paris Convention and the Berne Convention (2002, p. 768). Developing countries reckoned that international standards inclined toward plundering the knowledge rather than diffusing it. The strongest debate centered on the revision of compulsory licensing of patented technology in the Paris Convention in 1925.

The World Intellectual Property Organization (WIPO) was established in 1967 to found international IP architecture. It manages international IP treaties and serves as the hub for international cooperation in the area of IPRs protection. A hallmark of the WIPO is its the Patent Cooperation Treaty (PCT) passed in the 1970s which allows quasi-simultaneous patent filing around the world (Gorman, n.d.). This achievement has a sharp, direct link with the globalizing forces which bring the world even closer to a “global” patent.

International IP protection has far-reaching implications on public policy making; its complex nature and economic, social and environmental impacts are diverse and often difficult to measure (Oxfam, 2006; Khor, 2007). Experience shows that the appropriate level of IP protection in a country may vary greatly over time according to local models of production and levels of development. Experts and policy-makers have challenged the so-called “one-size-fits-all” approach to IP, arguing in favor of a rebalancing of the global IP architecture. Attention so far has focused on preserving and enhancing flexibilities under the TRIPS Agreement as

evidenced by the debates on international trade rules, global IP obligations and their impacts on global access to medicines (Oxfam, 2006).

2.2.3 Global trade and IP protection as one single package: The triple-track doctrines of multilateralism, bilateralism and unilateralism

Industrialized countries led by the US shifted their tactics to another bargaining stage which offered so-called multilateralism. They successfully pushed for the incorporation of IP agendas in the GATT - Uruguay Round (1986-1994). GATT evolved into the establishment of the WTO and the conclusion of the WTO-TRIPS Agreement in January 1995, after harsh protests against lack of legitimacy and failed negotiations. The Agreement sets international minimum requirements of IPRs standards as conditions for countries to accede to the WTO. Member countries are made to comply with the four IP Conventions and are subject to dispute settlement mechanisms under the administration of the WTO. Other provisions hinge on the WTO's principle of "non-discrimination" which requires member states to give equal treatment for foreign and national intellectual property and that states provide protection for plant varieties[5], computer programs, databases, and so forth. The WIPO's role was largely sidelined during the TRIPS negotiations. Thereafter, it revived its importance and has played a more significant role in supporting developing countries in preparations for accession to the TRIPS Agreement (La Croix, 1995, p. 2).

Since the 1970s, the US increasingly questioned multilateralism, which upholds the benefits of participation from as many parties as possible. Therefore, the US' desire for stringent international IP rules could not have been realized by a principal preference of multilateralism. Instead, the US then championed the one-sided action agenda of unilateralism. Two familiar and contentious systems are the "Generalized System of Preferences (GSP)" and "Special 301". GSP, instituted since

[5] with states' flexibilities to define their own unique protection system or the so-called "sui generis"

1976, is to promote economic growth by providing preferential duty-free entry for nearly 5,000 products from US trading partners (USTR, 2007a). The program has been renewed periodically and the current legislation in 2006-2008 was reauthorized by President George Bush. “Special 301”, with strong support from domestic industries, was amended to become the US’s Trade Act 1974 to report adequacy and effectiveness of IPR protection by US trading partners. The program annually and aggressively places countries into three categories of “Priority Foreign Country (PFC)”, “Priority Watch List (PWL)” and “Watch List (WL)” in order to restrict trade with these countries, basically by trade sanctions and disciplinary proceedings. In the 1990s, many Asian countries including Thailand were put on the list and threatened for their lack of standardized protection of patented pharmaceuticals, copyrighted Hollywood films, copyrighted music and computer software, and a range of entertainment and fashion trademarks (La Croix, 1995, p. 3). Therefore, countries gave in to raise their IP standard. Malaysia was hailed in 1995 for its steps toward IPRs legislation and enforcement in congruence with the US’s and the EU’s. In the same year, China agreed to amend its copyrights laws and closed CD factories that had violated US copyrights. The laws were amended because the US, a large export market of China, imposed high tariffs on many Chinese goods. China was aware that the US could have vetoed its accession to the WTO in 2001 if China did not take action on IPRs.

The EU has also taken a lead since 1993 in urging ASEAN countries excluding Myanmar in order to enhance all areas of the IPRs including raising public awareness, administration, legislation and enforcement (ECAP II, 2007). Under the names of two pre-eminent institutions – the European Patent Office (EPO) and the Office for Harmonization in the Internal Market (OHIM), the initiative called ECAP II or EC-ASEAN Intellectual Property Rights Cooperation Program has been institutionalized with its office in the premise of the Thailand Department of Intellectual Property (DIP). The initiative is now operational and transitioning into a

new phase[6]. Memorandums of Understanding (MoUs) have been signed as mutual obligations with Thailand, Cambodia, Vietnam, Laos, Singapore, etc.

Aside from unilateralism and multilateralism, since the early 1990s, bilateral free trade agreements (FTAs) have mushroomed and opened up a new landscape of geopolitics and global political economy. Having gained popularity among countries including economic powers such as the US, China, India, and Japan, FTAs have accelerated in both number and speed.

Two important observations are made from this section. First, the "forum shifting" allows the "North" countries with more control to lift up IP protection standards outside a specialized multilateral agency such as the WIPO. The collective multilateralism framework which upheld world peace during the Cold War was intensely undermined by the rise of bilateralism and the unilateralism (Cohen, 2003/2004). Second, the introduction of the TRIPS-Agreement as binding rules for country members to implement a minimum set of IPRs protection standard is undeniably weighty intervention in domestic public policy making, in particular when it comes to counterbalance trade and public healthcare. The following section describes how the TRIPS Agreement intervenes and how stringent pharmaceutical IP inflicts negative impacts on access to medicines.

2.3 Impacts of the TRIPS Agreement and pharmaceutical IP on national access to medicines

Medicines, which meet the real needs of people and are used rationally, can make strategic contributions to the health care system (Wagner & Schaaber, 2005). States are, at least in theory, entrusted by their citizenry to act in their best interest by providing basic needs, including pharmaceuticals services and healthcare. Government policy should enable the provision of good quality, affordable medicines,

[6] For an update on the status of the program extension and overview of activities, visit www.ecap- project.org

which are often perceived by citizens as overall indicators of government effectiveness. From a practical perspective, regular access to affordable essential medicines can in fact prevent or delay health conditions which require more costly care. It can substitute for less cost-effective interventions and reduce morbidity and mortality rates, thereby enhancing quality of life and lowering public health budget. However, the global medicine supply has been hampered. WHO (2004a) estimates that two billion people in developing countries or more than one-third of the world's population still lack regular access to essential drugs. This gap means incalculable human suffering and socio-economic impacts.

This section examines key concerns surrounding the TRIPS Agreement[7] and pharmaceutical IP in relation to access to medicines. It notes that the acute gap in drug access is caused by a number of factors including the lack of financing and distributive justice, and poverty. However, this section is limited to impacts predominantly imposed by the TRIPS Agreement and overarching pharmaceutical IP. This section begins with brief accounts on the TRIPS Agreement's interventions. Then it discusses devastating impacts by pharmaceutical IP over access to medicines, especially in developing countries. As main concerns are centered on innovation, price escalation, local production and policy implications, this section puts them in two main groups of market dominance and disparate local production capability. Both cannot be addressed in isolation.

[7] In general, the Agreement contains provisions which are of direct relevance to public health and access to medicines as follows:

- Article 6 - exhaustion of IPRs, parallel importation
- Article 7 and 8 - objective and principles
- Section 5 - patents, Article 27 product and process patent
- Article 31 and 31bis - compulsory licensing
- Article 39 - protection of undisclosed information, including Article 39.3 on test data
- Part VI - transitional arrangements and Article 70
- Section 8 - Article 40 - control of anti-competitive practices
- Part III - enforcement and measures against counterfeiting and Article 44 injunctions
- Article 65 and 66 - technology transfer

2.3.1 The TRIPS Agreement's interventions

The TRIPS Agreement has become a flash point of North-South conflict in this global trade and IP regime. The issues of access to medicines and public health care have been brought to the fore, among other social negative impacts. There is disagreement as to the need for innovation in pharmaceutical IP protection as demanded by industrialized economies and multinational corporations. Proposals have been opposed by developing countries on the ground that the Agreement has led to escalated pharmaceutical IP protection. This in turn leads to high prices of pharmaceuticals and a flow of royalties to the North licensers. Notably, these debates have gone into fundamental inquiries. What should deserve primacy in international and national policy-making – consideration of profit or consideration of human life? Should life-saving drugs and trivial goods be treated equally, and whose interests does the Agreement serve?

Despite difficulties in quantifying negative impacts of the TRIPS Agreement on access to medicines, the scope and use of IP in conjunction with global trade has made it very controversial. The Agreement requires that member countries extend patent protection to include both process and product to a minimum 20-year term from the filing date. This means countries that did not previously allow patent protection for pharmaceutical products are now obliged to do so. A strong impact is also in three transition periods in Articles 65 and 66. There is consensus that it is comparatively beneficial if developing countries are able to take such advantage (Musungu & Oh, 2006; WHO, 2004b). Developing countries had until the year 2000 to introduce national legislation and regulations in order to become fully TRIPS-compliant. By the end of 2005, additional time was provided to establish "product" patent protection for pharmaceuticals (and agrochemicals) for countries without such protection from the accession time. Lastly, least developed countries have until 2016.[8]

[8] It was changed from the 2006 deadline by the Doha Declaration paragraph 7. This issue will be discussed in point 2.4.2.

It is claimed that the TRIPS agreement, if fully implemented, will exclude many more million people from access to medicine (Balasubramaniam, 2002).

2.3.2 Market dominance

Market dominance brings about expensive medicines which in turn aggravate from affordability of existing medicines to availability of new ones.[9] The problem is pronounced in developing countries where public health expenditures are restricted, with low purchasing power of the people and relatively low public health subsidies. WHO Director-General Dr Margaret Chan claims that, in low-income countries, households' payments account for 40% of total health expenditure compared to a very different picture of 20% in OECD countries (Organization for Economic Cooperation and Development) (WHO, 2007a). Governments of affluent OECD countries provide a much greater share of domestic health expenditures. The figure is around 73% in OECD countries compared with merely over 50% in sub-Saharan Africa (WHO, 2007a). Then the reliance on household or out-of-pocket payments leads to two severe problems. First, many people often delay or do not seek and continue care because of the costs. Second, it deepens household poverty which also forces diversion of household expenditures from other essential areas such as education and food.

1) Affordability

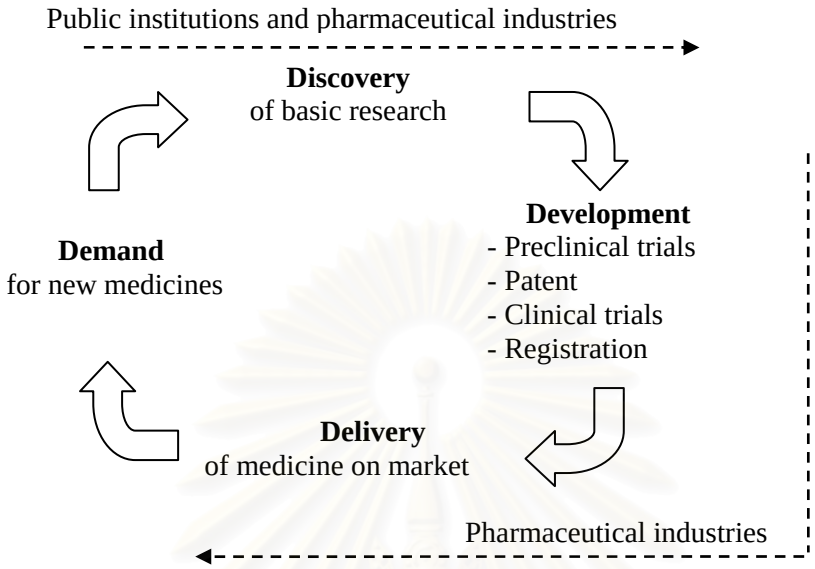
Patents are significantly more important for certain industries than others. Medicines are the one most reliant on R&D and patents (see Figure 2.1 for pharmaceutical R&D). The cost or affordability of a medicine is a direct product of patents that allow pharmaceutical industries to recoup development costs through market and price monopoly. Actual production cost of a drug makes up only a

[9] It is helpful to draw on the definition developed by Management Science for Health (MSH) and WHO (2000) which clarified dimensions and indicators to access to medicines as follow: *availability* – the interplay between the type and quantity of medicine demand and supply; *affordability* – the interplay between price of drugs and user's income; *acceptability* – the interplay between the user's attitude or expectations and drugs' characteristics; *accessibility* – the interplay between the user's location and drug supply location; and *quality of drugs* – cuts across all elements.

fraction. Commercial price is added also a large amount spent on marketing and administration. Unsurprisingly, public concerns have been on the rise regarding higher drugs prices, less competition to monopoly of drug markets, and relentless pressure on governmental public health care and private burden of the poor who proportionately spend more of their income on medicines. It is well documented that, where patents are expired or not enforced, generic entry to market competition results in a sharp price drop of branded drugs. Once again, the problem is more pronounced in low income countries where medicines have life and death implications. In a documentary "Dying for Drugs",[10] it revealed a brutal reality of Jairo, a 12 year-old orphan, who died of AIDS in Honduras because his family could not afford anti-retroviral drugs for him, nor the fluconazole (Diflucan) that Pfizer sold at $US 27-29 a capsule when he developed severe oral thrush. Jairo was taken after by his aunt. Her husband's wage is about $US 90 a week and Jairo's weekly supply of Diflucan would cost $189. In neighboring Guatemala, generic fluconazole was sold at $0.30 a capsule and people were forced to take risk smuggling it (BMJ, 2003; Martorell, 2003).

[10] The documentary's predisposition was that pharmaceutical company activities in developing countries mean deaths. Four cases made the point in Nigeria, Canada, South Korea and Honduras. The documentary was also shown at the event called "Dying for Drugs" organized on June 23, 2007 at the Faculty of Pharmaceutical Sciences, Chulalongkorn University, Bangkok. The event was organized by a coalition of university, public sector and health NGOs to bridge understanding gap on Thailand's CL with the public. For more information, see http://www.pharm.chula.ac.th/thaihealth/advertise/dying%20for%20drugs/pro%20for%20web.pdf

Figure 2.1 Pharmaceutical R&D



Source: data from Shiva M. (2007). *Innovation + access: Alternative R&D models*. Presentation made at the international conference on *Compulsory Licensing: Innovation and Access for All* held during November 21-23, 2007 in Bangkok.

2) Availability

Another interlocked problem is the availability of new medicines across their unbalanced development for life-style diseases and most neglected diseases. Studies show that the majority of global R&D does not address diseases prevalent in developing countries -- the diseases that do not offer satisfactory financial returns. Or if these diseases are addressed, R&D does not represent suitable solutions for developing countries which have different environment and characteristics of diseases. Even worse, much of the research carried out is in pursuit of higher priced versions of existing medicines, the so-called “me too” drugs equivalent to a monopoly extension of new uses of old drugs. These issues have grown steadily over the last three decades (WHO, 2006). Although there were few dramatic discoveries until the mid-1970s, these medicines merely offered incremental benefits in the treatment of tropical diseases such as malaria, leishmaniasis[11] and sleeping sickness. From the

[11] Leishmaniases are sores resulting from a tropical infection by protozoa of the genus Leishmania which are spread by sandflies. They currently threaten 350 million of people around the world. For background information, visit http://www.who.int/leishmaniasis/en/

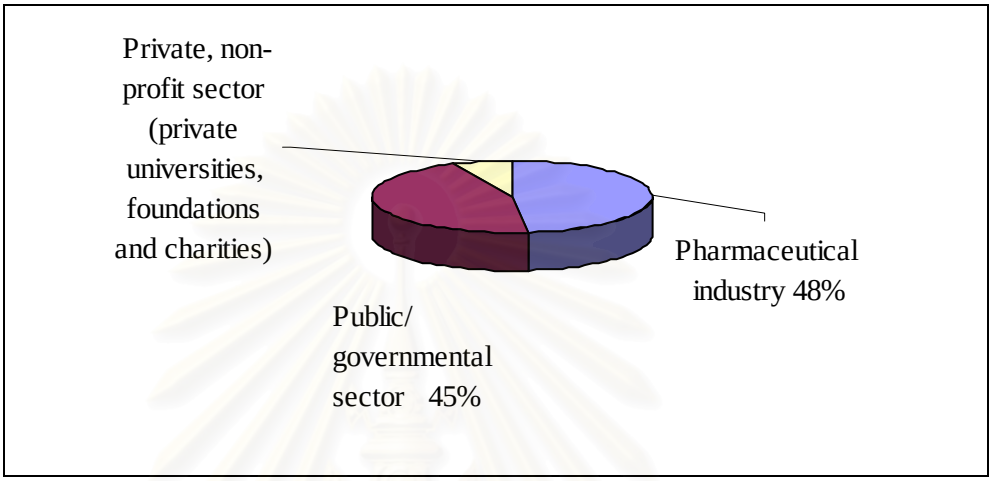
mid-1970s, this trend fell drastically. By early 2000, there were practically no new medicines being developed for tropical diseases. This is obviously a matter of great concern for the countries with tropical diseases. It also means that progress in the treatment of tropical diseases was either static or actually regressing. WHO studies in 2006 showed that out of the 1,556 new medicines discovered between 1975- 2004, only 21 medicines were for tropical diseases and tuberculosis, despite the fact that they affect at least half of the world's population (Chirac & Torreele, 2006).

A crucial question that should be answered is that how much the pharmaceutical industry actually spends for research and development of a medicine? The pharmaceutical industry claims that it spends US$ 100-200 million per medicine and it takes as long as 10 years (Schaaber, 2005). Transnational pharmaceutical industries claimed that they increased investments in R&D by 147% during 1993-2004. However, according to the American Food and Drug Administration (US FDA), the number of drug patents granted increased only 7% during this period. Critics note that most applications were modifications, rather than new molecular entities-NMEs (Jakkrit, 2007c).

Should medicines be viewed as public goods and a blessing for mankind? Paradoxically, medicine research does not come up to its own expectations of serving mankind. Medicines continue to be unaffordable even though 50% of medicine development worldwide comes from public funding and the majority of people contribute to the research though tax payment (de Francisco A. & Matlin S. (Eds.), 2006). Similar problem takes place not only in poor countries, but also rich countries including millions of the American who do not have health insurance. The Global Forum for Health Research identified three major sources than financed research on health in 2003, the latest year for which data are available (figure 2.2):

- private for-profit sector (pharmaceutical industry): US$ 60,600 million (48%)
- public/governmental sector: US$ 56,100 million (45%)
- private, non-profit sector (private universities, foundations and charities): US$ 9,000 million (7%).

Figure 2.2 Sources for the US$ 125,700 million expenditure on global health research funding in 2003



Source: Data from de Francisco A. & Matlin S. (Eds.). (2006). *Monitoring financial flows for health research 2006: The changing landscape of health research for development*. Geneva: Global Forum for Health Research.

2.3.3 Manufacture capability and the myths of technology transfer, local innovation, and R&D

Apart from affordability of existing drugs and availability of new ones, strengthening local production capacity is another crucial dimension sustaining access to medicines. Pro-IP claims are made that strong patent regime induces Foreign Direct Investment (FDI) inflow, local technologies and technology transfer. Developed countries shall transfer their technology to developing countries, the large firms to the small firms. However, evidence shows opposing results that tighter IP is not automatically translated into the proliferation of R&D and FDI in developing countries. On the contrary, it results in a 10/90 gap in global health research; only 10 percent of outlays are spent on the diseases that affect 90 percent of the world's population. Studies show that by maintaining strong IP, countries like Pakistan, if compared to India, are trapped with weaker development of local pharmaceutical industries, higher dependence on drug and substances imports, costlier technology

transfer, and lower investment in drug formulation. Studies further show that other factors such as infrastructure and education levels significantly enhance local production than patent and IP regime does.

To critics, hasty implementation of national IP and patent regime has a strong implication against the development of local pharmaceutical industries (Jakkrit, 2007a). In fact, developing countries share similar characteristics of the development by introducing process patents into national legislation prior product patents. After a country reaches a suitable development level, patentability criteria then cover pharmaceutical products and some live forms such as plants and animals.

Differing IP perceptions in various countries are also issues of controversy. Leading IP actors, the US, EU and Japan, have had different practices, particularly prior to the TRIPS' establishment. The European and Japanese systems allowed publication of patent application within 18 months after the filing date, regardless of whether or not the patent was granted. These systems, of course, helped disseminate knowledge to the public. On the contrary, the US system made available the publication to the public only when the patent was granted. However, the US has later adopted legislation which is more in line with those European and Japanese systems. Another critique lies in the degree of IP framework employed by the leading IP actors. EU and Japan seem to have the narrower sense of "inventable is patentable" while the US notoriously holds a broader philosophy of "everything is patentable".

Scholars make a striking conclusion that developing countries never gain from tighter IP until they are capable of engaging in R&D at the frontier of knowledge (La Croix, 1995, p. 4; and Juma, n.d.). Further, the developed countries gain at the expense of the developing countries when the developing countries adopted IP standard at a premature stage. IP scholar La Croix exemplified the case of Indonesia where transfer of knowledge failed due to the premature adoption of stronger IP (1995, p. 4). There was no domestic section capable of developing high technologies. Thus gains were then produced for the transnational firms from the developed

countries, rather than for the welfare of the Indonesian public. He noted that the transfer of knowledge can be more successful for relatively advanced countries like Singapore and Korea.

Prominent IP scholar Vandana Shiva should be right in dubbing “the myth of technological transfer, innovation and R&D” to which she gives statistical evidence that those claims do not exist. To borrow a question by Peter Drahos, does it make sense to set the same IP rules for the US and Cambodia which are both the WTO members (Cambodia became a member in 2004)? While there are 3,732 scientists and engineers per million population working in R&D in the US (Balasubramaniam, 2002, p.94), the figure of Cambodia is far beyond comparable. The one-size-fits-all rule for IP is unfair to developing countries. When the US and European countries were still developing countries, they ignored the fair deal of IP. During its first 100 year period, according to the US, its refusal was necessary to inject social and economic development (Balasubramaniam, 2002, p.105).

2.4 National measures to procure access to essential medicines

This section examines whether countries are left with some room to procure access to medicines as they are apparently unable to produce by themselves. It investigates provisions of the so-called TRIPS’ *flexibilities* that enable countries to use safeguards to protect access to medicines and public health. The *Doha Declaration on the TRIPS Agreement and Public Health* adopted in 2001 is also discussed in relation to its strong implication in affirming the rights of countries to exercise national safeguards to gain access to medicines. Lastly, some discussion is made on experience of countries that used to issue CL. Brief explanations are presented regarding their national context, challenges and success.

2.4.1 The TRIPS' *flexibilities*

A country's ability to produce or access to essential medicines is a key health strategy. While mandating that all country members allow medicine patenting, the TRIPS Agreement contains "flexibilities" by allowing several measures for countries wishing to increase their access to medicines. Most central are "parallel import" and "compulsory licensing-CL" that permit governments to balance the rights of patent holders and the broader public interest.

Article 6 of the TRIPS Agreement establishes that each Member country has the freedom to incorporate the principle of international exhaustion of rights that is the underlying justification for parallel imports in its national legislation (Correa, 2000, p. 75). It also allows that the issue of exhaustion of rights shall not be a matter of dispute settlement to the WTO (WTO, 2001). Parallel imports involve the import and resale in a country, without the consent of the patent holder of a patented product which was put on the market of the exporting country by the title holder or in another legitimate manner (Correa, 2000, p. 72). For example, a company may buy a patented machine sold in Germany and then resell it in Thailand - where the same patent is in force - without the patent holder's permission. The Doha Declaration on TRIPS and Public Health clarified that this means countries are free to set up their rules and procedures dealing with parallel imports. An importer needs neither the patent holder's consent, nor compensation to be paid to the patent holder. This tool is useful because it is common that drug industry sets far different price of patented medicines in different countries. A limitation is that pricing differential information is not always available for developing countries. By comparison, savings accrued through parallel importation of *patented* medicines are not as significant as those obtained through another measure of compulsory license or CL for generics.

Article 31 allows governments to issue CL to authorize a private company or a government agency to override a patent without the patent holder's consent (see appendix D for the TRIPS Agreement's Article 31 on compulsory licensing). It can

be accompanied by local manufacture of a generic, import, and export to countries with inadequate manufacturing capacity. Import of a generic can be done from a country where the drug is either not patented or patented. In the latter case, the exporting country has to issue its CL in parallel.

The Agreement does not restrict *grounds* and governments are free to determine for issuance CL if:

- the patent holder refuses to grant authorization
- in cases of national emergency and other extreme urgent circumstances
- to remedy anti-competitive practices
- for public non-commercial use
- to facilitate the use of dependent patents.

However, problems have arisen over conditions of the process and the use of CL (Article 31 (b)). Firstly, the Agreement mandates that in general CL can only be granted if an effort is carried out to obtain first voluntary license from the patent holder on commercial terms. This pre-step is not necessary on the grounds for public non-commercial use, for national emergency or situations of extreme urgency and to remedy anti-competitive practices. Secondly, the Agreement requires that the duration of the CL be limited, and that the generic manufacturer compensates the patent holder adequately in the form of royalties on drug sale volume. Thirdly, CL must be used "predominantly" for supplying the domestic market (Article 31 (f)). In this regard, the TRIPS Agreement creates barrier on the export rights of a generic manufacturer on one hand, and on access to majority of developing countries without manufacturing capacity which seek for imports of generics on the other hand. It is noted that this "predominantly" provision does not apply if CL is granted to correct anti-competitive practices.

2.4.2 Reclaiming rights in Doha for public health

There were widespread concerns that strengthened IP protection and the TRIPS Agreement had damaged access to medicines. Questions were raised as to whether the TRIPS' flexibilities could be interpreted by members in a broad, pro-public health way. Varying views were expressed on the ambiguous nature and scope of the flexibilities. And importantly, the flexibilities, particularly CL, had hardly been implemented by developing countries. A respected Thai law academic listed three main reasons why developing countries were reluctant to exercise CL (Jakkrit, 2007c, p. 12): (1) most importantly, lack of political will and concerns for pressure and retaliation by developed countries and trading partners; (2) lack of effective management system such as dispute settlement measures regarding remuneration; and (3) lack of "know-how" to copy patents due to sophisticated processes unspecified in a patent application.

Through active public campaigns and demands from developing countries, the *Doha Declaration on the TRIPS Agreement and Public Health* was adopted at the WTO's Ministerial Conference in 2001 (WHO, 2006, p. xxi). The Declaration is one of the best outcomes which opened political space for use of TRIPS-consistent measures to prioritize public health and access to essential medicine. It clarified and reaffirmed that the WTO "does not and should not prevent members from taking measures to protect public health…the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and… to promote access to medicine for all" (WHO, 2006, pp. 1-15). Members can exercise their right, to the fullest extent, in order to issue CL with freedom to determine relevant grounds. The Doha Declaration put in its content at least four crucial points (Watal, 2007, p. 8): 1) guidance for disputes with reference to objectives and principles; 2) clarifications on CL as to right to grant and freedom to determine the grounds; 3) clarification on emergency situations as to right to determine what constitutes a national emergency or other circumstances of extreme emergency; and 4) clarification of exhaustion that a member is "free to establish its own regime".

Importantly, Doha supports the implementation of CL by extending the transition period of LDCs (Leased Developed Countries) until January 2016 with regard to protection and enforcement of patent rights and undisclosed information in the field of pharmaceuticals.

Lastly, Doha implemented a "Paragraph 6 system"[12] in August 2003 which came up with clarified criteria and a process for member countries with insufficient and no manufacturing capacities in the pharmaceutical sector to make effective use of CL. It addressed health problem in importing members and legal problems in exporting countries.

2.4.3 Foreign experiences of CL implementation

Renowned health activists James Love[13] and Martin Khor[14] have substantially kept track of and drawn lessons from countries which issued or posed threats to CL. They attempt to identify pharmaceutical IP as the single greatest deterrent to drug access. They believe it is legitimate for developing countries to grant CL in order to safeguard public health. James Love has perhaps the largest pool of information. Love comprehensively looks into legislative and institutional changes in some 30 countries, no matter their economic status, to understand how countries worldwide recently reoriented themselves regarding CL and how each CL case was formed. He argued that, surprisingly, it is developed countries that issued many more CLs than developing countries. Canada and the US are in the top rank issuing both health related and non-health related CL.[15] In 2001, the US DHHS Secretary, Tommy Thompson, posed the threat to use "28 USC 1498" to authorize imports of generic ciprofloxacin, for stockpiles against the fear of possible anthrax attack (Love & Palmedo, 2001). In 2006, the US court also granted Microsoft a compulsory license to

[12] For more information on the implementation of Paragraph 6, visit WTO website (http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm)

[13] Director of Consumer Project on Technology

[14] Director of the Third World Network based in Kuala Lumpur.

[15] See a number of Canadian and US CL examples in Love, 2001.

use two patents held by “z4” Technologies that concern digital rights management systems used by the Microsoft for its Windows and Ms Office software program (Love & Palmedo, 2001).

Khor stressed the use of the flexibilities allowed under TRIPS closer to Thailand’s context. He pointed out that it is evident that more developing countries have made use of compulsory licensing after the Doha Declaration on TRIPS and Public Health in 2001. Malaysia became the first country in Asia after the Declaration to issue a “government use” license in 2003 (Khor, 2007, p. 5). This two-year license enabled imports of four generic antiretrovirals from an Indian company. Because of the much lower cost of treatment, it encouraged the Malaysian Ministry of Health to provide free antiretroviral treatment to all those who needed treatment. Indonesia also became the second Asian country in the post Doha Declaration period to grant a government use of a patent in 2004. The Presidential Decree No. 83 (2007, p. 6) authorized a domestic “pharmaceutical factory” to use the patent on two antiretrovirals on behalf of the government, given that recommendations were given by the head of the National Drug and Food Authority.

Two countries that are repeatedly mentioned in a range of literature dealing with foreign experiences of CL implementation are India and Brazil (Jakkrit, 2007a; Khor, 2007; Love 2007; MSF, 2007.). India has emerged as the “global drugstore” with proliferation of generic drug manufacturers; a quarter of the world’s generic pharmaceuticals are from India. This is because the country did not have to enforce its patent law in compliance with the TRIPS Agreement until 2005. Therefore, India has much longer time compared to Thailand which amended its patent provisions in 1992. Also, India largely differs from others countries in that the government has provided a strong support to their national drug producers.

Brazil is another example of a developing country that has long battled with multinational drug companies. The country had signaled threats over the issuance of CL rather than implementing it since 2001. Not until after Thailand set a precedence

of issuing CL and importing generics did Brazil took an action of importing *efavirenz* antiretroviral (Gerhardsen, 2007). In 2001, the Brazilian Health Minister declared that its government would issue a CL for a manufacture of the antiretroviral *nelfinavir* (Love, 2007, pp. 66-67). Only a week later, the government reached an agreement with the patent holder, Roche, who eventually sold the drug in Brazil at an additional 40% discount. Therefore, Brazil dropped the threat of CL. Early in the same year, the US Trade Representative (USTR) filed a complaint with the WTO Dispute Settlement Body against the Brazil compulsory licensing law (Love, 2007, p. 66). The complaint came as a result of Article 68 of Brazil's patent law which allowed compulsory license to be granted where the patent holder does not locally manufacture a patented product (Love, 2007, p. 66).

2.5 Thailand's experience on non-self reliant manufacture capability and the TRIPS-Plus

This section provides an illustrative example that IP rules and international trade do not generate benefits for developing countries by looking at the situation in Thailand. It discusses characteristics of the Thai pharmaceutical industry with an emphasis on its research and manufacture capability. It also examines possible adverse impacts on access to medicines as the country almost signed the *trendy* FTA with the US.

2.5.1 Thailand's pharmaceutical industry

The pharmaceutical industry in Thailand is technologically dependent on foreign interests and is insufficient in functional technological base (Suwit, Vichai & Sripen, 2002, p. 23). Typically, there are two types of pharmaceutical industry: research based and non-research based (Jakkrit, 2007b, p. 13). The former are mainly the drug TNCs with ample capital and research capability. They own the patents on NME and sell brand-registered medicines. The latter is generally known as generic companies which are unable to enjoy patent protection. India and China have emerged

from this generic category and currently expand their operation to become increasingly multinational. Thailand primarily deals with non-research based manufacture. To examine the global manufacture and supply of pharmaceuticals, three categories of countries may be categorized based on their capability (Jakkrit, 2007b, pp. 9-10) in which Thailand is ranked the second among the group, as follow:

1) Industrialized countries are major producers: e.g. Belgium, France, Germany, Italy, Japan, the Netherlands, Sweden, Switzerland, the United Kingdom and the United States. Some developing countries, such as Argentina, Brazil, Egypt, India, Mexico, South Korea, and China, may also be included in this group. These countries have been able to develop a substantial pharmaceutical industry; they are capable of manufacturing NMEs and other raw materials, and engage in the R&D of new drugs.
2) It is a group of countries with an intermediate stage of manufacturing capability includes Colombia, Kenya, Thailand, etc. These developing countries can produce some pharmaceutical intermediates from raw materials available in the country, and indigenous firms are able to carry out particular types of manufacturing such as formulation and packaging. However, there is no production of NMEs and therapeutic ingredients are mainly imported from countries from the first group above.
3) It is a group of countries with the lowest level of manufacturing capability heavily depends on imports of finished drugs in order to meet their health care requirements. Since there is no local formulation or packaging industry, the market shares of foreign firms are very high. Countries categorized in this group cover Laos, Cambodia, Costa Rica, and many African states.

In fact, Thailand has long recognized that there is a need to fulfill domestic pharmaceutical markets. Two state enterprises, the GPO and the Armed Forces Pharmaceutical Factory (AFPF), were established to manufacture medicines. The GPO, established since 1964 under the MoPH, however play more dominant roles. It

supports the MoPH's objectives and plans in serving as a source of affordable medicines. Its major activities are: to produce basic medicines, to procure medicines from other sources, to conduct quality control, and to supply medicines and pharmaceutical supplies to public hospitals (Jakkrit, 2007b, p.14). The GPO has a proven ability to produce generics and supply them to other developing countries including Malaysia, Myanmar, Nepal, Laos, Cambodia and African countries. Nevertheless, the GPO's R&D capability is in question and debates have taken place over the privatization of the GPO to increase its competitiveness (personal note, International Conference on *Compulsory Licensing: Innovation and Access for All*, November 21-23, 2007).

Even though R&D to search for new drugs by state universities and research program has been carried out, their achievement is in doubt. A number of barriers are identified including lack of finance and lack of skills on large-scale commercialization of research outcome.

Private pharmaceutical sector that constitute nearly 90% of pharmaceutical manufacture in Thailand has also faced difficulties. There were 165 firms involving in modern pharmaceutical manufacture in 2007 (Thai Drug Control Division, FDA, June, 2007,). Of which, affiliates of drug TNCs are much more dominant like elsewhere in terms of production, importation, and distribution. Thai-owned companies are small in size and deal primarily with formulating and packaging drugs. They cannot produce raw materials that involve R&D to search for new active ingredients. Therefore they generally import chemical ingredients and technologies from foreign sources. Drug TNCs view that Thailand is not appealing for establishing research units due to factors including the shortage of well-trained personnel, resources and raw material base, and technology capability, as well as the deficiency of the registration system of new drugs.

Thailand's lack of innovation is reflected in an uneven number of patents granted by the DIP. Thai nationals have been granted substantial fewer patents than

foreigners.[16] Between 1998 and 2006, the DIP granted a total of 14,718 patents. Out of which, Thai-owned patents (4,726) are over one-time fewer than foreign patents (9,992). The situation is exacerbated when the number of patents for inventions alone is considered. Out of 7,050patents granted for inventions, only 8% or 582were accounted for local inventions whereas 92% or 6,468 patents were owned by foreigners.

Apparently, Thailand does not have self-reliant pharmaceutical production and supply. This is evident in the increasing volume of imported medicines. Statistics from the Thai Drug Control Division, FDA revealed that in 2006 Thailand imported a value of 45,005 million baht of modern pharmaceuticals while produced locally 30,911 million baht. Similar situation is explicit in the growing trade deficit in this area. Statistics further stress that the deficit is continually widening. For instance, trade deficit in pharmaceutical products significantly rose from 12,847 million baht in 2001 to 17,234 million baht in 2004 (Jakkrit, 2007b, p. 17).

Table 2.1 Value of local production and imports of modern pharmaceuticals 1998-2006 (million baht)

Year	Local production	Imports
1998	16,726	9,739
1999	19,034	14,232
2000	20,996	16,700
2001	23,088	19,968
2002	24,145	19,868
2003	26,586	26,025
2004	31,708	30,546
2005	29,705	38,293
2006	30,911	45,005

Source: Drug Control Division, FDA. (2008).

[16] DIP. 2007. Statistics of granted patents during 1979-2007. Retrieved April 25, 2008, from http://www.ipthailand.org/dip/index.php?option=com_docman&task=cat_view&gid=135&Itemid=467

Thailand's lack of research and manufacture capability is not only translated into high dependency on foreign countries and outflow of resources. It also means that public healthcare service in Thailand has persistent problem in supplying and securing medicines. A worse scenario can be speculated during emergency or unexpected epidemics such as SARS and avian flu.

2.5.2 Thailand-US FTA: Key concerns for access to medicines

Whereas the TRIPS Agreement at least leaves some room for "flexibilities," the controversial "TRIPS-Plus" are undermining them. "TRIPS Plus" mean that developed countries try to introduce stringent intellectual property standards even beyond requirements by the TRIPS Agreement. There is consensus that this is taking place through the inclusion of such provisions in free trade agreements (FTA), especially FTAs between the US and other countries such as Morocco and Singapore. Concerns have been raised against provisions in the FTAs that likely limit access to medicines for those countries which had signed the FTA and those in process including Thailand (National Human Rights Commission (NHRC), 2006; Oxfam, 2006).Thailand was facing a similar situation during the negotiations on the Thailand-US FTA commencing in 2004. However, those negotiations were suspended by the interim Thai government following the political swing of the 19 September 2006 coup d'état.

The concerns regarding access to medicines are justified for two reasons. First, from evaluating FTAs that the US had previously settled with countries and region including Jordan, Chili, Singapore, Central America, Australia, Morocco and Bahrain, provisions are found to set stronger patent and drug marketing rules as well as restrict important TRIPS' flexibilities. Second, the Thai National Human Rights Commission presented a final report on examination of potential impacts from the proposed US-Thailand FTA in January 2007. The report reveals that Thailand's IP and access to

medicines would be considerably deteriorated under the provisions of the proposed FTA. (Smith, 2007).

Based on the NHRC report and other supporting documents, the following three sections discuss major overlying concerns, using the case of Thailand which share similar content with other US FTAs previously settled with other countries.

1) Making patents more stringent (scope, term, process and challenges)

The proposed FTA requires the affected parties (Thailand and the US) to make patents available on inventions concerning plants and animals, as well as diagnostic, therapeutic, and surgical procedures for the treatment of humans and animals (NHRC, 2006). It is criticized that, by this means, the US would gain from its superior technology of genetic-engineering of Thailand's rich of biodiversity. It is likely that Thailand would lose its sovereignty over its own resources and potentials to enhance indigenous herbal medication. For the case of diagnostic therapeutic and surgical patents, critics argue that this wealth of knowledge and expertise are deemed highly integrated and no single step should be separated and monopolized. Multiple monopolies would lead to higher cost of overall medications.

The FTA, as currently proposed, would also grant longer patent terms beyond the maximum 20-year period set under the TRIPS Agreement. It takes into account the delays in granting the patent (patent term restoration) or granting marketing approval (drug registration restoration). A two-year extension from application date or up to additional four years is requested to make up for such delays. This proposition undermines the fact that patent approval and product or medicine registration are two separate procedures. Both take time to ensure maximum safety for consumers. The so-called "evergreening patents" are well notorious among patent examiners who have to spend much time on frivolous to no innovation patents. Brand-name pharmaceutical manufacturer purposefully "stockpiles" 20-year patent protection on multiple and basic attributes of a single product (European Generics Medicines Association, 2004,

para 1). These patents can range from tablet color to manufacturing process, or even a chemical produced by the body when the drug is ingested and metabolized by the patient. Subsequently, patients have to shoulder higher price of medicines as lower-priced generic equivalents have to wait and could not be available in a fair competition.

The FTA also attempts to replace a patent process of “pre-grant opposition” to “post-grant opposition” to expedite granting of patents. This would limit public scrutiny before a patent is granted. Post grant opposition means more complex and time-consuming procedures. Another provision is to unnecessarily reserve for patent granting process. In the FTA, it is requested that an applicant is able to make at least one correction during the course of patent consideration. This could hinder a possible pre-grant opposition, only because any correction can be made by the applicant during a patent process, rather than being refused on the ground of invalidation.

2) Adding data exclusivity

The FTA would devise a new system of monopoly power of branded drugs separate from patents. As currently proposed, the FTA makes it possible to block the registration of generic pharmaceutical products for at least five years. This effectively hinders generic competition in the market. That is, generics which have been shown equivalent to the branded drugs are forced to repeat time-consuming and cumbersome procedures of clinical trials to obtain marketing approval. They cannot rely on the originator’s data. The TRIPS Agreement only protects “undisclosed data” from clinical trials by branded drug companies against unfair commercial use.

3) Restricting CL and parallel importation

To critics, the FTA seeks to limit grounds for Thailand to expand access to medicines by issuing CL only under emergency cases and for any other diseases (HIV/AIDS, TB) than life-style (cancer, cardiovascular) (Oxfam, 2006; Jakkrit,

2007c) The FTA overlooks prevailing over-exploitative drugs markets which consistently bring about higher prices and possible stock-outs (Oxfam, 2006). The TRIPS Agreement's flexibilities are undermined against fair price and fair equity of drug distributions through the added provisions of the proposed FTA.

Besides the TRIPS Agreement and free trade agreements, this research recognizes that there are other international trade agreements which affect Thailand's access to medicine to a more or less extent. Hopefully, they will be discussed in further detail in the future.

- General Agreement on Trade in Services (GATS)
- Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)
- Agreement on Technical Barriers to Trade (TBT)
- ASEAN Free Trade Area (AFTA)
- Asia-Pacific Economic Cooperation (APEC)

2.6 Conclusion

This chapter successfully addresses the hypothesis of this research. It found out that global trade liberalization and IP protection are significantly associated with access to medicines at the national level. Exploring the relationship, impacts and flexibilities of the global trade and IP regime over access to medicines at the national level is crucial for four main fronts.

First, by looking at the forces of neoliberal globalization and its central agenda of trade liberalization, it is underscored that the issue of access to medicines has been forcefully made a global issue. The interests of global trade and the notions of IP between private property and the commons' have blurred national boundaries. The 1990s were marked by the fact that global trade and IP regime became one single package to foster economic growth and stringent IP protection. It has been driven by the triple-track doctrines of multilateralism, bilateralism and unilateralism. Two important

drivers are the WTO's TRIPS Agreement and a proliferation of RTAs (Regional Trade Agreements) and bilateral FTAs. Increasingly, access to medicines and other national social policies have been no longer kept confined to the national context; the roles of states as caregiver and, at the same time, as economic maximizer are challenged more than ever before.

Second, the TRIPS Agreement and stringent global IP protection imposes negative impacts against access to medicines. In particular, they have led to strong market dominance by the major international pharmaceutical companies and impaired production capacities of medicines in developing countries. Although this disposition is difficult to quantify and debates have been statistically conflicting, problems on essential drugs are empirical in global medicines production and supply.

Third, the TRIPS Agreement's *'flexibilities'* address some opportunities for countries to implement and protect access to medicines. Two important safeguards of Compulsory Licensing and Parallel Importation are particularly important for developing countries. However, they are so cumbersome and complicated that the Doha Declaration in 2001 had to clarify how national implementation can be most effectively taken.

Fourth, by specifically examining Thailand's experience, it found out that the country does not benefit from IP rules and international trade in the sense that the country has been technologically dependent on industrialized countries. Further, after studying context and content of the proposed US-Thailand FTA, it is reaffirmed that the national safeguards to protect access to medicines are further restricted by the provisions of the TRIPS-Plus. This trend applies to many other countries that have signed and are about to sign FTAs and RTAs.

The next chapter forms the core analysis of this research. It closely looks at how Thailand's public sector, with strong support from health civil society, could exercise its right to issue CL and could stand international pressure to secure access to medicines.

CHAPTER III

FINDINGS AND ANALYSIS OF POLITICS AND BUREAUCRACY BEHIND THE THAI GOVERNMENT'S ISSUANCE OF COMPULSORY LICENSING (CL)

3.1 Introduction

This chapter presents the research findings and analysis that answer the research questioning the determining factors that led to Thailand's issuance of CL? It is divided into four sections.

Because Thailand's issuance of CL is the result of a long path of policy advocacy movements to improve access to medicines, the first section provides an overview of such a long fight in three major events, the establishment and amendments of Thai Patent Act, the ddI (Didanosine) case, and the Combid case. The section's main objective is to point out *how* Thailand has been submissive by trading off commercial benefits over people's welfare. This section, however, notes that there was a change in Thailand's political landscape due to the September 19, 2006 military coup d'état that was remarkably followed by Thailand's issuance of CL. A brief examination on characteristics of and debates over Thailand's CL is also presented.

The second section addresses the first research objective by providing a discussion on *why* the context of national politics and roles of concerned public sectors are accountable for constraints and opportunities for granting CL. This section applies the conceptual framework of Political Opportunity Structure (POS)**.** By focusing on the period of 1998-2006, an inquiry of the second administration under Chuan Leek-pai and the Thaksin administration was pursued in relation to constraints they imposed against CL. This section then leads to a core analysis on how the September 19 coup opened up political opportunities for passing CL. An emphasis is placed on the post-coup period, October 2006 – January 2008, under the military-installed government of General Surayud Chulanont.

The third section addresses the second research objectives by delineating *how* features of the MoPH's bureaucracy could contribute to the issuance of CL. It also seeks to explain the working relationship between the MoPH and health civil society concerning CL as set forward in the third research objective. This section applies the conceptual framework of Politico-Administrative Structure (PAS) to the MoPH's CL policy-making process.

Building on the second and third sections, the fourth section suggests that a reassessment of capacity, authority, and autonomy behind the Thai government's issuance of CL should be made. This helps identify the determining factor that led to the issuance of CL in a fundamental manner.

3.2 The trajectory of the Thai government's CL: From the early blocking of access to medicines to the September 19, 2006 coup d'état and the issuance of CL

The gravity of access and availability of essential medicines in Thailand has intensified public demands over protection and solution for the problem. Thailand has gone through a long battle, and a linear timeline of movements can be drawn. This section explains the background of Thailand's CL. First, it discusses how the early blocking of access to medicines took place in Thailand. It argues that the previous governments in Thailand and concerned authorities had been submissive and could not withstand international pressure and trade sanctions threatened if Thailand issued CL. Their roles and perspectives are plot in three popular movements: (1) the establishment of Patent Act B.E. 2522 (1979) and its two amendments B.E. 2535 (1992) and B.E. 2542 (1999); (2) the revocation of patent on ddI (Didanosine) during 1999-2004; and (3) the pre-grant opposition to block the patent for anti-retroviral Combid. Next, this section provides a brief account of the September 19 coup as it changed the political landscape of Thailand. Then it leads to a brief introduction of Thailand's CL and outlines relevant main issues and emerging debates.

3.2.1 Thailand has been *a good boy*![1]: The early blocking of access to medicines in Thailand

1) The establishment of Thai Patent Act B.E. 2522 (1979) and the amendments B.E. 2535 (1992) and B.E. 2542 (1999)

Thailand differs from many developing countries as it has never been under colonial rule and its patent laws were not imposed by colonial influences (Jakkrit, 2002, p. 5). However, Thailand is analogy to an economic colony and technology dependence by having adopted the patent system. The Thai government wanted to accelerate industrial and economic development and to facilitate technology transfer from overseas. As a result, it enacted the 1979 Thai Patent Act, B.E. 2522. Fortunately, public concerns for access to medicines were taken into account from the outset. Article 9 of the Act allowed only "process" patents, but not "product" patents. Health advocate groups, led by the Drug Study Group (DSG), argued that drug product patenting is harmful against pharmaceutical autonomy because an absolute monopoly is to be granted for a rights holder in order to produce, reproduce and sell that patented product. In comparison, a process patent only prohibits others from using the same process while it is possible to have available in the market similar products derived from different techniques. Hence, local drug factories could produce generic products within a few years after new R&D drugs appeared in the market and Thai consumers could enjoy low price generics.

Thailand has been submissive. Around 1985-1986 the USTR started to negotiate with the Thai government to amend the Patent Act 1979 to accept "product" patents (Social Research Institute, Chulalongkorn University, 1987; Suchart, 1996; Sutinna, 2003). Despite rising public oppositions, the government of Anand

[1] The term was used by Public Health Minister Mongkol Na Songkhla who reacted following negative criticisms against Thailand's CL "…We have consistently been warned about our compulsory licensing. Over the past 10 years, we have been *a good boy* and done things properly in spite of being always threatened. So it's not true to accuse us that we have violated over 30 patented drugs. Let me reiterate that we're not affected. We've done it in a transparent manner. Liars will definitely have to take the consequences of their actions. We've tried to negotiate for over two years, but they [drug companies] didn't give a dame…" (*Komchadluek Daily*, May 4, 2007, cited in Kannikar, 2007, p. 56)

Panyarachun, installed following a coup, made a hasty decision in 1992 to revise the Patent Act that introduced "product" patents and extended a patent term from 15 to 20 years (Suchart, 1996, p. 74). The administration opted for pleasing the US and for avoiding the US's trade sanctions under Special 301 of the Omnibus Trade and Competitiveness Act 1988. One may speculate that the amendment would have been worth legitimizing the coup government and gaining international acceptance. This Patent Act of B.E. 2535 was also amended in other areas, including an expansion of the scope of patentability and the modification of the process for the granting of compulsory licenses. 'Pipeline product protection' was introduced to provide market exclusivity for new drugs registered in Thailand that had been granted a patent elsewhere between 1986 and 1991. The provision, known as the 'Safety Monitoring Program or SMP', allowed a two-year period of market exclusivity for the purpose of collecting post-marketing surveillance data. As a safeguard, the government created the Pharmaceutical Patent Review Board[2] to control drug prices and prevent monopoly in the pharmaceutical industry (Nathan, Wilson, Costa Chaves, Lotrowska, & Kannikar, 2007, p. 24). The board had authority to collect economic data and production cost of pharmaceuticals. The US was against the set-up of this Board on the grounds that the Board was an obstacle to international free trade. They demanded that this Board be eliminated in order to satisfy the TRIPS Agreement.

The Thai Patent Act was amended again in 1999 to fully meet the standards under the TRIPS Agreement (Nathan, Wilson, Costa Chaves, Lotrowska, & Kannikar, 2007, p. 24). Within this amendment, the SMP was kept intact while the right to issue compulsory license for pharmaceuticals was restricted. It added that an amount of remuneration must be paid to the patent holder if CL is used. A provision was added that the patent holder shall be informed of the CL without delay. The Pharmaceutical Patent Review Board was disbanded, in spite of public demands for keeping the Board. Civil society was concerned that the elimination of the Board would only benefit drugs TNCs and that Thai people would be negatively impacted as they were

[2] Title of this board was used in different terms such as the Drug Price Review Committee (Jakkrit, n.d., para. 3) and the Drug Patent Committee (Suwit, 1999, para. 14).

already paying high drugs prices and could not enjoy health welfare like developed countries.

These expeditious amendments have strong implications against Thailand's development sovereignty. It was too early that Thailand made its Patent Act as nearly stringent as the TRIPS requirements. Therefore, Thailand's domestic pharmaceutical industries have been thwarted as they lost up to 13 years to develop affordable generic drugs, compared with India that only complied with the TRIPS Agreement in 2005.

CL as a key safeguard to national public health has been included since the first Patent Act in 1979. It is maintained thus far as a remedy for an abuse of monopoly rights and for counteracting monopolistic availability of essential medicines. Section 51 of the current amendment in 1999 broadly authorizes the government use of patent to "carry out any service for public consumption which is of vital importance to the defense of the country…..or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service" (Department of Intellectual Property-DIP, 1999, p. 30). The provision also allows the use by either the government themselves or by the third party.

Apart from CL, another legal measure is provided in the current Thai Patent Act B.E. 2542 Section 36 (7) to control the abusive practices of patent holders. It is known as "parallel importation"[3] which creates greater competition between a branded drug legally produced or sold in a country and the same drug acquired from parallel imports from other country. It was the most effective and flexible method of enhancing competition and curtailing the serious restrictions of non-working on a national economy. Unlike CL's process, the importation right of the third party was automatic and was not subject to lengthy time and complex granting procedures. The parallel import could pressurize patentees to perform their duty by carrying the patented invention into effect. Nonetheless, the use of parallel importation in Thailand

[3]All imported drugs need to be registered with the FDA and are assessed according to its principles of quality, safety and efficacy. The TRIPS Agreement explicitly states that if a country allows parallel imports - that is, imports of goods already put on the market in another country with the right holder's authorization - those practices cannot be challenged under the Agreement"

has faced obstacles. One such obstacle lies in the fact that Section 36 (7) mandates that [where the subject matter of a patent is a product or a process], the use, sale, having in possession for sale, offering for sale or *importation* of a patented product/ process cannot be done *without* the authorization or consent of the patentee. It means the patentee or patent holder has the monopolistic right to do by its own or give consent to a third party. It is apparent that a third party seeking for the consent from a patent holder is not unsophisticated.

2) ddI Legal battle

ddI Social movements during 1999-2004 are a good indicator that the problem of access to medicines in Thailand has been acute and that the public concerns have intensified (Ford, Wilson, Onanong, & Schoen Angerer, 2004; Weeraboon, 2004; Baker, 2007; Khor, 2007). ddI is an anti-retroviral essential for HIV/AIDS patients to be used in conjunction with other anti-retrovirals. The drug was initially researched by the American National Institute of Health (NIH), a government sector, which then granted the right of production to Bristol Myers Squibb (BMS). BMS filed the application for ddI tablet patent in Thailand in 1992 and was granted a 20 years patent in 1998 (Weeraboon, 2004, pp. 110-111). These incidents were not lost among Thai AIDS patients and health civil society. They realized that the ddI patent posed a critical threat against access to this essential drug in Thailand. In 1999, the ddI working group was formed with NGOs, academics and lawyers' council. They filed two lawsuits against the Thai Department of Intellectual Property (DIP) and the BMS on the grounds that the ddI patent application did not contain new invention and patent registration procedures were not transparent. The cases were resolved in 2004 by the BMS's agreement to voluntarily withdraw the ddI patent. This signified the first occasion PLHAs (People Living with HIV/AIDS) staged and won stigmatization by the public. Participants in the ddI social movements educated not only themselves, but also the public.

A compilation on "Civil society movements to revoke the Thai patent on ddI" used the successful outcome of this legal battle as a precedent (Weeraboon, 2004). It

emphasizes the growing web of health civil society networking and their learning process over time. Looking back earlier, health civil society had less understanding as to how to improve access to such essential anti-retrovirals as ddI. By 1998, in coincidence with an expansion of global civil society and expanding access to information, AIDS NGOs in Thailand began to concentrate on the issue of CL with strong support from pharmaceutical academics namely the AIDS Access Foundation, the Foundation for Consumers and the Drugs Study Group (Weeraboon, 2004, p. 29). The compilation also evidences the continuity of health civil society's networking. It refers to the period of 1985 – 1994 during which NGOs and academics joined hands to protest against the "product" patent in the amendment to the Thai Patent Act B.E.2522 (1979) (Weeraboon, 2004, p. 26).

Two diverse roles, fragmented and coordinated, were played by different concerned public agents in relation to the ddI legal battle, including the DIP, the GPO and the MoPH. The DIP tended to favor the BMS and drugs companies by granting the ddI patent. The Department was questioned conflict of interests for allowing the BMS to take out an important phase "from 5-100 mg per dose" from its application during the course of DIP's consideration (Weeraboon, 2004, p. 110). The DIP verified that the ddI was the new invention and possessed inventive steps in comparison with that of the Australian patent (Weeraboon, 2004, p. 110). In dissimilar, the GPO as a pharmaceutical state enterprise took a different stance. The GPO recognized that it was crucial for Thailand to ensure generic essential medicines and therefore had undertaken research and development of ddI generic since 1992. This conveys a message the GPO was much more oriented toward coordinative approach with health civil society at the early stage so that they could address public needs. In 1998, the GPO ordered raw materials ready for ddI tablets to be produced with an insoluble antacid buffer. However, their attempt was obstructed after the BMS was granted the ddI patent early the same year. The GPO received a letter from the BMS's lawyer which strongly advised that the GPO discontinue the production or further action would be taken. Therefore, the GPO decided to submit a request to the MoPH to grant CL for ddI.

The MoPH under Minister Korn Thapparansi (ministerial period of 1998-2000) was another precursor of obedient Thai state. With fear of trade sanctions, the MoPH rejected the GPO's proposal to utilize CL and to enable the GPO to produce ddI of the same formula as that of the BMS. The MoPH stood firm on their decision, regardless of clear-cut rationale and strong demands from the public. A ddI camp was then set up by HIV/AIDS patients and activists in front of the MoPH premises for two days, demanding moral, legal and ethical obligations of the state to use legal methods to intervene patent barriers. AIDS NGOs further approached the USTR in Bangkok and received its letter of confirmation that the US would not object if Thailand were to use CL. Their attempts bore no fruit and the MoPH did not grant ddI CL. The best agreement could only be reached in 2000 by allowing the GPO to produce ddI in power form which was not of convenient use.

3) Blocking Combid: A victory on pre-grant opposition

While the ddI case was against a granted patent, Combid case challenged Thailand's patent granting procedures or the so-called pre-grant opposition. In 1997, the US-based GlaxoSmithKline (GSK) submitted a request to patent Combid in Thailand. Combid is a widely used combination of 3TC and AZT which is important for first-line anti-retroviral (Lawan, 2007). AZT and 3TC have never been patented in Thailand. AIDS advocates were concerned that if Combid was patented, it would drastically increase the price of the medicine. It would end patients' right to access an affordable anti-retroviral and could gravely affect AIDS sufferers in the country. The government had to bear increasing budgets and the MoPH might have to pay 400 million baht more to procure the same Combid for 4,000 PLHAs during that time ("Ministry urged not to patent AZT+3TC", *Bangkok Post*, February 7, 2006).

In 2000, the Health and Development Foundation (H&DF) with an alliance of lawyers, academics and pharmacists lodged objections to the possible patent granting. They indicated that Combid is not qualified to be patented because it is not an innovation. It is a simple fixed-dose combination of two earlier discovered drugs and involved neither newness nor an inventive step. Remarkably, following massive

protests by health civil society in Thailand and India simultaneously, GSK withdrew its Combid patent application in 2006 in both India and Thailand.

What did state agencies play their role in this case? Conflicting roles were observed between the DIP and the MoPH. The DIP continued the patent process despite strong opposition from AIDS patients and activists. But they tended to be more cautious and took longer time to consider partly because of strong opposition from civil society which feared a patent would gravely affect HIV/AIDS sufferers in the country. The DIP also set up a committee to review this case in particular. However, AIDS activists led by the director of Aids Access Foundation came out to attack that the committee might have conflict of interests. It was found out that the committee chair's spouse worked as Human resort and Corporate Affair Director for the GSK. The MoPH took a supportive role toward health civil society. Public Health Minister Phinij Jarusombat who received the petition from AIDS alliance with an urge to intervene the DIP expressed his concerns in line with that of civil society ("Ministry urged not to patent AZT+3TC", *Bangkok Post*, February 7, 2006).

The GPO was obviously with civil society and took the same position as in the ddI case. The GPO was producing a five-time cheaper generic version of the same formula named "GPO-VIR". It costs 1,500 baht per course while Combid costs up to 8,340 baht per course. With Combid were to be patented, the GPO would be prohibited to produce GPO-VIR and this would pose huge negative impacts for PLHAs.

Two observations can be made from the above three events. Firstly, movements to improve access to medicines in Thailand have taken place for a long time. Unfortunately, they were repeatedly blocked by the state itself. The Thai state as represented by various public agencies could not endure commercial interests and international trade pressure. These interests were prioritized over people's welfare. Hence, Thailand allowed "product" patents at a premature stage and lost their potentials to develop generic industries. Neither were proposals to grant CL for ddI accepted as the government viewed that they would pose more risks than gains.

Nevertheless, a few observations can also be made regarding the changing roles and perspective of state agencies. While the GPO has coordinated closely with civil society and responded to the public needs, the MoPH and the DIP are likely to adjust their approaches. The DIP became cautious when they inspected the patent application of Combid and the MoPH was supportive than disruptive to the public demands in this case.

Secondly, amidst darkness, there has been the light at the end of the tunnel (Kannikar, 2007, p. 13). Heath civil society networks have strongly expanded over time. The ddI case is a good example and several movements result in educated Thai society. Civil society and the public have learned that CL is an effective mechanism to increase bargaining power with giant pharmaceutical industry. From the ddI case, it was the first time "consumers" could bring a case to the court according to the court verdict in which "interested parties" were extended to cover consumers and organizations operating for consumer rights protection, rather than conventional rival companies (Weeraboon, 2004). The three plaintiffs who were HIV/AIDS patients received widely public support.

3.2.2 September 19, 2006 coup d'état

Thailand was made international headlines right after the military staged the bloodless coup and overthrew the elected government of caretaker Prime Minister Thaksin Shinawatra on September 19, 2006. It caught most observers with surprise as they did not anticipate the coup's return to Thai politics. The coup[4], which marked the first non-constitutional change of Thai government in fifteen years, brought to an end the most successful period of democratic government in Thai history. Following a year-long political crisis involving Thaksin and political opponents, it took place less than a month before nation-wide House elections were originally scheduled to be held. The coup cancelled the upcoming elections, suspended the Constitution,

[4] The coup called itself the Council for Democratic Reform (CDR) and was transformed later into a permanent Council of National Security.

dissolved Parliament, banned protests and all political activities, suppressed and censored the media, declared martial law, and arrested Cabinet members.

The new rulers, led by General Sonthi Boonyaratglin, set out their reasons for taking power and gave a commitment to restore democratic government within one year. It was followed by the October appointment of a militarily-installed civilian government led by Prime Minister General Surayud Chulanont and the national referendum of the 2007 Constitution. Prime Minister General Surayud Chulanont administration was dubbed "Old Ginger" by the press because most of its Cabinet members are already past the age of retirement. One of the most appreciated cabinet members is former civilian Dr. Mongkol Na Songkhal who was appointed the MoPH minister.

3.2.3 The MoPH's issuance of CL: Contents and contentions

While criticisms over the September 19 coup remained intense, only two months later Thailand stroke international attention once again after the country announced a controversial CL on an anti-retroviral, followed by two more notifications for an anti-retroviral and a blood thinner. These three CLs were issued by the Department of Disease Control and the MoPH which granted the right to the GPO to import or produce generic medicines. The terms of CLs are valid for five years and only 200,000 people under three public healthcare schemes will be allowed the generic per year: 1) the National Health Security Scheme or Universal Coverage – UC; 2) the Social Security Scheme (SSS), and 3) the Civil Servant Medical Benefit Scheme (CSMBS). The terms also necessitate that 0.5 percent of the generic's total sale value shall be paid to each patent holder in royalty fees. As the coup government was about to expire, four additional CLs were granted on cancer medicines. A difference in the second batch issuance of CL is found in terms specifications. The period of use is left unspecified until patents of branded drugs are expired or the medicines are no longer under excessive demands. The royalty fees are raised to 3% and 5%. In sum, a total of seven CLs were issued during a 14-month period under the

coup government of General Surayud Chulanont. See table 3.1 for a summary of seven CLs and consequences on health care expansion.

Table 3.1 Thailand's seven CLs and public health benefits

	Medicine	Characteristics	Price of patented product (baht)	Price of generic product (baht) for same amount)	From initial access to extended access	Terms of government use
1	Efavirenz	• less severe side effects than nevirapine • needed by 20% of PLHAs on ART	1,400 (per bottle)	650/615	From 23,000 to 46,000 patients	• A 5-years period for government non-commercial use • 0.5% royalty rate
2	Lopinavir+ ritonavir	• second-line ARV • needed by 10% of PLHAs on ART in 2-3 yrs	5,900 (per person per month)	2,200	From 4,000 to 10,000 patients	• A 5-years period for government non-commercial use • 0.5% royalty rate
3	Clopidogrel	• more effective than ASA in preventing coronary obstruction	73 (per tablet)	1.1	From 10,000 to 350,000 patients	• A 5-years period for government non-commercial use • 0.5% royalty rate
4	Docetaxel	• treatment of breast and lung cancer	25,000 (per needle)	4,000	N/A	• non-specified period for government non-commercial use (until the expiry of patent or the demands are met) • 3% royalty rate
5	Letrozole	• treatment of breast cancer • 1 tablet per day per patient	230 (per tablet)	6-7	N/A	• non-specified period for government non-commercial use (until the expiry of patent or the demands are met) • 3% royalty rate
6	Erlotinib	• treatment of lung cancer • 1 tablet per day per patient	2,750 (per tablet)	735	N/A	• non-specified period for government non-commercial use (until the expiry of patent or the demands are met) • 5 % royalty rate
7	Imatinib	• treatment of leukemia and other cancers • needed a minimum of 400 grams per patient per day	917 (per 100 grams)	50-70	N/A	Note: subjected to a CL, but the license was not implemented after the patent holder Novartis agreed to give its drugs free to a Thai public health program.

Sources: Data from *Facts and evidences on the 10 burnings issues related to the government use of patents,* MoPH & NHSO, 2007; MoPH & NHSO, 2008

Thailand's CLs have provoked an assortment of debates which are listed below:

- Compliance with the TRIPS Agreement, the Doha Declaration and national patent law
  - Need for prior consultation with patent holders
  - Rationale for CL on non-communicable diseases. Invalid CL on heart disease drug and cancer drugs.
  - Legitimacy of CL for low-income countries only, not for Thailand as a middle-income country.
- Legitimacy of the coup government: health care cost containment to spend more on arm forces; hidden agenda to rebrand economic policies under Thaksin); etc.
- Government robs private assets (patents)
- Quality of generic products. GPO is not guaranteed by WHO standards.
- Conflict of interests between the MoPH minister or Thai FDA officials and Indian generic companies which provided generic drugs.
- Trade-off between gains from CL and other socio-economic loss and foreign relation

Proactively, the MoPH issued two White Papers on ten burning issues to explain the rationale, legitimacy, and transparency of Thailand's issuance of CL from socio-economic and legal context (MoPH & NHSO, 2007; MOPH & NHSO, 2008). The first report is dedicated to the first three CLs and the second report to the last four CLs. According to the first White Paper, Thailand's issuance of CL is considered "a form of social movement that aims at improving access to essential medicines and the health of the people" (MoPH and NHSO, 2007, p. preface). Success of the movement depends on knowledge and evidence, social support, and political commitment. The reports respond to critical questions arisen in the public such as regarding negotiations with patent holders and process, international and national law provisions, doubts against conflict of interests. The reports also disclose official CL notifications, letters of support and communications from various parties concerned. These documents include letters from the MoPH to drugs companies; letters from drugs companies that

provided reasons why prices could not be reduced, letters between USTR Susan Schwab and members of the US congress; a letter from the WHO Director General Margaret Chan to the Thai government; and several letters of support to the Thai government.

A highlight of the reports was in the detailed rationale behind the issuance of seven CLs. Lack of access to essential medicines among a large number of Thai people and lack of budget are detrimental. Based on the NLED,[5] those drugs in high demand were identified and explained by a major barrier of high cost as a consequence of pharmaceutical IP. Lack of access to treatment for three major threats to public health security in Thailand was accordingly prioritized, HIV/AIDS epidemic, heart disease, and cancers.

There are over a million Thai people that have contracted HIV/AIDS with more than 500,000 patients still living, while there are roughly 20,000 new infections each year (MoPH & NHSO, 2007, p. 38). A treatment program in line with prevention work is thus critical. Among 500,000 PLHAs, those who reach a certain level of immune deficiency found in blood test and the so-called CD4 test need the first line anti-retroviral treatment. This is to make sure that they do not develop more severe symptoms or opportunistic infections which are life threatening. Anti-retrovirals are proven life-saving treatments, but require lifetime use. An effective first line anti-retroviral is Efavirenz which is less toxic and yields less side-effect, compared with the locally produced GPO-VIR®. Around 20% of patients using GPO-VIR® will develop adverse reactions, either mild or severe.[6] Then they need to switch to the Efavirenz based treatment which costs 1,400 baht per month, more than twice the

[5] A renowned pharmacist scholar noted that the Cabinet has set up a national committee to revise the NLED that contained 900 items since 2004 (Sumlee Jaidee, personal communication, May 7, 2008). However, no concrete results were taken.

[6] The Department of Disease Control, Ministry of Public Health conducted a study on drug resistance among patients who take the first line drug. The study revealed that approximately 10% of patients will eventually resist the first line drugs in the first few years and need the second line drugs (Ministry of Public Health 2007:14). Since there are 500,000 PLHAs in Thailand, at least 50,000 people will require the second line antiretrovirals soon. One effective second-line ARV is the combination of Lopinavir and Ritonavir under the branded name Kaletra®, patented by Abbott Laboratories Limited.

price of GPO-VIR®. Unfortunately, Efavirenz has been patented by a foreign drug company – MSD (Merck Sharp and Dohme Thailand).

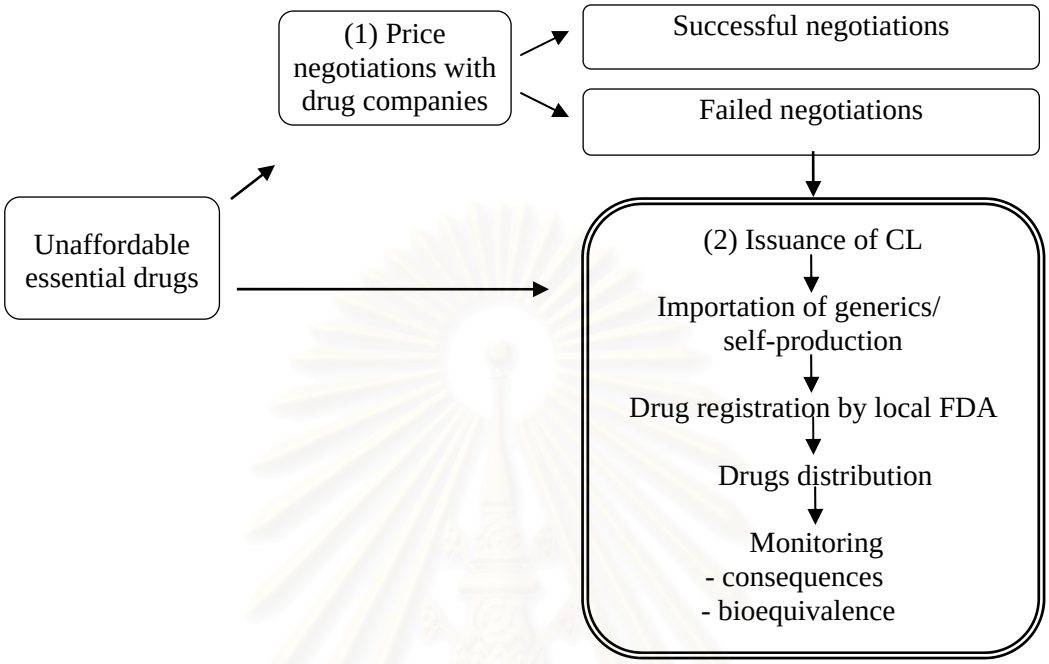
PLHAs in Thailand have suffered physically and mentally from having no access to affordable and effective anti-retrovirals. As Oxfam (2006) suggested, ARV treatments not only suppress mutable viruses and prevent opportunistic infections, but also alleviate stigmas among the public against the PHA. The PHA receiving ARV treatments can work and contribute to their families, communities, and the country as a whole. Initially, the treatment program in Thailand distributed branded antiretrovirals which cost more than 380,000 baht (US$ 10,000) per person per year. The cost was far beyond affordability by the Thai government, which is responsible for providing public healthcare. Only a minority of financially better-off patients would be able to afford such expensive treatments on their own. The white paper by the MoPH and NHSO and a report by Oxfam demonstrated that the Thai government has attempted to increase the budget allocation for antiretroviral treatments. It increased from 800 million baht in 2004 to 2,800 million baht in 2006 (Oxfam, 2006, p. 10; MoPH & NHSO, 2007, p. 38). Through an over three-fold increase in budget, the number of people on antiretroviral treatments expanded from 5,000 to 8,200. Nonetheless, a wide gap is still apparent when this number is compared to the 500,000 HIV/AIDS patients.

A similar scenario applies to heart diseases whose mortality rate tops the third annual ranking (MoPH & NHSO, 2007, p. 38). An effective drug to cure heart diseases is Clopidogrel which is able to prevent coronary obstruction for heart disease patients. It is practically considered the only drug to be used in the case of applying coronary artery stent. It is estimated that there are as many as 300,000 patients in Thailand. But, only 20% of patients can access the medicine under the national health coverage (Bureau of Policy and Strategy, MoPH, 2006, p. 45). The medicine is very expensive due to the fact that there is no competition resulting from its patent data exclusivity. It is estimated that a number of patients receiving the medicine will grow by 6 to 12 fold by virtue of CL (Bureau of Policy and Strategy, MoPH, 2006, p. 45).

Each year over 30,000 Thai people die as a result of cancer, with more than 100,000 new cases reported each year (MoPH & NHSO, 2008, p. 2). Many families are bankrupt because they try to treat family members. Patients decide to quit treatment in the middle after facing severe financial constraints. As a result of cancer CLs, Thailand would save budget as much as 3,219 – 7,937 million baht from 2008-2012, according to the NHSO Deputy Secretary General Winai Sawasdivorn (*Manager Online*, February 29, 2008, para. 8). The leading types of cancer in Thailand are lung and breast cancer. Whereas many new "chemotherapeutic and targeted therapies" have been recently developed, most of these new anti-cancer drugs are patented, costly, and unable to be accessed by the poor and even the middle-class. The national drug list does not include many these cancer drugs because of their high price. Neither are they under coverage of the National Health Security system.

During 2004-2005, the Department of Disease Control which is the biggest buyer of anti-retrovirals in Thailand requested discounts in patented anti-retrovirals in a number of meetings with the patent holders. Official correspondences were also sent in line with the requests. Some companies including MSD Thailand (MoPH, 2007, p. 73) replied officially to explain why prices could not be reduced, basically due to sales conditions and cost of shipment. Not until early 2006 with a sharp appreciation of Thai baht currency, did a few patent holders decide to reduce price of their medicines. Nonetheless, the best favorable reduction was less than 20%, not greater than the level of currency appreciation (MoPH & NHSO, 2007, p. 5). Then alternatives were studied in order to make the patented medicines cheaper and affordable. A substantial increase in national budget, leap-frog development of technology, and an installation of effective price control system are not likely to solve problems in due course. These alternatives require huge resources and time while the problems are severely pervasive and need prompt response. As a result, possible alternatives were limited to: (1) negotiations with the drug patent owners; or (2) the exercise of patent use by the government (CL) (see Figure 3.1).

Figure 3.1 Two alternatives to improve access to medicines



3.3 Political Opportunities Structure (POS) of the Thai government's issuance of CL

This section presents findings and analyzes the significance of the changed political context under the military-installed government of General Surayud Chulanont vis-à-vis Thailand's ability to issue CL. It responds to the first research objective and tests the hypothesis that Thailand's ability to issue CL was determined by particular properties of political opportunities brought about by the September 19 coup, coupled with the bureaucracy at the level of the MoPH itself.

This section sets out an overview of previous national political landscapes from which the political context and underlying constraints against possible issuance of CL in the past can be understood. The Chuan II government and the Thaksin government are placed a focus because movements for access to medicines in Thailand became intense during their administrations.

Subsequently, this section uses the modified framework called **"Political Opportunity Structure (POS)"** outlined in Chapter I to explain how the coup government of General Surayud Chulanont opened up political opportunities for the MoPH's mobilization and success to issue CL. It explains the changed setting, agenda and nature of the coup government.

3.3.1 Patronage bureaucracy and liberal corporatism[7]

The 1980s witnessed profound changes in Thailand (Suchit, 1996; Pawin and Pimchanok, 2004). Chatchai Choonhavan's government (1988-1991) was marked by a decline in internal insurgency and his proposition to transform Indochina "from a battlefield into a marketplace" (Suchit, 1996). With an emphasis on economic and trade policies, exports were diversified to cover more manufactured goods such as textiles, garments and canned food. Tourism was successfully promoted and became a leading source of national revenue. The country experienced for the first time a two-digit growth rate during 1986-1990 after it had been transformed from an import substituting to export-led economy.[8] Since then, Thailand has pursued a market-oriented economy and undergone a series of structural adjustments including harmonizing trade rules and regulations and raising IP protection measures. Thailand has adopted the "dual track" approach by strengthening the domestic economy while integrating more into the global market. Thailand was applauded as one of the fastest growing economies in the world (Bank of Thailand, 2003, cited in Tawin & Pimchanok, 2004).

[7] "Liberal corporatism" is used as a dominant model by scholars particularly Anek Laothamatas (1992, 1996) in explaining the Thai state since the late 1970s To Anek, the dramatic economic advancement of Thai state gave rise to an extra-bureaucratic force, i.e. business associations in central Bangkok and provinces. He asserted that their associations succeeded in advising, initiating, transforming, and blocking important economic policies and legislation laid by the governments. These associations were able to transform Thailand from an import-substitution economy with an agricultural base to an economy based on export-led strategies, tax and tariff reduction, removal of bureaucratic spoils, etc. He asserted that the liberal corporatism model applies to the Thai context and that the business realm could influence public policies through their strategic positioning in a capitalist economy, their cliental ties with high-ranking bureaucrats, and simply as an organized group (Anek, 1996, pp. 19-23).

[8] The transformation was noted by the year 1972 when the Industrial Promotion Act came into force. See Tawin & Pimchanok (2004), especially paragraphs 1-3.

An important turn in the role and scope of civil bureaucracy in Thai politics was marked in the 1990s as a consequence of a change in the nature of the national political regime (Yoshinori, 2002). It is in this period that Anek's liberal corporatism model perfectly applied to Thailand's politics and civil bureaucracy. The Thai polity by the mid1990s had advanced to a parliamentary democracy, which spawned a new political class of elected parliamentarians and political executives and led to an increased role of businessmen politicians. The rise of these professional politicians formed an unstable cabinet coalition which was loosely connected with political parties based on regional and local networks of businessmen and influential people. "Money politics" came to dominate the electoral and parliamentary processes. At this point, the civil bureaucracy could retain a stronghold on policy and administrative power, partly due to weak and indecisive coalition governments (Bidhya, 2001). Resource allocation and benefit sharing were increasingly shaped by the relations between individual ministers and civilian bureaucrats. Such relations notoriously induced an increase in grafts, bribery and political donations by prominent businessmen in exchange for government favors.

1) Chuan 2 government and agenda priorities (1997-2001)

The 1997 Asian financial crisis had a profound effect on Thai politics, particularly in terms of the national agenda. Economic revival became the dominant issue, taking priority over political reform and public healthcare. Although Thailand's economic growth was due to the state's crony capitalism and prevailing patronage bureaucracy, Thailand's economy ground to a halt and lost its shine as part of "Asian Economic Miracle". Prime Minister Chavalit Yongchaiyudh resigned following the collapse of the baht currency. The second administration under Chuan Leek Pai took office in late 1997 with the high expectation that they would restructure the economy. Despite all the ill effects, the 1997 financial crisis was not completely negative, as it was followed by at least two major agendas in Thai politics.

Economic revival came first! During the first year of the 1997 financial crisis, the depreciation of the Thai Baht by over 100% prompted the government to seek

loans from two global financial institutions, the World Bank and the International Monetary Fund (IMF) (Pasuk & Baker, 1998). They mandated semi-coercively that Thailand adopt a structural adjustment package in exchange for bailout loans. Therefore, Thailand was subject to loan conditions, including downsizing, de-bureaucratizing, restructuring (bankruptcy procedures), and establishing strong regulatory frameworks for banks and financial institutions. The Chuan government expressed earnestness in implementing these "bitter medicine" policies despite criticism that Thailand was the IMF's slave. Media, civil society, and scholars including Joseph E. Stiglitz, former Chief Economist and Senior Vice-President of the World Bank, joined the attack. Stiglitz contended that the IMF and World Bank only served the benefits of globalization and financial interests of advanced industrial countries (2002, p. 20) The IMF ruined livelihoods of the impoverished and its recovery measures could only exacerbate the East Asian Crisis (Stiglitz, 2002, p. 104).

At the same time, the crisis increased domestic public awareness for political reforms and gave rise to the 1997 "people constitution". Progressive civil society backed up by the urban middle class, who accumulated wealth in the boom and abruptly lost it in the bust, forged alliance with reform-minded members of the bureaucratic and political elites. The constitution, hailed as a landmark in Thai democratic constitutional reform, laid the underpinning of a political-cum-constitutional reform and put in measures aimed at curbing corruption in the political class. One series of the measures was setting up independent, quasi-judicial watchdogs as part of the state machinery (a constitutional court, anti-corruption commission, audit commission, etc.). Another set aimed to dilute the autonomy of political executives from parliament. Ministers, for instance, were prohibited from serving as constituency MPs as a means to remove them from influencing money politics. Lastly and most substantially, the constitution declared the virtue of "decentralization" as the most concrete aspect of a bureaucratic reform as well as devised mechanisms to assert civil rights, enable popular participation, and bring about administrative decentralization and stronger local self-government.

For health sector, the financial crisis resulted in significant budget cuts and reform of the economy and financial institutions.[9] Compared to the huge amount injected into economic healing, it is evident that public healthcare was sidelined. This had a major impact on access to essential medicines. The HIV/AIDS control budget, for instance, was reduced by 33%, affecting in particular the program to provide anti-retroviral drugs to HIV-positive pregnant women to prevent transmission of the virus to their infants (Toole et al., June, 2000, p. 6). Access to essential medicines was adversely affected not only because Thai Baht depreciated and resulted in much higher prices for imported medicines or substances. The proportion of the population below the poverty line immediately increased and people turned to utilize lower quality public healthcare as part of the general "belt tightening" among even middle and upper class.

So far the Chuan administration and its agenda priority shed some light on what blocked access to medicines, when referring to the case of ddI. Access to ddI agenda was simply not given priority, even though contributing factors such as legality and local production were well in place. The government might not have cared or merely wanted to be distracted at all. Also it is too simplistic to state that the Chuan administration lacked 'political will' as it is one of those catch-all phrases. Nonetheless, a broad structural barrier can be wrapped up because the MoPH bureaucracy was linked up with national politics. Public Health Minister Korn Thapparansi was put in the office under the Chuan 2 government. This government dealt largely with the aftermath management of the 1997 financial crisis and the institutionalization of political reforms. Any other risks should not be taken and the government did not want to do anything to antagonize trade partners, especially the US.

[9] The government cut back the health budget by 14.6% or a US$240 million decrease compared with the original proposed budget (Toole et al., June, 2000, p. 16). The budget cuts in health and other sectors while Thailand received as much as US$ 17.2 Billion financial support from the IMF and other bilateral and multilateral support (Photjanee, Doungdao, Nunthawadee & Chorthip, 2004, p. 26). The 1998 MOPH budget of 59.92 billion baht in 1998 compared with 66.544 billion baht in 1997 (Toole et al., June, 2000, p. 16). The most significant reductions within the health budget were in health promotion programs consisting of a 54% cut in nominal terms compared with 1997.

Nevertheless, the population became increasingly discontent with the lack of an economic recovery. The implementation of the IMF-sponsored structural adjustment agendas prompted a political reaction against the Chuan coalition and tapped sentiments of Thai nationalism. The Chuan administration had to dissolve the House of Representatives. This occurred just prior to the expiration of Chuan's second term in office, forcing an election in January 2001 which gave rise to Prime Minister Thaksin Shinawatra.

2) Thaksinomics, neo-liberalism, and conflict of interests (2001-2006)

The comfort in the 1997 Constitution and the aftermath of the 1997 Financial Crisis were swept aside by a political transformation of another kind – Thaksin Shinawatra's landslide election victories in 2001 and 2005.[10] The Thaksin administration brought to the forefront a shift in the political economy in favor of business dominance. It marked the full-blown liberal corporatism of the Thai state that regressed bureaucracy, went against civil society, and pushed the army back to the barracks. The capitalist class overridingly entered the cabinet, participated in public policy process, and took greater share of power from civil bureaucrats. In comparison, patronage bureaucracy was conspicuous during previous governments and the Chuan administration; businessmen were highly dependent on civil bureaucrats. Businessman-turned-politician Thaksin and his circles took root and became autonomous in gearing the country.

While the Thaksin phenomenon has received much attention in burgeoning studies, what most capture this section are key features in his economic policies orientation, the so-called Thaksinomics,[11] in relation to access to medicines and

[10] Thaksin's Thai Rak Thai (TRT) Party won a near-majority of seats and survived the full four year term through forging alliances with or absorbing other parliamentary political groups. The growing dominance of a unified political executive in this new political order was reaffirmed in the 2005 election, when TRT won approximately two-thirds of the popular vote and an increased parliamentary majority. This enabled it not only to rule without a coalition partner but also to forestall any parliamentary censure vote.

[11] Pasuk explained that the term Thaksinomics was first used by journalists in Thailand in 2001. It gained wider coinage after President Arroyo of the Philippines used it in 2003(Pasuk, 2003, p.1).

public healthcare in the country. Two fundamentals of Thaksinomics, growth and trade liberalization, are discussed below.

In a concerted effort to recover from the aftermath of the 1997 crisis, the Thaksin government continued the government's traditional commitment to prioritize economic growth with a high degree of external orientation. His tool-kit of techniques served the global ascendancy of neo-liberalism with "market-type-mechanisms[12]". Thaksin and his allies were clearly ambitious to drive Thailand into the ranks of the economically advanced countries by pursuing a new economic development strategy of *dual-track* model. The model mandated one half to focus on domestic stimulus to grass-root development and the other half on the external economy or outward orientation. In particular to attract FDI and to please foreign investors, Thaksin quietly abandoned the plan to pass a law restricting the role of foreign retailers.

To facilitate growth, free trade was a cornerstone of the Thaksin government's trade policy. In fact, free trade ideology is not new. It was prolonged from the liberalization policy attached to neo-liberalism the Anand Panyarachun government had started in the early 1990's. However, the issue was highly controversial when allegations and evidence unfolded conflict of interest in Thaksin's cabinet, which included a handful of businessmen-cum-politicians. Conflict of interest is referred to as a situation in which an individual, usually a politician or a public official, exploits official capacity in some way for his own personal benefits. Studies show that the signing of free trade agreements with China, Australia, New Zealand and some other countries benefits politicians' businesses in telecommunication, car manufacture, and big agricultural companies (NHRC, 2006; Oxfam, 2006). It harms small and medium farmers who are less competitive and less subsidized than farmers in those countries. It was also contended that the Thaksin government did not state its policy to open telecommunication sector to foreign competition under FTAs because of concern for their own interests.

[12]Thaksin stated his approach to government before becoming the Prime Minister that "a company is a country. A country is a company. They are the same. The management is the same. It is management by economics. From now onwards this is the era of management by economics, not management by any other means. Economics is the deciding factor" (Pasuk, 2003, p.8).

Internationally, the Thaksin administration actively responded to the world order of neoliberalism agendas by pushing free trade agreements and many other economic strategies. Domestically, it came out with a string of *populist* policies to maximize voting power. Welfare-type policies referred to as 'care' (*ua-athorn*) program were introduced to improve the quality of life and reduce social tensions, to share the benefits wider, and to make the formally excluded feel more a part of the process of economic growth. These covered a life insurance scheme for the poor; bicycle loans for 300,000 students living far from schools; scholarships for poor students; loans for the purchase of low-priced televisions and computers; loans for purchase of taxis; and cheap housing for middle income urban families.

Undeniably, one of the most successful populist policies of the deposed Thaksin government was the 30 baht-per-visit health scheme, which especially benefited the poor. However, the policy was not really the party's invention. The idea had been pioneered a year earlier by a network of medical professionals, health advocates and NGOs on consumer rights protection. Then Thaksin Shinawatra took up the idea and turned it into his party's campaign agenda, bringing it enormous political support.

3.3.2 How the September 19 coup opened up political opportunities for the Thai government's issuance of CL?

The September 19 coup is a good departure to explain how MoPH bureaucrats found opportunities to collectively mobilize for CL. Academics and civil servants shared a general view that the passing of Thailand's CL owed considerably to the coup (including Jiraporn Limpananont, personal interview, January 3, 2008; Sorachai Jamnian-damrongkarn, personal interview, January 3, 2008; Suchart Chongprasert, personal interview, February 4, 2008). However, they pointed out it was not due to the coup's steadfastness. Rather the post-coup administration, *by accident,* named Doctor Mongkol Na Songkhla as head of the MoPH or at least agreed to pick him as proposed by health advocate groups (Jiraporn Limpananont, personal interview,

January 3, 2008). Yet, social activist, Jon Ungpakorn, who was among the coup dissidents, believed that CL would be passed sooner or later as a result of patients' rising demands and of accumulated preparedness by health civil society had it not been passed under the military-installed Surayud Government (personal interview, December 18, 2007). Likewise, a top FDA official insisted "*We should not say that because of the coup, we could issue CL. We have had the legal option for a long time. The coming [of the Surayud government] was conditioned on national interests. Therefore implementing CL was not difficult.*" (personal interview, February 4, 2008).

The next section applies two concepts of national cleavage structure and institutional structure in explaining political opportunities that the coup government of General Surayud Chulanont opened up for the Thai government's issuance of CL.

1) National cleavage structure

By national cleavage structure, this research means political realignment and division of elites. The coup government brought an interlude to the Thai politics previously overwhelmed by the capitalist class during the Thaksin administration. A series of the Surayud government's policies were, of course, not a coincidence, e.g. rebranding Thaksinomics, halting Thailand-US FTA negotiation, and barring ex-TRT officials from all political participation. It would be too simplistic to judge if the coup wanted to uproot the Thaksin's legacy and to completely reject neoliberal agendas. Critics viewed that Surayud's rush signing of the Japan-Thailand Economic Partnership Agreement (JTEPA) sent a message that the coup government did not shut its door to globalization, despite its emphasis on the sufficiency.

Upon seizing power the reformist military gave four reasons for the coup. In short, the justifications read that the well-intentioned coup inevitably took place for the national interest because the Thaksin administration had widely devastated social division and corruption. The coup had no intention to rule but to return the power to the people as soon as possible. Therefore, the coup leaders put themselves in a situation to

prove their accusations and to convince their legitimacy. This can be explained in two phenomena.

Rebranding Thaksinomics - While badmouthing Thaksinomics and free-spending populism, the coup government kept but renamed several of Thaksin's key policy platforms, including a 30-baht universal health scheme, a village loan fund and cheap loans from state-owned banks. It imposed capital controls and revised foreign ownership rules that immediately damaged the investment climate. Critics, including Simon Montlake (2007), believe that these were the result of "political calculations" and that the coup government showed a clear signal to rebrand as much of Thaksin's legacy as possible. However, the coup government could not escape from "populist" policies, according to Montlake (2007).

Sufficiency economy - The September 19 coup was a royal coup, according to critics (Ivasson, 2007, Jiles, 2007). The King's philosophy of sufficiency economy was activated nationwide to increase a sense of political legitimacy for the coup itself and the coup government (Ivasson, December, 2007). The Interim Primer Minister Surayud Chulanont stated in his government's policy outline that it "will uphold market mechanisms in its economic policies, but good governance will be instilled under the philosophy of sufficiency economy to ensure economic fairness and minimize conflicts of interests as well as personal interests" ("Policies of Surayud Government", *The Nation*, October 28, 2006). The concept was incorporated into the draft constitution passed in August 2007 and the tenth National and Economic Development Plan. The coup government also drained 10 billion baht for projects in response to sufficiency economy ("Cabinet replaces Thaksin's SML policy", *The Bangkok Post*, February 13, 2007). Since then sufficiency economy was everywhere and functioned as the branding of the post-coup government versus the Thaksin administration. It gave a clear ideological clash of Thaksin's unbridled capitalism, consumption, and greed vis-à-vis sufficiency economy as guardian of ethics, Buddhist morality and the King. Yet, to critics, which appear to be a few, it is difficult to judge what adherence to this philosophy is in practice. It is a dangerous act that sufficiency economy be criticized due to the strict law of *lesè majesté* of the country.

The coup's reorientation of agendas discussed above was a contributing factor for the issuance of CL. Expanding number of patients for access to medicines with the same amount of budget or the slight increase in budget is aligned with sufficiency economy. CL policy makers claimed that they value morality and ethics for people welfare over capitalism. The MoPH Minister Mongkol Na Songklha revived a sense of nationalism that CL equates national sovereignty for which Thailand must not give in threats from industrialized countries (*Manager Daily*, January 26, 2007). The disadvantaged population's interests were ultimately considered. Another assumption was also possible. If the coup government blocked the use of CL as happened before, there was the most likelihood that the issue of conflict of interests would be raised by the public. Given that the coup leaders stated that they were against the conflict of interests, it makes sense that the coup government kept its hands off in this matter.

2) Institutional structure

A conceptualization of the overall institutional setting is often distinguished between strong and weak (Zysman cite in Kriesi, Koopmans, Duyvendak & Giugni, 2003, pp. 53-59). The internal structure of state institutions in general, i.e. the degree of its internal coherence and fragmentation as also discussed in the previous section, is believed to determine the overall strength and weakness of a given state. The administration following the September 2006 coup was supposed to be strong and its institutional setting closed. A change in state regime from a democratically elected government to authoritarianism generates a centralized political environment with effective policy instruments at its command. An authoritarian regime has capacity to implement public policies it chose to support, irrespective of the policies in favor of claims made by citizens and civil society. Nevertheless, there is no consensus on how to inclusively describe the Thai state during the General Surayud administration with regard to Thailand's CL. As strength and weakness of Thai state is relational, such values vary for different social actors and sectors of Thai state and according to how political opportunities evolve. There is a mix of 'open' and "closed" stances by the state if taking interviews and opinions of Prime Minister General Surayud Chulanont

as a key state actor. Public Health Minister Mongkol Na Songkhla repeatedly said that "the Primer Minister gave greenlight to issue CL.

In contrast to the predisposition above that the coup administration should be closed and centralized, scholars view that the coup civilian government showed some degree of decentralization (Sorachai Jamniandamrongkarn, personal interview, January 3, 2008; Suchart Chongprasert, personal interview, February 4, 2008). This characteristic may constitute a determining factor because the MoPH tends to have greater autonomy to issue CL. Having a status of a short-lived government can count, according to local media (*Matichon*, 2007, March 17). The coup government was opposite to the Thaksin administration which favored CEO style and centralization.

The discussions above demonstrate that Thailand's ability to issue CL derived from reconfigurations of national cleavage structure and institutional setting following the September 19 coup. By appointing the former bureaucrats Mongkol Na Songkhla as the new MoPH minister, it provided one of the great opportunities for reform-minded MoPH bureaucrats as well as public health advocates to mobilize for the issuance of CL. The reorientation of agendas by the coup government also has a significant implication from which CL decision makers can use for their grounds. A local newspaper viewed that the pro-poor idealism as expressed by the coup government was in proportion to the Thai government's issuance of CL (*Matichon*, 2007, March 17). With regard to institutional setting, this section found out that a determining factor is perceived by a decentralized characteristic of the coup administration.

After examining the context of national politics, the following section places its focus on how the administration at the level of the MoPH was accountable for the issuance of CL.

3.4 Politico-Administrative Structure (PAS) of the Thai government's issuance of CL

This section presents findings and analysis of key features (*cultural and structural/functional*) of the MoPH's bureaucracy that significantly contributed to the issuance of CL. It responds to the second and third objectives of this research as well as tests the research hypothesis. The **"Politico-Administrative Structure (PAS)**" framework is applied to the context of the MoPH. The PAS is generally offered in a public administration framework that characterizes a realm where a political executive (minister) bargains with a top bureaucrat (permanent secretary) or where political management corresponds to or collides with bureaucratic administration. In this research, the PAS is extended to a broader context in which relationship and bargaining space are not confined to state actors (minister versus bureaucrats), but integrate non-state actors, particularly health advocate groups and drug TNCs.

This research uses the term "bureaucracy" while recognizing that the term "bureaucracy" *per se* contains some discrepancies. "Bureaucracy" is not merely referred to as the civil service system. Being or having "bureaucracy" is attached to a variety of meanings, ranging from the notion of red-tape and obstructionism to the ruling of an oligarchy within both state and non-state institutions. Literally, the civil service would define accurate features and patterns of a state's administrative system. But civil bureaucracy would typically connote a hierarchical line of command and a complex decision-making process in a civil institution as the direct arm of a state. In any case, according to the Weberian sociological framework, a bureaucracy is considered the most efficient "type of organization designed to accomplish large scale administrative tasks by systematically coordinating the works of many individuals" (Gerth & Mills cited in Komatra, 2002, p. 17). This research will use the term "bureaucracy" in this sense.

3.4.1 Decoding philosophy and institutional perceptions behind the Thai government's issuance of CL

To decode cultural elements of Thailand's issuance of CL, this section sets forth two parts. The MoPH's philosophy is discussed as dominant administrative culture that could constitute to the issuance of CL. Next, overriding perceptions are examined on the human right to access to medicines as institutionally recognized in Thailand.

1) The MoPH's philosophy

The issuance of CL can be interpreted from the MoPH's philosophy. MoPH bureaucrats are, at least in theory, attached to some professional and ethical standards to safeguard public health, be they ministers, permanent secretaries, bureaucrats, doctors and pharmacists. The MoPH's bureaucracy is distinctive in the nature of the work and in the bureaucrats themselves. By putting doctors, pharmacists or dentists in office and giving them sovereign authority to manage the lives of people, public healthcare is extended from governing to caregiving under a set of medical and pharmaceutical morals and ethics. On the other hand, such professional sovereignty[13], when combined with civil bureaucracy, may exclude civic participation from policy process and mechanisms. Health development directions in the hands of the bureaucracy can also lead to the consolidation of power.

[13] Public health scholars explain public health professional sovereignty as a legacy that has resulted from the process of creating professional sovereignty in the past (Chanet, 2002; Komatra, 2005). From the onset of modern Thai healthcare, 'doctors' were made a special social class with professional prestige. This sovereignty has considerably led to a monopoly of the country's health authority by doctors, thereby depriving other stakeholders a role in defining and determining healthcare systems. This legacy was very much aggravated by the Rockefeller Foundation. Rockefeller provided assistance in upgrading Thai medical schools to meet international standards, following Thailand's request which was approved by King Rama VI. Rockefeller imposed stringent conditions in exchange for the Thai government's investment in resources to make the medical profession a prestigious career in Thailand as it is in the US. The employment of medical graduates was upgraded and the salary was first set at 160-240 Baht, two to three times higher than the normal wage of comparable professions at the time. The government was further obliged to invest in building medical infrastructure and a network of hospitals to serve graduates.

To generalize fundamental philosophy, non-issuance of CL is pro-business while issuance of CL is pro-health or pro-poor. Because CL is a trade-off policy, whether or not the MoPH decides to issue CL is largely dependent on how outcome is prioritized. Decision makers have to assure that issuance of CL is to achieve maximum social gains and the greatest benefit over cost. It is vital to weigh social, economic and political values at stake; judge pros and cons or calculate ratio of costs and benefits of issuance CL over each medicine; and finally to recommend the most efficient implementation of the CL. However, it is not always possible to quantify loss over gains and human life over trade benefits. *"If CL would save only one single life, we still want to do it"*, NHSO official said (Sorachai Jamniandamrongkarn, personal interview, January 3, 2008). Thus the issuance of CL prioritizes to increasing the welfare for people suffering from diseases rather than protecting commercial gains and the transnational pharmaceutical industry. Critics of CL believe that the Thai government's issuance of CL could lead to substantial loss in profits from international trade and in several hundred thousand jobs. For example, the US retaliated against Thailand's issuance of CL by downgrading Thailand to the PWL list and cut military aid as well as drug TNCs' threats to remove Foreign Direct Investment (FDI).

Individual leadership of top MoPH bureaucrats was a determining factor that led to the issuance of CL (Jon Unpakorn, personal interview, December 18, 2007; Suwit Wibulpolprasert, personal interview, January 3, 2008). The issuance of CL was largely dependent on the values, interests, and power of the MoPH minister who normally monopolizes decision-making capacity. Health Minister Mongkol Na Songkhla has been extensively hailed as a hero for his courage and decisiveness to fight for CL:

> *"…Don't worry that medicines will not be available. The companies won't close down factories and stop selling drugs. Thailand's compulsory licensing is not used out of spite, but because such patented drugs are very expensive. We have such a limited budget that we have to find ways to get drugs cheaply. On 25 January, I already signed the compulsory licensing announcement, which will officially come into effect on 29 January.* ***If we give in to their threats, we'll be enslaved forever."*** (bold by the author) (*Manager Daily*, January 26, 2007)

> *"…I don't know how to calculate a human life and compare its worth against the exports value to the US. I'm really at my wits' end and don't know how to solve the problems for our people, a lot of whom must die because they cannot*

> *afford to buy medicines. It's typical that foreigners will disagree with our CL. But it's a hundred times more painful to hear my Thai fellow call me a robber."* (*Daily News*, May 6, 2007, cited in Kannikar, 2007, p. 56)

2) Thailand's institutional perceptions on the human right to access to medicines

Access to healthcare is a constitutional right of the Thai people. Chapter 3, Part 9, Section 51 of the Constitution of the Kingdom of Thailand B.E. 2550 (2007) which is equivalent to Section 52 of the previous Constitution B.E. 2540 (1997) states that:

> *"A person shall enjoy an equal right to receive standard public health services and the impoverished shall have the right to receive free medical treatment from public health centers of the State.*
>
> *The public health service by the State shall be provided thoroughly and efficiently.*
>
> *The State shall prevent and eradicate harmful contagious diseases for the public free of charge in a timely manner."*

Medicine is one of the key components recognized by a national public health system. Thailand started developing a national plan called "National Drug Policy B.E. 2524" in 1981 (Health Consumer Protection Programme (HCP) et al., 2007).[14] It was a part of the public health section in the Fifth National Social and Economic Development Plan (B.E. 2525-2529) (1982-1986). The plan outlined five key components of national drug policies (HCP et al., 2007, pp. 4-5): 1) distribution of essential medicines; 2) promotion of rational use of medicines; 3) equal quality assurance of all medicines; 4) promotion of the use of local raw materials for drug manufacturing; and 5) utilization of herbal medication and traditional medication. The plan also endorsed the National List of Essential Drugs (NLED) B.E. 2524 (1981) and the regulation on drug procurement by public health centers under the MoPH. Therefore, as these public health facilities adopted the National List as criteria for the selection of drugs to be used, it could better ensure availability and affordability of drugs for all Thais, including marginalized groups (HCP et al., 2007). The National Drug Policy was amended in 1993, adding on two components: 1) encouraging and supporting the use of the National Essential Drug List in

[14] The plan followed the first WHO Model List of Essential Drugs which published in 1977. This WHO list contained 208 pharmaceutical products; essential drugs for basic needs, drugs which satisfy the health care needs of the majority of the population and should be available at all times in adequate amounts and in the appropriate dosage forms. The list is used as an effective a tool to ensure drug supplies for education and for highlighting lacunae in therapeutic needs.

both public and private health sectors; and 2) improving the efficiency in drug administration and legislative procedures, rules and regulation in favor of consumer protection (HCP et al., 2007, p. 5). Accordingly, the NLED's last revision was in 1999 to assure that all necessary drugs for healthcare were covered. A national List of Herbal Medicinal Products was established for the first time in the same year. These two drug lists have been groundbreaking 'on a sustainable and equitable basis' for health benefits under the current three national healthcare schemes (UC, SSS, and CSMBS).

Another milestone is found in the promulgation of the National Health Security Act B.E. 2542 (2002) by the virtue of the national Constitution B.E. 2540 (1997). To implement the Act, the National Health Security Board was set up accordingly. From the onset, the Act encourages active participation of nonprofit health community sectors. Its Chapter 2 Section 13 states that the Board shall be made up of, among others, five representatives from different nonprofit groups including children and adolescents, women, elderly, disabled, HIV or other chronic disease patients, labor, populous communities, agriculturists, and minorities. Therefore, these marginalized groups are able to make their voice heard.

3.4.2 Transforming structural limitations to active (functional) administrative policy for CL

Structural and *functional* elements are decoded from specific forms within the MoPH's bureaucracy in relation to the issuance of CL. Such forms are depicted by the set-up of concerned administrative bodies and by at least three sets of relationship: 1) MoPH minister vs MoPH bureaucrats; 2) MoPH minister vs other ministers and cabinet, and 3) MoPH minister and bureaucrats vs non-state actors (mainly health advocate groups and drug TNCs). In general structure and function may be viewed in, but not limited to, two basic dimensions: *vertical* and *horizontal.* The former refers to the degree of authority dispersion, centralized or decentralized. That is how far authority is shared among different groups/ levels. The latter concerns the degree of *horizontal* coordination in which the MoPH central executives (minister and top bureaucrats) are able to get their acts together in order to ensure that all concerned

ministries and the central government pull together in the same direction. Horizontal coordination can be broadly conceptualized as *highly coordinated* or *highly fragmented.* These two dimensions could overlap and induced bargaining space that was opened up not only in formal setting, but also informal setting for the passing of CL.

1) The MoPH's structural limitations

The MoPH's bureaucracy has gone through a series of organizational development during the past three decades. Management reforms with a core concept of "good health at low cost" have been discussed by the MoPH since the end of the 1990s (Kuwajima, 2003, p. 214). At the center, efforts have been put on a more unified integration of functions and roles of public health care administration by merging health departments and medical services and by enhancing the jurisdiction of permanent secretary. At the field level, attempts were made to develop provincial and district administrative arms. The MoPH's structure is insofar perceived in both centralized and decentralized manner. As a result of civil administration reform in October 2002 mandated by the Thaksin government, the MoPH was reorganized into three clusters (medical services development, public health development, and health services support) and the Office of Permanent Secretary (see Appendix F the MoPH's structure).

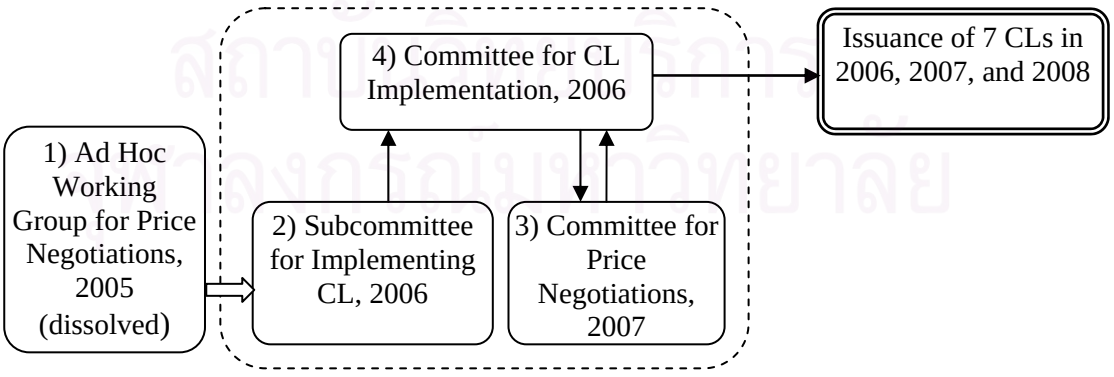
Issues on access to medicines are primarily concerned with two main MoPH clusters (Cluster of Public Health Development and its Department of Disease Control and Cluster of Public Health Services Support and its Food and Drug Administration) as well as the NHSO under the Supervision of the MoPH and the GPO as state enterprise. When various public agencies are involved, making it awkward for the overall institutional setting of the MoPH to process CL. Past experience on the ddI case also showed that such institutional setting that was subject to hierarchy of decision making was prone to the minister and bureaucrats' conflict of interests (Sorachai Jamniandamrongkarn, personal interview, January 3, 2008).

2) CL as an active administrative policy

This section defines Thailand's CL as an active administrative policy as intentional efforts were made by transforming the structure, function, and personnel of pubic health sectors (mainly the MoPH and NHSO) How the CL as an administrative policy has been mobilized is conceptualized into two dimensions, *vertical* and *horizontal*. The former refers to the degree of authority dispersion, centralized or decentralized. That is how far authority is shared among different groups/ levels. The latter concerns the degree of *horizontal* coordination in which the MoPH central executives (minister and top bureaucrats) are able to get their acts together in order to ensure that all concerned ministries, the central government, beneficiaries and affected parties pull together in the same direction. Horizontal coordination can be broadly conceptualized as highly coordinated or highly fragmented.

For ***vertical dimension***, findings show some degree of authority dispersion to mobilize for Thailand's CL. By means of decentralization, CL has been driven by four working groups, one was dissolved (see figure 3.2). There is a high degree of shared responsibility and specialized functions among different working groups.

Figure 3.2 CL as active administrative policy



In 2005, an ad hoc working group was set up by the public health ministerial order to negotiate prices of patented essential drugs. The working group was chaired by the Thai FDA Secretary General and comprised of representatives from concerned

departments in the MoPH and the MoC. One year later, the working group concluded their failure in a brief report indicating that they hardly received cooperation from drug patent holders (MoPH & NHSO, 2007)

Following the disbanding of the ad-hoc working group for price negotiations in 2005, a subcommittee for implementing the government use of patent on essential patented drugs, which was set up in April 2006, is another landmark. The NHSO as chairing representative plays a consistent role in identifying choice, means, and end and pushing for CL. This working group was initiated during the term of former Public Health Minister Pinij Jarusombat of the Thaksin administration. The subcommittee for CL implementation is chaired by the NHSO Secretary General and comprised of representatives from the MoPH, the MoC, law society, and civil society groups including consumer and health organizations, health professionals and people living with diseases (HIV/AIDS and cancer). The subcommittee is commissioned to (MoPH & NHSO, 2007, pp. 82-83): 1) develop and propose criteria for the selection of medicines and medical equipment subjected to CL; 2) select medicines or medical equipment and propose them to the NHSO for further undertaking on CL; and 3) monitor consequences following CL's implementation and propose recommendations.

Table 3.2 Four working groups mobilizing the issuance of CL

	Ministerial order	Responsibilities	Chaired by	Report to
1	**Ad-hoc Working Group for Price Negotiations 2005** (dissolved)	• studied and analyze problems arising from price of patented drugs; • specified patented drugs whose price negotiation is needed; • negotiated for reasonable price of the specified patented drugs; etc.	Professor Dr. Pakdee Pothisiri, Secretary-General, FDA	MoPH Minister
2	**Subcommittee for CL Implementation 2006**	• develop and propose criteria for the selection of medicines or medical equipment for CL; • select items in 1) and propose them to the NHSO for further CL undertaking; and • monitor consequences following CL's implementation and propose recommendations; etc.	Dr. Sanguan Nitayarumphong, Secretary-General, NHSO	Committee for CL Implementation, 2007 (no. 4)
3	**Committee for Price Negotiations 2007**	• similar to those of the negotiation working group 2005; • negotiate for reasonable price and/or for technology transfer through voluntary licensing of certain essential drugs (including those that have been already had CL and those that have not yet been exercised such right); • study and set plans and guidelines and necessary measures to facilitate the successful negotiation; etc.	Dr. Siriwat Thiptaradol, Secretary-General, FDA	Committee for CL Implementation, 2007 (no. 4)
4	**Committee for CL Implementation 2007**	• submit proposals to issue CL to the MoPH Minister • serve as core contact in minimizing and settling disputes effected by the issuance of CL	Dr. Vichai Chokevivat, Advisor the MoPH Minister	MoPH Minister

Source: MoPH & NHSO. (2007). *Facts and evidences on the 10 burnings issues related to the government use of patents on three patented essential drugs in Thailand.* Bangkok: Sangsue Co.,Ltd.

The proposals that were approved by the Health Minister Mongkol Na Songkhla in order to exercise the right to issue CL were initially submitted for the signature of the former Health Minister Pinij Jarusombat. The Subcommittee conducted extensive research in order to assure that a decision would be made in a most efficient manner (Suwit Wibulpolprasert, personal interview, January 3, 2008). They studied pertinent factors, conditions, domestic law, international law, etc. Experiences from foreign countries both developed and developing countries which formerly issued CL were assessed on their success and failure. Health Minister Pinij Jarusombat delayed his decision and had not signed approval to the proposed CLs until he had to leave the office following the September 19 coup that overthrew the Thaksin administration.

Following the issuance of the first three CLs, the Committee for Price Negotiations was additionally set up. The Committee, which is chaired by the FDA's Secretary General, is assigned two major tasks. Fist is to study, analyze and negotiate for reasonable prices for both medicines having been exercised CL and those with potentials. Second, it deals with all necessary procedures following the issuance of CL, i.e. importation of generics and/or coordination for local production, registration of generics, distribution of generics and monitoring of generics consequences and bioequivalence (see figure 3.1). This committee has a strong implication in proving to the public that formal negotiations have actually taken place (Vichai Chokevivat, personal interview, January 3, 2008). However, a senior MoPH official cautioned that it is also necessary to distinguish between "undertaking negotiations" and "demanding negotiations acknowledgement" (personal interview, February 4, 2008).

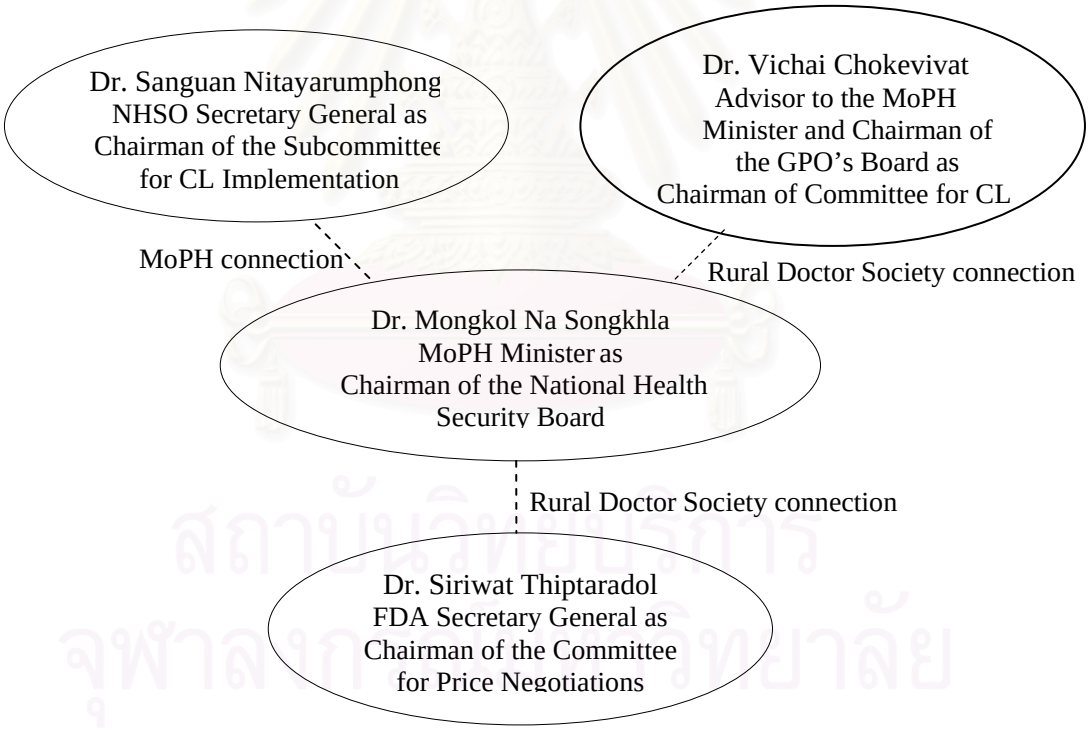
The final panel called the Committee for CL Implementation as chaired by Dr Vichai Chokevivat also contains a significant implication. The panel under direct supervision of the MoPH Minister significantly bypassed any unnecessary steps and could prompt decision-making (Suwit Wibulpolprasert, personal interview, January 3, 2008).). This committee received proposals and reports from previous two working groups for CL implementation and for price negotiations. Yet, the top decision-making authority was deferred to the MoPH Minister. A senior FDA official pointed

out that in the future lower levels of bureau and department leaders should be able to make decision as fundamentally mandated by the Thai Patent Act. The Act rules that the right to grant is bound to any of the three authorities of department, bureau, and ministry. The former Director General of Disease Control Department could have issued CL in the past without necessarily extending the issue to the MoPH minister (a senior FDA official, personal interview, February 4, 2008). This statement revealed that senior bureaucrats could be normally hesitant to take risks because they could be sued by drug companies and negatively impacted (a senior FDA official, personal interview, February 4, 2008).

The above discussions on CL as an active administrative policy help us understand vertical dimensions of CL operations. However, they do not illuminate how the MoPH could ensure that all different working groups worked in harmony. Thus it is helpful to examine the *alliance structure* underpinning the current three panels to explain how allies could bring about CL when they became influential and when their ideology toward CL became congruent. This builds on an insight that state action is fundamentally shaped by the type of alliance structures upon which states base their power (Tarrow, 1994, p. 85). An entry point emerged from the arrival of the coup government that was accompanied by the presence of influential allies. The new Health Minister, Mongkol Na Songkhla, served as a rural doctor for several years and deeply understands the context of the poor people going bankrupt from paying for costly healthcare. In principle MoPH political and civilian bureaucrats have ethical consideration to seek for people welfare and to issue CL. However, two fractions of MoPH bureaucrats are distinct between *huakaonah* (progressive) and *non-huakaonah* (non-progressive) when taking the case of CL (Suwit Wibulpolprasert, personal interview, January 3, 2008; Jon Ungpakorn, personal interview, December 18, 2007). Pro-CL orientation is accommodated within *hua kaonah* bureaucrats who are relatively more decisive to stand firm for CL rather than taking hesitant stances because CL would negatively impact their rank and position. Minister Mongkol Na Songkhla and chairs of CL committees and sub-committee are fit in this category. Findings significantly show that the clique and group-based connections among and across CL administrative bodies constituted an important factor. CL was speedily made

possible within only 45 days following the Health Minister Mongkol Na Songkhla took office.[15] Figure 3.3 simplifies an alliance structure in which the Health Minister had close connections with each chairman of the current three panels through Rural Doctor Society and the MoPH. These key figures have in-dept understanding of the rationale behind CL. For instance, by his position of the MoPH minister Dr. Mongkol Na Songkhal also served as the chairman of the National Health Security Board and was consistently informed on problems surrounding access to medicines. Dr. Vichai Chokevivat who was appointed advisor to the Dr. Mongkol Na Songkhla and chairman of the CL Implementation Committee performed concurrently as the chairman of the GPO's board. A similar structure applies across each chairman and among other board members as well.

Figure 3.3 Alliance structure of the Thai government's issuance of CL



Horizontal **dimension** – Because CL has a profound effect on other state-actors and non-state actors. It is worth examining how the MoPH, which is directly in charge of CL, coordinated with other state actors, beneficiaries and affected parties.

[15] Public Health Minister Mongkol Na Songkhla officially commenced the post on October 12, 2006 (*Thansettakij,* December 28-30, 2006). He signed the first CL notification on November 25, 2006.

Two sets of coordination are illustrated: 1) interministerial coordination, 2) prevailing strategies in dealing with non-state actors (mainly civil society groups and drug TNCs).

Findings show that Health Minister and MoPH high-ranking bureaucrats act together in a coordinated manner to ensure that other ministers pull in the same direction for CL. In the public health ministerial order which appointed the committee for price negotiation following Thailand's issuance of CL, three departmental director-generals from different ministries were appointed committee members. The Department of Trade Negotiations and the Department of Internal Trade, MoC and the Department of International Economic Affairs, MoF have been thus involved and informed on the situation. Likewise, the DIP, MoC is in the panel of the Subcommittee for CL Implementation.

A note from the Foreign Affairs Commission meeting held in May 2007 at the National Legislative Assembly of Thailand revealed supporting evidence of interministerial coordination (National Legislative Assembly of Thailand, 2007). It called for the attendance of all ministries involved in Thailand's issuance of CL to discuss consequences and measures to be taken as the US had just moved Thailand to the PWL. Based on the transcript, representatives tended to have consensus to stand for Thailand's CL. A MoF representative said that Thailand's CL should not substantively impact the relationship between Thailand and the US (National Legislative Assembly of Thailand, 2007, pp. 8-10). CL is only another small false impression of mutual broad and complicated relations (National Legislative Assembly of Thailand, 2007, p. 8). The DIP Director General further supported that CL should not be solely held responsibility being downgrading and that copyrights and piracy are in fact major reasons (National Legislative Assembly of Thailand, 2007, pp. 24-25).

In a personal interview, Dr. Vichai Chokevivat, Chairman of the Committee to Implement CL, agreed that the MoPH should have earlier involved external ministries so that responses from public sectors concerned would be better synchronized (January 3, 2007). Access to medicines campaigner Kannikar Kijtiwatchakul

(personal interview, January 4, 2008) and academic pharmacist Jiraporn Limpananont (personal interview, January 3, 2008) questioned sound cooperation by the MoC and the MoF. To them, the two ministers showed some hesitancy to support the MoPH's issuance of CL until they were pressured by the public.

Examining the MoPH's prevailing strategies with respect to CL is another worthwhile aspect across *horizontal* dimensions. Findings show that the MoPH under Minister Mongkol Na Songkhla used dominantly coordinated and integrative approach toward health civil society groups while comparatively fragmenting drug TNCs.

Notably health civil society mobilized in support of CL under an assimilative framework rather than challenged and disrupted the public sector as conventionally perceived in other cases such as dam construction and development projects. The manner in which MoPH bureaucrats work with civil society has significantly evolved; horizontal approach principally replaces top-down approach. HIV/AIDS advocacy groups claimed that they are the leading civil society in the country (Kannikar Kijtiwatchakul, personal interview, January 4, 2008). Their growth has been accrued from long-standing fight for their rights and civic concerns as discussed in Chapter I.

Strong support by local civil society groups was eminent. The Thai Network of People Living with HIV/AIDS launched their statement right after the MoPH issued the first CL (TNP+, November 29, 2006). A strong alliance is also perceived from a press release of joint statement called "Thai Civil Society Supports the Health Ministers of Thailand and Brazil and Calls on Pharmaceutical Companies and lobbyists to Stop Abusing their Power" by 16 Thai civil society Groups (May 10, 2007). A list of civil society supporting CL in the statement is as follows:

Thai Network of People Living With HIV/AIDS
Thai NGO Coalition on AIDS
AIDS Access Foundation
Drug Study Group
Rural Pharmacist Foundation
Confederation of Consumer Organization

Foundation for Consumers

Biodiversity and Community Rights Action Thailand

Alternative Agriculture Network

FTA Watch

Corporate Watch, Thailand

Focus on the Global South (Thailand)

The Strategic Policy on Natural Resources Base

Project, National Human Right Commission

The Rural Reconstruction Alumni and Friends Association

Medecins Sans Frontiers-Belgium (Thailand)

The strength of health civil society groups is significantly due to an operation at a global level. Local civil society groups succeeded in gaining attention from a range of international alliance groups. Campaigner Kannikar Kijtiwatchakul explained that it was crucial that local civil society kept reporting actions of TDCc and government representatives in Thailand (personal interview, January 4, 2008). For example, local civil society reported that the US Ambassador and the EC Commissioner lobbied Thai MoC representatives. In this manner, international advocate groups were kept informed and could be able to lobby their federal governments.

Compared with civil society, the MoPH used an exclusive approach in dealing with drug TNCs[16] regarding CL. Drug TNCs were not integrated in any CL panels. A NHSO official pointed out that, drug TNCs would be a strong obstacle and it is proper that they were incorporated (Sorachai Jamniandamrongkarn, personal interview, January 3, 2008). In Thailand, drug TNCs have waged a lengthy battle to protect their monopolistic market and commercial interests. They are the main actor advocating for Thailand's stronger IPRs protection in order to protect their expensive products. One

[16]A drastic growth of pharmaceuticals was perceived since wartime with high demands of aspirin and medicines (Suchart, 1996). After WW II, the proliferation of drug TNCs became a common incidence as a product of accelerated internationalization and globalization and they remain influential economically and politically on a global scale. He summed up the mechanisms which make these drug TNCs very influential over four key elements in dominating and monopolizing the global pharmaceutical market: (1) technology, (2) finance, (3) pricing transfer, and (4) political power (Suchart, 1996, pp. 21-24).

of their triumphs was the amendment to the Thai Patent Act 2522 (1999). Looking at drug TNCs' reaction to Thailand's CL, a good case is when Abbott Laboratories Limited (an affected patent holder) threatened to not register seven new drugs in Thailand in order to retaliate against the CL. Drugs companies antagonistically lobbied the Thai government and their own governments (i.e. through their embassy and the USTR) (*Manager Daily*, 2007; *Matichon*, 2007). A notable aspect is also found in the fact that drug TNCs sought a coalition with mighty allies such as the US Chamber of Commerce and PReMA (Pharmaceutical Research and Manufacturers Association) (*Bangkok Post*, 2007; MSF, 2007). Hence, each individual TDC may not stand in a front line against Thailand. PReMA is a very interesting association since it has been established to protect the interests for its members, drug TNCs in Thailand. Soon after the government declared CLs, PReMA announced that their members would slow down investments in Thailand as a retaliation measure. PReMA, which is an "internal" actor, may be reminiscent of another similar "external" actor standing out in the past. The Pharmaceutical Manufacturers Association (PMA) based in the US in 1989 actively lobbied the US government and Thailand was later cut GSP (Generalized System of Preferences). PMA claimed that Thailand did not provide adequate protection to US pharmaceutical products and this resulted in a loss of over US$ 100 million (Sutinna, 2003, p. 59; Ford et al., 2004).

Drumming up with reaction against Thailand's CL, a non-government agency based in Washington DC called "USA for Innovation" which has a close link to American pharmaceutical industries staged a radical reaction by creating the webpage "ThaiMyths.com". They argued in one of the ten myths against Thailand's CLs that Thailand is wrong to claim that other countries issue compulsory licenses all the time (www.thaimyths.com). Those countries take a broadened definition of "compulsory license" to list examples of consent decrees and to claim them as compulsory licenses. The very name "consent decree" determines that it is with the "consent" of the company – far different from the forced "compulsory" license. Many types of "compulsory licenses" cited by activists should not be regarded as compulsory licenses. They are merely a form of legal remedy to penalize a patent holder; they are result of a judicial process and usually a violation of anti-competition laws. The huge

expansion of drug TNCs, the scale of their activities, and the complexity of their transactions set hurdles on local public policymaking.

3.5 Re-assessing capacity, authority, and autonomy behind the issuance of CL

Findings and analysis in the two preceding sections have demonstrated how the national politics and the core features of the MoPH's bureaucracy could block and contribute to the issuance of CL. This section builds on that analysis and draws a particular attention to a reassessment of capacity, authority, and autonomy aspects behind the Thai government's issuance of CL. It takes into consideration the context from the intra-MoPH's bureaucracy and concerned public agencies as well as from these agencies versus national politics.

In fact, the MoPH and concerned public agencies, particularly the NHSO, the GPO, and the FDA, have been endowed with capacity to issue CL and have a high degree of organizational readiness. Based on the MoPH's philosophy and the institutional perceptions on the human rights to gain access to medicines at both the national level and the level of public health sectors, top leaders and bureaucrats are supposed to possess a high level of consciousness. Sets of relevant knowledge have been researched and resources have been prepared in relation to national legal options, the TRIPS' flexibilities and the Doha Declaration, scope, grounds, procedures, royalties, etc. The MoPH and the NHSO do not lack personnel, either top leaders or operation staff, who are knowledgeable in the area of CL. The GPO is proved its capability to produce generics, provided that raw materials are available and a product or a process is not patented. The FDA has developed its capacity on drug registration throughout the principles of quality, safety and efficacy. They also had experience in negotiating for price reduction even though little cooperation could merely be sought from drugs companies.

Section 51 of the Thai Patent Act defines the right of "any ministry, bureau or department of the Thai government" to exercise the right to issue CL. It means the right can be utilized by minister, permanent secretary, and director-general (MoPH &

NHSO, 2008, p. 17). They can do in any patent "by themselves or through others" for "public consumption". Specifically the Thai Patent Act states:

> ***Section 51:*** *In order to carry out any service* ***for public consumption*** *or which is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service,* ***any ministry, bureau or department of the Government*** *may****, by themselves or through others****, exercise any right under Section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of Section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of Section 46, 46 bis and 47.*
>
> *In the circumstances under the above paragraph, the ministry or bureau or department shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General. The royalty rate shall be as agreed upon by the ministry or bureau or department and the patentee or his licensee, and the provisions of Section 50 shall apply mutatis mutandis* (bold by the author).

To examine the Thai government's issuance of CL, it is lawful for the MoPH to issue CL. Two levels of licensing authority, ministry and department, exercised its right to issue CL while the level of bureau is still left out (table 3.2). Three important points should be highlighted. First, the Thai Patent Act does not indicate that it is obliged to confer such right to the cabinet. Without realizing this fact, some cabinet members were not satisfied that they were not informed on the issue prior to the issuance (Sumlee Jaidee, personal communication, May 7, 2008). Second, it is observed that the licensing authority is more clustered by the MoPH' highest level of minister. Only two anti-retrovirals were issued by the Department of Disease Control which is responsible for HIV/AIDS matters and the biggest buyer of anti-retrovirals. To take cancer drugs into consideration, their licensing authority is possibly accommodated on a lower level such as the Department of Medical Services that directly oversees the National Cancer Institute. It is unnecessary that the right to issue CL for four cancer drugs was conferred to the MoPH Minister. Third, the current issuance of CL is undeniably cumbersome in the sense that the licensing authority was monopolized by the MoPH. In fact, other state agencies, in particular, the NHSO and the GPO are largely concerned with the issue to increase access to medicines for Thai population. Therefore, they could have been entitled to issue CL so that CL would be comprehensively implemented. For example, the NHSO which is mandated

by the National Health Security Act, B.E. 2545, directs the UC scheme that indicates the basic right of all Thai people to obtain universal access to healthcare and medicines. The scheme covers 47-48 million Thai people ("Dr. Sanguan preparing to submit proposals to the MoPH to issue 4 CL on cancer drugs", *cl4life*, 2008, para.1). The NHSO, which is well informed of the problem of access to medicines, has persistently pushed for CL. However, the organization itself is not interpreted by the Office of the Council of State that the NHSO is not categorized in any one of those three licensing authority. Based on the MoPH's formal structural chart, the NHSO is a "state agency under the supervision of the MoPH" (see Appendix F). A scholar pharmacist noted that by function the NHSO is equivalent to a "bureau" that manages lives of millions of people and supervises an annual budget of hundreds of thousand million baht (Sumlee Jaidee, personal communication, May 7, 2008). The similar case is applied to the GPO defined as a "state enterprise" when earlier enquiry was sought as to whether the GPO could exercise such right.

Table 3.2 Level of licensing authority that exercised the right to issue CL

No	CL	Issued by	Level of licensing authority
1	Efavirenz	Director General, Department of Disease Control, MoPH	Department
2	Lopinavir+ ritonavir	Director General, Department of Disease Control, MoPH	Department
3	Clopidogrel	Permanent Secretary, MoPH	Ministry
4	Docetaxel	MoPH Minister	Ministry
5	Letrozole	MoPH Minister	Ministry
6	Erlotinib	MoPH Minister	Ministry
7	Imatinib	MoPH Minister	Ministry

Source: Data from the MoPH and the NHSO. (2007). *Facts and evidences on the 10 burnings issues related to the government use of patents on three patented essential drugs in Thailand.* Bangkok: Sangsue Co.Ltd.; MoPH & NHSO. (2008). *Facts and evidences on the 10 issues related to the government use of patents on four patented cancer drugs in Thailand.*

Therefore, among three key aspects of capacity, authority, and autonomy, autonomy is deemed as a determining factor for the Thai government's issuance of CL. During the Chuan 2 administration and the Thaksin administration, autonomy blocked CL because political power dominated bureaucratic power and political masters were superior to bureaucrats (a senior GPO official, personal interview, December 26, 2007). In fact, the Thai Patent Act Section 51 have long existed and mandated that licensing authority is not cemented in the cabinet. Despite having licensing authority, the MoPH bureaucrats dared not to exercise their right and to overlook political masters and the cabinet. They were afraid that CL would negatively impact interests of oligarchic political masters and circles. Consequently, their status and rank would be most likely impacted too. As a result of the September 19 coup, political masters' conflict of interests was removed, if only temporarily. To take Dr. Mongkol Na Songkhla as an example, he firmly stated *"I am not a politician and I have nothing to lose. The true politician will not do this (CL). They are afraid of some consequences"* ("Interview-Thailand fed up with high drug prices – minister", *Reuters*, Feb 18, 2007. Therefore, the MoPH could exercise its autonomy to issue CL at the levels of ministry and department. Based on a total of seven CLs, it notes, however, that most of autonomy was kept monopolistically within the ministry level as five CLs were issued by the minister and only two CLs were done by the director-general.

3.6 Conclusion

To answer the research questions about the determining factors that led to Thailand's issuance of CL, this chapter revealed prospects from a change in the national political landscape and from key features of the MoPH's bureaucracy. The following discussions elucidate a subsequent question on *how and to what extent?*

This chapter found out that national politics is most likely associated with the early blocking of access to patented medicines in Thailand, specifically in the context of policy priority and conflict of interests. The Thai state as represented by various

public agencies could not endure commercial interests and international trade pressure. In cases including the Thai Patent Act, ddI and Combid, the Thai state gave up welfare interests of the people. This chapter also identifies the post-coup opportunities in reconfiguring national cleavage structure (to reorient policy agendas of rebranding Thaksinomics & sufficiency economy) and national institutional structure with the coup having a degree of decentralization that enabled the MoPH to have its autonomy to issue CL.

With regard to the MoPH's bureaucracy, this chapter shows its key features of cultural and structural and functional elements are significantly accountable for determining factors. *Cultural* elements that underlay the issuance of CL are understood by two factors. One factor is decoded from the MoPH's philosophy regarding the provision of public healthcare. Another factor lies in institutional perceptions on the right to access healthcare and medicines at both the national level and the level of the MoPH.

Structural and *functional* dimensions are summarized in three main points. First, by means of decentralization or by creating and sharing responsibilities among current three different administrative panels surrounding CL, it is beneficial in assuring that relevant preparations and responses are firmly undertaken. This could bypass unnecessary steps and delay. Each mission concentrated on a specialized task and united when necessary, even though each could possibly take on excessive workforce and resources. Second, by putting an administrative body under the direct supervision of the MoPH Minister, it creates both opportunities and constraints on CL. Opportunities lie in the fact that it can relay directly with the Minister. Adversely, decision-making authority is largely constrained by the individuality (interest, value and power) of each Minister. Third, by not deferring the final decision from the cabinet and the existing Thai Patent Act that the authority to issue CL is given to the three levels of ministry, bureau, and department, it was made possible to mobilize CL through avoiding possible disruption at a higher level such as the cabinet if required.

To answer the last research question on the working relationship between the MoPH and health civil society, this chapter reveals that the MoPH uses a prevailing strategy of *highly coordinated* in dealing with health civil society. This approach is proved beneficial for the MoPH's ability to issue CL in that civil society forms a strong base to provide the legitimacy for the MoPH to issue CL.

Lastly, this chapter suggests a reassessment of capacity, authority, and autonomy behind the Thai government's issuance of CL. It found that while capacity and authority have existed, it was the autonomy that blocked or drove the Thai government to issue CL. The Thai government's issuance of CL was possible because political power and politicians' conflict of interests were removed, if only temporarily. Therefore, the autonomy was dispersed from the national politics to the ministry level and from the ministry to the department to issue CL. This chapter also revealed that the autonomy at the bureau level has not been exercised its right to issue CL.

CHAPTER IV

CONCLUSION

4.1 Introduction

Thailand has recognized the gravity of access to essential medicines. To address this need, the country jointly proposed a draft text for the ministerial declaration on IP rights and public health together with developing countries (Jakkrit, 2007b, p. 42). This effort by Thailand and developing countries resulted in the adoption of the Doha Declaration in 2001, which acknowledges the significance of access to medicines and reaffirms the rights of WTO members to use the flexibilities laid down by the TRIPS Agreement to ensure access to medicines. Chapter II revealed that Thailand does not benefit from IP rules and international trade. Thailand has been technologically dependent on industrialized countries. The country's attempt to secure access to medicines would be further undermined if it signs the FTA with the US in the future.

This conclusion chapter brings together the research findings and analysis from Chapter III to discuss the determining factors that led to the Thai government's issuance of CL. Confirmation of the validity of the POS and PAS conceptual frameworks is also discussed. Finally, suggestions are offered for future research.

4.2 National politics

Based on the research findings, national politics is a determining factor that serves as both a constraint and opportunity for Thailand's issuance of CL.

4.2.1 Constraints

Chapter III revealed that previous Thai governments and concerned authorities were submissive and could not withstand international pressure and trade sanctions. According to a health activist, the Thai government has a "slavery mindset" under the

economic superpowers and neoliberalism (Kannikar Kijtiwatchakul, personal interview, January 4, 2008). That Thailand is submissive is evidenced in three popular movements: (1) the establishment of Patent Act B.E. 2522 (1979) and its two amendments B.E. 2535 (1992) and B.E. 2542 (1999); (2) the revocation of the patent on ddI (Didanosine) during 1999-2004; and (3) the pre-grant opposition to block the patent for the anti-retroviral Combid.

Reasons why the Thai state successfully blocked the early popular movements to increase access to medicines is explained in two main accounts. Firstly, access to medicines was not prioritized, even though contributing factors such as legality and local production were well in place. The Chuan 2 government was preoccupied with managing the aftermath of the 1997 financial crisis and institutionalizing political reforms. The government did not want to take any risks or do anything to antagonize trade partners, especially the US. Along this line, the MoPH's bureaucracy that was linked to national politics was made to ensure that the Ministry responded to national politics. Even though the Thaksin government was overwhelmingly dubbed a "populist" regime, the government showed a high degree of serving the neoliberalism agenda, as it was active in negotiating the Thai-US FTA, increasing the limits of foreign shares in conducting business in Thailand, pushing for the privatization of state enterprises, etc.

4.2.2 Opportunities

The September 19, 2006 coup that changed the political landscape of Thailand has strong implications for Thailand's ability to issue CL. It opened up opportunities to reconfigure national cleavage structure in which the new political alignment and new division of elites brought about the reorientation of policy agendas (rebranding Thaksinomics & sufficiency economy). The coup also reconfigured institutional structure. Even though it is difficult to characterize the coup government in terms of closed and strong state, the coup government had a certain degree of decentralization that enabled the MoPH to have autonomy to issue CL. It notes that the military-installed government of General Surayud Chulanont was in a dilemma. While it

needed to gain acceptance from the international community, it also had to please the Thai public in order to gain legitimacy for the coup and the military-installed government. The issuance of CL showed that the coup government opted for the latter.

4.2.3 Confirmation of the validity of the conceptual framework

The POS conceptual framework is defined by this research as changed and stable dimensions of the political environment within the Thai state that provided incentives for MoPH bureaucrats to undertake collective action and to eventually bring about Thailand's CL. The research translates such changed dimensions into opportunities that were opened up in Thailand's new political landscape after the Thaksin government was replaced by the coup-installed government of General Surayud Chulanont. However, it notes that the framework also contains some limitations. Basically, it is difficult to quantify opportunities. Also, opportunities are *relative* subjects. One has to perceive such opportunities before being able to utilize them.

4.3 The MoPH's bureaucracy

Research findings showed that the MoPH's bureaucracy is a determining factor that led to the issuance of CL. Even though public support and legal options have been available for the issuance of CL, the MoPH which has the authority to issue CL, took a long time before being able to exercise this authority. Key features (cultural and structural/functional) of the MoPH's bureaucracy were examined regarding their supporting roles and dynamics.

4.3.1 Cultural

Cultural elements that contributed to the issuance of CL were divided into two aspects. Firstly, the MoPH's philosophy is unique, as it values providing public healthcare and prioritizes the people's welfare. This statement is well expressed by

the former Health Minister Mongkol Na Songkhla, who adheres to *rural doctor* values. Secondly, institutional perceptions of the right to access healthcare and medicine at both the national level and the level of the MoPH play a significant role. Actually, Thailand is not considered a 'welfare' state when compared to advanced states that assume primary responsibility for the comprehensive welfare of their citizens. However, Thailand shows a high degree of realization on public health welfare in its Constitution, National Drug Policy, National List of Essential Drugs (NLED), and National Health Security Act.

4.3.2 Structural/functional

Structural and functional dimensions significantly contributed to the issuance of CL. First, decentralization, or creating and sharing responsibilities among three different administrative panels surrounding CL, assured that relevant preparations and responses were firmly undertaken. This may have bypassed unnecessary steps and delays. Each mission concentrated on a specialized task and worked together when necessary, even though each mission could have possibly taken on extra workforce and resources. Second, putting an administrative body under the direct supervision of the Minister of the MoPH creates both opportunities for and constraints on CL. An opportunity lies in the fact that the Ministry can relay directly with the Minister. Adversely, decision-making authority is largely constrained by the individual interests, value, and power of each Minister. Third, it was possible to mobilize CL without disrupting higher levels of government because the existing Thai Patent Act authorizes the three levels of ministry, bureau, and department to issue CL without the authority of the cabinet if required.

Lastly, the research findings also showed that the MoPH uses a prevailing strategy of *highly coordinated* in dealing with health civil society. This approach is beneficial for the MoPH's ability to issue CL in that civil society forms a strong base to legitimize the MoPH's to issuance of CL.

4.3.3 Confirmation of the validity of the conceptual framework

The PAS framework could capture major variables in the MoPH's bureaucracy in explaining dynamics of the CL process. Hence this research confirms the validity of the framework, which was applied by using these key features as most likely to affect the CL process: *cultural, structural, and functional.* The framework was also extended to cover the relationship and bargaining space that integrate non-state actors (particularly civil society groups and drug TNCs) with state actors (minister and bureaucrats).

4.4 Capacity, authority, and autonomy

In an effort to identify a determining factor behind the Thai government's issuance of CL in a fundamental manner, this research suggested a reassessment of capacity, authority, and autonomy. By building on findings and analysis regarding national politics and the MoPH's bureaucracy, research findings revealed that autonomy is a determining factor that drove the Thai government to issue CL. During the Chuan 2 administration and the Thaksin administration, autonomy blocked CL because political power dominated bureaucratic power and political masters were superior to bureaucrats. Apparently, the Thai Patent Act Section 51 has mandated that licensing authority can be utilized by any ministry, bureau and department. There is no such provision that demands that authority be conferred to the cabinet. However, due to political masters' conflict of interest, authorizing bureaucrats (either the permanent secretary or director general) decided not to issue CL for fear of political power. Under the Surayud administration, such political power was removed, if only temporarily. Therefore, the MoPH could exercise its autonomy to issue CL at the levels of ministry and department. It notes that the MoPH has not exercised the right at the bureau level.

4.5 Suggestions for further research

Pharmaceutical IP is built on the premise that it provides incentives for innovation and economic growth. This claim has largely prevented the use of CL in Thailand and many developing countries. Based on this research, Thailand needs certain determining factors to make CL possible. CL as a policy option to increase access to medicines deserves greater exploration. Three subject matters for further research are suggested.

Firstly, as this research revealed, autonomy is a determining factor for the Thai government's ability to issue CL. It would be beneficial to examine how mechanisms can be created for lower levels of government to exercise autonomy. How can a licensing authority at the levels of bureau and department be better encouraged to utilize their right to issue CL and any other key public policies? Should there be further consideration over revising or interpreting the existing Patent Act to provide autonomy to public agencies such as the NHSO and the GPO?

Secondly, pro-compulsory licensing movements have been carried out earlier in parallel with the anti-FTA movements and as a continuation of the Thai Patent Act movements. It would be interesting to see how anti-FTA and Thai Patent Act movements have contributed to the success of CL, or, how CL's movements and outcomes are related to and contribute to these movements.

Thirdly, changing and conflicting roles of concerned state agencies, mainly the MoPH, the MoC, and the MoF, have been perceived. It would be beneficial to investigate and compare their responses, roles, and perspectives on CL. This may help identify how the issue of access to medicine, CL, and other options to secure access to medicines in the country could be managed harmoniously.

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APPENDICES

APPENDIX A
INTERVIEWS

Public sector

1. **Achara Eksaengsri (December 26, 2007)**
   Deputy Director, Research and Development Institute, Government Pharmaceutical Organization (GPO)
   Board member, the Subcommittee for Implementing the Government Use of Patent on Essential Patented Drugs 2006

2. **Jiraporn Limpananont (January 3, 2008)**
   Associate Professor, Social Pharmacy Research Unit (SPRU), Faculty of Pharmaceuticals Science, Chulalongkorn University
   Board member, the Committee for Price Negotiation of the Patented Essential Drugs 2007
   Chair, Foundation for Consumer
   Founding member and academic advisor, Drug Study Group (DSG)
   (a network of university academics who have fought for improved access to medicines in Thailand)

3. **Sorachai Jamniandamrongkarn (January 3, 2008)**
   Acting Director, Policy and Planning Bureau, National Health Security Office (NHSO)
   Editor, the report *Sovereignty Not for Sale* co-written by a number of scholars on the impacts of the US-Thai FTA on Thailand

4. **Suchart Chongprasert (February 4, 2008)**
   Food and Drug Administration, Ministry of Public Health (MoPH)
   Board member, the Committee for Price Negotiation of the Patented Essential Drugs 2007
   Board member, the Ad-hoc Working Group for Price Negotiation of the Patented Essential Drugs 2005

UNCTAD / ICTSD expert

5. **Suwit Wibulpolprasert (January 3, 2008)**
Senior Advisor in Disease Control, Ministry of Public Health (MoPH)
Senior Advisor in Health Economics (2003-2006) (also responsible for health policy and international health works of the MoPH)

Chairman, the Boards of the Health Metrics Network; the Steering Committee of Asia Partnership on Avian Influenza Research and Steering Committee of the Asia-Pacific Action Alliance on HRH
Chairman, the Program and Policy Committee of the Interim Board of the Global Health Workforce Alliance

6. **Sripen Tantivess (January 3, 2008)**
Researcher, International Health Policy Program, Thailand (IHPP), Ministry of Public Health (MoPH)

7. **Vichai Chokevivat (January 3, 2008)**
Chairman, the CL Implementation Committee
Advisor to Public Health Minister Mongkol Na Songkhla

NGOs

8. **Jon Ungpakorn (December 18, 2007)**
Chairman, AIDS Access Foundation
2005 Magsaysay Award for Governmental Services

9. **Kannikar Kijtiwatchakul (January 4, 2008)**
Access to Essential Medicines Campaigner, Medecins Sans Frontieres-Belgium (MSF) (Thailand)
Author of *The Right to Life* which provides an informative read of Thailand's path to CL

Co-author of Public Health Minister Mongkol Na Songkhla's biography which explains rationale and legitimacy behind Thailand's issuance of CL and the Minister's background and insight on CL

** The biography is titled in Thai "*eek kao tee kla khong moh kee ma klaeb* (Another Brave Step of a Doctor Riding a Small Pony).

APPENDIX B

SAMPLE SEMI-STRUCTURED INTERVIEW QUESTIONS

1. Brief background of interviewee
(role and responsibility in relation to CL, number of years of involvement)

2. Political opportunities, national and internal the Ministry of Public Health (MoPH)

   2.1 Did political opportunities, either at the national level or the level of the MoPH, lead to Thailand's issuance of CL? For instance, do you agree that the Coup and the reshuffle in the MoPH played a key role in the issuance of CL?

   2.2 How do you perceive such opportunities, at the national level and at the level of the MoPH, in terms of:
   2.2.1 closed setting for external input or open setting for it;

   2.2.2 stability and instability of political alignments;

   2.2.3 divisions among top political masters and civil servants; and

   2.2.4 policy making capacity and autonomy

   2.3 How do you conceptualize prevailing strategies of the MoPH toward other actors concerned like drugs companies and health civil society, *integrative* (facilitative, cooperative, assimilative) *or exclusive* (repressive, confrontational, polarizing)? If integrative, to what extent or level? If exclusive, to what extent or level? Are there any significant differences between this managerial/ministerial term and the past? How?

   2.4 Regarding alliance structures in the MoPH, how do you perceive the working/political relationship between the MoPH and drug companies and health civil society in relation to CL? How did such relationship affect the decision for CL?

3. Political-administrative structure of the MoPH

   3.1 Can you explain the structural or/and functional structure of the MoPH in relation of the issuance of CL? In other words, do you understand the path, legality and formality which brought about CL? If yes, how?

3.2 Do you agree that bureaucratic cultures of the MoPH account for the issuance of CL? If yes, to what extent, what are those cultures or can you explain them as of: 1) individual leaders (bureaucrats/politicians); 2) clique, group-based; and 3) organizational culture

OR/AND in terms of: 1) behaviors; 2) values, attitudes and sets of thinking; and 3) paradigms concerning public health care provision?

4. Bargaining space for CL

4.1 Do you agree that before CL was passed out, it had been negotiated in not only formal space, but also informal setting? (*informal means a certain degree of confidentiality and privacy)

4.2 Do you know or have you ever joined some formal bargaining for CL? When, where, who were participants, what was your role and what were the results?

4.3 Do you know or have you ever joined some informal bargaining for CL? When, where, who were participants, what was your role and what were the results?

5. In your opinion, what are determining factor(s) that led to Thailand's issuance of CL? (whether or not the factor in the MoPH)

APPENDIX C

FIELD NOTES FROM NON-PARTICIPATORY OBSERVATION AT EVENTS AND CONFERENCE RELATED TO THAILAND'S CL

Dying for Drugs. This movie festival with talks and exhibition on Thailand's CL was held on June 23, 2007 at the Faculty of Pharmaceuticals Science, Chulalongkorn University. The event was co-organized by Health Consumer Protection Program (HCP) and Pharmacy Network for Health Promotion (PNHP), Chulalongkorn University, TNP+, AIDS ACCESS Foundation, MSF-Belgium (Thailand) and Oxfam.

Another Courageous Step of a Doctor Riding Small Pony (eek kao tee kla khong moh khee mah gleap). The launch of biography of the MoPH Minister Mongkol Na Songkhla was held on August 1, 2007 at the B2S Bookstore, Central World Plaza, Bangkok. Published by *Moh Chao Baan* Publishing House, the biography together with substantial reference to Thailand's CL was co-written by Kannikar Kijtiwatchakul and Auyporn Taechootrakul.

Compulsory Licensing: Innovation and Access for All. This International Conference was held during November 21-23, 2007 at Asia Hotel, Bangkok. It was co-organized by an alliance group for CL including academia (Chulalongkorn University), public sector (the MoPH), and health civil society (Health & Development Foundation, AIDS Access Foundation, TNP+, Pharmacy Network for Health Promotion, Foundation for Consumer, MSF, Oxfam, etc.).

APPENDIX D

AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[1] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public noncommercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

[1] "Other use" refers to use other than that allowed under Article 30.

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and

(f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

APPENDIX E

DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

   In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

   a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
   b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
   c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme 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.

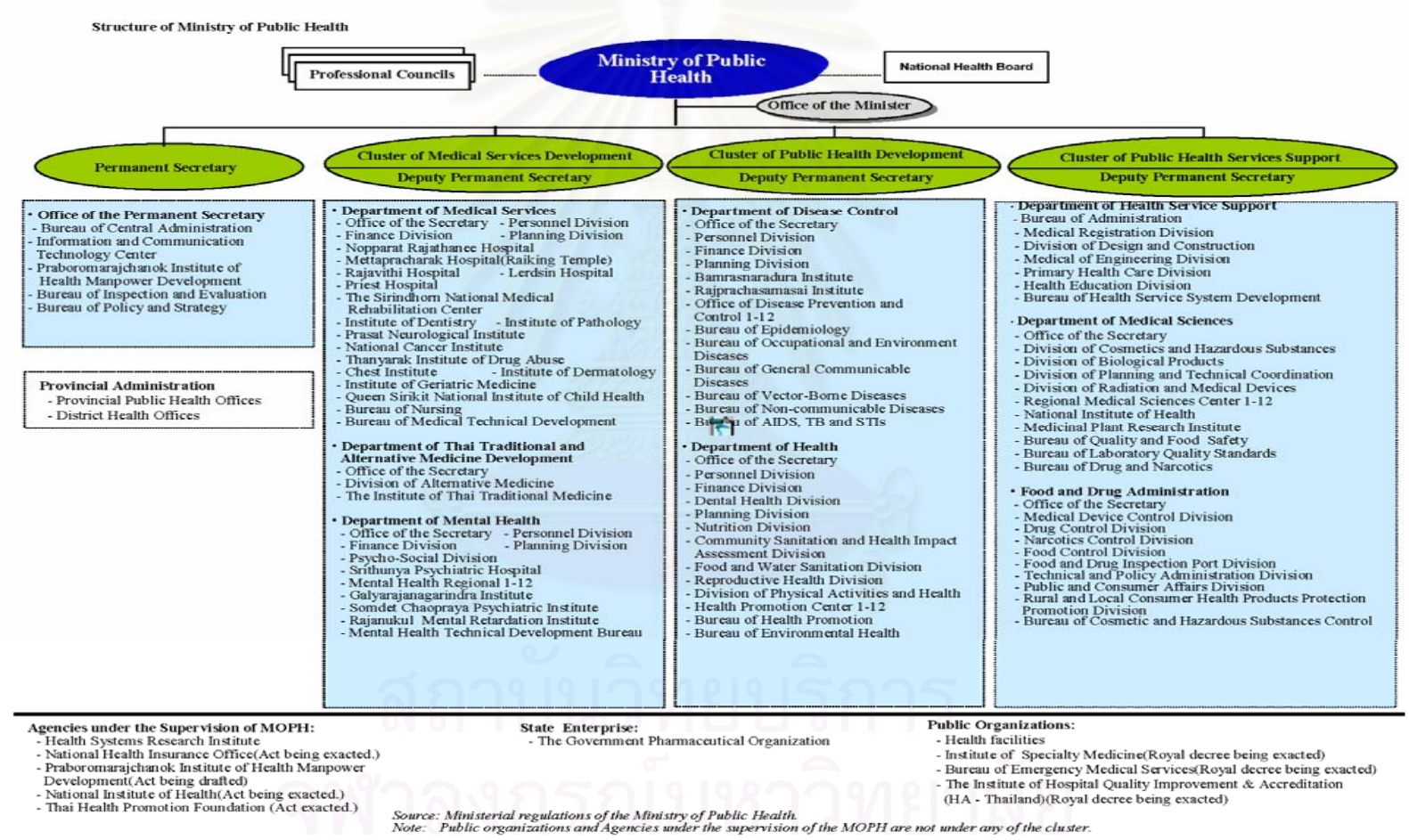
d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

APPENDIX F

THE MOPH'S STRUCTURE



BIOGRAPHY

With a B.A. degree in English from Thammasat University, Ms. Kamolrat Chotesungnoen or Dao commenced her first career as an academic officer for a US-Thailand collaborative program called International Law Enforcement Academy (ILEA-Bangkok). The Academy's principal objectives are to enhance effective law enforcement cooperation within ASEAN and to strengthen each country's criminal justice institution. The Academy provided training against various forms of transnational crime threats in the region, ranging from terrorism to financial crime, illicit drug trafficking, post blast investigation, money laundering, alien smuggling, and intellectual property rights.

Before becoming a full-time Master's degree student, she served as Administrative Assistant for the European Commission initiative "EC-ASEAN Intellectual Property Rights Cooperation Programme or ECAP II" located at the premises of the Thai Department of Intellectual Property (DIP), Ministry of Commerce. The ECAP II program aims to strengthen partnership and enhance Intellectual Property Rights (IPRs) protection and promotion in the ASEAN, whereby increasing the region's competitiveness. The Programme provided training courses, seminars, workshops, study tours, and technical assistance for ASEAN partners.